



2025 Evolent Clinical Guidelines for Medical Necessity Review

Cardiology Guidelines

Guidelines for Clinical Review Determination

Preamble

Evolent is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines for the provision of diagnostic imaging. These criteria are designed to guide both providers and reviewers to the most appropriate diagnostic tests based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice will be used when applying the guidelines. Determinations are made based on both the guideline and clinical information provided at the time of the request. It is expected that medical necessity decisions may change as new evidence-based information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient.

Guideline Development Process

These medical necessity criteria were developed by Evolent for the purpose of making clinical review determinations for requests for therapies and diagnostic procedures. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, cardiology, and other specialty groups. Evolent's guidelines are reviewed yearly and modified when necessary following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

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Evolut Clinical Guideline 7251 for Abdominal Aortic Ultrasound

Guideline Number: Evolut_CG_7251	<u>Applicable Codes</u>	
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Original Date: July 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for an abdominal aortic ultrasound.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR ABDOMINAL AORTIC ULTRASOUND

Screening for Abdominal Aortic Aneurysm

- One-time ultrasound screening ^(6,7) in men \geq 65 years old who have ever smoked ^(8,9) **(AUC Score 8)** ⁽¹⁰⁾
- In men or women \geq 65 years old with first-degree relatives having abdominal aortic aneurysm (AAA) ^(6,8) **(AUC Score 8)** ⁽¹⁰⁾
- One-time ultrasound screening ⁽⁶⁾ in women \geq 65 years old who have ever smoked ⁽⁸⁾ **(AUC Score 7)** ⁽¹⁰⁾
- In men or women $<$ 65 years old with multiple risk factors (such as having smoking history, hypertension, hyperlipidemia, inherited vascular connective tissue disorder and atherosclerotic cardiovascular disease) **OR** a first-degree relative with AAA ^(7,8)
- In patients with abdominal pain, flank pain, and lower back pain ^(6,11)
- In patients with femoral or popliteal aneurysms ⁽¹²⁾

- In patients with palpable or pulsatile abdominal mass or abdominal bruit ⁽¹¹⁾
- In patients with lower extremity peripheral artery disease (LE-PAD) presenting with intermittent claudication symptoms ⁽¹³⁾
- In patients with thromboembolic events or neurologic deficit in LE ⁽¹⁴⁾

Surveillance of Abdominal Aortic Dilation and Aneurysm

- In patients with an AAA of 2.5 cm to < 3.0 cm every 4 years and life expectancy > 2 years ⁽⁹⁾
- In patients with an AAA of 3.0 cm to < 4.0 cm every 3 years ^(6,8,9)
- In men with an AAA of 4.0 cm to < 5.0 cm **AND** in women with an AAA of 4.0 cm to < 4.5 cm every 6 months ^(8,9) **(AUC Score 8-7)** ⁽¹⁰⁾
- In men with an AAA of ≥ 5.0 cm (threshold for AAA repair is ≥ 5.5 cm diameter in men with unruptured AAA) **AND** women with an AAA of ≥ 4.5 cm every 6 months (threshold for AAA repair is ≥ 5.0 cm diameter in women with unruptured AAA) ^(8,9)
- In patients with infrarenal or juxtarenal AAAs of 4.0 to 5.4 cm every 6 months to detect expansion ⁽¹²⁾

Surveillance of Iliac Artery Aneurysm

- In patient with iliac artery aneurysm ⁽¹⁵⁾:
 - 2.0 - 2.4 cm in diameter every 3 years
 - 2.5 - 2.9 cm in diameter every 2 years
 - ≥ 3.0 cm in diameter every year

Surveillance after Abdominal Aortic Aneurysm Intervention

- In patients with AAA after open repair within 1 post-operative year and every 5 years thereafter ⁽⁹⁾
- In patients with AAA treated with EVAR (endovascular abdominal aortic aneurysm repair), baseline surveillance imaging with cardiovascular CT is typically performed within 1 month postoperatively ⁽⁹⁾, and timing of an ultrasound is defined as follows:
 - In the absence of endoleak or sac enlargement, ultrasound can be done at 12 months and then every year ^(6,8,9) **(AUC Score 7)** ⁽¹⁰⁾
 - In patients with type II endoleak observed, ultrasound can be done one month after EVAR and at 6-month interval ⁽⁶⁾ during the first year and every 2-3 thereafter ⁽⁹⁾
 - In patients with type II endoleak associated with an aneurysm sac, ultrasound can be done at 6-month intervals for 24 months and then annually ⁽⁶⁾ **(AUC score 8)** ⁽¹⁰⁾
 - In low-risk patients (early sac shrinkage > 10 mm and < 70 years old with no endoleak), ultrasound can be done every 2 years ⁽⁹⁾

CODING AND STANDARDS

Coding

CPT Codes

76706, 93978, 93979

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

An abdominal ultrasound uses reflected sound waves to obtain anatomic and physiologic information of the abdominal aorta. It is commonly performed to diagnose an abdominal aortic aneurysm. An abdominal aortic aneurysm is defined as an increased internal diameter of the abdominal aorta of 3.0 cm or greater.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AAA: Abdominal aortic aneurysm

EVAR: Endovascular abdominal aortic aneurysm repair

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1126 Abdominal Aortic Ultrasound ● Updated indications for Abdominal Aortic Ultrasound and organized into subsections for clarity ● Removed Special Note and Limitation sections ● Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Chaikof E, Dalman R, Eskandari M, Jackson B, Lee W et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *Journal of Vascular Surgery*. 2018; 67: 2-77.e2. <https://doi.org/10.1016/j.jvs.2017.10.044>.
7. Owens D K, Davidson K W, Krist A H, Barry M J, Cabana M et al. Screening for Abdominal Aortic Aneurysm: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2019; 322: 2211-2218.
8. Isselbacher E, Preventza O, Black III J, Augoustides J, Beck A et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2022; 80: e223 - e393. 10.1016/j.jacc.2022.08.004.
9. Mazzolai L, Teixido-Tura G, Lanzi S, Boc V, Bossone E et al. 2024 ESC Guidelines for the management of peripheral arterial and aortic diseases. *European heart journal*. 2024.
10. Mohler III E R, Gornik H L, Gerhard-Herman M, Misra S, Olin J W et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/ SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing. *Journal of the American College of Cardiology*. 2012; 60: 242-76.
11. American College of Radiology. ACR–AIUM–SRU Practice Parameter for the Performance of Diagnostic and Screening Ultrasound of the Abdominal Aorta in Adults. 2020; Accessed: 30-Oct-2024. <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Abd-Aorta.pdf>.
12. Anderson J, Halperin J, Albert N, Bozkurt B, Brindis R et al. Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations): A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*. 2013; 61: 1555 - 1570. 10.1016/j.jacc.2013.01.004.
13. Giugliano G, Laurenzano E, Rengo C, De Rosa G, Brevetti L et al. Abdominal aortic aneurysm in patients affected by intermittent claudication: prevalence and clinical predictors. *BMC surgery*. 2012; 12 Suppl 1: S17.
14. Gibbons R C, Singh G, Donuru A, Young M. Abdominal Aortic Aneurysm Imaging. *StatPearls [Internet]*. 2023; Accessed: 30-Oct-2024. <https://www.ncbi.nlm.nih.gov/books/NBK470373/>.

15. Wanhainen A, Van Herzele I, Bastos Goncalves F, Bellmunt Montoya S, Berard X et al. European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms. Journal of Vascular Surgery. 2024; 79: 10.1016/j.jvs.2024.01.006.

Evolut Clinical Guideline 7252 for Ambulatory Rhythm Monitoring

Guideline Number: Evolut_CG_7252	<u>Applicable Codes</u>	
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General Information

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- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

To identify appropriate use for ambulatory rhythm monitoring.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR AMBULATORY RHYTHM MONITORING ⁽⁶⁾

- Palpitations are the most common indication for ambulatory heart rhythm monitoring
- Evaluation of arrhythmia drug therapy change including dosage alterations
- Patients with suspected epilepsy in whom treatment has been ineffective ⁽⁷⁾
- Patients with unexplained falls suspected to have an arrhythmic origin ⁽⁷⁾
- Suspected pacemaker malfunction, based on history and physical exam
- Syncope
 - Symptom/rhythm correlation remains the cornerstone of the diagnostic efforts in syncope to confirm the involvement of the cardiac electrical system in the origin of syncope. The choice of monitoring modality depends on the frequency of the events
- Symptoms (listed below) that may be due to cardiac arrhythmias and for which ambulatory monitoring is appropriate, include:

- Shortness of breath
- Transient chest pain
- Palpitations (when physical examination and/or standard EKG have not satisfactorily explained the patient's complaints)
- Transient episode of cerebral ischemia, documented cerebrovascular accident (CVA), or recent evidence of cryptogenic stroke, to evaluate for a causation rhythm disturbance (e.g., atrial fibrillation or flutter) ⁽⁸⁾
- Patient with a recent acute coronary syndrome:
 - ST-elevation myocardial infarction (STEMI) and non-STEMI when the ejection fraction is borderline (35-40%), or when frequent ventricular ectopy was noted during hospitalization
- Cardiomyopathy
 - Hypertrophic cardiomyopathy
 - Arrhythmogenic right ventricular cardiomyopathy
 - Dilated or restrictive cardiomyopathy
- For patients found to have a significant cardiac arrhythmia or conduction disorder (**see list below**) in whom cardiac monitoring is planned for the evaluation and management of the patient:
 - Frequent Ectopy
 - Premature ventricular contraction (PVCs) ⁽⁹⁾
 - Premature atrial contraction (PACs)
 - Supraventricular tachycardia (SVT) (sustained or non-sustained) ⁽⁹⁾
 - Ventricular tachycardia (VT) (sustained or non-sustained) ⁽⁹⁾
 - Ventricular fibrillation/flutter ⁽⁹⁾
 - Unexplained or symptomatic bradycardia
 - Suspected sinus node dysfunction
 - Paroxysmal atrial fibrillation/flutter ⁽⁸⁾
 - Torsade de pointes
 - Wandering atrial pacemaker
 - Cardiac arrest ⁽⁹⁾, when electrophysiology testing or ICD implantation are not planned
- Post Cardiovascular surgery
 - Indicated for outpatient arrhythmia monitoring
- Inherited channelopathies
 - First degree relatives of patients with idiopathic ventricular fibrillation
 - Long and short QT syndromes
 - Brugada syndrome
 - Early repolarization with high-risk features (see **background**)

- Catecholaminergic polymorphic ventricular tachycardia
- Conduction disorders
 - New or intermittent Left Bundle Branch Block (LBBB)
 - High-degree Atrioventricular (AV) block
 - Second Degree AV Block
 - Transient complete Heart Block
 - Preexcitation on ECG (Wolf-Parkinson-White), symptomatic or asymptomatic
- Congenital Heart Disease (CHD)
 - Congenital aortic stenosis
 - Pediatrics patients with repaired CHD or with significant residual hemodynamic abnormalities
 - In adults with CHD at risk for tachyarrhythmia, bradyarrhythmia, heart block, or symptoms of arrhythmic origin ⁽¹⁰⁾
 - In adults with dextro-Transposition of the Great Arteries (d-TGA) with Atrial Switch (including those treated with beta blockers or other rate-lowering drug therapy) ⁽¹⁰⁾
- Autonomic Function Analysis
 - Heart rate variability may be performed using Holter monitoring. It provides sudden cardiac death risk stratification data post-MI and in patients with heart failure. It has proved useful in patients with resynchronization devices (CRT) to evaluate optimal timing of biventricular pacing.

INDICATIONS FOR REMOVAL OF LOOP RECORDER SYSTEMS

- ILR may be removed for:
 - End of battery life
 - Pain, discomfort, infection at ILR site, or patient desires the device to be removed ⁽¹¹⁾

SELECTION OF DEVICES FOR AMBULATORY RHYTHM MONITORING

Holter Monitor

Holter monitoring is used for the evaluation of a patient with symptoms suggestive of cardiac arrhythmia or conduction abnormality that occur frequently enough to be detected within a short period (24–72 h) of monitoring, preferably daily or several times a day.

Holter monitoring is useful to assess the presence and frequency of asymptomatic but potentially significant dysrhythmias, including, but not limited to atrial fibrillation, ventricular ectopy, and bradycardias.

Holter monitoring is typically used for **short term (1-2 days), and rarely longer term (up to 2 weeks)** study duration. ⁽¹²⁾

Event Recorder

Event Recorders are indicated for evaluation of frequent, but typically not daily spontaneous symptoms potentially related to tachycardia, bradycardia or conduction disorder, and likely to recur within 2–6 weeks. This form of monitoring is most useful for evaluation of symptomatic rhythm problems, as patient activation is typically needed.

Wireless Patch Monitoring Systems

Can be used as an alternative to external loop recorder or Holter Monitor for both symptomatic and asymptomatic dysrhythmias, likely to occur within 2-4 weeks.

Since it is leadless, can be accurately self-applied, and is largely water resistant, it may be more comfortable and less cumbersome than an external loop recorder, potentially improving compliance.

Unlike Holter monitors and other external monitors, it offers only 1-lead recording.

Mobile Cardiac Outpatient Telemetry

MCOT is appropriate in the evaluation of spontaneous symptoms, potentially related to tachycardia, bradycardia or conduction disorder, that are too brief, too subtle, or too infrequent to be readily documented with patient-activated monitors or Holter monitors.

MCOT is useful to assess the presence and frequency of asymptomatic but potentially significant dysrhythmias, including, but not limited to atrial fibrillation, ventricular ectopy, and bradycardias.

MCOT may be utilized when other forms of monitoring do not identify the source of symptoms (e.g., Holter Monitoring).

Implantable Loop Recorder

The implantable loop recorder (ILR) is a subcutaneous monitoring device used to monitor electrical activity of the heart over an extended period, **for up to 3 years**, to capture a spontaneous event when symptoms occur less than monthly or a few times per year.

Used for recurrent, infrequent, unexplained symptoms, potentially related to tachycardia, bradycardia or conduction disorder after a nondiagnostic initial workup (including Holter, Patch Monitor, or MCOT), with or without structural heart disease.

LIMITATIONS

- Loop recorder implantation in presence of another electrical device (AICD/PPM/CRT device etc.) is not indicated
- Loop recorder implantation post atrial fibrillation ablation is not routinely indicated and will be addressed on a case by case basis

CODING AND STANDARDS

Coding

CPT Codes

33285, 33286, 93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, 93272

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Ambulatory EKG Monitoring

Ambulatory EKG Monitoring is the continuous monitoring on an outpatient basis of the electrical activity of the heart while the patient undergoes their usual activities. The duration of the monitoring period should be long enough to capture heart rhythm abnormalities based on the patient's description of the frequency of their symptoms.

Holter Monitor

Holter monitors are continuous single and multi-lead external recorders wire-lead devices. These utilize standard wet gel electrodes worn continuously to record ECG data. Recordings may be in 2-channel (two independent bipolar leads), 3-channel, 12-channel, or EASI lead formats. They are traditionally used for 24–48 hr., although some models permit recording periods up to 30 consecutive days. They are most effective when patients maintain a diary of activities and symptoms, and mark occurrence of symptoms by pressing a button on the device. Data are analyzed post recording on a dedicated workstation.

Event Recorders

External event recorders are activated and record only at the time of detection (either automatically by the device, or manually activated by the patient). They use gel electrodes connected via wires to the recording device. Event recorders are worn continuously, for varying periods of time, typically 2-weeks to one-month. They record the rhythm in a continuously renewed loop, but when activated, will store the data from the rhythm in memory. This information can be downloaded to the physician's office at the convenience of

the patient post-event. Newer models can transmit triggered data automatically over a cellular network to a remote monitoring system.

Simpler non-looping post event recorders are not worn continuously. Rather, these portable devices with built-in electrodes are applied directly on the chest (or held by both hands) to record a very brief duration single-lead ECG signal during symptoms. They require that the patient be aware of the rhythm disturbance, that it lasts long enough to mobilize the device, and that the patient is able to cooperate with its use.

Patch ECG Monitors

Continuous, usually single-lead external recorders with wireless transmission (patch ECG monitors) are wearable adhesive patches with embedded electrodes that store rhythm data collected either automatically or when activated by the patient. These on-skin wearable devices eliminate the need for patient cable wires and discrete electrodes; they are comfortable to wear and water-resistant, and do not interfere with patients' daily routines. Patients can press a button to mark symptomatic episodes. Up to 7–14 days of ambulatory monitoring yields a high rate of arrhythmia identification.

MCOT

Mobile cardiac outpatient telemetry (MCOT) devices are worn continuously and have been produced with varying monitor configurations. They are capable of real-time streaming, transmitting a loop, or a single event electrogram directly to the reading center via a wireless link. Newest iterations can connect via Wi-Fi to transmit data.

The MCOT data are processed in a reading center on the back end of the monitoring system. The arrhythmic events are analyzed by trained technicians, and alarms are distributed to patient caregivers. Many MCOT devices are also equipped with real-time signal processing algorithms providing detection of cardiac arrhythmias.

ILR

The implantable loop recorder (ILR) is a patient-activated monitoring system that records ECG tracings and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia. The device is a programmable cardiac event recorder with looping memory and is implanted subcutaneously usually in a left pectoral or mammary location with a battery life of 15-36 months. The electrodes that sense the heart's activity are on the surface of the device, so no trans venous leads are required. This device allows continuously looping rhythm monitoring. Data are stored either when manually activated by a patient or automatically when high or low-rate parameters are met.

Early Repolarization Syndrome (ERS) High Risk Features ⁽⁹⁾

- Family history of unexplained SD < 40 years
- Family history of ERS
- High risk Early Repolarization Pattern (ERP)
 - J-waves > 2mm
 - Dynamic changes in J point and ST morphology

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AICD: automatic implanted cardioverter defibrillator

AUC: appropriate use score

AV: atrioventricular

BBB: bundle branch block

BrS: Brugada Syndrome

CHD: congenital heart disease

CRT: cardiac resynchronization therapy

CVA: cerebrovascular accident

d-TGA: dextro-Transposition of the Great Arteries

EASI: A modified set-up that can derive 12-lead ECG signals from only 5 ECG channels

ECG/EKG: electrocardiogram

ERP: early repolarization pattern

ERS: early repolarization syndrome

ICD: implantable cardioverter defibrillator

ILR: implantable loop recorder

LBBB: left bundle branch block

MCOT: mobile cardiac outpatient telemetry

MCT: mobile cardiac telemetry

MI: myocardial infarction

mm: millimeter

PAC: premature atria complexes

PPM: permanent pacemaker

PVC: premature ventricular complexes

QT: QT interval is section on EKG

s: seconds

SCD: sudden cardiac death

SD: sudden death

ST: ST segment on ECG
 STEMI: ST elevation myocardial infarction
 SQTS: Short QT Syndrome
 SVT: supraventricular tachycardia
 VT: ventricular tachycardia
 WPW: Wolfe-Parkinson-White

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM Cardio 1082 Cardio Policy Ambulatory EKG Monitoring ● This guideline replaces UM Cardio 1085 Cardio Policy Patient Activated Event Recorder ● This guideline replaces UM Cardio 1112 Cardio Policy Cardiac Telemetry ● This guideline replaces UM Cardio 1146 Cardio Policy Implantation of Loop Recorder Systems

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Steinberg J S, Varma N, Cygankiewicz I, Aziz P, Balsam P et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. *Heart rhythm*. 2017; 14: e55-e96. 10.1016/j.hrthm.2017.03.038.
7. Brignole M, Moya A, de Lange F J, Deharo J, Elliott P M et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *European heart journal*. 2018; 39: 1883-1948. 10.1093/eurheartj/ehy037.
8. Dilaveris P E, Antoniou C K, Caiani E G, Casado-Arroyo R, Climent A M et al. ESC Working Group on e-Cardiology Position Paper: accuracy and reliability of electrocardiogram monitoring in the detection of atrial fibrillation in cryptogenic stroke patients : In collaboration with the Council on Stroke, the European Heart Rhythm Association, and the Digital Health Committee. *European heart journal. Digital health*. 2022; 3: 341-358. 10.1093/ehjdh/ztac026.
9. Zeppenfeld K, Tfelt-Hansen J, de Riva M, Winkel B G, Behr E R et al. 2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *European heart journal*. 2022; 43: 3997-4126. 10.1093/eurheartj/ehac262.
10. Stout K K, Daniels C J, Aboulhosn J A, Bozkurt B, Broberg C S et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2019; 73: e81-e192. 10.1016/j.jacc.2018.08.1029.
11. Vilcant V, Kousa O , Hai O. Implantable Loop Recorder. [Updated 2023 Jul 24]. StatPearls Publishing [Internet]. 2023; Accessed: August 2024. <https://www.ncbi.nlm.nih.gov/books/NBK470398/>.
12. Hassani S, El Hussein N, Feng W, Lloyd M, Quyyumi A. A Patient-Centered Approach to Cardiac Monitoring After Cryptogenic Stroke: A Review. *Stroke: Vascular and Interventional Neurology*. 2024; 4: true. 10.1161/SVIN.123.001126.



Evolut Clinical Guideline 7253 for Ankle-Brachial Index in Peripheral Artery Disease

Guideline Number: Evolut_CG_7253	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for ankle-brachial index in lower extremity peripheral artery disease.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR ANKLE-BRACHIAL INDEX IN PERIPHERAL ARTERY DISEASE

Ankle Brachial Index (ABI) With or Without Pulse Volume Recording (PVR)

- History or physical exam findings (see **Background**) suggestive of peripheral artery disease (PAD) ⁽⁶⁾ **(AUC Score 9)** ⁽⁷⁾
- Known PAD ⁽⁷⁾:
 - New or worsening signs or symptoms
 - No prior revascularization:
 - Normal baseline study **(AUC Score 7)**
 - Abnormal baseline study **(AUC Score 8)**
 - After revascularization **(AUC Score 9)**

- Surveillance after revascularization (asymptomatic or stable signs/symptoms) ^(7,8):
 - Baseline (generally within 30 days post procedure) **(AUC Score 8)**
 - 3-, 6-, 9-, 12 and months post procedure and *annually* following vein bypass graft **(AUC Score 6-8)** with more frequent surveillance when:
 - Uncorrected abnormalities are detected
 - Vein conduit other than great saphenous vein was used
 - 6-, 9-, 12- months post procedure and then *every 6 months* following angioplasty/stent **(AUC Score 6-7)**
 - 6- and 12 months post procedure and *annually* following prosthetic bypass graft **(AUC Score 7)**

ABI Only

- Screening for lower extremity PAD ^(6,7,9) **(AUC Score 7)**
 - Patients at increased risk for PAD (see **Background**)

Exercise ABI ⁽⁶⁾

- Further evaluation of suspected chronic symptomatic PAD with normal or borderline resting ABI (see **Background**)
- PAD with abnormal resting ABI (see **Background**) to assess functional status and walking performance

CODING AND STANDARDS

Coding

CPT Codes

93922, 93923, 93924

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Ankle Brachial Index (ABI) ⁽⁶⁾

The Ankle Brachial Pressure Index, known more commonly as an ABI, is calculated by dividing the resting systolic blood pressure at the ankle by the systolic blood pressures in the arm and is expressed as a ratio.

- **ABI Reference Ranges:**
 - Abnormal: ≤ 0.90
 - Borderline: 0.91-0.99
 - Normal: 1.00-1.40
 - Noncompressible: > 1.40

Pulse Volume Recording (PVR) ⁽¹⁰⁾

PVR is a non-invasive method of evaluating the arterial pressure waveform profile. A strain gauge or plethysmograph is applied in a sequential manner from thigh to ankle to assess changes in limb volume between systole and diastole. Data obtained correlates with large vessel patency and blood flow.

Patients at Increased Risk for PAD ⁽⁶⁾

- Age ≥ 65 years old
- Age 50-64 years old, with risk factors for atherosclerosis (eg, diabetes, history of smoking, dyslipidemia, hypertension), chronic kidney disease, or family history of PAD
- Age < 50 years old, with diabetes and an additional risk factor for atherosclerosis
- Known atherosclerotic disease in another vascular bed (eg, coronary, carotid, subclavian, renal, mesenteric artery stenosis, or abdominal aortic aneurysm)

History and Physical Examination Findings Suggestive of PAD ⁽⁶⁾

- History
 - Typical claudication:
 - Pain type: aching, burning, cramping, discomfort, or fatigue
 - Location: buttock, thigh, calf, or ankle
 - Onset/offset: exertional, relief after rest (< 10 min for typical claudication)
 - Atypical claudication:
 - Other nonjoint-related exertional lower extremity symptoms or symptoms of impaired walking function
 - Lower extremity muscular discomfort associated with walking that requires > 10 min rest to resolve
 - Leg weakness, numbness, or fatigue during walking without pain
 - Ischemic rest pain
 - History of nonhealing or slow-healing lower extremity wound ≥ 2 -week duration
 - Erectile dysfunction

- Physical Examination
 - Abnormal lower extremity pulse palpation (femoral, popliteal, dorsalis pedis, or posterior tibial arteries)
 - Vascular bruit (eg, epigastric, periumbilical, groin)
 - Nonhealing lower extremity wound \geq 2-week duration
 - Lower extremity gangrene
 - Evidence of atheroemboli in the lower extremities
 - Other physical findings suggestive of ischemia (eg, asymmetric hair growth, nail bed changes, calf muscle atrophy, or elevation pallor/dependent rubor)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Guideline-Directed Medical Therapy ⁽¹¹⁾

Patients with peripheral artery disease (PAD) require a comprehensive program of guideline-directed management and medical therapy (GDMT) including:

- Pharmacotherapy
 - Pharmacological treatment for PAD typically includes antiplatelet and statin medication
- Structured exercise
- Lifestyle modifications
 - Risk factors such as diabetes mellitus and hypertension should be appropriately managed
 - Smoking cessation is also a crucial part of therapy for patients who are smokers

Acronyms/Abbreviations

ABI: Ankle-brachial index

PAD: Peripheral artery disease

PVR: Pulse volume recording

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline merges and replaces UM CARDIO_1077 Arterial PVR and Stress Arterial PVR and UM CARDIO_1078 Ankle Brachial Index ● Updated clinical indication and background sections ● Removed Limitation and Special Note sections

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Journal of the American College of Cardiology*. 2011; 58: 1517-38.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Gornik H L, Aronow H D, Goodney P P, Arya S, Brewster L P et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2024; 83: 2497 - 2604. 10.1016/j.jacc.2024.02.013.
7. Mohler 3rd E R, Gornik H L, Gerhard-Herman M, Misra S, Olin J W et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/ SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing - A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. *Journal of the American College of Cardiology*. 2012; 60: 242-76.
8. Zierler R E, Jordan W D, Lal B K, Mussa F, Leers S et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *Journal of vascular surgery*. 2018; 68: 256-284.
9. Nordanstig J, Behrendt C, Baumgartner I, Belch J, Bäck M et al. European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Asymptomatic Lower Limb Peripheral Arterial Disease and Intermittent Claudication. *European journal of vascular and endovascular surgery*. 2024; 67: 9-96.
10. Hirsch A, Haskal Z, Hertzner N, Bakal C, Creager M et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral. *Circulation*. 2006; 113: e463-654.
11. Gerhard-Herman M, Gornik H, Barrett C, Barshes N, Corriere M et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity. *Circulation*. 2017; 135: e686-e725.

Evolut Clinical Guideline 7254 for Coronary Artery Bypass Graft

Guideline Number: Evolut_CG_7254	<u>Applicable Codes</u>	
<p><i>"Evolut" refers to Evolut Health LLC and Evolut Specialty Services, Inc.</i> © 2011 - 2025 Evolut. All rights Reserved.</p>		
Original Date: April 2011	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Coronary Artery Bypass Graft.

Special Note

- To review for medical determination, the following items must be submitted for review
 - Cardiothoracic Surgeon and or Cardiologist Progress Note
 - Cardiac Catheterization report

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CABG

Stable Ischemic Heart Disease ^(6,7)

One-Vessel Disease

- Proximal LAD or LCX involvement
 - With ischemic symptoms on 1 antianginal drug
 - Intermediate or high-risk findings on non-invasive stress imaging **(AUC 7)**
 - With ischemic symptoms on ≥ 2 antianginal drugs

- Low-risk findings on non-invasive stress imaging (**AUC 7**)
- Intermediate or high-risk findings on non-invasive stress imaging (**AUC 8**)
- No stress test/indeterminate stress test results and $FFR \leq 0.80$ (**AUC 7**)

Two-Vessel Disease

- No proximal LAD involvement
 - With ischemic symptoms on ≥ 2 antianginal drugs
 - Intermediate or high-risk findings on non-invasive stress imaging (**AUC 7**)
 - No stress test/indeterminate stress test results and $FFR \leq 0.80$ in both vessels (**AUC 7**)
- Proximal LAD involvement
 - Asymptomatic
 - Intermediate or high-risk findings on non-invasive stress imaging with diabetes (**AUC 7**)
 - With ischemic symptoms without antianginal drugs
 - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (**AUC 7**)
 - No stress test/indeterminate stress test results and $FFR \leq 0.80$ in both vessels with diabetes (**AUC 7**)
 - With ischemic symptoms on 1 antianginal drug
 - Low-risk findings on non-invasive stress imaging with diabetes (**AUC 7**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC 7**) or with diabetes (**AUC 8**)
 - No stress test/indeterminate stress test results and $FFR \leq 0.80$ in both vessels without diabetes (**AUC 7**) or with diabetes (**AUC 8**)
 - With ischemic symptoms on ≥ 2 antianginal drugs
 - Low-risk findings on non-invasive stress imaging without diabetes (**AUC 7**) or with diabetes (**AUC 8**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC 8**) or with diabetes (**AUC 9**)
 - No stress test/indeterminate stress test results and $FFR \leq 0.80$ in both vessels with or without diabetes (**AUC 8**)

Three-vessel Disease (or more)

- Low disease complexity
 - Asymptomatic with or without antianginal drug
 - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (**AUC 7**)
 - Symptomatic without antianginal drug
 - Intermediate or high-risk findings on non-invasive stress imaging without

- diabetes (**AUC 7**) or with diabetes (**AUC 8**)
- Symptomatic on 1 antianginal drug
 - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (**AUC 8**)
 - Low-risk findings on non-invasive stress imaging with diabetes present (**AUC 7**)
- Symptomatic on ≥ 2 antianginal drugs
 - Low-risk findings on non-invasive stress imaging without diabetes present (**AUC 7**) or with diabetes present (**AUC 8**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC 8**) or with diabetes present (**AUC 9**)
- Intermediate or high disease complexity
 - Asymptomatic with or without antianginal drugs
 - Low-risk findings on non-invasive stress imaging with diabetes present (**AUC 7**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC 7**) or with diabetes (**AUC 8**)
 - Symptomatic without antianginal drugs
 - Low-risk findings on non-invasive stress imaging with or without diabetes present (**AUC 7**)
 - Intermediate or high-risk findings on non-invasive stress imaging without diabetes (**AUC 7**) or with diabetes (**AUC 8**)
 - Symptomatic on 1 antianginal drug
 - Low-risk findings on non-invasive stress imaging with diabetes present (**AUC 7**) or with diabetes present (**AUC 8**)
 - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (**AUC 8**)
 - Symptomatic on ≥ 2 antianginal drugs
 - Low-risk findings on non-invasive stress imaging without diabetes present (**AUC 8**) or with diabetes present (**AUC 9**)
 - Intermediate or high-risk findings on non-invasive stress imaging with or without diabetes (**AUC 9**)

Left Main Coronary Artery Stenosis

- Asymptomatic with or without antianginal drugs
 - With or without additional CAD, without multivessel involvement or with low disease burden in other vessels, with ostial, midshaft, or bifurcation involvement (**AUC 8**)
 - With bifurcation involvement and intermediate or high disease burden in other vessels (**AUC 8**)
 - With ostial or midshaft stenosis and intermediate or high disease burden in other

vessels **(AUC 9)**

- Symptomatic without antianginal drugs
 - With ostial, midshaft, or bifurcation involvement, without multivessel involvement or with low disease burden in other vessels **(AUC 8)**
 - With ostial, midshaft or bifurcation involvement, with low disease burden in LMCA and/or intermediate or high disease burden in other vessels **(AUC 9)**
- Symptomatic on ≥ 1 antianginal drug **(AUC 9)**

Prior IMA to LAD Graft that is not Patent

- Symptomatic without antianginal drugs or with 1 antianginal, stenoses affecting multiple territories, intermediate or high-risk findings **(AUC 7)**
- Symptomatic on ≥ 2 antianginal drugs, stenoses affecting multiple territories, intermediate or high-risk findings on non-invasive stress imaging **(AUC 8)** or stenoses affecting ≥ 3 territories and low-risk findings on non-invasive stress imaging **(AUC 7)**

NOTE: CABG can be considered as a concurrent procedure for patients with SIHD and AUC scores ≥ 7 undergoing other surgical procedures.

CODING AND STANDARDS

Coding

CPT Codes

33508, 33510, 33511, 33512, 33513, 33514, 33516, 33517, 33518, 33519, 33521, 33522, 33523, 33530, 33533, 33534, 33535, 33536

Place/Site of Service

Inpatient hospital (21)

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Coronary Artery Disease (CAD) is narrowing or blockage of the coronary arteries (blood vessels that carry blood and oxygen to the heart). Coronary artery disease is usually caused by atherosclerosis (a buildup of fatty material and plaque inside the coronary arteries) which may cause chest pain, shortness of breath during exercise, and heart attacks.

Ischemic symptoms, aka angina pectoris, include tightness, heaviness, pressure, squeezing, or other discomfort in the chest or adjacent areas. Ischemia may also present with fatigue, faintness, or dyspnea.

Non-invasive testing includes stress testing and imaging modalities with or without contrast.

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: coronary artery bypass graft

FFR: fractional flow reserve

GDMT: guideline directed medical therapy

IMA: Internal Mammary Artery

LAD: left anterior descending coronary artery

LCA: Left coronary artery

LCX: left circumflex coronary artery

LMCA: left main coronary artery

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This Guideline replaces UM Cardio 1096 Aorta Coronary Bypass Surgery ● Corrected typo under “Three-Vessel Disease” heading ● Edited “Three-Vessel Disease” to “Three-Vessel Disease (or more)”

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Lawton J S, Tamis-Holland J E, Bangalore S, Bates E R, Beckie T M et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145: e4-e17. 10.1161/CIR.0000000000001039.
7. Patel M R, Calhoun J H, Dehmer G J, Grantham J A, Maddox T M et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease. *Journal of nuclear cardiology*. 2017; 24: 1759-1792. 10.1007/s12350-017-0917-9.

Evolut Clinical Guideline 7255 for Aortic Valve Replacement

Guideline Number: Evolut_CG_7255	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Aortic Valve Replacement. Aortic valve replacement is a cardiac surgery in which a patient's failing aortic valve is replaced with an alternate healthy valve.

Special Note

- To review for medical determination, the following items must be submitted for review
 - Latest cardiology or cardiothoracic surgeon's progress note
 - Most recent echocardiogram or TEE
 - Cardiac catheterization report

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR AORTIC VALVE REPLACEMENT (AVR)

Asymptomatic ^(6,7,8)

- AVR is recommended for asymptomatic patients with severe aortic stenosis (AS) and left ventricular ejection fraction (LVEF) < 50% **(AUC Score 8)**

- AVR is reasonable for asymptomatic patients with very severe AS and low surgical risk (**AUC Score 8**)
- AVR is indicated for asymptomatic patients with chronic severe aortic regurgitation (AR) and LV systolic dysfunction (LVEF < 50%)
- AVR is reasonable for asymptomatic patients with severe AR with normal LV systolic function (LVEF < 50%) but with severe LV dilation (LVESD < 50 mm)

Symptomatic ^(6,7)

- AVR is recommended with severe high-gradient AS who have symptoms by history or on exercise testing
- AVR is reasonable in symptomatic patients with:
 - Low-flow/low-gradient severe AS with reduced LVEF **AND**
 - With a low dose Dobutamine stress study that shows an aortic velocity > 4.0 m/s (or mean pressure gradient > 40 mm Hg) **AND**
 - With a valve area > 1.0 cm² at any Dobutamine dose
- AVR is indicated for symptomatic patients with severe AR regardless of LV systolic function

During other Interventions ⁽⁶⁾

- AVR is indicated for patients with severe AR while undergoing cardiac surgery for other indications
- AVR is indicated for patients with severe AS when undergoing other cardiac surgery

Potential Exclusions

Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed.

CODING AND STANDARDS

Coding

CPT Codes

33405, 33406, 33410, 33411, 33412, 33530

Place/Site of Service

Inpatient hospital (21)

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

- **Dimensionless index or Velocity ratio (DI)** is expressed as a simple ratio of velocities (or velocity-time integrals) in left ventricular outflow track and across the valve. It can be used to measure the severity of aortic stenosis especially in prosthetic aortic valve and thereby avoiding use of LV outflow tract diameter which is a common source of error in calculating Aortic Valve area by continuity equation. DI is not influenced by conditions producing high flow across the valve. $DI < 0.25$ is severe aortic stenosis.
- **Severe aortic insufficiency** is defined as vena contracta $> 0.6\text{cm}$, holodiastolic flow reversal in descending aorta, regurgitation volume $\geq 60\text{ml/beat}$, effective orifice area $\geq 0.3\text{cm}^2$ on trans thoracic echocardiogram or 3+ grade on angiography with LV dilation.
- **Severe aortic stenosis** is defined as an aortic velocity $\geq 4.0\text{ m/s}$ and/or mean pressure gradient $\geq 40\text{ mm Hg}$ and/or valve area $\leq 1.0\text{ cm}^2$ and/or an indexed valve area $\leq 0.6\text{ cm}^2/\text{m}^2$ on trans thoracic echocardiogram or Dimensionless index < 0.25 on trans thoracic echocardiogram.
- **Very severe aortic stenosis** is defined as an aortic velocity $> 5\text{m/s}$ and/or mean pressure gradient $\geq 60\text{ mmHG}$ and/or valve area $< 0.6\text{ cm}^2$ and/or an indexed valve area $< 0.4\text{cm}^2/\text{m}^2$ or Dimensionless index < 0.20 .

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

- AUC: appropriate use criteria
- AR: aortic regurgitation
- AS: aortic stenosis
- AVR: aortic valve replacement
- cm: centimeter
- DI: dimensionless index
- LV: left ventricular
- LVEF: left ventricular ejection fraction
- LVESD: left ventricular end-systolic dimension
- m: meter
- mm: millimeter
- TEE: transesophageal echo

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1095 Cardio Policy Aortic Valve Replacement

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Isselbacher E M, Preventza O, Hamilton Black J 3, Augoustides J G, Beck A W et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease. *Circulation*. 2022; 146: e334-e482. 10.1161/CIR.0000000000001106.
7. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *European heart journal*. 2022; 43: 561-632. 10.1093/eurheartj/ehab395.
8. Bonow R O, Brown A S, Gillam L D, Kapadia S R, Kavinsky C J et al. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients with Severe Aortic Stenosis. *Journal of the American Society of Echocardiography*. 2018; 31: 117-147. 10.1016/j.echo.2017.10.020.

Evolut Clinical Guideline 7256 for Aorto-Renal Endarterectomy or Bypass Surgery

Guideline Number: Evolut_CG_7256	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Medical Necessity

In order to review a request for medical necessity, the following items must be submitted for review:

- Cardiologist/Nephrologist/Vascular Surgeon note that prompted request
- Renal Artery Duplex/Retroperitoneal Duplex/MRA Renal/CTA Renal/Renal Angiogram reports

Purpose

Indications for determining medical necessity for Aorto-Renal Endarterectomy or Bypass Surgery. Renal artery stenosis (RAS) is the narrowing of one or both renal arteries. Surgery may be recommended for people with RAS caused by fibromuscular dysplasia or RAS that does not improve with medication. In an endarterectomy, the plaque is cleaned out of the artery, leaving the inside lining smooth and clear. To create a bypass, a vein or synthetic tube is used to connect the kidney to the aorta.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR AORTO-RENAL ENDARTERECTOMY OR BYPASS SURGERY

NOTE: For patients who are not a candidate for percutaneous intervention (PI) ^(6,7)

- Patients with fibro-muscular dysplastic RAS with:
 - complex disease that extends into the segmental arteries **AND**
 - macro-aneurysms **AND**
- Patients with atherosclerotic RAS with multiple small renal arteries **OR** early primary branching of the main renal artery
- Patients with atherosclerotic RAS in combination with pararenal aortic reconstructions (in treatment of aortic aneurysms or severe aortoiliac occlusive disease).

Potential Exclusions

- Advanced disease - Creatinine level > 3-4 mg/dL; kidney length < 8 cm
- Limited life expectancy
- Bleeding diathesis; recent myocardial infarction (MI)
- Pregnancy
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

CODING AND STANDARDS

Coding

CPT Codes

35560

Applicable Lines of Business

☒	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

MI: myocardial infarction

PI: percutaneous intervention

RAS: renal artery stenosis

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM 1268 Aorto-Renal Endarterectomy or Bypass Surgery
March 2024	<ul style="list-style-type: none"> • Updated references • Updated AUC scores • Added Clinical Reasoning for AUC scores

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Aboyans V, Ricco J, Bartelink M, Björck M, Brodmann M et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS): Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries Endorsed by: the European Stroke Organization (ESO) The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). *Eur Heart J*. 2018; 39: 763 - 816. 10.1093/eurheartj/ehx095.
7. Anderson J, Halperin J, Albert N, Bozkurt B, Brindis R et al. Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations): A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*. 2013; 61: 1555 - 1570. <https://doi.org/10.1016/j.jacc.2013.01.004>.



Evolut Clinical Guideline 7257 for Arterial Duplex in Peripheral Artery Disease

Guideline Number: Evolut_CG_7257	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for arterial duplex of the extremities. Duplex ultrasound imaging of the major arteries in the extremities is for assessing any abnormalities in the blood flow.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR ARTERIAL DUPLEX OF EXTREMITIES

Lower Extremity PAD ^(6,7,8,9)

- Suspected acute limb ischemia (i.e., pale, pulseless, cold, painful limb) **(AUC Score 9)** ⁽⁸⁾
- History or physical exam findings (see **Background**) suggestive of peripheral artery disease (PAD) **(AUC Score 9)** ⁽⁷⁾
- Known PAD ⁽⁸⁾:
 - New or worsening signs or symptoms
 - No prior revascularization:
 - Normal baseline study **(AUC Score 7)**

- Abnormal baseline study **(AUC Score 8)**
 - After revascularization **(AUC Score 9)**
- Functionally limiting claudication with inadequate response to GDMT when revascularization is being considered ⁽⁷⁾
- Annual surveillance of known PAD on GDMT (stable signs/symptoms) ⁽⁷⁾
- Chronic limb threatening ischemia (CLTI) to assist in revascularization strategy ⁽⁷⁾
 - Includes evaluation of great saphenous vein for use as bypass conduit
- Suspected PAD with inconclusive resting ABI and physiological testing (including exercise ABI) ⁽⁷⁾
- Palpable popliteal mass to exclude popliteal aneurysm ⁽⁶⁾
- Femoral or popliteal aneurysms to exclude contralateral femoral or popliteal aneurysms ⁽⁶⁾
- Suspected femoral artery pseudoaneurysm following a catheter-related procedure ⁽⁸⁾:
 - Initial evaluation:
 - Pulsatile groin mass **(AUC Score 9)**
 - Bruit or thrill over groin **(AUC Score 8)**
 - Significant hematoma **(AUC Score 7)**
 - Severe pain within groin post procedure **(AUC Score 7)**
 - Follow-up examination 1 month after the original injury for asymptomatic femoral artery pseudoaneurysm
- Surveillance after revascularization (asymptomatic or stable signs/symptoms) ^(8,9):
 - Baseline (generally within 30 days post procedure) **(AUC Score 8)**
 - 3-, 6-, 9-, 12 and months post procedure and *annually* following vein bypass graft **(AUC Score 6-8)** with more frequent surveillance when:
 - Uncorrected abnormalities are detected
 - Vein conduit other than great saphenous vein was used
 - 6-, 9-, 12- months post procedure and then *every 6 months* following angioplasty/stent **(AUC Score 6-7)**
 - 6- and 12 months post procedure and *annually* following prosthetic bypass graft **(AUC Score 7)**
- Aneurysm surveillance ⁽⁶⁾:
 - Annual follow-up asymptomatic femoral artery true aneurysm
 - Annual follow-up asymptomatic popliteal artery aneurysm

Upper Extremity PAD ⁽⁸⁾

- Arm or hand claudication **(AUC Score 8)**
- Finger discoloration or ulcer **(AUC Score 8)**
- Unilateral cold painful hand **(AUC Score 8)**

- Raynaud's phenomenon (**AUC Score 5**)
- Suspected positional arterial obstruction (e.g., thoracic outlet syndrome) (**AUC Score 7**)
- Upper extremity trauma with suspicion of vascular injury (**AUC Score 8**)
- Discrepancy in arm pulses or blood pressure discrepancy of > 20 mm Hg between arms (**AUC Score 6**)
- Peri-clavicular bruit (**AUC Score 5**)
- Pre-op radial artery harvest (e.g., for CABG) (**AUC Score 7**)
- Presence of pulsatile mass or hand ischemia after upper extremity vascular access (**AUC Score 8**)
- Presence of bruit after upper extremity access for intervention (**AUC Score 8**)
- Post revascularization:
 - Baseline within 30 days (**AUC Score 8**)
 - New or worsening symptoms
 - Following stent or bypass (**AUC Score 8**)
 - Post trauma (**AUC Score 8**)
 - Surveillance (asymptomatic or stable signs/symptoms)
 - After 6 months, then annually following vein bypass graft (**AUC Score 7**)
 - After 6 months (**AUC Score 6**), then annually (**AUC Score 7**) after prosthetic bypass graft

CODING AND STANDARDS

Coding

CPT Codes

- 93925: Bilateral lower extremity
- 93926: Unilateral lower extremity
- 93930: Bilateral upper extremity
- 93931: Unilateral upper extremity

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

History and Physical Examination Findings Suggestive of PAD (7)

- **History**
 - Typical claudication:
 - Pain type: aching, burning, cramping, discomfort, or fatigue
 - Location: buttock, thigh, calf, or ankle
 - Onset/offset: exertional, relief after rest (< 10 min for typical claudication)
 - Atypical claudication:
 - Other nonjoint-related exertional lower extremity symptoms or symptoms of impaired walking function
 - Lower extremity muscular discomfort associated with walking that requires > 10 min rest to resolve
 - Leg weakness, numbness, or fatigue during walking without pain
 - Ischemic rest pain
 - History of nonhealing or slow-healing lower extremity wound ≥ 2-week duration
 - Erectile dysfunction
- **Physical Examination**
 - Abnormal lower extremity pulse palpation (femoral, popliteal, dorsalis pedis, or posterior tibial arteries)
 - Vascular bruit (e.g., epigastric, periumbilical, groin)
 - Nonhealing lower extremity wound ≥ 2-week duration
 - Lower extremity gangrene
 - Evidence of atheroemboli in the lower extremities
 - Other physical findings suggestive of ischemia (e.g., asymmetric hair growth, nail bed changes, calf muscle atrophy, or elevation pallor/dependent rubor)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Guideline-Directed Medical Therapy ⁽¹⁰⁾

Patients with peripheral artery disease (PAD) require a comprehensive program of guideline-directed management and medical therapy (GDMT) including:

- Pharmacotherapy
 - Pharmacological treatment for PAD typically includes antiplatelet and statin medication
- Structured exercise
- Lifestyle modifications
 - Risk factors such as diabetes mellitus and hypertension should be appropriately managed
 - Smoking cessation is also a crucial part of therapy for patients who are smokers

Acronyms/Abbreviations

ABI: Ankle brachial index

ALI: Acute limb ischemia

CKD: Chronic kidney disease

CLTI: Chronic limb-threatening ischemia

GDMT: Guideline-directed medical therapy

PAD: Peripheral artery disease

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1076 Arterial Duplex ● Updated clinical indication and background sections ● Removed Limitation and Special Note sections

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Anderson J, Halperin J, Albert N, Bozkurt B, Brindis R et al. Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations): A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*. 2013; 61: 1555 - 1570. 10.1016/j.jacc.2013.01.004.
7. Gornik H, Aronow H, Goodney P, Arya S, Brewster L et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2024; 83: 2497 - 2604. 10.1016/j.jacc.2024.02.013.
8. Mohler E R 3, Gornik H L, Gerhard-Herman M, Misra S, Olin J W et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/ SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing - A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. *Journal of the American College of Cardiology*. 2012; 60: 242-76.
9. Zierler R E, Jordan W D, Lal B K, Mussa F, Leers S et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *Journal of vascular surgery*. 2018; 68: 256-284.
10. Gerhard-Herman M, Gornik H, Barrett C, Barshes N, Corriere M et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity. *Circulation*. 2017; 135: e726-e779.

Evolut Clinical Guideline 7259 for Aortic Root, Ascending Aorta and Aortic Arch Surgery

Guideline Number: Evolut_CG_7259	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Ascending Aortic Open or Endovascular Surgery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

Although there may be guidelines on whether open, endovascular or hybrid procedures should be used, surgeon experience and preference is also important. Accordingly, prior authorization will not be dependent on the type of procedure requested.

For *elective* procedures notes must demonstrate that the member has been involved in a shared decision-making process involving the provider as well as relevant physicians to determine the optimal medical, endovascular, and open surgical therapies. This process should be reflected in notes provided. It is understood that those indications listed below with a “*” may be appropriate if the procedure is performed by an experienced surgeon in a multidisciplinary aortic team.

INDICATIONS ⁽⁶⁾

Aortic Root and Ascending Thoracic Aneurysm

Procedures for ruptured aneurysms will be approved irrespective of etiology.

- Requests for concomitant subclavian, innominate, or carotid artery bypass should be approved as well as CPT codes referencing Access sites, or adjunctive endovascular procedures
- Sporadic Aneurysms:
 - ≥ 5.5 cm
 - < 5.5 cm with growth rate of ≥ 0.3 cm/y in 2 consecutive years or ≥ 0.5 cm in one year
 - ≥ 5.0 cm
 - ≥ 5.0 cm undergoing repair or replacement of a tricuspid aortic valve
 - ≥ 4.5 cm undergoing repair or replacement of an aortic bicuspid valve.
 - ≥ 5.0 cm concomitant with cardiac surgery for indications other than aortic valve repair or replacement
 - *In patients with a height more than 1 standard deviation above or below the mean who have an asymptomatic aneurysm of the aortic root or ascending aorta and a maximal cross-sectional aortic area/height ratio of ≥ 10 cm²/m.
 - *In patients who have either an aortic size index of ≥ 3.08 cm/m² or an aortic height index of ≥ 3.21 cm/m².
- Nonsyndromic Aneurysm and no identifiable genetic cause
 - Timing and size are informed by known aortic diameters at the time of aortic dissection, thoracic aortic aneurysm repair, or both in affected family members
 - ≥ 5.0 cm when there is no information on aortic diameters at the time of dissection or aneurysm repair in affected family members, and there are no high-risk features for adverse aortic events
 - ≥ 4.5 cm, no identical genetic cause, high risk aortic events, or who are undergoing cardiac surgery for other indications provided aortic repair
- Syndromic HTAD
 - Marfan Syndrome
 - ≥ 5.0 cm
 - ≥ 4.5 cm with increased risk of dissection.
 - *In patients with an aortic root area (cm²) to patient height (m) ratio of ≥ 10 .
 - < 5 cm but who are candidates for valve sparing root replacement and have a very low surgical risk.
- Loeys-Dietz, Ehlers-Danlos, Turner Syndromes and Other Genetic Variants
 - The surgical threshold for prophylactic replacement should be informed by the specific genetic variant, aortic diameter, aortic growth rate, extra aortic features, family history, patient age and sex, patient and physician's preference and experience, and must be discussed fully in the notes provided.

Thoracic Arch Aneurysms

ANY of the following:

- ≥ 5.5 cm asymptomatic with low operative risk

- Symptoms attributable to the aneurysm and the member is at low or intermediate operative risk
- Concurrent with an ascending aortic aneurysm repair
- Concurrent with an elephant trunk procedure or replacement of the descending thoracic aorta

Acute Aortic Syndromes

Type A Aortic Dissection, Intramural Hematoma (IMH) and Penetrating Aortic Ulcer (PAU)

- Open surgical repair, Endovascular, or Hybrid Aortic Repair should be approved for hyperacute or acute pathology unresponsive to supportive medical therapy and is not dependent on any variable.
- Procedures will be approved if a member is readmitted with new symptoms or evolving limb, organ or life-saving complications.
- If surgery is not performed and aneurysm results, treatment of the aneurysm will follow the guidelines for Aneurysms listed above

Blunt Traumatic Thoracic Aortic Injury (BTTAI)

- Open surgical repair, Endovascular, or Hybrid Aortic Repair should be approved for Grade 3 to 4 BTTAI and is not dependent on any variable.
- Grade 2 BTTAI with ANY high-risk imaging features:
 - Posterior mediastinal hematoma more >10 mm
 - Lesion to normal aortic diameter ratio more >1.4
 - Mediastinal hematoma causing mass-effect
 - Pseudocoarctation of the aorta
 - Large left hemothorax
 - Ascending aortic, aortic arch, or great vessel involvement
 - Aortic arch hematoma

Other Conditions

- Takayasu and Giant cell Aortitis
 - Patients in remission with aortic and branch vessel complications e.g. TIA, stroke, limb ischemia
- Surgery to remove and/or replace infected aorta or aortic grafts
- Surgery to treat aortic tumors
- Bicuspid Aortic Valve

CODING AND STANDARDS

Coding

CPT Codes

33530, 33858, 33859, 33863, 33864, 33866

Applicable Lines of Business

☒	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Dilation of the ascending aorta (Thoracic Aortic Aneurysms (TAA)) is often detected during other cardiovascular imaging. Ascending aortic graft surgery is an excision and surgical replacement of the most proximal portion of the diseased thoracic aorta with a graft.

Definitions

- Acute is 1-14 days since onset of symptoms whereas Hyperacute is >24 hours since onset of symptoms.
- **Endograft** is a preconstructed graft that is inserted via a remote access site. There are commercial variants where the manufacturers' Instructions For Use (IFU) should be followed. There are surgeon modified grafts but these should only be used in institutions where the graft has been approved by an Institutional Review Board (IRB) or in a Government approved clinical trial.
- **Favorable anatomy for TEVAR** is anatomy that is consistent with the Instructions for Use (IFU) of the endograft that will be inserted.
- **Heritable Thoracic Aortic Disease (HTAD)** is an aortic condition related to a genetic or heritable condition some of which associated with multisystem features (considered syndromic HTAD) or others with abnormalities limited to the aorta with or without its branches (known as nonsyndromic HTAD). Examples include Marfan, Loeys-Dietz, Turner and Ehlers-Danlos syndromes, Familial Thoracic aortic aneurysms, and possibly bicuspid aortic valve.
- **High risk** is a member who has significant comorbidities increasing the risk of death, renal failure, stroke, or spinal ischemia and paraplegia.
- **Low risk** is a member who does not have significant comorbidities.

- **Intramural hematoma** in the wall of the artery without an identifiable communication between the true and false lumens. It is characterized by hyperdense, crescent-shaped hemorrhage within they wall best seen on non-contrast enhanced computed tomography.
- **Penetrating aortic ulcer (PAU)** is an atherosclerotic lesion that penetrates the internal elastic lamina of the aortic wall. It was also referred to as ulcer-like projections. It is often associated with IMH.
- **Unfavorable anatomy for TEVAR** is anatomy that would not be suitable for the IFU of any commercially available endograft.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate Use Criteria

BTTA: Blunt Traumatic Thoracic Aortic Injury

CPT: Current Procedural Terminology

CTA: Computed Tomographic Angiography

IMH: Intramural Hematoma

MRA: Magnetic Resonance Angiography

PAU: Penetrating Aortic Ulcer

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1097 for Ascending Aortic Graft Surgery <ul style="list-style-type: none"> ○ Guideline name was changed to Aortic Root, Ascending Aorta and Aortic Arch Surgery ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Isselbacher E M, Preventza O, Hamilton Black J, Augoustides J G, Beck A W et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 146: e334-e482. 10.1161/CIR.0000000000001106.



Evolut Clinical Guideline 7260 for Automated Ambulatory Blood Pressure Monitoring

Guideline Number: Evolut_CG_7260	<u>Applicable Codes</u>	
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Original Date: November 2014	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Automated Ambulatory Blood Pressure Monitoring.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR AUTOMATED AMBULATORY BLOOD PRESSURE MONITORING ⁽⁶⁾

- Suspected white-coat hypertension:
 - Grade I hypertension (SBP is 140-159 mmHg and/or DBP is 90-99 mmHg) on office BP (blood pressure) measurement
 - Marked office BP elevation without HMOD (hypertension-mediated organ damage)
 - 130 mmHg < untreated SBP < 160 mmHg or 80 mmHg < untreated DBP < 100 mmHg ⁽⁷⁾
- Suspected masked hypertension:
 - High-normal office BP
 - Normal office BP in individuals with HMOD or at high total CV (cardiovascular) risk

- Untreated office BPs consistently between 120 mmHg and 129 mmHg for SBP or between 75 mmHg and 79 mmHg for DBP ⁽⁷⁾
- In treated individuals:
 - Confirmation of uncontrolled and true resistant hypertension (defined as SBP is \geq 140 mmHg or DBP is \geq 90 mmHg despite being on maximally GDMT with various causes of pseudo-resistant hypertension and secondary hypertension excluded)
 - Evaluation of 24-hour BP control (especially in high-risk patients)
 - Evaluating symptoms indicating hypotension (especially in older patients)
 - Suspected postural or postprandial hypotension
- Exaggerated BP response to exercise
- Considerable variability in office BP measurements
- Assessment of nocturnal BP and dipping status (e.g. sleep apnea, CKD, diabetes, endocrine hypertension, or autonomic dysfunction). Repeating ABPM is necessary for reproducibility
- Patients incapable or unwilling to perform reliable HBPM (Home BP monitoring), or anxious with self-measurement
- Pregnancy
- As periodic monitoring for confirmation of white-coat hypertension or masked hypertension in untreated or treated individuals to timely identify sustained hypertension or new HMOD
- As periodical follow-up for HMOD assessment in patients with true resistant hypertension to monitor kidney function and serum potassium levels

Note: The recommended time interval between measurements should be 20 minutes during day and night to minimize the risk of missing day or night periods. ⁽⁶⁾

CODING AND STANDARDS

Coding

CPT Codes

- 93784: Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report.
- 93786: Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; recording only.
- 93788: Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; scanning analysis with report.
- 93790: Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; review with interpretation and report

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Ambulatory blood pressure monitoring (ABPM) involves the use of a non-invasive device which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by the physician.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABPM: Ambulatory blood pressure monitoring

CKD: Chronic kidney disease

DBP: Diastolic blood pressure

GDMT: Guideline-directed medical therapy

HBPM: Home blood pressure monitoring

HMOD: Hypertension-mediated organ damage

SBP: Systolic blood pressure

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1336 Automated Ambulatory Blood Pressure Monitoring ● Updated indications for Automated Ambulatory Blood Pressure Monitoring ● Removed Special Note and Limitation sections ● Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Journal of the American College of Cardiology*. 2011; 58: 1517-38.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Mancia G, Kreutz R, Brunström M, Burnier M, Grassi G et al. 2023 ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the International Society of Hypertension (ISH) and the European Renal Association (ERA). *Journal of hypertension*. 2023; 41: 1874-2071.
7. Whelton P K, Carey R M, Aronow W S, Casey D E, Collins K J et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2018; 71: e127 - e248. 10.1016/j.jacc.2017.11.006.



Evolut Clinical Guideline 7261 for Device (AICD, CRT and/or Pacemaker) Battery Replacement

Guideline Number: Evolut_CG_7261	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for device (AICD, CRT, and/or Pacemaker) battery replacement.

Special Note

- To review a request for medical necessity, the following items must be submitted for review
 - Progress note that prompted request
 - Device analysis data that triggered battery replacement
 - Most recent Echocardiogram (for primary prevention ICDs)

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Battery Replacement

- Recent interrogation shows battery voltage in elective replacement indicator range or end of life indicator range (may differ by device type and manufacturer)

Lead Replacement

- Lead repositioning/replacement/removal may be performed when there is evidence of lead malfunctioning on recent interrogation or if a lead recall has been issued

Device Relocation

- Repositioning/relocation of the skin pocket for the device may be performed in the presence of infection, the development of overlying skin erosion/tissue necrosis, if any other anatomical factor prevents the device from properly functioning, or if device migration has resulted in significant patient discomfort

CODING AND STANDARDS

Coding

CPT Codes

33210, 33211, 33214, 33215, 33216, 33217, 33218, 33220, 33222, 33223, 33227, 33228, 33229, 33233, 33234, 33235, 33236, 33237, 33238, 33241, 33244, 33262, 33263, 33264, 93640, 93641

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

The automatic implantable cardioverter defibrillator (AICD) is an electronic device designed to detect and treat life-threatening tachyarrhythmias or brady arrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing, and defibrillation. Subcutaneous ICDs do not include transvenous leads and cannot provide pacing for bradycardia.

The AICD is checked periodically, amongst other parameters, for battery voltage. Once its longevity reaches the effective replacement indicator (ERI) or once it has reached end of life (EOL) the defibrillator will generate an alert for replacement.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AICD: automatic internal cardiac defibrillator

AUC: appropriate use criteria

CRT: cardiac resynchronization therapy

EOL: end of life

ERI: effective replacement indicator

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1144 Automatic Implantable Cardioverter Defibrillator Battery Replacement • This guideline replaces UM Cardio 1145 Pacemaker Battery Replacement

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required



by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.

Evolut Clinical Guideline 7262 for Diagnostic Electrophysiologic Testing

Guideline Number: Evolut_CG_7262	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

For the performance of diagnostic electrophysiologic testing in patients with symptoms suspected to be caused by disturbances in the conduction or maintenance of cardiac rhythm.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR DIAGNOSTIC ELECTROPHYSIOLOGIC TESTING ^(6,7)

Sustained Narrow Complex Tachycardia

- To establish the mechanism of the rhythm when ablation is planned, including patients with preexcitation syndromes (WPW)

Frequent Ventricular Extrasystoles, Couplets, and Nonsustained VT ^(8,9)

- Patients with other risk factors for future arrhythmic events, such as a low LVEF, positive signal-averaged ECG, and non-sustained VT on ambulatory ECG recordings in whom EPS will be used for further risk assessment and for guiding therapy in patients with inducible VT

- Patients with highly symptomatic, monomorphic premature ventricular complexes (PVCs), couplets, and NSVT who are considered as potential candidates for catheter ablation
- In patients with a prior MI, LVEF < 40%, and nonsustained VT, performance of an EPS with programmed ventricular stimulation is indicated for selecting suitable candidates for ICD implantation

Sustained Ventricular Tachycardia ⁽⁸⁾

Structurally normal hearts

- Sustained monomorphic ventricular tachycardia in patients with structurally normal hearts:
 - Before catheter ablation, an EPS should be offered to symptomatic patients with documented sustained monomorphic ventricular tachycardia

Structurally abnormal hearts

- Sustained monomorphic ventricular tachycardia in patients with structurally abnormal hearts:
 - EPS should be performed preceding catheter ablation in patients with monomorphic sustained VT in candidates suitable for catheter ablation, typically in the same procedure
 - EPS is indicated in patients with wide QRS complex tachycardia in whom correct diagnosis is unclear after analysis of available ECG tracings, when knowledge of the correct diagnosis is required for patient care
 - EPS with standby catheter ablation should be considered in patients who develop VT following valvular surgery to identify and cure potential bundle branch re-entry VT
 - After catheter or surgical ablation of ventricular tachycardia, in patients with implantable defibrillators (ICD), programmed extra stimulation to assess the inducibility of clinically significant VT may be performed using the ICD when clinically indicated

After Surgical VT Ablation ⁽⁹⁾

- EPS may be performed in patients who have undergone surgical ablation of ventricular tachycardia, to determine inducibility of ventricular tachycardia and risk stratification for ICD implantation

Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) ⁽⁸⁾

- In patients with ARVC and documented sustained and hemodynamically well-tolerated ventricular tachycardia, EPS may be performed if ablation of the arrhythmia is planned. (Hemodynamically poorly tolerated VT in this entity is an indication for ICD, and EPS should not be done)
- EPS may be performed in patients with ARVC and symptoms suggestive of malignant arrhythmia (palpitations and syncope) or NSVT when no documentation of

sustained monomorphic VT exists.

NOTE: EPS is not indicated in **asymptomatic** patients with AVRC without documented sustained VT, due to the poor predictive value of programmed extrastimulation in these patients.

NOTE: Diagnostic EPS has no place in the evaluation of patients with documented **polymorphic ventricular tachycardia (PMVT)**. Similarly, EPS is not indicated in the evaluation of patients with Catecholaminergic Polymorphic Ventricular Tachycardia, although it may be considered for the ablation of the PVCs that initiate PMVT

Syncope⁽¹⁰⁾

- EPS is indicated for the evaluation of syncope when noninvasive testing has been unrevealing; relevant clinical scenarios include:
 - Syncope with suspected sinus node dysfunction
 - Patients with syncope and left bundle branch block or bifascicular block (right bundle branch block and left anterior fascicular or left posterior fascicular block)
 - Patients with syncope and ischemic or other structural heart disease in which ventricular tachycardia is a potential cause for symptoms
 - Syncope in patients employed in high-risk occupations (airline pilots, bus drivers, police, firefighters, etc.)
 - Syncope immediately preceded by palpitations
 - Syncope or resuscitated sudden death in patients with preexcitation pattern on the ECG (Wolf Parkison White (WPW))
 - Unexplained syncope

Conduction Disturbances^(11,12,13)

EPS is indicated for:

- Symptomatic Type 2 AV block, to determine the site of block. (since permanent pacemaker implantation is indicated for block in or below the bundle of His)
- Adult patients with myotonic muscular dystrophy, even in the absence of surface ECG abnormalities, to identify patients with a prolonged HV interval (>70 msec) in whom permanent pacemaker implantation should be considered
- Risk stratification of asymptomatic preexcitation (WPW pattern on ECG) to determine the refractory period of the accessory pathway and/or the shortest pre-excited R-R interval in atrial fibrillation
- Ventricular programmed extrastimulation may be performed in patients with cardiac sarcoidosis with a LVEF >35%, for risk stratification and consideration of ICD therapy

Coronary Artery Disease

- EPS is indicated in patients with CAD with remote MI with symptoms suggestive of ventricular tachyarrhythmias, including palpitations, presyncope, and syncope
- EPS may be performed in patients with ischemic cardiomyopathy with LVEF 35-40% and non-sustained ventricular tachycardia (since inducible VT/VF is Class 1 indication for ICD)

Wide Complex Tachycardia

- EPS is indicated in evaluation of wide complex tachycardias, including left bundle branch block, to establish the mechanism of the rhythm disturbance and to aid in determining correct management (i.e., to exclude pre-excited tachycardia in WPW or Mahaim-related tachycardia mimicking ventricular tachycardia), and to determine eligibility for catheter ablation or ICD implantation

Congenital Heart Disease ⁽¹²⁾

- EPS is indicated in adults with congenital heart disease and life-threatening arrhythmias or resuscitated sudden cardiac death, when the cause for the event is unknown or there is potential for therapeutic intervention (ablation) at the time of the electrophysiological procedure
- EPS may be performed in patients with congenital heart disease with unexplained syncope with impaired ventricular function (LVEF <50%). In these patients, in the absence of a defined and reversible cause, ICD implantation is considered reasonable.
- EPS may be used for risk stratification in adults with Tetralogy of Fallot (TOF) **who have additional risk factors** for sudden cardiac death, defined as left ventricular systolic or diastolic dysfunction, nonsustained VT, QRS duration of ≥180 msec, and extensive right ventricular scarring.

Note: EPS/programmed extrastimulation is **not indicated** in the evaluation of Long QT Syndromes, Short QT Syndromes, or Early Repolarization. Studies of EPS in Brugada Syndrome have demonstrated poor correlation between inducibility and prognosis, and EPS is not recommended

In survivors of cardiac arrest not due to a reversible cause, ICD implantation without prior performance of an EPS is appropriate, with rare exceptions.

CODING AND STANDARDS

Coding

CPT Codes

93619, 93620, 93642, 93644

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Invasive Cardiac Electrophysiology Studies (EPS) involve the use of multielectrode catheters introduced into the cardiac chambers, and typically positioned in the right atrium, right ventricle, region of the A-V Node and the Bundle of His, and frequently the coronary sinus.

Several vascular access sites are typically needed, and may include the femoral vein(s), jugular vein(s), subclavian vein(s) and the brachial vein(s). Under certain circumstances, access to the left heart may require either transseptal puncture or a retrograde approach via the femoral artery across the aortic valve. In these cases, systemic anticoagulation is mandated.

After initial recordings of baseline electrograms from the catheters, programmed extrastimulation of the various cardiac chambers may be undertaken to study conduction characteristics, physiology of the conduction system, and in an attempt inducibility of clinically relevant tachydysrhythmias. Provocation with drugs that affect electrical conduction, including atropine, isoproterenol, and adenosine, is commonly utilized to enhance the inducibility of abnormal heart rhythms.

EPS is typically performed in conjunction with catheter ablation of previously documented tachydysrhythmias, to confirm the mechanism of the rhythm disturbance and to facilitate its induction, which is required to identify the critical site(s) for ablation.

Definitions

Sustained Tachycardia: tachycardia lasting 20 seconds or longer, or requiring cardioversion because of hemodynamic collapse

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ARVC: arrhythmogenic right ventricular cardiomyopathy

A-V Node: atrioventricular node

AUC: appropriate use criteria

CAD: Coronary Artery Disease

ECG: electrocardiogram

EPS: Electrophysiology studies

ICD: implantable Cardioverter-Defibrillator

LVEF: Left ventricular ejection fraction

MI: Myocardial Infarction

NSVT: non-sustained ventricular tachycardia

PMVT: polymorphic ventricular tachycardia

PVC: premature ventricular complexes

QRSd: Duration of the QRS complex

TOF: Tetralogy of Fallot

VT: Ventricular tachycardia

VF: Ventricular fibrillation

WPW: Wolff-Parkinson-White

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces Evolent Utilization Management Cardio Policy 1101: Cardiac Electrophysiology Study without Arrhythmia Induction • This guideline replaces Evolent Utilization Management Cardio Policy 1139: Cardiac Electrophysiology Study with Arrhythmia Induction • This guideline replaces Evolent Utilization Management Cardio Policy 1143: Non-Invasive Programmed Stimulation of AICD

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Muresan L, Cismaru G, Martins R P, Bataglia A, Rosu R et al. Recommendations for the use of electrophysiological study: Update 2018. *Hellenic journal of cardiology*. 2019; 60: 82-100.
7. Page R L, Joglar J A, Caldwell M A, Calkins H, Conti J B et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia. *Circulation*. 2016; 133: e471-505. 10.1161/CIR.0000000000000310.
8. Al-Khatib S M, Stevenson W G, Ackerman M J, Bryant W J, Callans D J et al. 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Journal of the American College of Cardiology*. 2018; 72: e91-e220. 10.1016/j.jacc.2017.10.054.
9. Frankel D S, Mountantonakis S E, Zado E S, Anter E, Bala R et al. Noninvasive Programmed Ventricular Stimulation Early After Ventricular Tachycardia Ablation to Predict Risk of Late Recurrence. *Journal of the American College of Cardiology*. 2012; 59: 1529 - 1535. <https://doi.org/10.1016/j.jacc.2012.01.026>.
10. Brignole M, Moya A, de Lange F J, Deharo J, Elliott P M et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *European heart journal*. 2018; 39: 1883-1948. 10.1093/eurheartj/ehy037.
11. Dhingra R C, Wyndham C, Bauernfeind R, Swiryn S, Deedwania P C et al. Significance of block distal to the His bundle induced by atrial pacing in patients with chronic bifascicular block. *Circulation*. 1979; 60: 1455-64. 10.1161/01.cir.60.7.1455.
12. Khairy P, Van Hare G F, Balaji S, Berul C I, Cecchin F et al. PACES/HRS Expert Consensus Statement on the Recognition and Management of Arrhythmias in Adult Congenital Heart Disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). *Heart rhythm*. 2014; 11: e102-65. 10.1016/j.hrthm.2014.05.009.
13. Kusumoto F M, Schoenfeld M H, Barrett C, Edgerton J R, Ellenbogen K A et al. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay. *Circulation*. 2019; 140: e382 - e482. 10.1161/CIR.0000000000000628.

Evolut Clinical Guideline 7263-01 for Cardiac Resynchronization Therapy

Guideline Number: Evolut_CG_7263-01	<u>Applicable Codes</u>	
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Original Date: February 2013	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

This guideline describes the medical necessity for cardiac resynchronization therapy (CRT). Indications for CRT for patients are based upon left ventricular (LV) ejection fraction (LVEF), QRS duration, New York Heart Association (NYHA) functional class (presence or absence of symptoms) and need for ventricular pacing regardless of etiology (ischemic or non-ischemic cardiomyopathy).^(1,2,3)

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care.^(4,5,6,7,8)

INDICATIONS FOR CARDIOMYOPATHY

NOTE: The following indications only apply to patients:

- Who have been on GDMT for 3 months or
- Who have been on GDMT and are 40 days after MI, or
- With implantation of pacing or defibrillation device for special indications (class indicates NYHA functional class)

Class I Through Class IV (1,2,9)

- Ischemic cardiomyopathy, LVEF \leq 30%, QRS \geq 150, LBBB, Sinus Rhythm (**AUC 7-9**)

Class II Through Class IV (1,2,9)

- Ischemic and non-ischemic cardiomyopathy, LVEF \leq 35%, QRS \geq 120ms, LBBB, Sinus Rhythm (**AUC 7-9**)
- Nonobstructive HCM, LVEF $<$ 50%, LBBB, CRT therapy for symptom reduction

Class III Through Class IV (1,10)

- Ischemic and non-ischemic cardiomyopathy, LVEF \leq 35%, QRS \geq 150ms, non-LBBB, Sinus Rhythm (**AUC 7**)

Special Situations: Independent/Regardless of NYHA Heart Failure Class

- Patients with an indication for ventricular pacing and high degree AV block or are expected to be paced more than 40% of the time; this includes patients with Atrial fibrillation ^(1,10)
- Patients with Atrial fibrillation and LVEF \leq 35% who requires ventricular pacing or otherwise meets CRT criteria; **AND** AV nodal ablation or pharmacologic rate control will allow nearly 100% ventricular pacing with CRT
- For patients with atrial fibrillation and LVEF \leq 50%, if a rhythm control strategy fails and ventricular rates remain rapid despite medical therapy, atrioventricular nodal ablation with implantation of a CRT device is reasonable ⁽⁹⁾
- As CRT has not been studied in ATTR-CM, those with HFrEF should follow guidelines for Class II-Class IV indications

Not Indicated

- NYHA class I and non-LBBB pattern with QRS duration $<$ 150 ms, ^(1,2) except as in Special Situations section above
- Comorbidities and/or frailty expected to limit survival with good functional capacity to $<$ 1 year ⁽¹¹⁾
- Active bloodstream infection
- Reversible causes are present such as toxic-, metabolic- or tachycardic-mediated cardiomyopathy, would require reassessment once the situation is corrected
- Cardiogenic shock or symptomatic hypotension while in stable baseline rhythm

INDICATIONS FOR ADULT CONGENITAL HEART DISEASE

Class I Through Class IV

- Systemic ventricle with any EF (not restricted), intrinsic narrow QRS complex, and undergoing new device placement or replacement with anticipated requirement for significant ($>$ 40%) ventricular pacing (**AUC 7-8**). ^(1,11)

Class II Through Class IV

- Systemic LV EF \leq 35%, sinus rhythm and wide QRS complex \geq 130 ms ⁽¹¹⁾
- Any CHD, wide QRS complex \geq 150 ms due to a complete RBBB, with a severe sub-pulmonary RV dysfunction and dilatation despite interventions to decrease RV volume overload ⁽¹¹⁾

Class IV

- Severe ventricular dysfunction, and would otherwise be candidates for heart transplantation or mechanical circulatory support ⁽¹¹⁾

Not Indicated

- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to $<$ 1 year ⁽¹¹⁾

INDICATIONS FOR CRT

- As the appropriate pacing modality in special situations with $<$ 3 months of GDMT ^(1,12)
- Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or pacemaker and based upon the low likelihood of improvement in symptoms and adequate recovery of LVEF, despite less than 3 months GDMT for heart failure or $<$ 40 days post myocardial infarction or 3 months post revascularization, criteria for CRT are otherwise met. This avoids a second implantation procedure within less than 3 months.

CODING AND STANDARDS

Coding

CPT Codes

33221, 33224, 33225, 33231, 33241, 33249

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁵⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Overview

CRT, which paces the left and right ventricle in rapid sequence, also known as biventricular pacing, improves coordination of ventricular contraction in the presence of a wide QRS complex in systolic heart failure.

CRT improves cardiac function and quality of life, and it decreases cardiac events and mortality among appropriately chosen patients. In the proper patient population, improved survival in patients with CRT can be greater than that provided by ICD insertion alone.

Guiding principles in the consideration of CRT:

- NYHA class is an important qualifying factor, with candidacy based on functional class, EF, and QRS duration.
- Bundle branch block or intraventricular conduction delay should be persistent, not rate related. ⁽¹⁾
- GDMT should have been in place continuously for at least 3 months and recovery of LVEF from myocardial infarction (40 days) if no intervening revascularization or > 3 months if revascularization was performed. Reversible causes (e.g., ischemia) should be excluded. ^(2,9)
- The patient should have expected survival with reasonably good functional status for more than 1 year. ^(2,11)

Definitions

NYHA Class Definitions ^(1,3)

- Class I: No limitation of functional activity. Ordinary physical activity does not cause symptoms of HF
- Class II: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF
- Class III: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF
- Class IV: Unable to continue any physical activity without symptoms of HF, or symptoms of HF at rest

Heart Block Definitions ⁽²⁾

- First Degree: All atrial beats are conducted to the ventricles, but with a delay of > 200

ms

- Second Degree: Intermittent failure of conduction of single beats from atrium to ventricles.
 - Type I: Conducted beats have variable conduction times from atrium to ventricles.
 - Type II: Conducted beats have uniform conduction times from atrium to ventricles.
 - Advanced: Two or more consecutive non-conducted beats (premature atrial beats might not normally be conducted).
- Third Degree: No atrial beats are conducted from atrium to ventricle.

Guideline-Directed (or Optimal) Medical Therapy in Heart Failure ⁽⁹⁾

- Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker

Other options/considerations for GDMT

- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans, NYHA class III-IV
- Addition of an aldosterone antagonist, provided eGFR is ≥ 30 ml/min/1.73m² and K⁺ < 5.0, NYHA class II-IV
- Not required for consideration of CRT: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm.

Acronyms/Abbreviations

ACE-I: Angiotensin converting enzyme inhibitor

ARB: Angiotensin receptor blocker

ARNI: Combined angiotensin receptor inhibitor and neprilysin inhibitor

AV: Atrioventricular

CAD: Coronary artery disease, same as ischemic heart disease

CHD: Congenital heart disease

CHF: Congestive heart failure

CRT: Cardiac resynchronization therapy (also known as biventricular pacing)

CRT-D: Cardiac resynchronization therapy defibrillator

ECG: Electrocardiogram

EF: Ejection Fraction

eGFR: Estimated glomerular filtration rate

EPS: Electrophysiologic Study

GDMT: Guideline-Directed Medical Therapy
 HCM: Hypertrophic Cardiomyopathy
 HF: Heart failure
 HFrEF: Heart failure with reduced ejection fraction
 HV: His-ventricular
 ICD: Implantable cardioverter-defibrillator
 LBBB: Left bundle branch block
 LV: Left ventricular/left ventricle
 LVEF: Left ventricular ejection fraction
 MI: Myocardial infarction
 ms: Milliseconds
 NYHA: New York Heart Association
 RBBB: Right bundle branch block
 RV: Right ventricle
 SND: Sinus node dysfunction
 SR: Sinus rhythm
 STEMI: ST-Elevation Myocardial Infarction
 VT: Ventricular tachycardia

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1149 Cardiac Resynchronization Therapy Implantation ● Added Clinical Reasoning and AUC Score sections ● Added missing CPT code 33241

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Russo A, Stainback R, Bailey S, Epstein A, Heidenreich P et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. *J Am Coll Cardiol*. Mar 26, 2013; 61: 1318-68. 10.1016/j.jacc.2012.12.017.
2. Epstein A, DiMarco J, Ellenbogen K, Estes N 3, Freedman R et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation*. Jan 22, 2013; 127: e283-352. 10.1161/CIR.0b013e318276ce9b.
3. Goldman L, Hashimoto B, Cook E, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. *Circulation*. Dec 1981; 64: 1227-34. 10.1161/01.cir.64.6.1227.
4. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
5. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
6. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
7. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
8. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483 - 1502. 10.1161/CIR.0b013e31822935fc.
9. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. May 3, 2022; 145: e876-e894. 10.1161/cir.0000000000001062.
10. McDonagh T A, Metra M, Adamo M, Gardner R S, Baumbach A et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). With the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur J Heart Fail*. 2022; 24: 4-131. 10.1002/ejhf.2333.
11. Hernández-Madrid A, Paul T, Abrams D, Aziz P, Blom N et al. Arrhythmias in congenital heart disease: a position paper of the European Heart Rhythm Association (EHRA), Association for European Paediatric and Congenital Cardiology (AEPC), and the European Society of Cardiology (ESC) Working Group on Grown-up Congenital heart disease, endorsed by HRS, PACES, APHRS, and SOLAECE. *Europace*. Nov 1, 2018; 20: 1719-1753. 10.1093/europace/eux380.
12. Kusumoto F, Calkins H, Boehmer J, Buxton A, Chung M et al. HRS/ACC/AHA expert consensus statement on the use of implantable cardioverter-defibrillator therapy in patients who are not included

or not well represented in clinical trials. Heart Rhythm. Jul 2014; 11: 1271-303.
10.1016/j.hrthm.2014.03.041.



Evolut Clinical Guideline 7265 for Cardiovascular Stress Test

Guideline Number: Evolut_CG_7265	<u>Applicable Codes</u>	
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Original Date: July 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Cardiovascular Stress Test (walking exercise treadmill ECG test)

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care ^(1,2,3,4,5).

INDICATIONS FOR CARDIOVASCULAR STRESS TEST

Known or Suspected Coronary Artery Disease (CAD) ⁽⁶⁾

- Symptoms suggesting myocardial ischemia
 - When a non-cardiac explanation is provided for symptoms, no testing is required **(AUC Score 8)** ⁽⁶⁾
- Asymptomatic patient
 - Prior to initiation of an unsupervised exercise program, with or without known CAD **(AUC Score 7)** ⁽⁶⁾
 - Prior to cardiac rehabilitation **(AUC Score 7)** ⁽⁶⁾
- Syncope/presyncope
 - When initial evaluation suggests cardiovascular abnormalities **(AUC Score 7)** ⁽⁶⁾

- Arrhythmias
 - In patients with frequent PVCs (premature ventricular contraction) or non-sustained ventricular tachycardia (**AUC Score 7**)⁽⁶⁾
 - Evaluation of patients with known or suspected exercise-induced arrhythmias⁽⁷⁾
 - Evaluation of patients with suspected chronotropic incompetence⁽⁸⁾
 - In patients with suspected long QT syndrome for diagnosis and therapy response⁽⁹⁾
 - In selected first-degree relatives of patients with arrhythmogenic right ventricular cardiomyopathy⁽⁹⁾
 - In first-degree relatives of subjects ≤ 40 years old who died suddenly and whose death could reasonably be attributed to unexplained sudden cardiac death (SCD), for comprehensive cardiac evaluation (including exercise stress testing)⁽⁹⁾
 - Identification of appropriate settings in patients with rate-adaptive pacemakers⁽⁷⁾
 - Evaluation of congenital complete heart block in patients considering increased physical activity or participation in competitive sports⁽⁷⁾
- Hypertrophic Cardiomyopathy (HCM)⁽¹⁰⁾
 - To determine functional capacity and to provide prognostic information as part of initial evaluation
- Valvular Disease
 - Aortic stenosis in asymptomatic patients with severe aortic stenosis (Stage C1) to assess physiological changes with exercise and to confirm the absence of symptoms⁽¹¹⁾
 - Chronic aortic regurgitation^(7,11):
 - with equivocal symptoms, to assess functional capacity and symptoms
 - to assess symptoms and functional capacity prior to participation in athletic activity
 - prognostic assessment before aortic valve replacement in asymptomatic or minimally symptomatic patients with left ventricular dysfunction
 - In asymptomatic women with severe valve disease (Stage C1) considering pregnancy⁽¹¹⁾
- Coarctation of the Aorta⁽¹²⁾
 - In adults, for exercise-induced hypertension
- Prior to Elective Non-Cardiac Surgery in asymptomatic patient^(13,14,15)
 - An intermediate- or high-risk surgery with of one or more risk factors (see below), **AND** there has not been an ischemia evaluation within 1 year
 - Risk factors: history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine > 2.0 mg/dL
 - Surgical Risk:
 - High risk surgery: Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated

with large fluid shifts and/or blood loss

- Intermediate risk surgery: Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
- Low risk surgery: Endoscopic procedures, superficial procedure, cataract surgery, breast surgery

LIMITATIONS FOR CARDIOVASCULAR STRESS TEST

- Abnormal ST changes on resting ECG, digoxin, left bundle branch block, Wolff-Parkinson-White pattern, ventricular paced rhythm (unless test is performed to establish exercise capacity and not for diagnosis of ischemia) ⁽¹⁶⁾
- Unable to achieve ≥ 5 METs or unsafe to exercise ⁽¹⁶⁾
- High-risk unstable angina or acute myocardial infarction, active acute coronary syndrome ⁽¹⁶⁾
- Uncontrolled heart failure ⁽¹⁶⁾
- Significant cardiac arrhythmias such as ventricular tachycardia, complete atrioventricular block or high risk for arrhythmias caused by QT prolongation ⁽¹⁶⁾
- Severe symptomatic aortic stenosis ⁽¹⁶⁾
- Severe systemic arterial hypertension (e.g., $\geq 200/110$ mmHg) ⁽¹⁶⁾
- Acute illness such as acute pulmonary embolism, acute myocarditis/pericarditis, and acute aortic dissection ⁽¹⁶⁾
- Routine periodic stress testing is not recommended in patients with chronic coronary artery disease (CCD) without clinical or functional status changes ⁽¹⁷⁾

CODING AND STANDARDS

Coding

CPT Codes

93015, 93016, 93017, 93018

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Cardiovascular stress test is a test used to measure cardiovascular response to external stress through treadmill/bicycle exercise in a controlled clinical environment.

Cardiovascular stress tests compare the coronary circulation while the patient is at rest with the same patient's circulation observed during maximum physical exertion, showing any abnormal blood flow to the myocardium as depicted by the continuously monitored EKG/ECG. The results can also be interpreted as a reflection on the general physical condition of the test patient (blood pressure response and exercise tolerance).

Definitions

- Duke Exercise ECG Treadmill Score - Calculate risk from ECG Treadmill Score ⁽¹⁸⁾
 - The equation for calculating the Duke treadmill score (DTS) is: $DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score})$, with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
 - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of $\geq + 5$), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of ≤ -11) categories.
- Global Risk of Cardiovascular Disease
 - Global risk of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to asymptomatic patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging. There are rare exemptions, such as patients requiring IC antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug.
 - CAD Risk—Low
 - 10-year absolute coronary or cardiovascular risk less than 10%.
 - CAD Risk—Moderate
 - 10-year absolute coronary or cardiovascular risk between 10% and 20%.

- CAD Risk—High
 - 10-year absolute coronary or cardiovascular risk of greater than 20%.

Websites for Global Cardiovascular Risk Calculators* (19,20,21,22,23)

Risk Calculator	Link to Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clinicalcalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have known CAD are already at high global risk and are not applicable to the calculators

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Guideline-Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a

cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

Acronyms/Abbreviations

- CAD: Coronary artery disease
- DTS: Duke treadmill score
- EKG/ECG: Electrocardiogram
- GDMT: Guideline directed medical therapy
- HCM: Hypertrophic cardiomyopathy
- MET: Metabolic equivalent
- PVC: Premature ventricular contraction
- SCD: Sudden cardiac death

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1114 Cardiovascular Stress Test ● Updated clinical indication, limitation and background sections ● Removed Special Note section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Journal of the American College of Cardiology*. 2011; 58: 1517-38.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Winchester D E, Maron D J, Blankstein R, Chang I C, Kirtane A J et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *Journal of the American College of Cardiology*. 2023; 81: 2445 - 2467. 10.1016/j.jacc.2023.03.410.
7. Gibbons R J, Balady G J, Bricker J T, Chaitman B R, Fletcher G F et al. ACC/AHA 2002 guideline update for exercise testing: summary article. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1997 Exercise Testing Guidelines). *Journal of the American College of Cardiology*. 2002; 40: 1531-40.
8. Kay G N. Quantitation of chronotropic response: comparison of methods for rate-modulating permanent pacemakers. *Journal of the American College of Cardiology*. 1992; 20: 1533-41.
9. Al-Khatib S M, Stevenson W G, Ackerman M J, Bryant W J, Callans D J et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*. 2018; 72: e91 - e220. 10.1016/j.jacc.2017.10.054.
10. Ommen S R, Ho C Y, Asif I M, Balaji S, Burke M A et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2024; 83: 2324-2405.
11. Otto C M, Nishimura R A, Bonow R O, Carabello B A, Erwin J P et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2021; 77: e25 - e197. 10.1016/j.jacc.2020.11.018.
12. Stout K K, Daniels C J, Aboulhosn J A, Bozkurt B, Broberg C S et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2019; 73: e81 - e192. 10.1016/j.jacc.2018.08.1029.
13. Kristensen S D, Knuuti J, Saraste A, Anker S, Bøtker H E et al. 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management: The Joint Task Force on non-cardiac surgery: cardiovascular assessment and management of the European Society of Cardiology

(ESC) and the European Society of Anaesthesiology (ESA). *European journal of anaesthesiology*. 2014; 31: 517-73.

14. Fleisher L A, Fleischmann K E, Auerbach A D, Barnason S A, Beckman J A et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Journal of nuclear cardiology*. 2015; 22: 162-215.

15. Velasco A, Reyes E, Hage F G. Guidelines in review: Comparison of the 2014 ACC/AHA guidelines on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery and the 2014 ESC/ESA guidelines on noncardiac surgery: Cardiovascular assessment and management. *Journal of nuclear cardiology*. 2017; 24: 165-170.

16. Gulati M, Levy P D, Mukherjee D, Amsterdam E, Bhatt D L et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021; 144: e368 - e454. 10.1161/CIR.0000000000001029.

17. Virani S S, Newby L K, Arnold S V, Bittner V, Brewer L C et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2023; 148: e9 - e119. 10.1161/CIR.0000000000001168.

18. Shaw L J, Peterson E D, Shaw L K, Kesler K L, DeLong E R et al. Use of a Prognostic Treadmill Score in Identifying Diagnostic Coronary Disease Subgroups. *Circulation*. 1998; 98: 1622 - 1630. 10.1161/01.CIR.98.16.1622.

19. Arnett D K, Blumenthal R S, Albert M A, Buroker A B, Goldberger Z D et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2019; 140: e596 - e646. 10.1161/CIR.0000000000000678.

20. D'Agostino R B, Vasan R S, Pencina M J, Wolf P A, Cobain M et al. General Cardiovascular Risk Profile for Use in Primary Care: The Framingham Heart Study. *Circulation*. 2008; 117: 743 - 753. 10.1161/CIRCULATIONAHA.107.699579.

21. Goff D C, Lloyd-Jones D M, Bennett G, Coady S, D'Agostino R B et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014; 129: S49 - S73. 10.1161/01.cir.0000437741.48606.98.

22. McClelland R L, Jorgensen N W, Budoff M, Blaha M J, Post W S et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *Journal of the American College of Cardiology*. 2015; 66: 1643-53.

23. Ridker P M, Buring J E, Rifai N, Cook N R. Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *JAMA*. 2007; 297: 611-9.

Evolut Clinical Guideline 7266 for Carotid Artery Stenting

Guideline Number: Evolut_CG_7266	<u>Applicable Codes</u>	
<p><i>"Evolut" refers to Evolut Health LLC and Evolut Specialty Services, Inc.</i></p> <p><i>© 2011 - 2025 Evolut. All rights Reserved.</i></p>		
Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided*

Purpose

Indications for determining medical necessity for Carotid Artery Stenting.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CAROTID ARTERY STENTING BY TRANSFEMORAL (TFS) OR TRANSCAROTID REVASCULARIZATION (TCAR)

- Symptomatic carotid artery stenosis $\geq 50\%$ **AND** all of the following:
 - Duplex ultrasound ^(7,9) demonstrating the following:
 - Systolic velocity ≥ 125 cm/sec and ICA/CCA ratio ≥ 2 ⁽⁷⁾
 - Computed tomography angiography (CTA) or magnetic resonance angiography (MRA), if not contraindicated, confirming $\geq 50\%$ stenosis and providing additional information about the aortic arch, and extra- and intra-cranial circulation. ^(7,9)
 - Diagnostic cerebrovascular arteriogram confirming $\geq 50\%$ stenosis if CTA and

MRA contraindicated ⁽⁷⁾

- Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional
- Stenting will be performed more than 14 days after the onset of symptoms and **ANY** of the following:
 - In a patient with moderate to high-risk concomitant medical conditions ⁽⁹⁾
 - In a patient with fibromuscular hyperplasia ⁽⁶⁾
 - In patients with ischemic neurological symptoms that have not responded to antithrombotic therapy after acute carotid dissection ⁽⁶⁾
 - By TFS in a patient with anatomical conditions that increase the risk of carotid endarterectomy or TCAR ^(8,10)
 - Neck stoma
 - Severe external radiation-induced skin and local tissue induration
 - Neck infection
 - Cervical instability or fixation
 - In a patient with significant tandem lesions
 - In a patient with disease extending above C2
- Asymptomatic carotid stenosis > 70%
 - Stenting is performed in a low-risk patient
 - Duplex ultrasound ^(7,9) demonstrating the following
 - Systolic velocity \geq 230 cm/sec and ICA/CCA ratio \geq 4 and end diastolic velocity of \geq 100 cm ⁽⁷⁾
 - CTA or MRA, if not contraindicated, confirming \geq 70% stenosis and providing additional information about the aortic arch, and extra- and intra-cranial circulation. ^(7,9)
 - After diagnostic cerebrovascular arteriogram if CTA and MRA contraindicated

LIMITATIONS FOR CAROTID ARTERY STENTING

- Stent/s within 48 hours of a stroke ⁽⁹⁾
- Carotid stenosis < 50% ^(6,7)
- Chronic total occlusion of the targeted carotid artery ⁽⁶⁾
- Patients with severe disability caused by cerebral infarction that precludes preservation of useful function ⁽⁶⁾
- Patients with 50-99% stenoses who experience a disabling stroke (modified Rankin score \geq 3), or whose area of infarction exceeds one third (> 30%) of the ipsilateral

middle cerebral artery territory, or who have altered consciousness/drowsiness ^(8,9)

- Asymptomatic patients with < 70% carotid stenosis ⁽⁶⁾
- Patients with asymptomatic FMD of a carotid artery, regardless of the severity of stenosis ⁽⁶⁾
- Patients with 70-99% asymptomatic carotid stenosis in order to prevent cognitive decline ⁽⁸⁾
- Patients presenting with carotid territory symptoms in the previous six months and who have < 50% stenosis ⁽⁸⁾
- Patients with carotid near occlusion and distal vessel collapse ⁽⁸⁾
- Staged or synchronous stent/CABG to prevent stroke in the presence of an asymptomatic unilateral 70-99% carotid stenosis ⁽⁸⁾
- Prophylactic carotid stent for an asymptomatic patient with 50-99% carotid stenosis undergoing a major non-cardiac surgical procedure ⁽⁸⁾
- Transfemoral stent in the presence of severe aortic calcification, atherosclerosis or tortuosity ⁽⁸⁾
- TCAR in the presence of a tracheal stoma, or ANY of the following ⁽¹⁰⁾
 - Situation where local tissues are scarred and fibrotic from prior ipsilateral surgery or external beam radiotherapy
 - Lesion < 5 cm from the clavicle
 - Severe calcification
 - Local infection

CODING AND STANDARDS

Coding

CPT Codes

37215, 37216

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- **Carotid stenting:** A procedure that opens clogged arteries to prevent or treat stroke. The carotid arteries are located on each side of the neck and are the main arteries supplying blood to the brain. The procedure involves temporarily inserting and inflating a tiny balloon where the carotid artery is clogged to widen the artery and placement of a small metal coil called a stent in the clogged artery. The stent helps prop the artery open and decreases the chance of it narrowing again.
- **Rankin Score:** The degree measurement of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability.
- **Shared decision process:** A member-provider interaction that must include a discussion of alternative treatments. The discussion includes complications, recurrent symptoms, and future reinterventions. The phrase “risks and alternatives have been described” is not sufficient
- **Transfemoral stent (TFS):** A stent inserted via a remote puncture of the femoral artery, and which involves traversing the aortic arch and which is usually supplemented by distal filter placement to prevent embolization
- **Transcarotid Revascularization (TCAR):** A process involves a small cutdown on the cervical common carotid artery and placing the stent during reversal of flow out of the brain to prevent distal embolization

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary artery bypass graft

CAS: Carotid artery stenting

CEA: Carotid endarterectomy

CTA: Computed tomography angiography

FMD: Fibromuscular dysplasia

GDMT: Guideline-directed medical therapy

MRA: Magnetic resonance angiography

NCD: National Carrier Determination

PTA: Percutaneous Transluminal Angioplasty

RPVI: Registered Physician in Vascular Interpretation

RVT: Registered Vascular Technologist

TCAR: Transcarotid Revascularization

TFS: Transfemoral stent

TIA: Transient ischemic attack

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1171 Carotid Artery Stenting ● Added general statement for share-decision making ● Updated clinical indications, limitation, and background sections ● Removed Special Note section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; Accessed 08/09/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Brott T G, Halperin J L, Abbara S, Bacharach J M, Barr J D et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery Developed in Collaboration With the American Academy of Neurology and Society of Cardiovascular Computed Tomography. *Journal of the American College of Cardiology*. 2011; 57: e16 - e94. 10.1016/j.jacc.2010.11.006.
7. Kleindorfer D O, Towfighi A, Chaturvedi S, Cockroft K M, Gutierrez J et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association. *Stroke*. 2021; 52: e364-e467.
8. Naylor R, Rantner B, Ancetti S, de Borst G J, De Carlo M et al. European Society for Vascular Surgery (ESVS) 2023 Clinical Practice Guidelines on the Management of Atherosclerotic Carotid and Vertebral Artery Disease. *European journal of vascular and endovascular surgery*. 2023; 65: 7-111.
9. AbuRahma A F, Avgerinos E D, Chang R W, Darling R C 3, Duncan A A et al. Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease. *Journal of vascular surgery*. 2022; 75: 4S-22S.
10. Lewis A J, Maningat A, Salzier G G, Ryer E J. Avoiding complications with trans carotid artery revascularization. *Ann Vasc Surg*. 2024; S0890-5096(24)00588-0



Evolut Clinical Guideline 7267 for Carotid Duplex

Guideline Number: Evolut_CG_7267	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Carotid Duplex.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CAROTID DUPLEX

- Asymptomatic patients
 - With known carotid stenosis (greater than 30% narrowing), 30–50% stenosis followed on an annual basis, and > 50% stenosis followed every six months ^(6,7)
 - With carotid bruit to detect hemodynamically significant carotid stenosis ^(6,8)
 - With clinical evidence of atherosclerosis and ≥ 50% carotid stenosis in previous diagnosis treated with therapeutic interventions as annual surveillance to assess disease's progression ⁽⁶⁾ (**AUC Score 7**) ⁽⁷⁾
 - With symptomatic PAD (peripheral artery disease), CAD (coronary artery disease), or atherosclerotic aortic aneurysm, with or without carotid bruit to detect hemodynamically significant carotid stenosis ^(6,8)
 - ≥ 55 years old with two or more of the following risk factors ^(6,8):
 - hypertension, hyperlipidemia, tobacco smoking, amaurosis fugax, diabetes, renal failure, a family history in a first-degree relative of atherosclerosis manifested before 60 years old, or a family history of ischemic stroke

- With clinically occult cerebral infarction noted on brain imaging studies to detect significant carotid artery stenosis ⁽⁸⁾
- With FMD (Fibromuscular Dysplasia) of carotid artery as annual surveillance to detect changes in the extent or severity of disease ⁽⁶⁾
- Symptomatic patients
 - With focal neurological symptoms corresponding to the territory supplied by the left or right internal carotid artery ⁽⁶⁾
 - With nonspecific neurological symptoms when cerebral ischemia is a plausible cause ⁽⁶⁾
 - In symptomatic patients with atherosclerotic subclavian artery disease (TIA/stroke, coronary subclavian steal syndrome, ipsilateral hemodialysis access dysfunction, severe ischemia) ^(6,9)
 - With vasculitis involving the extra cranial carotid arteries ⁽⁷⁾
 - With pulsatile neck mass and no prior carotid duplex performed within the last 6 months ⁽⁷⁾
- Cardiac surgery
 - Before elective CABG surgery ⁽⁸⁾ in patients ≥ 65 years old and in those with left main coronary stenosis, known PAD, a history of cigarette smoking, a history of stroke or TIA (transient ischemic attack), or carotid bruit ^(6,10) (**AUC Score 6**) ⁽⁷⁾
 - In patients undergoing or are candidates for CEA (carotid endarterectomy) or CAS (carotid artery stenting) for completion imaging to reduce the risk of peri-operative stroke ⁽¹⁰⁾
 - After revascularization at 1-month baseline, and every 6 months for 2 years, then annually to assess patency and exclude the development of new or contralateral lesion ⁽⁶⁾

Note: Duplex ultrasonography may overestimate the severity of stenosis contralateral to internal carotid occlusion, suggesting the need for further confirmation with another imaging modality, especially in asymptomatic patients who are candidates for carotid revascularization ⁽⁶⁾

CODING AND STANDARDS

Coding

CPT Codes

93880, 93882

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Non-invasive extra cranial arterial studies involve the use of direct methods of ultrasound. Duplex ultrasound is the first-line imaging modality for carotid artery imaging, screening, and examination the anatomy and physiology of the carotid artery. ⁽⁸⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary artery bypass graft

CAD: Coronary artery disease

CAS: Carotid artery stenting

FMD: Fibromuscular dysplasia

PAD: Peripheral artery disease

TIA: Transient ischemic attack

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1081 Carotid Duplex ● Updated indications for Carotid Duplex ● Updated references ● Removed Special Note and Limitation sections

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Brott T G, Halperin J L, Abbara S, Bacharach J M, Barr J D et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery Developed in Collaboration With the American Academy of Neurology and Society of Cardiovascular Computed Tomography. *Journal of the American College of Cardiology*. 2011; 57: e16 - e94. 10.1016/j.jacc.2010.11.006.
7. Mohler III E R, Gornik H L, Gerhard-Herman M, Misra S, Olin J W et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing- A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. *Journal of the American College of Cardiology*. 2012; 60: 242-76.
8. AbuRahma A F, Avgerinos E D, Chang R W, Darling R C 3, Duncan A A et al. Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease. *Journal of vascular surgery*. 2022; 75: 4S-22S.
9. Mazzolai L, Teixido-Tura G, Lanzi S, Boc V, Bossone E et al. 2024 ESC Guidelines for the management of peripheral arterial and aortic diseases. *European heart journal*. 2024.
10. Naylor R, Rantner B, Ancetti S, de Borst G J, De Carlo M et al. European Society for Vascular Surgery (ESVS) 2023 Clinical Practice Guidelines on the Management of Atherosclerotic Carotid and Vertebral Artery Disease. *European journal of vascular and endovascular surgery*. 2023; 65: 7-111.



Evolut Clinical Guideline 7268 for Carotid Endarterectomy

Guideline or Policy Number: Evolut_CG_7268	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Carotid Endarterectomy. Carotid endarterectomy (CEA) is a surgical procedure used to prevent stroke, by correcting stenosis (narrowing) in the common or internal carotid artery. Endarterectomy is the removal of material on the inside of an artery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Symptomatic Patients

- Patients with greater than or equal to 50% stenosis, and low to standard surgical risk (when a patient doesn't have high-risk medical or surgical factors) ^(6,7)
 - For patients with high grade carotid artery stenosis, intervention is most successful within 2 weeks of symptom onset ⁽⁷⁾
- Patients with history of stroke
 - For neurologically stable patients with recent stable stroke or TIA and >50% stenosis between 48 hours and 14 days after symptom onset ^(6,7,8)
 - In patients with 70-99% stenosis and nondisabling TIA or stroke within the past 6 months ⁽⁸⁾
 - In patients 70 years or older with stroke or TIA, CEA is appropriate instead of

CAS to reduce periprocedural stroke rate ⁽⁸⁾

- In patients with carotid web and history of stroke ⁽⁸⁾

Asymptomatic Patients

- For patients at high risk of stroke in conjunction with medical therapy, when the perioperative risk is less than 3% ⁽⁷⁾
- For patients with > 70% stenosis and low surgical risk in conjunction with best medical therapy ⁽⁶⁾

NOTE: Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risk and benefits of the procedure with an understanding of patient's preferences.

CODING AND STANDARDS

Coding

CPT Codes

35301

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CAS: Carotid Artery Stenosis

CEA: Carotid Endarterectomy

TIA: Transient Ischemic Attack

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none">• This guideline replaces UM CARDIO_1163 for Carotid Endarterectomy• Updated references• Reorganized and clarified indications

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. AbuRahma A, Avgerinos E, Chang R, Darling R I, Duncan A et al. Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease. *Journal of Vascular Surgery*. 2022; 75: 4S - 22S. 10.1016/j.jvs.2021.04.073.
7. Mohd A, Alabdallat Y, Mohd O, Ghannam R, Sawaqed S et al. Medical and Surgical Management of Symptomatic and Asymptomatic Carotid Artery Stenosis: A Comprehensive Literature Review. 2023; 15: true. 10.7759/cureus.43263.
8. Kleindorfer D, Towfighi A, Chaturvedi S, Cockroft K, Gutierrez J et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association. *Stroke*. 2021; 52: e364 - e467. 10.1161/STR.0000000000000375.

Evolut Clinical Guideline 7269 for Catheter Based Carotid and Brachiocephalic Artery Digital Angiography

Guideline Number: Evolut_CG_7269	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Catheter Based Carotid Artery Digital Angiography.

Note: Indications related to evaluation of the brain, cerebral perfusion and anatomy are not included in this guideline

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CATHETER BASED CAROTID ARTERY DIGITAL ANGIOGRAPHY ⁽⁶⁾

- When there are conflicting or inconclusive results from prior duplex scan, CTA and/or MRA and carotid revascularization is being contemplated.
- When there is/are contraindications to CTA/MRA and carotid artery revascularization is being contemplated
- In patients with renal dysfunction to limit exposure to contrast material during evaluation of a single vascular territory
- For the diagnosis of cervical artery dissection
- For the evaluation of carotid fibromuscular dysplasia

- For the evaluation of vertebral artery dissection and obstructive lesions

INDICATIONS FOR HEMODIALYSIS-RELATED ISSUES (7,8)

Hemodialysis fistula complications can occur outside the fistula, necessitating further visualization. Arteriography may be performed when **ALL** of the following conditions are met:

- **The catheter is inserted either:**
 - Through a puncture at a different site than the dialysis circuit, or
 - Within the dialysis circuit, positioned in a thoracic or brachiocephalic branch (more than 2 centimeters from the arterial anastomosis).
- **Arteriography is employed to examine possible inflow pathologies when the following applies:**
 - Steal syndrome or distal limb ischemia is suspected to be affecting the hemodialysis circuit or
 - A fistulogram has been performed for hemodialysis issues, and no cause for decreased flow was found.

LIMITATIONS FOR CATHETER BASED CAROTID ARTERY DIGITAL ANGIOGRAPHY

- Catheter-based angiography is unnecessary for diagnostic evaluation of most patients with ECVD (Extracranial Carotid and Vertebral Artery Disease), especially preoperatively before CEA (carotid endarterectomy) ⁽⁹⁾ and is used increasingly as a therapeutic revascularization maneuver in conjunction with stent deployment ⁽⁶⁾

CODING AND STANDARDS

Coding

CPT Codes

36215, 36216, 36217, 36218, 36221, 36222, 36223, 36224, 36225, 36226, 36227, 36228

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Carotid angiography is a procedure performed in order to visualize the arterial supply to the brain and to ascertain presence of blockage in the extra cranial carotid arteries.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CEA: Carotid endarterectomy

ECVD: Extracranial Carotid and Vertebral Artery Disease

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1169 Catheter Based Carotid Artery Digital Angio • Updated according to societal guidelines • Added missing CPT code 36228 • Added hemodialysis-related indication section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; Accessed 08/09/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Brott T G, Halperin J L, Abbara S, Bacharach J M, Barr J D et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease. *Journal of the American College of Cardiology*. 2011; 57: e16 - e94. 10.1016/j.jacc.2010.11.006.
7. Shin, D S, Magill, D B, Johnson, G E, Ingraham, C R, Kogut, M J, Monroe, E J. Upper Extremity Catheter Angiography: Indications, Techniques, Anatomy, and Classic Cases. *Journal of Clinical Interventional Radiology ISVIR*. 2018; 2(2): 87-94. 10.1055/s-0038-1666966.
8. Roddy, S P, Lerner, Benjamin M. New bundled CPT codes for dialysis circuit interventions. *Journal of Vascular Surgery*. 2017; 65(6): 1859 – 1861.
9. AbuRahma A F, Avgerinos E D, Chang R W, Darling III R C, Duncan A A et al. Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease. *Journal of vascular surgery*. 2022; 75: 4S-22S.



Evolut Clinical Guideline 7270 for Central Venous Access Procedure

Guideline Number: Evolut_CG_7270	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Central Venous Access Device implantation and removal.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CVAD IMPLANTATION ^(6,7)

Indications	Usually Appropriate	May Be Appropriate	Usually Not Appropriate
Administration of IV medication (> 2 weeks) (excluding chemotherapy)	PICC, Tunneled CVC	Chest port, Arm port	Nontunneled CVC
Administration of IV medication that may irritate peripheral endothelium	Nontunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port
Frequent blood sampling	Nontunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port

Indications	Usually Appropriate	May Be Appropriate	Usually Not Appropriate
Hemodialysis prior to AVF creation	Nontunneled CVC (≤ 2 weeks), Tunneled CVC	Nontunneled CVC (> 2 weeks)	Arm port, Chest port, PICC
Hemodynamic monitoring	Nontunneled CVC, PICC	Tunneled CVC, Midline catheter	Arm port, Chest port
Administration of chemotherapy (> 2 weeks)	Chest port, Arm port	PICC, Tunneled CVC	Nontunneled CVC

INDICATIONS FOR CVAD REMOVAL

- If the central venous access is no longer clinically needed
- Catheter occlusion
- Central venous thrombosis
- Fibrin sheath formation
- Catheter-related infection
- Catheter kinking

CODING AND STANDARDS

Coding

CPT Codes

- CVAD Insertion: 36556, 36558, 36561, 36563, 36565, 36566
- CVAD Removal: 36589, 36590
- CVAD Replacement: 36578, 36580, 36581, 36583
- CVAD Repair: 36575, 36576, 36582, 36597
- Fluoroscopic Guidance/Contrast: 32552, 36598, 76000, 77001

Place of Services Codes

Inpatient hospital (21)

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Central Venous Access Device (CVAD): a catheter that is placed in a vein that leads directly to the right side of the heart. There are a number of central veins and for each of these there are a variety of techniques. Catheters are available which differ in length, internal diameter, number of channels, method of insertion, material and means of fixation.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AVF: Arteriovenous fistula

CVAD: Central venous access device

CVC: Central venous catheter

IV: Intravenous

PICC: Peripherally inserted central catheter

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1166 Central Venous Access Procedures

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Massouh A, Kwan S W, Fidelman N, Higgins M, Abujudeh H et al. ACR Appropriateness Criteria® Central Venous Access Device and Site Selection. *Journal of the American College of Radiology*. 2023; 20: S3-S19.
7. Tse A, Schick M A. Central Line Placement. *StatPearls*. 2022; Accessed: August 19, 2024. <https://www.ncbi.nlm.nih.gov/books/NBK470286/>.



Evolut Clinical Guideline 7271 for Coronary Fractional Flow Reserve

Guideline Number: Evolut_CG_7271	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Coronary Fractional Flow Reserve

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CORONARY FRACTIONAL FLOW RESERVE ⁽⁶⁾

- In patients with angina or an anginal equivalent, undocumented ischemia, and angiographically intermediate stenoses (defined as a diameter stenosis severity of 40% to 69%) to guide the decision to proceed with PCI (percutaneous coronary intervention)
- In patients undergoing valve surgery, aortic surgery, or other cardiac operations with intermediate CAD (defined as 40%–69% stenosis) to guide the decision to proceed with or without concomitant CABG (coronary artery bypass graft)

CODING AND STANDARDS

Coding

CPT Codes

93571, 93572

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Fractional flow reserve (FFR) is used to determine the functional significance of a coronary stenosis in angiographically “intermediate” or “indeterminant” lesions which allows the operator to decide when PCI may be beneficial or safely deferred. During coronary catheterization, a catheter is inserted into the femoral (groin) or radial arteries (wrist) using a sheath and guidewire. FFR is calculated as the ratio of distal coronary pressure to aortic pressure measured during maximal hyperemia. A normal value for FFR is 1.0. FFR \leq 0.80 in an angiographically intermediate lesion (50-70% stenosis) is considered to be a significant coronary lesion (>70% stenosis). ⁽⁷⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary artery bypass graft

CAD: Coronary artery disease

FFR: Fractional flow reserve

PCI: Percutaneous coronary intervention

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1269 Coronary Fractional Flow Reserve ● Updated indications for Coronary Fractional Flow Reserve ● Updated Background and references ● Removed Special Note section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Lawton J S, Tamis-Holland J E, Bangalore S, Bates E R, Beckie T M et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2022; 79: e21 - e129. 10.1016/j.jacc.2021.09.006.
7. Balanescu S. Fractional Flow Reserve Assessment of Coronary Artery Stenosis. *European cardiology*. 2016; 11: 77-82.

Evolut Clinical Guideline 7272-01 for Electron-Beam Tomography or Non-Contrast Coronary Computed Tomography

Guideline Number: Evolut_CG_7272-01	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

This guideline includes clinical criteria for coronary artery calcium scoring, by either EBCT or non-contrast CCT. CAC testing provides a quantitative assessment of coronary artery calcium content in Agatston units, as an adjunct to the estimation of global risk[†] for coronary or cardiovascular events over the next 10 years. A CAC Score > 0 is a highly specific feature of coronary atherosclerosis. ^(1,2)

Special Note

See Legislative Language for specific mandates in: [State of New Mexico](#), [State of Texas](#), and [State of Washington](#).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(3,4,5,6,7)

INDICATIONS FOR CORONARY ARTERY CALCIUM (CAC) TESTING

Patients, regardless of age, can be considered for CAC testing when there is well-documented evidence of one of the following ^(8,9,10,11):

- For asymptomatic patients, without known coronary disease, at intermediate global risk (7.5%-19.9%) **(AUC 8)**

- For asymptomatic patients, without known coronary disease, at or below borderline global risk (5%-7.4%) (**AUC 7**) but are suspected to be at elevated ASCVD risk because of any of the following: ^(1,8,10,12,13,14,15):
 - Family history of premature ASCVD
 - Persistently elevated LDL-C > 160 mg/dl or non-HDL-C > 190 mg/dl
 - Chronic kidney disease
 - Metabolic syndrome
 - Conditions specific to women (e.g., pre-eclampsia, premature menopause) ⁽¹⁵⁾
 - Inflammatory diseases (HIV, psoriasis, RA)
 - Ethnicity (e.g., South Asian ancestry)
 - Persistently elevated triglycerides (> 175 mg/dl)
 - hsCRP > 2 mg/L
 - Lp(a) levels > 50 mg/dl
 - apoB > 130 mg/dl
 - ABI < 0.9, 15
- For asymptomatic patients, without known coronary disease, where there is a need for alternative lipid-lowering strategies when statin therapy is contraindicated, due to adverse effects or patient reluctance ^(13,14)
- CAC testing may be repeated indefinitely for re-assessment of the asymptomatic patient without known coronary disease after a minimum of 5 years until the calcium score breaches 400 or up to twice if the calcium score remains zero.

LEGISLATIVE LANGUAGE

State of New Mexico

591-23-7.16 ⁽¹⁶⁾

Applicable to: Commercial and Medicaid

- A group health plan, other than a small group health plan or a blanket health insurance policy or contract that is delivered, issued for delivery or renewed in this state shall provide coverage for eligible insureds to receive a heart artery calcium scan.
- Coverage provided pursuant to this section shall:
 - be limited to the provision of a heart artery calcium scan to an eligible insured to be used as a clinical management tool;
 - be provided every five years if an eligible insured has previously received a heart artery calcium score of zero; and
 - not be required for future heart artery calcium scans if an eligible insured receives a heart artery calcium score greater than zero.

- At its discretion or as required by law, an insurer may offer or refuse coverage for further cardiac testing or procedures for eligible insureds based upon the results of a heart artery calcium scan.
- The provisions of this section do not apply to short-term travel, accident-only or limited or specified-disease policies, plans or certificates of health insurance.
- As used in this section:
 - "eligible insured" means an insured who:
 - is a person between the ages of forty-five and sixty-five; and
 - has an intermediate risk of developing coronary heart disease as determined by a health care provider based upon a score calculated from an evidence-based algorithm widely used in the medical community to assess a person's ten-year cardiovascular disease risk, including a score calculated using a pooled cohort equation;
 - "health care provider" means a physician, physician assistant, nurse practitioner or other health care professional authorized to furnish health care services within the scope of the professional's license; and
 - "heart artery calcium scan" means a computed tomography scan measuring coronary artery calcium for atherosclerosis and abnormal artery structure and function.

State of Texas

HB 1290 Sec 1376.003 (17)

Applicable to: Commercial, Market, and Exchange

- A health benefit plan that provides coverage for screening medical procedures must provide the minimum coverage required by this section to each covered individual:
 - who is:
 - a male older than 45 years of age and younger than 76 years of age; or
 - a female older than 55 years of age and younger than 76 years of age; and
 - who:
 - is diabetic; or
 - has a risk of developing coronary heart disease, based on a score derived using the Framingham Heart Study coronary prediction algorithm, that is intermediate or higher.
- The minimum coverage required to be provided under this section is coverage of up to \$200 for one of the following noninvasive screening tests for atherosclerosis and abnormal artery structure and function every five years, performed by a laboratory that is certified by a national organization recognized by the commissioner by rule for the purposes of this section:
 - computed tomography (CT) scanning measuring coronary artery calcification;

or

- ultrasonography measuring carotid intima-media thickness and plaque.

State of Washington

20091120A ⁽¹⁸⁾

Number and Coverage Topic

20091120A – Coronary Artery Calcium Scoring

HTCC Coverage Determination

Cardiac Artery Calcium Scoring is a **non-covered benefit**.

HTCC Reimbursement Determination

- Limitations of Coverage
 - Not Applicable
- Non-Covered Indicators
 - Coronary Artery Calcium Scoring

CODING AND STANDARDS

Coding

CPT Codes

75571

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

General Overview

CAC testing is for cardiovascular risk assessment in individuals aged 40-75 years who have an intermediate (5-19.9%) 10-year ASCVD risk based upon the ACC/AHA pooled cohort risk calculator. Documentation is required that the results of the study will affect decision making

for preventative actions (i.e., statin therapy). CAC testing is a cardiovascular risk assessment tool, applicable only to the patient without known cardiovascular disease, for the purpose of primary prevention. It is not for the patient with suspected or known cardiovascular disease, coronary or otherwise, who already requires aggressive risk factor modification. This test is not to be utilized for symptomatic patients in active ischemic evaluation.

CAC score > 100 can also provide support for aspirin therapy and statin therapy ^(1,14).

Calcium scores are used to help determine the use and dosage of statin therapy in patients with various risks of developing clinically symptomatic atherosclerotic disease. Once symptomatic coronary disease has been established or once the patient is considered high risk, the usefulness of calcium scoring falls away as patients should be on high dose therapy and the results of a calcium score would add no further benefit. If a patient is symptomatic, non-invasive or invasive testing should remain first line.

‡ Global risk of CAD is defined as the probability of an asymptomatic patient without known CAD developing CAD, including myocardial infarction or CAD death, over a given period of time. Risk categories include:

- Low risk (<5%)
- Borderline risk (5% - 7.4%)
- Intermediate risk (7.5% to 19.9%)
- High risk (≥ 20%)

Links to Global Cardiovascular Risk Calculators

Risk Calculator	Website for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms / Abbreviations

ASCAD: Atherosclerotic coronary artery disease

ASCVD: Atherosclerotic cardiovascular disease

CAC: Coronary artery calcium

CAD: Coronary artery disease

CCT: Cardiac computed tomography

EBCT: Electron beam computed tomography

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1458 Coronary Artery Calcium Scoring by Electron Beam Tomography or Non-Contrast Coronary Computed Tomography
February 2024	<ul style="list-style-type: none"> ● Formatting change ● Addition of clinical reasoning statement with AUC scoring described ● AUC scores added to bullet points ● Clarifying statement that this test is not to be utilized for symptomatic patients ● References updated

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Greenland P, Blaha M J, Budoff M J, Erbel R, Watson K E. Coronary Calcium Score and Cardiovascular Risk. *J Am Coll Cardiol*. 2018; 72: 434-447. 10.1016/j.jacc.2018.05.027.
2. McClelland R L, Jorgensen N W, Budoff M, Blaha M J, Post W S et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *J Am Coll Cardiol*. 2015; 66: 1643-53. 10.1016/j.jacc.2015.08.035.
3. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCf/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
4. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
5. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
6. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
7. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
3. Goff D, Lloyd-Jones D M, Bennett G, Coady S, D'Agostino R et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2014; 63: 2935 - 2959. 10.1016/j.jacc.2013.11.005.
4. Arnett D K, Blumenthal R S, Albert M A, Buroker A B, Goldberger Z D et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019; 74: e177-e232. 10.1016/j.jacc.2019.03.010.
5. Pender A, Lloyd-Jones D M, Stone N J, Greenland P. Refining Statin Prescribing in Lower-Risk Individuals: Informing Risk/Benefit Decisions. *J Am Coll Cardiol*. 2016; 68: 1690-1697. 10.1016/j.jacc.2016.07.753.
6. Piepoli M F, Hoes A W, Agewall S, Albus C, Brotons C et al. 2016 European Guidelines on cardiovascular disease prevention in clinical practice: The Sixth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of 10 societies and by invited experts) Developed with the special contribution of the European Association for Cardiovascular Prevention & Rehabilitation (EACPR). *Eur Heart J*. 2016; 37: 2315-2381. 10.1093/eurheartj/ehw106.
7. Hecht H, Blaha M J, Berman D S, Nasir K, Budoff M et al. Clinical indications for coronary artery calcium scoring in asymptomatic patients: Expert consensus statement from the Society of Cardiovascular Computed Tomography. *J Cardiovasc Comput Tomogr*. 2017; 11: 157-168. 10.1016/j.jcct.2017.02.010.
8. Michos E D, Blaha M J, Blumenthal R S. Use of the Coronary Artery Calcium Score in Discussion of Initiation of Statin Therapy in Primary Prevention. *Mayo Clin Proc*. 2017; 92: 1831-1841. 10.1016/j.mayocp.2017.10.001.

9. Blankstein R, Gupta A, Rana J S, Nasir K. The Implication of Coronary Artery Calcium Testing for Cardiovascular Disease Prevention and Diabetes. *Endocrinol Metab (Seoul)*. 2017; 32: 47-57. 10.3803/EnM.2017.32.1.47.
10. Winchester D, Maron D, Blankstein R, Chang I, Kirtane A et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *Journal of cardiovascular magnetic resonance: official journal of the Society*. 2023; 25: 58. 10.1186/s12968-023-00958-5.
11. New Mexico Legislature. Coverage for health artery calcium scan. 2020.
12. Texas Constitution and Statutes. Texas Statutes Insurance Code Title 8 - Health Insurance and Other Health Coverages Subtitle E - Benefits Payable Under Health Coverages Chapter 1376 - Certain Tests for Early Detection of Cardiovascular Disease. 2023.
13. Washington State Health Care Authority. WSHCA Health Technology Clinical Committee Coverage Decision 20091120A Coronary Artery Calcium Scoring. 2010; <https://www.hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/computed-tomographic-angiography-cta>.
14. Mortensen M B, Falk E, Li D, Nasir K, Blaha M J et al. Statin Trials, Cardiovascular Events, and Coronary Artery Calcification: Implications for a Trial-Based Approach to Statin Therapy in MESA. *JACC Cardiovasc Imaging*. 2018; 11: 221-230. 10.1016/j.jcmg.2017.01.029.



Evolut Clinical Guideline 7273 for Coronary Atherectomy

Guideline Number: Evolut_CG_7273	<u>Applicable Codes</u>	
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Original Date: May 2016	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Indications for Coronary Atherectomy ⁽⁶⁾

- Rotational atherectomy is reasonable as primary procedure for fibrotic or heavily calcified de novo lesions for lesion modification prior to angioplasty and stenting.
- Rotational atherectomy can be used as secondary approach after unsuccessful attempt to dilate calcified lesion by balloon angioplasty.
- Laser Coronary atherectomy is reasonable to perform for in stent restenosis ⁽⁷⁾

Limitations for Coronary Atherectomy ⁽⁸⁾

- Rotational atherectomy is not recommended for below scenarios:
 - Occlusions for which a guidewire will not pass (risk of perforation)
 - Degenerated SV Graft lesion or thrombus
 - Lack of cardiac surgery
 - Patient is ineligible for CABG
 - Left ventricular dysfunction
 - Severe multivessel or unprotected left main coronary artery disease lesion length

>25mm and lesion angulation >45°

- Rotational atherectomy should be used cautiously in presence of coronary dissection for plaque modification as guidewire is in true lumen of coronary artery

CODING AND STANDARDS

Coding

CPT Codes

92924, 92925

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- Coronary Atherectomy is a procedure that utilizes a catheter device that is inserted into coronary artery percutaneously to remove plaque from the inside of artery.
- In the presence of coronary artery calcification with an arc >50%, thickness >0.5 mm and length >5 mm, adjunctive therapies for calcium modification should be considered, which are:
 - Rotational atherectomy, involves the use of a special burr or drill on the tip of a catheter that rotates to shave the plaque into tiny pieces
 - Directional atherectomy, a technique in which a small cutting device is pushed against the plaque to cut it away from the artery. The process can be repeated at the time the treatment is performed to remove a significant amount of disease from the artery, thus eliminating a blockage from atherosclerotic disease. Devices for directional coronary atherectomy are no longer marketed in the United States.
 - Excimer Laser atherectomy involves use of xenon chloride laser generator to generate laser (pulsating beams of light) to vaporize the calcified plaque in coronary arteries.
 - Orbital atherectomy uses a unique mechanism of action incorporating centrifugal forces via a standard 1.25mm eccentrically mounted and diamond coated burr to

ablate calcified plaque to facilitate stent expansion.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary Artery Bypass Graft

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM 1291 Coronary Atherectomy

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACCC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Lawton J, Tamis-Holland J, Bangalore S, Bates E, Beckie T et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145: e4 - e17. 10.1161/CIR.0000000000001039.
7. Farag M, van den Buijs D, Loh S X, Poels E, Ameloot K et al. Long-term clinical outcomes of excimer laser coronary atherectomy for the management of recurrent in-stent restenosis. *The Journal of invasive cardiology*. 2023; 35: E365-E374.
8. Sharma S, Tomey M, Teirstein P, Kini A, Reitman A et al. North American Expert Review of Rotational Atherectomy. *Circulation: Cardiovascular Interventions*. 2019; 12: true. 10.1161/CIRCINTERVENTIONS.118.007448.



Evolut Clinical Guideline 7274 for Coronary Intra Vascular Arterial Ultrasound

Guideline Number: Evolut_CG_7274	<u>Applicable Codes</u>	
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Original Date: May 2016	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Coronary Intra Vascular Arterial Ultrasound (IVUS).

Special Note

- To review a request for medical necessity, the following items must be submitted for review:
 - Progress note that prompted request
 - Prior Diagnostic coronary angiogram

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

IVUS is recommended for:

- Assessing angiographically indeterminate left main (LM) artery lesion severity prior to revascularization. ⁽⁶⁾
- Post cardiac transplantation within 4 to 6 weeks and 1 year to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information ⁽⁶⁾

- Evaluating the mechanism of stent failure, stent restenosis and stent thrombosis ^(6,7,8)
- Assessing non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis) ⁽⁶⁾
- Coronary stent implantation guidance, particularly in cases of LM coronary artery stenting or complex coronary artery stenting including but not limited to ^(6,7,8,9):
 - adequate expansion and apposition in selected patients
- Assessing plaque extent (burden) and characteristics within the LM ⁽⁹⁾, particularly ostial stenosis in LM and daughter branches ^(8,9)
- Assessing the severity and optimizing the treatment of unprotected LM lesions ⁽⁸⁾

Limitations

IVUS is **NOT** indicated for:

- Routine lesion assessment when revascularization with PCI or CABG is not being contemplated. ⁽⁶⁾
- Extreme vessel tortuosity and angulation ⁽¹⁰⁾
- Patients not suitable for systemic anticoagulation or angiography or cardiac catheterization ⁽¹⁰⁾

CODING AND STANDARDS

Coding

CPT Codes

92978, 92979

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

IVUS is a specially designed catheter with a miniaturized ultrasound probe attached to the distal end of the catheter. IVUS when introduced in a coronary artery during cardiac catheterization, provides more precise information about the severity of stenosis and plaque morphology than does coronary angiography such as for the lumen of ostial lesions or where angiographic images do not visualize lumen segments adequately, such as regions with multiple overlapping arterial segments. It is also used to assess the effects of treatments of stenosis such as with hydraulic angioplasty expansion of the artery, with or without stents, and the results of medical therapy over time.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary artery bypass grafting

IVUS: Intra Vascular Arterial Ultrasound

LMCAD: Left main coronary artery disease

PCI: Percutaneous coronary intervention

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM 1292 Coronary Intra Vascular Arterial Ultrasound

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Levine G N, Bates E R, Blankenship J C, Bailey S R, Bittl J A et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. *Circulation*. 2011; 124: e574 - e651. 10.1161/CIR.0b013e31823ba622.
7. Lawton J, Tamis-Holland J, Bangalore S, Bates E, Beckie T et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145: e4 - e17. 10.1161/CIR.0000000000001039.
8. Neumann F, Sousa-Uva M, Ahlsson A, Alfonso F, Banning A et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. *Eur Heart J*. 2019; 40: 87 - 165. 10.1093/eurheartj/ehy394.
9. Ramadan R, Boden W, Kinlay S. Management of Left Main Coronary Artery Disease. *Journal of the American Heart Association*. 7: true. 10.1161/JAHA.117.008151.
10. Shlofmitz E, Kerndt C, Parekh A, et al. Intravascular Ultrasound. *StatPearls* [Internet]. [Updated 2023 May 22]; Accessed: September 24, 2024. <https://www.ncbi.nlm.nih.gov/books/NBK537019/>.

Evolut Clinical Guideline 7275-01 for Coronary CT Angiography

Guideline Number: Evolut_CG_7275-01	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Coronary and/or Cardiac Computed Tomographic Angiography (CCTA). Patients should be on maximally tolerated guideline directed medical therapy (GDMT), when applicable.

Special Note

See legislative language for specific mandates in Washington State.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CORONARY COMPUTED TOMOGRAPHIC ANGIOGRAPHY (CCTA) ^(6,7,8,9)

Evaluation in Suspected Coronary Artery Disease (CAD) ^(10,11,12,13,14)

Probability

- Low pretest probability patients should be considered for exercise treadmill test (ETT) unless other criteria for CCTA are met ⁽⁶⁾
- Intermediate and high pretest probability patients ⁽¹⁵⁾

- Exercise ECG stress test with intermediate Duke Treadmill (- 10 to + 4)

Asymptomatic Patients

- Asymptomatic patients without known CAD:
 - Previously unevaluated ECG evidence of possible myocardial ischemia including ischemic ST segment or T wave abnormalities (see Uninterpretable baseline ECG section)
 - Previously unevaluated pathologic Q waves (see Uninterpretable baseline ECG section)
 - Previously unevaluated left bundle branch block

Symptomatic Patients

- CCTA is being performed to avoid performing cardiac catheterization in patients with chest pain syndrome with intermediate pretest probability of CAD, uninterpretable ECG and are not able to exercise with no prior CCTA done within the last 12 months who have ^(15,16):
 - Equivocal, borderline, or discordant stress evaluation with continued symptoms concerning for CAD **(AUC 8)** ⁽⁸⁾
 - Repeat testing in patient with new or worsening symptoms since prior normal stress imaging **(AUC 7)** ⁽⁸⁾
 - Chest pain of uncertain etiology, when non-invasive tests are negative, but symptoms are typical and management requires that significant coronary artery disease be excluded **(AUC 7)** ⁽⁸⁾

Heart Failure

- Newly diagnosed clinical systolic heart failure or diastolic heart failure, with reasonable suspicion of cardiac ischemia unless invasive coronary angiography is planned (SE diversion not required) ^(17,18) **(AUC 7)** ⁽⁸⁾

Heart Valve

- Before valve surgery or transcatheter intervention as an alternative to coronary angiography ^(16,19,20)
- To establish the etiology of mitral regurgitation ⁽²⁰⁾
- Pre-TAVR evaluation as an alternative to coronary angiography ^(21,22)

Heart Anomaly or Aneurysm

- Evaluation of coronary anomaly or aneurysm ^(23,24,25,26,27)
 - Evaluation prior to planned repair
 - Evaluation due to change in clinical status and/or new concerning signs or symptoms
 - Kawasaki disease and MIS-C follow up – for medium sized or greater aneurysms ⁽²⁸⁾ periodic surveillance can be considered every 2-5 years. Once aneurysmal size has reduced to small aneurysms, surveillance can be performed

every 3-5 years. No further surveillance once normalized.

- Evaluation of suspected pulmonary embolism

NOTE: CMR is favored in younger patients for coronary anomaly evaluation ^(23,29)

PCI or CABG

- Prior PCI or CABG history
 - Symptomatic patient with prior PCI or CABG history, with angina interfering in performing daily activities, despite being on guideline directed medical therapy, and with an equivocal stress test results. No prior CCTA done within the last 12 months **(AUC 7)** ⁽⁸⁾
- Evaluation of coronary artery bypass grafts, to assess ^(8,30):
 - Patency and location when invasive coronary arteriography was either nondiagnostic or not performed/planned **(AUC 7)** ⁽⁸⁾
 - Location of grafts prior to cardiac or another chest surgery **(AUC 7)** ⁽⁸⁾

Limited Prior or Replacement Imaging

- CCTA may be performed in patients who cannot tolerate moderate sedation that is required during TEE, for pre procedural evaluation for Left Atrial Appendage Occlusion to look for LA/LAA thrombus, spontaneous contrast, LAA morphology and dimensions. *TEE however remains the preferred choice of modality for this procedure.*

Electrophysiologic Procedure Planning

- Evaluation of anatomy (pulmonary vein isolation planning) prior to radiofrequency ablation

LEGISLATIVE LANGUAGE

Washington

20211105A - Noninvasive Cardiac Imaging for Coronary Artery Disease ⁽³¹⁾

Washington State Health Care Authority Technology Assessment

HTCC coverage determination:

Noninvasive cardiac imaging is a **covered benefit with conditions.**

HTCC reimbursement determination:

Limitations of coverage: The following noninvasive cardiac imaging technologies are **covered with conditions:**

- Stress echocardiography for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of Coronary Artery Disease (CAD), or

- Adult patients with known CAD who have new or worsening symptoms.
- Single Positron Emission Tomography (SPECT) for:
 - Patients under the same conditions as stress echocardiography when stress echocardiography is not technically feasible or clinically appropriate.
- Positron Emission Tomography (PET) for:
 - Patients under the same conditions as SPECT, when SPECT is not technically feasible or clinically appropriate.
- Coronary Computed Tomographic Angiography (CCTA) for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of CAD, or
 - Adult patients with known CAD who have new or worsening symptoms.
- CCTA with Fractional Flow Reserve (FFR) for:
 - Patients under the same conditions as CCTA, when further investigation of functional significance of stenoses is clinically indicated.

Non-covered indicators:

N/A

Notes:

- Out of scope/data not reviewed for this decision:
 - Asymptomatic individuals, follow up of prior abnormal cardiac imaging studies, myocardial viability, preoperative evaluation
 - Patients presenting for evaluation of cardiac pathologies other than CAD
- This determination supersedes the following previous determinations:
 - Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease (20081114A)
 - Cardiac Nuclear Imaging (20130920A)

CODING AND STANDARDS

Coding

CPT Codes

75574

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

A coronary computerized tomography angiogram (CCTA) is a noninvasive imaging study that uses intravenously administered contrast material and high-resolution, rapid imaging computed tomography (CT) ^(32,33)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽¹⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score – 4-6
- Rarely Appropriate Care - Median Score 1-3

Reduction in CCTA test quality

- The following can reduce the quality of the test in patients with ⁽⁸⁾:
 - Morbid Obesity
 - High or irregular heart rates
 - Severe coronary calcification

Patient Selection Criteria

- Patient selection for CCTA must be considered and may be inappropriate for the following:
 - Known history of severe and/or anaphylactic contrast reaction
 - Inability to cooperate with scan acquisition and/or breath-hold instructions
 - Pregnancy
 - Clinical instability (e.g., acute myocardial infarction, decompensated heart failure, severe hypotension)
 - Renal Impairment as defined by local protocols

- Image quality depends on keeping HR optimally < 60 bpm (after beta blockers), a regular rhythm, stents > 3.0 mm in diameter, and vessels requiring imaging ≥ 1.5 mm diameter ⁽³⁴⁾

Definitions

- Stable patients without known CAD fall into 2 categories ^(6,7,8):
 - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section)
 - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant CAD
- Three Types of Chest Pain or Discomfort:
 - **Typical Angina (Definite)** is defined as including ALL **3** characteristics:
 - Substernal chest pain or discomfort with characteristic quality and duration
 - Provoked by exertion or emotional stress
 - Relieved by rest and/or nitroglycerin
 - **Atypical Angina (Probable)** has only **2** of the above characteristics
 - **Nonanginal Chest Pain/Discomfort** has only **0 - 1** of the above characteristics
- The medical record should provide enough detail to establish the type of chest pain. From those details, the pretest probability of significant CAD is estimated from the Diamond Forrester Table below, recognizing that additional coronary risk factors could increase pretest probability ⁽⁸⁾:

Diamond Forrester Table ^(35,36)

Age (Years)	Gender	Typical/ Definite Angina Pectoris	Atypical/ Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Very Low: < 5% pretest probability of CAD

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

High: > 90% pretest probability of CAD

- An uninterpretable baseline ECG includes ⁽⁶⁾:
 - ST segment depression is considered significant when there is 1 mm or more, not for non-specific ST - T wave changes
 - Ischemic-looking T waves are considered significant when there are at least 2.5 mm inversions (excluding V1 and V2)
 - LVH with repolarization abnormalities, WPW, a ventricular paced rhythm, or left bundle branch block
 - Digitalis use with associated ST - T abnormalities
 - Resting HR under 50 bpm on a beta blocker and an anticipated suboptimal workload
 - Note: RBBB with less than 1 mm ST depression at rest may be suitable for ECG treadmill testing
- Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
 - > 40 ms (1 mm) wide
 - > 2 mm deep
 - > 25% of depth of QRS complex
- ECG Stress Test Alone versus Stress Testing with Imaging
 - Prominent scenarios suitable for an ECG stress test **WITHOUT** imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise ⁽⁸⁾:
 - The (symptomatic) low pretest probability patient who can exercise and has an interpretable ECG ⁽⁸⁾
 - The patient who is under evaluation for exercise-induced arrhythmia
 - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
 - For the evaluation of syncope or presyncope during exertion ⁽³⁷⁾
- Duke Exercise ECG Treadmill Score ⁽³⁸⁾
 - Calculates risk from ECG treadmill alone:
 - Duke treadmill score (DTS) equation is: $DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score})$, with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting
 - The score ranges from - 25 to + 15 with values corresponding to low-risk (score of $\geq + 5$), intermediate risk (scores ranging from - 10 to + 4), and high-risk (score of $\leq - 11$) categories
- Scenarios that can additionally support a CCTA over a regular exercise treadmill test in the low probability scenario ⁽³⁹⁾
 - Inability to Exercise

- Physical limitations precluding ability to exercise for at least 3 full minutes of Bruce protocol
- The patient has limited functional capacity (< 4 METS) such as **ONE** of the following:
 - Unable to take care of their activities of daily living (ADLs) or ambulate
 - Unable to walk 2 blocks on level ground
 - Unable to climb 1 flight of stairs
 - Unable to vacuum, dust, do dishes, sweep, or carry a small grocery bag
- Other Comorbidities
 - Prior cardiac surgery (coronary artery bypass graft or valvular)
 - Left ventricular ejection fraction $\leq 50\%$
 - Severe chronic obstructive pulmonary disease (COPD) with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
 - Poorly controlled hypertension, with systolic blood pressure (BP) > 180 or Diastolic BP > 120
- ECG and Echo-Related Baseline Findings
 - Pacemaker or implantable cardioverter defibrillator (ICD)
 - Resting wall motion abnormalities on echocardiography
 - Complete LBBB
- Risk-Related scenarios
 - Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs
 - Arrhythmia risk with exercise
- Global Risk of Cardiovascular Disease
 - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years.
 - **CAD Risk—Low**
 - 10-year absolute coronary or cardiovascular risk less than 10%
 - **CAD Risk—Moderate**
 - 10-year absolute coronary or cardiovascular risk between 10% and 20%
 - **CAD Risk—High**
 - 10-year absolute coronary or cardiovascular risk of greater than 20%

Websites for Global Cardiovascular Risk Calculators* (40,41,42,43,44)

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clinicalcalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

- **Definitions of Coronary Artery Disease** (6,7,45,46,47)
 - Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
 - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a **risk stratification** tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.
 - Stenoses $\geq 70\%$ are considered obstructive coronary artery disease (also referred to as clinically significant), while stenoses $\leq 70\%$ are considered non-obstructive coronary artery disease (45)
 - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; intermediate lesions are 50 – 69% (8)
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ or

- minimum luminal cross-sectional area on IVUS ≤ 6 square mm ^(6,46,47)
- FFR (fractional flow reserve) ≤ 0.80 for a major vessel ^(46,47)
- iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel ^(47,48,49,50)
- Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
- A major vessel would be a coronary vessel that would be amenable to revascularization, if indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
- FFR is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
- Newer technology that estimates FFR from CCTA images is covered under the Evolent Clinical Guideline 062-1 for Fractional Flow Reserve CT.
- Anginal Equivalent ^(6,37,51)
 - Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam, etc. (as well as D-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope, per se, is not an anginal equivalent.

Acronyms/Abbreviations

ACS: Acute coronary syndrome

ADLs: Activities of daily living

CABG: Coronary artery bypass grafting surgery

CAD: Coronary artery disease

CCS: Coronary calcium score

CCTA: Coronary computed tomography angiography

CT(A): Computed tomography (angiography)

COPD: Chronic obstructive pulmonary disease

DTS: Duke Treadmill Score

ECG: Electrocardiogram

EF: Ejection fraction

FFR: Fractional flow reserve

ICD: Implantable cardioverter-defibrillator

iFR: Instantaneous wave-free ratio or instant flow reserve

IVUS: Intravascular ultrasound

LBBB: Left bundle branch block
 LVH: Left ventricular hypertrophy
 MESA: Multi-Ethnic Study of Atherosclerosis
 METS: Metabolic equivalents
 MI: Myocardial infarction
 MPI: Myocardial perfusion imaging
 PCI: Percutaneous coronary intervention
 PFT: Pulmonary function test
 RBBB: Right bundle branch block
 SE: Stress echocardiography
 TTE: Transthoracic echocardiography
 WPW: Wolff-Parkinson-White syndrome

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> <li data-bbox="533 1081 1326 1144">This guideline replaces UM Cardio 1115 Coronary and/or Cardiac Computed Tomographic Angiography

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
2. Hendel R, Patel M, Allen J, Min J, Shaw L et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *J Am Coll Cardiol*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
3. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
4. Fitch K, Bernstein S, Aguilar M, Burnand B, LaCalle J et al. The RAND/UCLA Appropriateness Method User's Manual. 2001;
5. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *J Am Coll Cardiol*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Fihn S D, Gardin J M, Abrams J, Berra K, Blankenship J C et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation*. 2012; 126: e354-471. 10.1161/CIR.0b013e318277d6a0.
7. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J*. 2013; 34: 2949-3003. 10.1093/eurheartj/eh296.
8. Winchester D, Maron D, Blankstein R, Chang I, Kirtane A et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *J Cardiovasc Magn Reson*. 2023; 25: 58. 10.1186/s12968-023-00958-5.
9. Bandettini W P, Kwong R Y, Patel A R, Plein S, Resonance Society for Cardiovascular Magnetic. Society for Cardiovascular Magnetic Resonance perspective on the ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 multi-modality appropriate use criteria for the detection and risk assessment of chronic coronary disease. *J Cardiovasc Magn Reson*. 2023; 25: 59. 10.1186/s12968-023-00959-4.
10. Cheng V, Berman D, Rozanski A, Dunning A, Achenbach S et al. Performance of the traditional age, sex, and angina typicality-based approach for estimating pretest probability of angiographically significant coronary artery disease in patients undergoing coronary computed tomographic angiography. *Circulation*. 2011; 124: 2423-32, 1-8. 10.1161/CIRCULATIONAHA.111.039255.
11. Foy A, Dhruva S, Peterson B, Mandrola J, Morgan D. Coronary Computed Tomography Angiography vs Functional Stress Testing for Patients With Suspected Coronary Artery Disease: A Systematic Review and Meta-analysis. *JAMA Intern Med*. 2017; 177: 1623-1631. 10.1001/jamainternmed.2017.4772.
12. Newby D, Williams M, Hunter A, Pawade T, Shah A et al. CT coronary angiography in patients with suspected angina due to coronary heart disease (SCOT-HEART): an open-label, parallel-group, multicentre trial. *Lancet*. 2015; 385: 2383-91. 10.1016/S0140-6736(15)60291-4.
13. Tzolos E, Newby D. Coronary Computed Tomography Angiography Improving Outcomes in Patients with Chest Pain. *Curr Cardiovasc Imaging Rep*. 2019; 12: 15. 10.1007/s12410-019-9492-6.

14. Adamson P D, Newby D E, Hill C L, Coles A, Douglas P S. Comparison of International Guidelines for Assessment of Suspected Stable Angina: Insights From the PROMISE and SCOT-HEART. *JACC Cardiovasc Imaging*. 2018; 11: 1301-1310. 10.1016/j.jcmg.2018.06.021.
15. Gulati M, Levy P D, Mukherjee D, Amsterdam E, Bhatt D L et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021; 144: e368-e454. 10.1161/CIR.0000000000001029.
16. Gatti M, Gallone G, Poggi V, Bruno F, Serafini A et al. Diagnostic accuracy of coronary computed tomography angiography for the evaluation of obstructive coronary artery disease in patients referred for transcatheter aortic valve implantation: a systematic review and meta-analysis. *Eur Radiol*. 2022; 32: 5189-5200. 10.1007/s00330-022-08603-y.
17. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease : A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and the Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2019; 73: 488-516. 10.1016/j.jacc.2018.10.038.
18. Patel M R, White R D, Abbara S, Bluemke D A, Herfkens R J et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR appropriate utilization of cardiovascular imaging in heart failure: a joint report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. 2013; 61: 2207-31. 10.1016/j.jacc.2013.02.005.
19. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J*. 2022; 43: 561-632. 10.1093/eurheartj/ehab395.
20. Otto C, Nishimura R, Bonow R, Carabello B, Erwin 3rd J et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021; 143: e72-e227. 10.1161/CIR.0000000000000923.
21. Achenbach S, Delgado V, Hausleiter J, Schoenhagen P, Min J. SCCT expert consensus document on computed tomography imaging before transcatheter aortic valve implantation (TAVI)/transcatheter aortic valve replacement (TAVR). *J Cardiovasc Comput Tomogr*. 2012; 6: 366-80. 10.1016/j.jcct.2012.11.002.
22. Blanke P, Weir-McCall J, Achenbach S, Delgado V, Hausleiter J et al. Computed Tomography Imaging in the Context of Transcatheter Aortic Valve Implantation (TAVI)/Transcatheter Aortic Valve Replacement (TAVR): An Expert Consensus Document of the Society of Cardiovascular Computed Tomography. *JACC Cardiovasc Imaging*. 2019; 12: 1-24. 10.1016/j.jcmg.2018.12.003.
23. Bluemke D, Achenbach S, Budoff M, Gerber T, Gersh B et al. Noninvasive coronary artery imaging: magnetic resonance angiography and multidetector computed tomography angiography: a scientific statement from the american heart association committee on cardiovascular imaging and intervention of the council on cardiovascular radiology and intervention, and the councils on clinical cardiology and cardiovascular disease in the young. *Circulation*. 2008; 118: 586-606. 10.1161/CIRCULATIONAHA.108.189695.
24. Gräni C, Bigler M, Kwong R. Noninvasive Multimodality Imaging for the Assessment of Anomalous Coronary Artery. *Curr Cardiol Rep*. 2023; 25: 1233 - 1246. 10.1007/s11886-023-01948-w.
25. Newburger J W, Takahashi M, Burns J C. Kawasaki Disease. *J Am Coll Cardiol*. 2016; 67: 1738-49. 10.1016/j.jacc.2015.12.073.
26. Sachdeva R, Valente A M, Armstrong A K, Cook S C, Han B K et al. ACC/AHA/ASE/HRS/ISACHD/SCAI/SCCT/SCMR/SOPE 2020 Appropriate Use Criteria for

Multimodality Imaging During the Follow-Up Care of Patients With Congenital Heart Disease: A Report of the American College of Cardiology Solution Set Oversight Committee and Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Pediatric Echocardiography. *J Am Soc Echocardiogr.* 2020; 33: e1-e48. 10.1016/j.echo.2020.04.026.

27. Singhal M, Pilia R, Gupta P, Johnson N, Singh S. Emerging role of computed tomography coronary angiography in evaluation of children with Kawasaki disease. *World J Clin Pediatr.* 2023; 12: 97-106. 10.5409/wjcp.v12.i3.97.

28. McCrindle B W, Rowley A H, Newburger J W, Burns J C, Bolger A F et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the American Heart Association. *Circulation.* 2017; 135: e927-e999. 10.1161/cir.0000000000000484.

29. Weberling L, Lossnitzer D, Frey N, André F. Coronary Computed Tomography vs. Cardiac Magnetic Resonance Imaging in the Evaluation of Coronary Artery Disease. *Diagnostics (Basel).* 2022; 13: 125. 10.3390/diagnostics13010125.

30. Seraphim A, Knott K, Augusto J, Menacho K, Tyebally S et al. Non-invasive Ischaemia Testing in Patients With Prior Coronary Artery Bypass Graft Surgery: Technical Challenges, Limitations, and Future Directions. *Front Cardiovasc Med.* 2021; 8: 795195. 10.3389/fcvm.2021.795195.

31. Washington State Health Care Authority. WSHCA Health Technology Clinical Committee: 20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease. [Final Adoption: March 18, 2022]. 2022; <https://www.hca.wa.gov/assets/program/noninvasive-cardiac-imaging-final-findings-and-decision-2022-03-18.pdf>.

32. Sliwicka O, Sechopoulos I, Baggiano A, Pontone G, Nijveldt R. Dynamic myocardial CT perfusion imaging-state of the art. *Eur Radiol.* 2023; 33: 5509-5525. 10.1007/s00330-023-09550-y.

33. Pugliese L, Ricci F, Sica G, Scaglione M, Masala S. Non-Contrast and Contrast-Enhanced Cardiac Computed Tomography Imaging in the Diagnostic and Prognostic Evaluation of Coronary Artery Disease. *Diagnostics (Basel).* 2023; 13: 2074. 10.3390/diagnostics13122074.

34. Abbara S, Blanke P, Maroules C D, Cheezum M, Choi A D et al. SCCT guidelines for the performance and acquisition of coronary computed tomographic angiography: A report of the society of Cardiovascular Computed Tomography Guidelines Committee: Endorsed by the North American Society for Cardiovascular Imaging (NASCI). *J Cardiovasc Comput Tomogr.* 2016; 10: 435-449. 10.1016/j.jcct.2016.10.002.

35. Diamond G, Forrester J. Analysis of probability as an aid in the clinical diagnosis of coronary-artery. *N Engl J Med.* 1979; 300: 1350-8. 10.1056/NEJM197906143002402.

36. Wolk M J, Bailey S R, Doherty J U, Douglas P S, Hendel R C et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2014; 63: 380-406. 10.1016/j.jacc.2013.11.009.

37. Shen W K, Sheldon R S, Benditt D G, Cohen M I, Forman D E et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol.* 2017; 70: 620–663. 10.1016/j.jacc.2017.03.002.

38. Shaw I, Peterson E, Shaw L, Kesler K, DeLong E et al. Use of a prognostic treadmill score in identifying diagnostic coronary disease subgroups. *Circulation*. 1998; 98: 1622-30. 10.1161/01.cir.98.16.1622.
39. Henzlova M J, Duvall W L, Einstein A J, Travin M I, Verberne H J. ASNC imaging guidelines for SPECT nuclear cardiology procedures: Stress, protocols, and tracers. *J Nucl Cardiol*. 2016; 23: 606-39. 10.1007/s12350-015-0387-x.
40. D'Agostino Sr R B , Vasan R S, Pencina M J, Wolf P A, Cobain M et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation*. 2008; 117: 743-53. 10.1161/CIRCULATIONAHA.107.699579.
41. Arnett D K, Blumenthal R S, Albert M A, Buroker A B, Goldberger Z D et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019; 74: e177-e232. 10.1016/j.jacc.2019.03.010.
42. Goff D C J, Lloyd-Jones D M, Bennett G, Coady S, D'Agostino R B et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014; 129: S49-73. 10.1161/01.cir.0000437741.48606.98.
43. McClelland R L, Jorgensen N W, Budoff M, Blaha M J, Post W S et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *J Am Coll Cardiol*. 2015; 66: 1643-53. 10.1016/j.jacc.2015.08.035.
44. Ridker P M, Buring J E, Rifai N, Cook N R. Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *JAMA*. 2007; 297: 611-9. 10.1001/jama.297.6.611.
45. Patel M R, Calhoun J H, Dehmer G J, Grantham J A, Maddox T M et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2017; 69: 2212-2241. 10.1016/j.jacc.2017.02.001.
46. Shlofmitz E, Ali Z, Maehara A, Mintz G, Shlofmitz R. Intravascular Imaging-Guided Percutaneous Coronary Intervention: A Universal Approach for Optimization of Stent Implantation. *Circ Cardiovasc Interv*. 2020; 13: e008686. 10.1161/CIRCINTERVENTIONS.120.008686.
47. Lotfi A, Davies J E, Fearon W F, Grines C L, Kern M J. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society of cardiac angiography and interventions. *Catheter Cardiovasc Interv*. 2018; 92: 336-347. 10.1002/ccd.27672.
48. Davies J E, Sen S, Dehbi H M, Al-Lamee R, Petraco R et al. Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI. *N Engl J Med*. 2017; 376: 1824-1834. 10.1056/NEJMoa1700445.
49. Götzberg M, Christiansen E H, Gudmundsdottir I J, Sandhall L, Danielewicz M et al. Instantaneous Wave-free Ratio versus Fractional Flow Reserve to Guide PCI. *N Engl J Med*. 2017; 376: 1813-1823. 10.1056/NEJMoa1616540.
50. Verdoia M, Rognoni A. Coronary Physiology: Modern Concepts for the Guidance of Percutaneous Coronary Interventions and Medical Therapy. *J Clin Med*. 2023; 12: 2274. 10.3390/jcm12062274.
51. Brignole M, Moya A, de Lange F, Deharo J, Elliott P et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J*. 2018; 39: 1883-1948. 10.1093/eurheartj/ehy037.

Evolut Clinical Guideline 7276 for Descending Thoracic Aortic Open or Endovascular Surgery

Guideline Number: Evolut_CG_7276	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for procedures on the descending thoracic aorta.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

Thoracic Endovascular Aortic Repair (TEVAR) is preferred over open surgery in all instances where the anatomy is favorable (see **Definitions**). Open surgery is usually reserved for unfavorable anatomy or patients with Connective Tissue Disorders (CTD) or Heritable Thoracic Aortic Diseases (HTAD). When open surgery is requested, the reason must be included in the notes provided. Hybrid procedures may be required especially for thoracoabdominal aneurysms.

Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS (6,7,8)

Descending Thoracic Aneurysm and Thoracoabdominal Aneurysm

Open surgical repair and TEVAR procedures should be approved for ruptured Descending thoracic aortic aneurysm (DTA) and thoracoabdominal aneurysm and is not dependent on any variable

- Requests for concomitant subclavian, carotid, or iliac artery bypass should be approved as well as access site, or adjunctive endovascular procedures
- Descending Thoracic Aneurysm (DTA) has been defined by fine-cut (<0.2 mm) CTA of the entire aorta and iliac arteries or MRA, and ANY of the following:
 - DTA \geq 5.5 cm in a low-risk member
 - DTA \geq 6.0 cm in a high-risk member
 - DTA \geq 5.0 cm in members in women or anyone with Marfan syndrome
 - DTA <5.0 cm may be appropriate in pregnant women, other HTAD or CTD but the reason must be included in the notes provided
 - DTA <5.5cm with:
 - Aneurysm growth of >0.5 cm in 12 months
 - Symptoms or findings consistent with impending rupture: e.g. but not limited to, appropriate pain, periaortic hematoma, pleural effusion
 - Saccular configuration
 - Mycotic aneurysm
 - Family or personal history of any non-cerebral artery rupture
 - Persistent endoleak after prior Endograft

Other Descending Thoracic Aortic Conditions

This section contains indications regarding descending aortic dissection involving the aortic arch.

- Open surgical repair and TEVAR (Thoracic Endovascular Aortic Repair) procedures for hyperacute or acute pathology unresponsive to supportive medical therapy, including concomitant subclavian, carotid, or iliac artery bypass, as well as referencing access sites and adjunctive endovascular procedures.
- New symptoms or signs of evolving limb, organ or life-saving complications attributable to the aortic pathology or its treatment
- ANY findings consistent with impending rupture
 - Descending thoracic aortic dissection
 - New periaortic hematoma or pleural effusion
 - Continued aortic growth \geq 5mm in 6 months
 - False lumen expansion \geq 2.2 cm
 - Aortic diameter \geq 5.5 cm

- Endoleak after prior stent
- Intramural hematoma (IMH), or IMH with Penetrating Aortic Ulcer (PAU) with:
 - Progression on follow-up imaging (maximum aortic diameter ≥ 4.5 cm, IMH wall thickness ≥ 10 mm, presence of ulcer-like projections after a period of hypertension control: OR
 - Concern for rupture as explained in the notes provided
- Isolated Penetrating Aortic Ulcer with
 - Diameter >13 mm -20mm or depth ≥ 10 mm; OR
 - Concern for rupture as explained in the notes provided
- Aorto-enteric fistula
- Aorto-bronchial fistula
- Infected aorta or aortic grafts
- Aortic tumors
- Kommerell's Diverticulum when diameter exceeds 30mm or the diameter of the descending aorta adjacent to the diverticulum exceeds 50 mm.
- Symptomatic Aberrant right or left subclavian artery
- Coarctation of the aorta

CODING AND STANDARDS

Coding

CPT Codes

33530, 33875, 33877, 33880

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Dilation of the descending aorta (TAA) is often detected during other cardiovascular imaging. Descending aortic graft surgery is defined as excision and surgical replacement of the most distal portion of the diseased thoracic aorta with a graft.

Definitions

- **Acute** is 1-14 days since onset of symptoms, whereas Hyperacute is <24hrs since onset of symptoms.
- **Endograft** is a preconstructed graft that is inserted via a remote access site. There are multiple commercial variants where the manufacturers' Instructions For Use (IFU) should be followed. There are surgeon modified grafts, but these should only be used in institutions where the graft has been approved by an Institutional Review Board (IRB) or in a Government approved clinical trial.
- **Favorable anatomy for TEVAR** is anatomy that is consistent with the Instructions For Use (IFU) of the endograft that will be inserted.
- **Heritable Thoracic Aortic Disease (HTAD)** is an aortic condition related to a genetic or heritable condition some of which associated with multisystem features (considered syndromic HTAD) or others with abnormalities limited to the aorta with or without its branches (known as nonsyndromic HTAD). Examples include Marfan, Loeys-Dietz, Turner and Ehlers-Danlos syndromes, Familial Thoracic aortic aneurysms, and possibly bicuspid aortic valve.
- **High risk** is a member who has significant comorbidities increasing the risk of death, renal failure, stroke, or spinal ischemia and paraplegia.
- **Low risk** is a member who does not have significant comorbidities.
- **Intramural hematoma** in the wall of the artery without an identifiable communication between the true and false lumens. It is characterized by hyperdense, crescent-shaped hemorrhage within the wall and is best seen on noncontrast enhanced computed tomography.
- **Penetrating aortic ulcer (PAU)** is an atherosclerotic lesion that penetrates the internal elastic lamina of the aortic wall. It was also referred to as ulcer-like projections. It is often associated with IMH.
- **Pregnancy** can significantly impact the disease process and must be taken into consideration when considering surgical intervention.
- **Unfavorable anatomy for TEVAR** is anatomy that would not be suitable for the IFU of any commercially available endograft.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

- AUC: Appropriate Use Criteria
- CTD: connective tissue disorders
- CTA: Computed Tomography Angiography
- DTA: Descending Thoracic Aneurysm
- IFU: Instructions For Use
- IMH: Intramural hematoma
- HTAD: Heritable Thoracic Aortic Disease
- sHTAD: syndromic Heritable Thoracic Aortic Disease
- nsHTAD: non-syndromic Heritable Thoracic Aortic Disease
- MRA: Magnetic Resonance Angiography
- PAU: Penetrating Aortic Ulcer
- TEVAR: Thoracic Endovascular Aortic Repair

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1098 for Descending Thoracic Aortic Graft Surgery <ul style="list-style-type: none"> ○ Guideline name changed to Descending Thoracic Aortic Open or Endovascular Surgery ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this



Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Isselbacher E, Preventza O, Hamilton Black J, Augoustides J, Beck A et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 146: e334-e482. 10.1161/CIR.0000000000001106.
7. Lombardi J, Hughes G, Appoo J, Bavaria J, Beck A et al. Society for Vascular Surgery (SVS) and Society of Thoracic Surgeons (STS) reporting standards for type B aortic dissections. *Journal of Vascular Surgery*. 2020; 71: 723-747. 10.1016/j.jvs.2019.11.013.
8. Upchurch G, Escobar G, Azizzadeh A, Beck A, Conrad M et al. Society for Vascular Surgery clinical practice guidelines of thoracic endovascular aortic repair for descending thoracic aortic aneurysms. *Journal of Vascular Surgery*. 2021; 73: 55S-83S. 10.1016/j.jvs.2020.05.076.



Evolut Clinical Guideline 7277 for Device (PPM, AICD, CRT-D, Subcut-ICD, ILR) Programming

Guideline Number: Evolut_CG_7277	<u>Applicable Codes</u>	
<p><i>"Evolut" refers to Evolut Health LLC and Evolut Specialty Services, Inc.</i> © 2011 - 2025 Evolut. All rights Reserved.</p>		
Original Date: March 2011	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Device Programming of an Automatic Implantable Cardioverter Defibrillator (AICD), Subcutaneous Implantable Cardioverter Defibrillator (SICD), Cardiac Resynchronization Therapy-Defibrillator (CRT-D) or -Pacemaker (CRT-P), Permanent Pacemaker (PPM), Implantable Loop Recorder (ILR), or Life Vest/Wearable Defibrillator.

Special Note

Medical Necessity

- Request for medical determination (the following items must be submitted for review):
 - Progress note that prompted request
 - Latest device interrogation report with strips

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Routine Device Programming

- Device Programming is indicated within 72 hours of device implantation or pulse generator change and may be indicated during a routine follow-up visit 2-12 weeks

after device implantation. ^(6,7)

- Device Programming may also be indicated during routine follow-up visits that occur every 3-12 months for pacemakers, and every 3-6 months for ICDs and resynchronization devices. ⁽⁷⁾

Patient-related Indications

- Changes in the clinical status or cardiovascular symptom frequency/severity that may affect device function. ⁽⁸⁾
- Changes in disease therapy or medication regimen if the change may influence the underlying cardiac rhythm or device functioning ⁽⁹⁾
 - A lower rate cutoff is recommended for patients taking antiarrhythmic medications (e.g., Amiodarone, Multaq, Propafanone) that may reduce the heart rate at which clinical tachycardia is achieved

Disease-specific Programming ⁽⁷⁾

- In patients with heart failure, AICD or CRT-D device programming through AV optimization to prevent recurrent heart failure decompensation is recommended
- Unnecessary shocks due to rapid responses to supraventricular tachydysrhythmias (e.g., atrial fibrillation and flutter) and T-wave oversensing in channelopathies may occur. Device reprogramming may be indicated to reduce these occurrences.

Device-related Indications

- Device evaluation during Interrogation demonstrates lead malfunctioning, lead recall(s), or that the battery is approaching its end of life ⁽⁷⁾
- When the device delivers frequent or inappropriate shocks, device programming is indicated to optimize the programming therapy zones by modifying the device's operational parameters. Examples of operational parameters that can be adjusted during device programming include, but are not limited to ^(9,10):
 - Rate Threshold Sensing for identifying VT/VF
 - The duration of an identified VT/VF that partitions non-sustained vs. sustained VT/VF
 - Antitachycardia pacing
 - Discrimination of SVT vs VT
 - T-wave and lead-related oversensing
- Device programming is indicated when one or more of the operational parameters are causing excessive battery depletion ⁽⁷⁾
- Device programming is also indicated when new permanent changes were done during the last device evaluation or deemed necessary after a recent remote interrogation.

Indications related to Remote Monitoring ⁽⁸⁾

- For patients with devices that permit remote monitoring, alert parameters for cardiac

events should be optimized to the patient’s unique pathophysiology during office visit. Accordingly, device programming may be indicated if the device is over- or under-reporting actionable cardiac events and/or shock therapies.

- For patients with ILR, Programming is indicated when there is frequent under sensing and/or oversensing. Alerts relating to actionable cardiac events, electrograms should be immediately reviewed to exclude misdiagnosis

Other Considerations

- Defibrillation threshold (DFT) testing for SCD, including for unique lead configurations, may be appropriate at the time of device implantation or generator replacement. ⁽⁹⁾ Examples of changeable parameters include shock vectors and timing.

Limitations

- When a patient is monitored both during clinic visits and trans-telephonically or remotely, the combined frequency of monitoring will be considered in evaluating the reasonableness of the frequency of monitoring services received by the patient.
- There are no frequency guidelines available for programming of Life Vest after initial set up.

CODING AND STANDARDS

Coding

CPT Codes

93260, 93279, 93280, 93281, 93282, 93283, 93284, 93285, 93640, 93641, 93644, 93745

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

1. **Device Programming** (is a non-invasive process that allows the physician to set, or modify, the operational parameters of the implanted cardiac device. Examples of Device Programming include:

- For AICD, SICD, CRT-D, CRT-P, and PPM:
 - Documented manual iterative temporary or permanent changes of capture and sensing thresholds.
 - Changes in the pacing output of a pacing lead, heart rhythm, upper and lower heart rates, sensor rate response, AV intervals, pacing voltage, pulse duration, sensing value and checking battery voltage.
 - In addition to these programming parameters, ventricular tachycardia detection and therapies are programmed based on device interrogation when medically necessary.
- For an ILR:
 - Tachycardia and bradycardia rate adjustment based on interrogation when medically necessary.
- For a Life Vest/Wearable Defibrillator:
 - Sensing thresholds and ventricular tachycardia detection and defibrillation therapies based on device interrogation when medically necessary. Note, there are no pacing capabilities in a Life Vest, and Programming is usually done during the initial setup of the device.

2. An **Automatic Implantable Cardioverter Defibrillator (AICD)** or Implantable Cardioverter Defibrillator (ICD), is an electronic device designed to detect and treat life-threatening tachyarrhythmias or bradyarrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing, and defibrillation.

3. A **Subcutaneous ICD** (pulse generator) is implanted under the skin on the side of the chest below the arm pit. The pulse generator is connected to the electrode which is implanted under the skin from the device pocket along the rib margin to the breastbone with the use of the insertion tool. There are no electrodes/leads placed on (epicardial) or in (endocardial) the heart.

4. **Cardiac Resynchronization Therapy-Defibrillators (CRT-D) and Cardiac Resynchronization Therapy-Pacemakers (CRT-P)** are cardiac device with pacing and sensing function in three or more chambers of heart.

5. A **Pacemaker** is a medical device that uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system.

6. **Implantable cardiac loop recorders** continuously monitor and record ECG tracings, are indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia. The physician utilizes a programmer to retrieve, display and print stored data.

7. A **Life Vest/Wearable Defibrillator** is worn by patients that are at risk for sudden cardiac death (SCD) and allows their physician time to assess their long-term arrhythmic risk

and make appropriate plans. It continuously monitors the patient’s heart and, if a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm.

8. Defibrillator Threshold (DFT) Test - It is an integral part of implantable cardioverter-defibrillator implantation. It is usually performed at the time of initial implantation or after generator replacement. It involves testing of the device and leads by arrhythmia induction and termination by delivering shock therapy through programmed parameters.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AICD: Automatic Implantable Cardioverter Defibrillator

AUC: Appropriate Use Criteria

AV: Atrioventricular

CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRT-P: Cardiac Resynchronization Therapy Pacemaker

DFT: Defibrillation Threshold

ECG: Electrocardiogram

ICD: Implantable Cardioverter Defibrillator

ILR: Implantable Loop Recorder

OOS: Out of Scope

PPM: Permanent Pacemaker

SICD: Subcutaneous Implantable Cardioverter Defibrillator

SVT: Supraventricular tachycardia

VF: Ventricular Fibrillation

VT: Ventricular Tachycardia

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM 1257 Device (PPM, AICD, CRT-D, Subcut-ICD, ILR) Programming

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Glikson M, Nielsen J, Kronborg M, Michowitz Y, Auricchio A et al. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) With the special contribution of the European Heart Rhythm Association (EHRA). *Eur Heart J*. 2021; 42: 3427 - 3520. 10.1093/eurheartj/ehab364.
7. Slotwiner D, Varma N, Akar J, Annas G, Beardsall M et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. *Heart Rhythm*. 2015; 12: e69 - e100. 10.1016/j.hrthm.2015.05.008.
8. Ferrick A, Raj S, Deneke T, Kojodjojo P, Lopez-Cabanillas N et al. 2023 HRS/EHRA/APHRS/LAHR expert consensus statement on practical management of the remote device clinic. *Heart Rhythm*. 2023; 20: e92 - e144. 10.1016/j.hrthm.2023.03.1525.
9. Wilkoff B, Fauchier L, Stiles M, Morillo C, Al-Khatib S et al. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. *Heart Rhythm*. 2016; 13: e50 - e86. 10.1016/j.hrthm.2015.11.018.
10. Madhavan M, Friedman P. Optimal Programming of Implantable Cardiac-Defibrillators. *Circulation*. 2013; 128: 659 - 672. 10.1161/CIRCULATIONAHA.112.000542.

Evolut Clinical Guideline 7278 for Device Interrogation

Guideline Number: Evolut_CG_7278	<u>Applicable Codes</u>	
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Original Date: August 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

The purpose of device interrogation is to monitor the device's performance and adjust the settings as needed.

Special Note

- In order to review a request for medical necessity, the following items must be submitted for review:
 - Progress note that prompted request
 - Latest device interrogation report with strips

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR DEVICE INTERROGATION ⁽⁶⁾

In-Person Device Interrogation and Programming

- Recommended at 2-12 weeks after implantation
- May be performed routinely every 6-12 months for pacemakers and every 3 months for implantable ICDs to ensure the integrity of the device components and to improve longevity
- Should be performed for any CIED when alerts are triggered by remote monitoring

Transtelephonic Monitoring

- Used only in patients with CIEMs that do not have remote monitoring or remote interrogation capabilities

Remote Monitoring

- Recommended for all patients with CIEMs equipped with this capability
- Should be utilized for all patients whose CIEMs or leads are under recall or advisory status
- Frequency should be programmed to minimize pacemaker battery drain (typically every three months), unless circumstances (such as lead or pulse generator advisory or patient rhythm disturbances) demand closer surveillance

Remote Pacemaker Interrogation ^(7,8)

- Routine remote interrogation may be performed every 3 months from last interrogation
- CRT-P interrogation may be performed every 3 months, either in-person or remotely
- When device interrogation reveals that the battery is approaching elective replacement indicator (90 days or less), interrogation may be performed monthly

NOTE: Interrogation includes device programming, if performed on the same day

AICD Interrogation ^(7,8)

- Routine/surveillance AICD/CRT-D/ subcutaneous ICD interrogation may be performed every 3 months, either in-person or remotely
- When device interrogation reveals that the battery is approaching elective replacement indicator (90 days or less), interrogation may be performed monthly

NOTE: Interrogation includes device programming, if performed on the same day

Wearable ICD Interrogation ⁽⁹⁾

- Life Vest™ or wearable defibrillator interrogation may be performed every 30 days

Loop Recorder Interrogation ⁽⁶⁾

- Routine loop recorder interrogation in person or remotely may be done monthly

Urgent Interrogation ⁽⁷⁾

- Appropriate when recent shock therapy from an ICD or any symptom or finding since previous CIED (ICD, pacemaker, or loop recorder) evaluation for which an interrogation earlier than recommended guideline frequency could help yield a diagnosis, or if permanent adjustment(s) were made during the last evaluation
- Indicated when recent interrogation shows battery voltage in elective replacement indicator range or end of life indicator range (may differ by device type and manufacturer)

NOTE: Interrogation includes device programming, if performed on the same day

Physiologic Interrogation ⁽⁶⁾

- Available when the patient has an implanted device which monitors transthoracic impedance as an index of fluid volume status, or the patient has an implanted device that monitors pulmonary artery pressure
- Monitoring may be performed in-person or remotely every 30 days when there is documentation that the data will be used to adjust diuretic or other heart failure therapies
- Monitoring may be performed urgently when the patient reports new or worsening symptoms of heart failure when the information obtained will be used to adjust medical therapy

Exclusions

- Remote and in-person interrogation cannot be reported at the same time

CODING AND STANDARDS

Coding

CPT Codes

93261, 93288, 93289, 93290, 93291, 93292, 93293, 93294, 93295, 93296, 93297, 93298, 93724, G2066

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

1. **CIED: Cardiac Implantable Electrical Device:** An implanted device that either monitors, or regulates the heart rate, rhythm, or function. These devices include permanent pacemakers (PPM), implantable cardioverter-defibrillators (ICD), and implantable loop recorders (ILR).

2. **AICD/CRT-D, PPM/CRT-P/Subcutaneous ICD interrogation:** Measurement of previously programmed parameters including but not limited to, battery voltage, lead capture and sensing function, heart rhythm, absence, or presence of therapy for ventricular tachyarrhythmias. Once the device battery longevity is reaching effective replacement indicator (ERI) or once it has reached end of life (EOL) the device will create an alert for replacement.
3. **Automatic implantable cardioverter defibrillator (AICD) or implantable cardioverter defibrillator (ICD):** Electronic device designed to detect and treat life-threatening tachyarrhythmia or brady-arrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing and defibrillation.
4. **CRT-D/CRT-P:** Cardiac device with multiple leads for defibrillation and cardiac pacing, capable of pacing and sensing function in the right atrium and both ventricles of the heart. Resynchronization of left ventricular depolarization is achieved by coordinating the excitation of the septum and the lateral wall, improving LV efficiency.
5. **Implantable loop recorder (ILR):** Patient- and auto-activated monitoring system that records ECG tracings and is indicated for patients who experience transient symptoms that suggest a cardiac arrhythmia. The physician utilizes a programmer to retrieve, display, and print data.
6. **ILR interrogation:**
7. Downloading previously programmed parameters and the heart rate and rhythm during recorded episodes from both patient-initiated, and device detected events, when present.
8. **Life Vest/Wearable Defibrillator (WCD) Interrogation:**
9. Previously programmed parameters, battery status, and the heart rate and rhythm during recorded episodes from both patient-initiated, and device detected events, when present.
10. **Life Vest/Wearable Defibrillator (WCD):**
11. Worn by patients with medical issues that place them at risk for sudden cardiac death (SCD) ⁽⁹⁾: Use of the wearable ICD (WCD) permits time to assess a patient's long-term arrhythmic risk and to determine if permanent ICD implantation is appropriate. It continuously monitors the patient's heart rate and, if a life-threatening heart rhythm is detected, delivers a shock intended to restore normal heart rhythm. ⁽⁹⁾ Current WCDs have embedded remote monitoring capability, allowing clinicians to monitor data downloaded from a patient's WCD. The patient downloads through the base station/battery charger. The device is connected via Bluetooth, signals are encrypted and sent wirelessly via cellular networks to the secure network website where it is archived for review. ⁽¹⁰⁾
12. **Pacemaker:** Medical device which uses electrical impulses, delivered by electrodes in contact with heart muscle, to regulate the heart rate when the normal pacemaker is too slow or there is a block in the electrical conduction system.
13. **Remote Interrogation (RI):** Remote evaluation of CIEDs using a wand-based radiofrequency platform to transfer data from patient's device to a home transceiver, then via telephone (analog phone line or cellular wireless data network) to a central repository. ⁽⁶⁾
14. **Remote Monitoring (RM):** Remote evaluation of CIEDs using automated platform by set radiofrequency transmissions sent wirelessly to a transceiver (located near the patient) then to central repository by analog landline or wireless data networks.

Minimal information includes battery status, lead integrity, and arrhythmic events. ⁽⁶⁾

15. **Subcutaneous ICD:** A defibrillator system in which shocks are delivered between a pulse generator and an electrode implanted under the skin. No intravascular leads are employed.
16. **Trans telephonic Monitoring (TTM):** Remote evaluation of CIEDs by analog transmission over a telephone line. Very limited information is available, and this method of monitoring has largely been supplanted by remote monitoring and interrogation. ⁽⁶⁾
17. **Leadless Pacemaker:** A self-contained medical device that includes pacemaker electronics and battery that is inserted directly into right side of the heart without the need for a surgical pocket and pacemaker leads. ⁽¹¹⁾
18. **Physiologic Data Interrogation:** Some devices are equipped to provide information related to the patient's volume status. The Optivol™ system uses transthoracic impedance calculated between the CIED's endocardial lead and pulse generator to reflect blood volume and lung water. This has yielded mixed clinical results. Multicenter trials have calculated positive predictive values ranging from 38.1% to 60% for the worsening of systolic heart failure. Another device using a remotely monitored implantable pulmonary artery hemodynamic sensor was tested in a large, randomized trial. Its utilization was shown to reduce HF hospitalization by 37%. ⁽⁶⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AICD: Automatic Implantable Cardiac Defibrillator

AUC: appropriate use criteria

CIEDs: Cardiovascular Implantable Electronic Devices

CIEM: Cardiovascular Implantable Electronic Monitoring

CRT-D: Cardiac Resynchronization Therapy with ICD

CRT-P: Cardiac Resynchronization Therapy with Pacemaker

ECG: electrocardiogram

EOL: end of life

ERI: elective replacement indicator

ICD: Implantable Cardioverter Defibrillator

ILR: Implantable Loop Recorder

PPM: Permanent Pacemaker

RI: Remote Interrogation
 RM: Remote Monitoring
 SCD: sudden cardiac death
 TTM: Transtelephonic Monitoring
 WCD: Wearable Cardiac Defibrillator

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1256 Cardio Policy Device Interrogation • This guideline replaces UM Cardio 1152 Cardio Policy Device Physiologic CV Data Element Interrogation

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Slotwiner D, Varma N, Akar J G, Annas G, Beardsall M et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. *Heart rhythm*. 2015; 12: e69-100. 10.1016/j.hrthm.2015.05.008.
7. Ferrick A M, Raj S R, Deneke T, Kojodjojo P, Lopez-Cabanillas N et al. 2023 HRS/EHRA/APHRS/LAHR expert consensus statement on practical management of the remote device clinic. *Heart Rhythm*. 2023; 20: e92 - e144. 10.1016/j.hrthm.2023.03.1525.
8. Madhavan M, Mulpuru S K, McLeod C J, Cha Y, Friedman P A. Advances and Future Directions in Cardiac Pacemakers: Part 2 of a 2-Part Series. *Journal of the American College of Cardiology*. 2017; 69: 211-235. 10.1016/j.jacc.2016.10.064.
9. Khan H M, Leslie S J. Risk factors for sudden cardiac death to determine high risk patients in specific patient populations that may benefit from a wearable defibrillator. *World journal of cardiology*. 2019; 11: 103-119. 10.4330/wjc.v11.i3.103.
10. Steinberg J S, Varma N, Cygankiewicz I, Aziz P, Balsam P et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. *Heart rhythm*. 2017; 14: e55-e96. 10.1016/j.hrthm.2017.03.038.
11. Vouliotis A I, Roberts P R, Dilaveris P, Gatzoulis K, Yue A. Leadless Pacemakers: Current Achievements and Future Perspectives. *European cardiology*. 2023; 18: e49. 10.15420/ecr.2022.32.



Evolut Clinical Guideline 7280 for Duplex Scan of Hemodialysis Access

Guideline Number: Evolut_CG_7280	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for duplex scan of hemodialysis (HD) access.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care ^(1,2,3,4,5).

INDICATIONS FOR DUPLEX SCAN OF HEMODIALYSIS ACCESS

- In patients at high risk of AV (arteriovenous) access failure for vascular mapping ⁽⁶⁾ or AV access insufficiency ⁽⁷⁾:
 - Access collapse suggesting poor arterial inflow
 - Poorly matured fistula
 - Loss of thrill
 - Palpable “water hammer” pulse
 - Abnormal bruit over fistula
 - Distal limb ischemia
 - Clinical signs of infection
 - Perigraft mass, aneurysm, or pseudoaneurysm
- In patient with abnormal fistula function ⁽⁷⁾:

- Elevated venous pressure greater than 200 mmHg on a 300 cc/min pump
- Elevated recirculation time of 15% or greater
- Low urea reduction rate of less than 60%.
- For evaluation of suspected central vein occlusion to determine the suitability of AV access creation ⁽⁶⁾
- In patients suspected with clinically significant AV access lesion, further confirmatory evaluation including imaging of the dialysis access circuit within less than two weeks is recommended ⁽⁶⁾
- In cannulation complication for flow direction and proper needle placement in AV access ⁽⁶⁾
- In corroboration with physical examination in confirming AV access infection, AV access aneurysm/pseudoaneurysm, vessel size, presence of stenosis/thrombus, and AV flow parameters (such as flow rate, arterial inflow and venous outflow) ⁽⁶⁾
- In patients with complicated AVG (arteriovenous graft) seroma for careful monitoring ⁽⁶⁾
- As post-operative examination within 6 - 8 weeks and 2 - 4 months after AVF (arteriovenous fistula)/AVG creation to validate maturation of newly created AVF/AVG ⁽⁸⁾
- In patients with prolonged immaturity \geq 6 weeks of a surgically created AVF ⁽⁸⁾

CODING AND STANDARDS

Coding

CPT Codes

93990

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow) combines Doppler and conventional ultrasound to see the structure of blood vessels, how the blood is flowing through the vessels, and whether there is any obstruction in the vessels. Combining spectral Doppler analysis and color flow doppler images provide anatomic and hemodynamic information.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AV: Arteriovenous

AVF: Arteriovenous fistula

AVG: Arteriovenous graft

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1079 Duplex Scan of Hemodialysis Access ● Updated indications for Duplex Scan of Hemodialysis Access ● Removed Special Note and Limitation sections ● Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Journal of the American College of Cardiology*. 2011; 58: 1517-38.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Lok C E, Huber T S, Lee T, Shenoy S, Yevzlin A S et al. KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. *American journal of kidney diseases*. 2020; 75: S1-S164.
7. Teodorescu V, Gustavson S, Schanzer H. Duplex ultrasound evaluation of hemodialysis access: a detailed protocol. *International journal of nephrology*. 2012; 2012: 508956.
8. Schmidli J, Widmer M K, Basile C, de Donato G, Gallieni M et al. Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). *European journal of vascular and endovascular surgery*. 2018; 55: 757-818.



Evolut Clinical Guideline 7281 for Guideline Directed Medical Therapy – Heart Failure and Coronary Artery Disease

Guideline Number: Evolut_CG_7281		
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Original Date: May 2024	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Heart failure with reduced ejection fraction (HFrEF) is a complex condition that can arise from multiple factors, including coronary artery disease, hypertension, myocardial infarction, valvular heart disease, and cardiomyopathies. These underlying conditions collectively impair the heart's ability to effectively pump blood, leading to a reduction in ejection fraction. Similarly, heart failure with preserved ejection fraction (HFpEF) presents with comparable symptoms but is distinguished by a left ventricular ejection fraction (LVEF) of 50% or higher.

Medical management is of utmost importance in addressing both HFrEF and HFpEF, aiming to alleviate symptoms, improve quality of life, and extend lifespan. Medications play a crucial role in reducing cardiac workload, enhancing cardiac function, and managing fluid overload. Before considering invasive procedures, the administration of medications is essential to stabilize the patient's condition, optimize cardiac function, and minimize the risks associated with such interventions.

Guideline-Directed Medical Therapy (GDMT) serves as the cornerstone of management for both heart failure and coronary artery disease (CAD). Evidence-based guidelines universally recommend GDMT for individuals diagnosed with CAD, particularly as a primary treatment for stable CAD and as a crucial component of secondary prevention following coronary revascularization procedures like percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). GDMT has been associated with a significant reduction in death rates and the risk of myocardial infarction (MI), and in some cases, its impact on mortality reduction may even surpass that of selecting a specific revascularization method. Notably, GDMT for CAD intersects with recommendations for heart failure management, emphasizing the importance of comprehensive and integrated care for individuals with these conditions.

Purpose

GDMT must be administered before further consideration of additional imaging and/or initial or additional procedures. This document outlines the requirements based on the current ACC and AHA recommendations.

Clinical Reasoning

The current ACC/AHA clinical practice guidelines have established the requirements for pharmacologic therapy considered for patients with chronic CAD and/or NYHA Class II-IV.

When applicable, optimal GDMT shall focus on therapies with Class I recommendations that have demonstrated reductions in morbidity, mortality, and improvements in patient quality of life, unless specified. The beneficial effects of medications can become apparent within weeks of initiation. These drugs have additive effects and in most cases the effects are dose related. As a result, GDMT stipulates that all medications be initiated and then titrated to the maximal tolerated dose (or a target dose) as quickly as possible. ^(1,2,3,4,5)

INDICATIONS

Guideline Directed Medical Therapy (GDMT) for HFrEF (non-ischemic) ^(6, 7)

Documentation must be provided of all the following:

- **NYHA functional class (see Definitions)**
- **The report of the last modality having measured the ejection fraction (EF)**
 - MUGA
 - Echocardiography
 - Left Ventriculogram
 - Nuclear stress test (SPECT)
 - Cardiac MRI
 - Cardiac CT
 - Cardiac PET
- **An up-to-date list of heart failure medications and their dosages (see Definitions).** The following medications need to be addressed along with any intolerance or reason a medication cannot be titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)
 - ACE inhibitor/ARB OR angiotensin receptor neprilysin inhibitor (ARNI)
 - Beta blocker (bisoprolol, carvedilol, and metoprolol succinate)
 - MRA
 - SGLT2 Inhibitor
- **Last vital signs measured while on medications**
 - Vital signs must be reasonably controlled (i.e., BP <140/90mmHg, HR <100)
- **Documentation of Time since GDMT has been optimized:**
 - Patients diagnosed with non-ischemic heart failure with reduced ejection fraction (HFrEF) should be maintained on maximal tolerated GDMT **for a period of 12 weeks** before moving forward with any additional testing or invasive/interventional procedures.

Guideline Directed Medical Therapy (GDMT) for HFrEF (Ischemic) ^(6, 7)

ISCHEMIC CARDIOMYOPATHY: In addition to the recommendations for GDMT in heart failure for non-ischemic cardiomyopathy (SEE ABOVE), those with suspected or known CAD should additionally document all of the following:

- **The report of the last modality having demonstrated coronary disease**
 - Non-Invasive testing
 - Nuclear stress test (SPECT)
 - Stress Echocardiography
 - Coronary CTA
 - Cardiac PET scan
 - Cardiac MRI
- Within the up-to-date list of medications and their dosages, as stated for heart failure in non-ischemic cardiomyopathy, **additional medications should document:**
 - Antiplatelet Therapy
 - Statin Therapy
- Patients diagnosed with ischemic heart failure with reduced ejection fraction (HFrEF) should be maintained on maximal tolerated GDMT for a period time before moving forward with any additional testing or invasive/interventional procedures.
 - The following time periods have been established post MI:
 - **Non-revascularized: 40 days**
 - **Revascularized: 12 weeks**

Guideline Directed Medical Therapy (GDMT) for HFpEF ^(7, 8)

Heart Failure with preserved Ejection Fraction (HFpEF) is diagnosed clinically when the Left Ventricular Ejection Fraction (LVEF) is equal to or greater than 50%. It should be noted that HFpEF is not interchangeable with diastolic dysfunction, as the presence of diastolic dysfunction on echocardiogram lacks the specificity required for clinical diagnosis or condition. A comprehensive diagnostic evaluation is warranted to ascertain underlying etiologies that may mimic HFpEF. Following confirmation of HFpEF, therapeutic interventions should prioritize addressing comorbidities and adhering to guideline-directed medical therapy (GDMT) to optimize patient outcomes, including enhancing quality of life, reducing hospitalizations, and improving survival rates. This guideline is specifically dedicated to delineating the medical management strategies post-confirmation of HFpEF diagnosis (GDMT).

Documentation must be provided of all of the following:

- **NYHA functional class (see Definitions)**
- **The report of the last modality having measured the Ejection Fraction**

- MUGA
- Echocardiography
- Left Ventriculogram
- Nuclear stress test (SPECT)
- Cardiac MRI
- Cardiac CT
- Cardiac PET
- **Documentation that other conditions that mimic HFpEF have been considered**
- **An up-to-date list of heart failure medications and their dosages (see Definitions).** The following medication needs to be addressed along with any intolerance or reason it cannot be titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)
 - SGLT2 Inhibitor
- **Last Vital signs measured while on medications**
 - Vital signs must be reasonably controlled (i.e., BP <140/90mmHg)
- **Documentation of Time since GDMT has been optimized**

Guideline Directed Medical Therapy (GDMT) for CAD with Preserved Ejection Fraction ⁽⁹⁾

All of the following must be documented for GDMT:

- **Canadian Class for angina (see Definitions) or description of ongoing symptoms despite medications**
- **The report of the last modality having demonstrated coronary disease**
 - Non-Invasive testing
 - Nuclear stress test (SPECT)
 - Stress Echocardiography
 - Coronary CTA
 - Cardiac PET scan
 - Cardiac MRI
- **An up-to-date list of anti-anginal and risk modifying medications and their dosages (see Definitions).** At least two of the following medications need to be addressed along with any intolerance or reason at least two medications cannot be titrated (when titration is indicated) to maximal dosing (i.e. renal dysfunction, side effects, blood pressure, heart rate limitations, etc.)
 - ACE inhibitor/ARB OR angiotensin receptor neprilysin inhibitor (ARNI)

- Beta blocker if between 0- 3 years from MI (myocardial infarction)
- Nitrates
- Calcium channel blockers
- Ranolazine
- **Last vital signs measured while on medications**
 - Vital signs must be reasonably controlled (i.e., BP <140/90mmHg, HR <100)
- **Documentation of Time since GDMT has been optimized**
- **Exceptions for GDMT documentation:** The following **does not require** GDMT documentation:
 - Class I indications for revascularization inclusive of high-risk non-invasive testing, or prior invasive testing demonstrating high risk left main (LM) CAD and multivessel CAD associated with diabetes.

CODING AND STANDARDS

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

- **Heart failure with reduced ejection fraction (HFrEF)**, also known as systolic heart failure, occurs when the left ventricle of the heart is unable to pump blood efficiently. In this condition, the heart’s pumping function is weakened, resulting in less blood being ejected into the body. HFrEF is characterized by a left ventricular ejection fraction (LVEF) of ≤40%. Patients with HFrEF may experience symptoms such as fatigue, shortness of breath, and fluid retention.
- **Heart failure with preserved ejection fraction (HFpEF)** occurs when the heart’s main

pumping chamber (left ventricle) has a normal or near-normal ejection fraction (EF). In HFpEF, the EF is $\geq 50\%$. As opposed to HFrEF, the hallmark of HFpEF is stiffening of the heart muscle, particularly in the left ventricle. This stiffness impairs the heart's ability to relax and fill with blood properly causing similar symptoms as HFrEF.

- **Guideline-Directed Medical Therapy (GDMT):** Evidence-based treatment regimens recommended by clinical practice guidelines for managing specific medical conditions. These guidelines are developed by expert panels and professional organizations to provide standardized, effective, and safe approaches to patient care. GDMT typically includes medications, lifestyle modifications, and other interventions that have demonstrated efficacy in improving patient outcomes. Evidence based pharmacologic therapies used in treatment of HFrEF have demonstrated a reduction in morbidity, mortality, and rate of hospitalization. Efficacious therapies used in HFpEF are directed towards the treatment of the underlying condition (e.g., HTN, AF) rather than on HR. Unless otherwise indicated, class 1 level of evidence will be used as the basis of the recommendations outlined in this document
- **American College of Cardiology/American Heart Association (ACC/AHA) Stages of HF ⁽⁷⁾:**
 - Stage A: At high risk for HF but without structural heart disease or symptoms of HF
 - Stage B: Structural heart disease but without signs or symptoms of HF
 - Stage C: Structural heart disease with prior or current symptoms of HF
 - Stage D: Refractory HF requiring specialized interventions
- **New York Heart Association (NYHA) Functional Classification ⁽⁸⁾:**
 - Class I: No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF
 - Class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF
 - Class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF
 - Class IV: Unable to perform any physical activity without symptoms of HF, or symptoms of HF at rest

Medications HFref⁽⁷⁾:

Drug Class	Starting dose	Target dose
Beta-Blockers		
Bisoprolol	1.25 mg once daily	10 mg once daily
Carvedilol	3.125 mg twice daily	25 mg twice daily for weight <85 kg and 50 mg twice daily for weight ≥85 kg
Metoprolol succinate	12.5–25 mg daily	200 mg daily
ARNIs		
Sacubitril/valsartan	24/26 mg–49/51 mg twice daily	97/103 mg twice daily
ACEIs		
Captopril	6.25 mg 3× daily	50 mg 3× daily
Enalapril	2.5 mg twice daily	10–20 mg twice daily
Lisinopril	2.5–5 mg daily	20–40 mg daily
Ramipril	1.25 mg daily	10 mg daily
ARBs		
Candesartan	4–8 mg daily	32 mg daily
Losartan	25–50 mg daily	150 mg daily
Valsartan	40 mg twice daily	160 mg twice daily
Aldosterone antagonists		
Eplerenone	25 mg daily	50 mg daily
Spirolactone	12.5–25 mg daily	25–50 mg daily
SGLT2 inhibitors		
Dapagliflozin	10 mg daily	10 mg daily
Empagliflozin	10 mg daily	10 mg daily
Vasodilators		
Hydralazine	25 mg 3× daily	75 mg 3× daily
Isosorbide Dinitrate	20 mg 3× daily	40 mg 3× daily
Fixed-dose combination	20 mg/37.5 mg (1 tab) 3× daily	2 tabs 3× daily
<p>ACC = American College of Cardiology; ACEI = angiotensin-converting enzyme inhibitor; AHA = American Heart Association; ARB = angiotensin receptor blocker; ARNI = angiotensin receptor-neprilysin inhibitor; GDMT = guideline-directed medical therapy; HF = heart failure; HFref = heart failure with reduced ejection fraction; HFSA = Heart Failure Society of America; SGLT2 = sodium-glucose cotransporter-2.</p>		

Medications HFpEF ⁽⁷⁾:

Drug Class	Starting dose	Target dose
SGLT2is		
Dapagliflozin	10 mg daily	10 mg daily
Empagliflozin	10 mg daily	10 mg daily
Aldosterone antagonists		
Spirolactone	25 mg daily	50 mg daily
ARNIs		
Sacubitril/valsartan	24 mg/26 mg twice daily	97 mg/103 mg twice daily
ARBs		
Candesartan	4 mg to 8 mg daily	32 mg daily
ARB = angiotensin receptor blocker; ARNI = angiotensin receptor–neprilysin inhibitor; GDMT = guideline-directed medical therapy; HFpEF = heart failure with preserved ejection fraction; SGLT2 = sodium-glucose cotransporter-2.		

- **The Canadian Cardiovascular Society (CCS)** provides a grading system for angina pectoris, which helps classify the severity of angina based on the patient’s limitations during physical activity. Here are the four classes in the CCS angina grading scale ⁽¹⁰⁾:
 - **Class I:** Patients experience angina only during strenuous or prolonged physical activity (such as walking or climbing stairs). Ordinary physical activity does not cause angina
 - **Class II:** Patients have slight limitation of ordinary activity. Angina occurs during vigorous physical activity, rapid walking, walking uphill, after meals, in cold or windy conditions, under emotional stress, or only during the few hours after awakening. They can still walk more than two blocks on level ground and climb more than one flight of ordinary stairs at a normal pace and in normal conditions
 - **Class III:** Patients experience marked limitation of ordinary physical activity. They can walk only one or two blocks on level ground and climb one flight of stairs at a normal pace and in normal conditions
 - **Class IV:** Patients have inability to carry on any physical activity without discomfort. Anginal symptoms may even be present at rest. Non-Pharmacological Therapy – While not explicitly listed as a prerequisite in this guideline, it is still important to mention for the sake of completeness, other crucial facets of treatment

- **Non-Pharmacological Therapy – While not explicitly listed as a prerequisite in this guideline, it is still important to mention for the sake of completeness, other crucial facets of treatment** ^(7,8):
 - Smoking and alcohol cessation counseling
 - Weight management- restrict fluid intake if serum sodium is low; reduce weight if obese
 - Lifestyle modifications (e.g., diet, exercise program)
 - Limit dietary sodium intake (1500 mg/day for most patients with stage A and B HF; < 3g/day in patients with stage C and D HF)
 - Control diabetes mellitus (with DM- HbA1c level ≤ 6.5%) and hypertension (HTN- BP goal < 130/80 mm Hg)
 - Cardiac rehabilitation: patient evaluation and monitoring to support drug titration, monitor symptoms, improve health status, and increase exercise tolerance should continue after start of GDMT at least monthly for 3 months and every 3 months thereafter (more frequent follow up may be necessary for select patients)

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1462 for Guideline Directed Medical Therapy (GDMT) for Heart Failure and Coronary Artery Disease (CAD)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. [10.1161/CIR.0b013e31822935fc](https://doi.org/10.1161/CIR.0b013e31822935fc).
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. [10.1016/j.jacc.2018.01.007](https://doi.org/10.1016/j.jacc.2018.01.007).
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. [10.1016/j.jacc.2013.01.025](https://doi.org/10.1016/j.jacc.2013.01.025).
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. [10.1016/j.jacc.2005.08.030](https://doi.org/10.1016/j.jacc.2005.08.030).
6. Maddox, T, Januzzi, J. et al. 2024 ACC Expert Consensus Decision Pathway for Treatment of Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2024; 83(15), 1444-1488. <https://doi.org/10.1016/j.jacc.2023.12.024>
7. Heidenreich, P. A., Bozkurt, B., Aguilar, D., Allen, L. A., Byun, J. J., Colvin, M. M., ... & Milano, C. A. (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145(18), e895-e1032. <https://doi.org/10.1161/CIR.0000000000001063>
8. Kittleson, M, Panjra, G, Amancherla, K. et al. 2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure With Preserved Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2023; 81 (18), 1835–1878. <https://doi.org/10.1016/j.jacc.2023.03.393>
9. Virani, S. S., Newby, L. K., Arnold, S. V., et al. (2023). 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease. *Circulation*. 2023; 148(9), e9–e119
10. Campeau L. (1976). Letter: Grading of angina pectoris. *Circulation*, 54(3), 522–523.

Evolut Clinical Guideline 7282 for Atrial Fibrillation Ablation

Guideline Number: Evolut_CG_7282	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Define indications for approval of ablation in the management of atrial fibrillation.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CATHETER ABLATION OF ATRIAL FIBRILLATION (AF) ^(6,7,8)

Failed Antiarrhythmic Therapy

Catheter ablation is recommended or reasonable for any of the following that are refractory or intolerant to at least one Class I or III antiarrhythmic medication:

- Symptomatic paroxysmal AF
- Symptomatic persistent AF
- Symptomatic long standing persistent AF

First Line Therapy for Symptomatic Atrial Fibrillation

Catheter ablation is recommended or reasonable for the following patients:

- Symptomatic paroxysmal or persistent atrial fibrillation who have not undergone trial(s) of class I or III antiarrhythmic therapy

- Long-standing persistent atrial fibrillation (defined as continuous AF for >12 months) who have not undergone trial(s) of class I or III antiarrhythmic therapy

INDICATIONS FOR RECURRENCE OF ATRIAL FIBRILLATION OR ATRIAL TACHYCARDIA (AT) AFTER ABLATION (6,8)

- Early recurrence after AF ablation has been defined as any recurrence of AF or AT lasting 30 seconds during the first 3 months of follow-up

NOTE: 50% of early tachycardias are reentrant atrial tachycardias, and 49% resolve spontaneously over the first year. They should be treated with Class III antiarrhythmic therapy unless intolerable symptoms persist after this therapy is attempted. (Class Ic drugs are relatively contraindicated, as they tend to promote and prolong these reentrant arrhythmias).

- Late term recurrence has been defined as any recurrence of AF or AT lasting 30 seconds between 3 and 12 months after AF; mapping and ablation of these rhythm disturbances is recommended

INDICATIONS FOR SURGICAL ABLATION OF ATRIAL FIBRILLATION (6,8)

Concomitant “Open” Surgical Ablation

Concomitant "Open" surgical ablation (such as mitral or tricuspid valve surgery) for patients with any of the following:

- Symptomatic AF, refractory or intolerant to at least one Class I or III antiarrhythmic drug, and any form of AF (paroxysmal, persistent, or long-standing persistent), surgical ablation is recommended
- Symptomatic AF prior to a trial of antiarrhythmic therapy with a Class I or III antiarrhythmic drug and any form of AF, surgical ablation is recommended

Concomitant “Closed’ Ablation

Concomitant “Closed’ Ablation (CABG, aortic valve surgery, etc.) for patients with any of the following:

- Symptomatic AF refractory or intolerant to at least one Class I or III antiarrhythmic drug and any form of AF, surgical ablation is recommended
- Symptomatic AF prior to a trial of antiarrhythmic therapy with a Class I or III antiarrhythmic drug and any form of AF, surgical ablation is reasonable

Stand Alone and Hybrid (catheter- and surgical-) Ablation

- Stand Alone and/or Hybrid surgical ablation for patients (after review of the relative safety and efficacy of catheter ablation versus a stand-alone surgical approach:

- Who have failed one or more attempts at catheter ablation
- Who are intolerant or refractory to antiarrhythmic drug therapy and prefer a surgical approach

INDICATIONS FOR AV NODAL ABLATION AND PERMANENT PACEMAKER IMPLANTATION (6,8)

- Implantation of a permanent pacemaker, followed by ablation of the AV node, should be reserved for patients in whom rhythm control with antiarrhythmic drugs or catheter ablation, and rate control with pharmacological therapy has failed or is contraindicated or has been refused by the patient ⁽⁷⁾
- AV nodal ablation is approvable in patients with atrial fibrillation and with existing bi-ventricular pacing systems, to increase the percentage of resynchronized pacing and efficacy of the pacing system

CODING AND STANDARDS

Coding

CPT Codes

93623, 93650, 93653, 93656, 93657

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Pulmonary vein isolation (PVI) is the cornerstone of atrial fibrillation (AF) ablation, and the primary target endpoint for first-time AF ablation. Because the substrate for atrial fibrillation is typically left atrial, transseptal puncture for access to the left atrium is required in all AF ablation procedures. ^(6,7)

Risk of atrial fibrillation does not increase appreciably in the setting of heart failure or advancing age (up to age 80).

The most common energy source for atrial fibrillation ablation is radiofrequency (RF) energy. In recent years, cryoablation using a balloon catheter has become a reliable alternative to RF energy. Other techniques for ablation include laser balloon systems, multielectrode arrays and balloon-based ultrasound ablation systems. ⁽⁶⁾

Patients with ostensibly asymptomatic atrial fibrillation are often discovered to have been symptomatic once a “trial of sinus rhythm” after cardioversion has been undertaken. Based on this observation, AHA/ACC/HRS guidelines recommend ablation of atrial fibrillation in asymptomatic patients after careful discussion of the risks, benefits, and alternatives of this approach. ⁽⁶⁾

Atrio-Esophageal Fistula (AEF) is a rare but life-threatening complication of atrial fibrillation ablation. After ablation, symptoms and findings suggesting the possibility of evolving AEF include chest pain, painful swallowing, fever, leukocytosis, TIA, and/or stroke typically occurring between 1- and 3-weeks post ablation. If esophageal injury is suspected, CT imaging with intravenous and water- soluble oral contrast is recommended. Surgical resection of the fistula may be lifesaving. ⁽⁶⁾

Pacemaker implantation followed by AV nodal ablation (“ablate-and-pace”) is typically performed in older patients. It has the advantage of improving symptoms related to irregular and rapid heartbeats and may improve LVEF in patients with tachycardia-associated cardiomyopathy. It exposes the patient to the potential complications of long-term indwelling hardware and pacemaker-dependency. ⁽⁷⁾

Definitions

- Long-standing atrial fibrillation: continuous atrial fibrillation for greater than 12 months
- Class I antiarrhythmic therapy: Produce Na⁺ channel block and reduce AP phase 0 slope and overshoot with variable effects on AP duration (APD) and effective refractory period (ERP) ⁽⁹⁾
- Class II antiarrhythmic therapy: Class II drugs, comprising β -adrenergic inhibitors, reduce sino-atrial node (SAN) pacing rates and slow atrioventricular node (AVN) conduction ⁽⁹⁾
- Class III antiarrhythmic therapy: Comprising K⁺ channel blockers, prolong AP phase 3 repolarization and lengthen ERP ⁽⁹⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ACC: American College of Cardiology

AEF: Atrio-Esophageal Fistula

AF: Atrial fibrillation

AHA: American Heart Association
 AP: action potential
 APD: action potential duration
 AT: Atrial tachycardia
 AUC: appropriate use criteria
 AV: atrioventricular
 AVN: atrioventricular node
 CABG: coronary artery bypass graft
 CT: computed tomography
 ERP: effective refractory period
 HRS: Heart Rhythm Society
 LVEF: left ventricular ejection fraction
 PVI: pulmonary vein isolation
 RF: radiofrequency
 RFA: Radiofrequency ablation
 TIA: transient ischemic attack

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> <li data-bbox="531 1279 1353 1346">● This guideline replaces UM Cardio 1141 Cardio Policy EPS with AI, Pacing after DI and Atrial or SVT and AP Ablation <li data-bbox="531 1361 1353 1429">● This guideline replaces UM Cardio 1142 Cardio Policy EPS with AI for AFib AVN and AP Ablation

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Calkins H, Hindricks G, Cappato R, Kim Y, Saad E B et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart rhythm*. 2017; 14: e275-e444. 10.1016/j.hrthm.2017.05.012.
7. Gupta D, Rienstra M, van Gelder I C, Fauchier L. Atrial fibrillation: better symptom control with rate and rhythm management. *The Lancet regional health. Europe*. 2024; 37: 100801. 10.1016/j.lanepe.2023.100801.
8. Joglar J, Chung M, Armbruster A, Benjamin E, Chyou J et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024; 149: e1-e156. 10.1161/CIR.0000000000001193.
9. Lei M, Wu L, Terrar D A, Huang C L. Modernized Classification of Cardiac Antiarrhythmic Drugs. *Circulation*. 2018; 138: 1879 - 1896. 10.1161/CIRCULATIONAHA.118.035455.

Evolut Clinical Guideline 7283 for Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff

Guideline Number: Evolut_CG_7283	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff.

Special Note

Decisions regarding the potential utility of invasive therapeutic interventions (percutaneous or surgical) in patients with lower extremity peripheral arterial disease should be made with a complete anatomic assessment of the affected arterial territory, including imaging of the occlusive lesion, as well as arterial inflow and outflow with angiography or a combination of angiography and noninvasive vascular techniques.

Noninvasive imaging modalities, including MRA, CTA, and color flow duplex imaging, may be used in advance of invasive imaging to develop an individualized diagnostic strategic plan, including assistance in selection of access sites, identification of significant lesions, and determination of the need for invasive evaluation.

Diagnostic peripheral angiography performed at the time of an interventional procedure is separately reportable if at least one indication for medical necessity for a stand-alone lower extremity is met AND one of the following is also met:

- No prior catheter-based angiographic study is available, and a full diagnostic study is performed, and the decision to intervene is based on the diagnostic study, or
- A prior study is available, but as documented in the medical record:
 - the patient's condition with respect to the clinical indication has changed since the prior study; or
 - there is inadequate visualization of the anatomy or pathology; or
 - there is a clinical change during the interventional procedure that requires new evaluation outside the target area of intervention.

Guideline Directed Medical Therapy

Documentation is required confirming that patient is receiving optimal GDMT for heart failure, including standard medication (and, as indicated, coronary revascularization and biventricular pacing).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS ^(6,7)

- Significant disability despite medical therapy (GDMT) with documentation of outflow or inflow peripheral arterial disease by prior non-invasive study and further study is needed by angiography with the intent of subsequent intervention
- Following:
 - detection of aneurysm and other primary vascular abnormalities that require further investigation for effective treatment
 - the detection of occlusive disease, including evaluation for acute or chronic intestinal ischemia
 - stabilization of GI hemorrhage as an outpatient/elective procedure

CODING AND STANDARDS

Coding

CPT Codes

36200, 36245, 36246, 36247, 36248, 75625, 75630, 75710, 75716, 75726, G0278

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM 1170 Abdominal Aortography with Bilateral Iliofemoral Lower Extremity Runoff

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Bailey S, Beckman J, Dao T, Misra S, Sobieszczyk P et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine. *Journal of the American College of Cardiology*. 2019; 73: 214 - 237. <https://doi.org/10.1016/j.jacc.2018.10.002>.
7. Gerhard-Herman M, Gornik H, Barrett C, Barshes N, Corriere M et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017; 135: e686 - e725. 10.1161/CIR.0000000000000470.



Evolut Clinical Guideline 7284 for Catheter Ablation of Reentrant or Focal Tachydysrhythmias

Guideline Number: Evolut_CG_7284	<u>Applicable Codes</u>	
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Original Date: January 2025	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

To identify the indications for catheter ablation of focal or reentrant cardiac tachydysrhythmias.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR CATHETER ABLATION OF CARDIAC ARRHYTHMIAS

Supraventricular Tachycardias ^(6,7)

Ablation of Supraventricular Tachycardias

Patients with any of the following:

- Frequent or poorly tolerated episodes of sustained tachycardia that do not adequately respond to drug therapy
- Who prefer ablative therapy compared to pharmacological treatment
- Frequent episodes of tachycardia requiring drug treatment when there is concern about side effects of the antiarrhythmic drug

Supraventricular Tachycardia Amenable to Ablation

- Inappropriate Sinus Tachycardia: Sinus node modification should be considered only for patients who are highly symptomatic and cannot be adequately treated by medication, and then only with documentation of informing the patient that the risks may outweigh the benefits.
- Focal Atrial Tachycardia (AT): patients with symptomatic focal AT as an alternative to pharmacological therapy
- Patients with Atrioventricular Nodal Reentrant Tachycardia (AVNRT—the most common form of SVT)
- Manifest and Concealed Accessory Pathways (WPW with or without atrioventricular reentrant tachycardia (AVRT)), catheter ablation of accessory pathway for any of the following:
 - AVRT and/or pre-excited atrial fibrillation
 - EPS demonstrates a high risk of dangerous events, including rapidly conducting pre-excited atrial fibrillation (shortest R-R interval \leq 250 msec)
 - Asymptomatic persons with high-risk occupations (airline pilots, police, firefighters, etc.)
- Atrial Flutter:
 - Catheter ablation of cavo-tricuspid-dependent (typical type 1 or 2) atrial flutter is recommended as an alternative to pharmacological therapy for symptomatic patients
 - For asymptomatic patients when drug therapy fails to achieve adequate rate control
 - Catheter ablation of non-cavo-tricuspid-dependent (atypical and left sided) atrial flutter is recommended for symptomatic recurrent flutter after failure of at least one antiarrhythmic drug. It may be performed in patients who prefer ablation therapy over pharmacological treatment after thorough discussion of the risks and complexity of ablation.
- Junctional Tachycardia:
 - Catheter ablation of accelerated junctional rhythm may be performed in symptomatic patients who have failed medical therapy with beta blockers, calcium channel blockers, or Class IC drugs, or when medical therapy is contraindicated

Catheter Ablation in Pediatric Patients: Elective catheter ablation is reserved for patients > 15 kg. Ablation of SVT in smaller patients (< 15 kg) should be reserved for arrhythmias refractory to drug therapy or resulting in tachycardia-related cardiomyopathy.

Ventricular Arrhythmias (6,8,9)

Ventricular Extrasystoles

- Isolated frequent monomorphic PVCs resulting in tachycardia-associated cardiomyopathy (LVEF <50%) are an indication for mapping and ablation of the source of the extrasystoles
- PVC ablation may be performed in patients with **highly symptomatic**, monomorphic

premature ventricular complexes (PVCs), couplets, or NSVT, independent of ejection fraction

- Mapping and ablation of frequent monomorphic ventricular extrasystoles may be performed in patients with other risk factors for future arrhythmic events, such as:
 - Positive signal-averaged ECG
 - Nonsustained VT on ambulatory ECG recordings with inducible sustained monomorphic ventricular tachycardia on EPS

NOTE: Catheter ablation is **NOT** indicated for asymptomatic patients with PVCs, couplets, and nonsustained VT without other risk factors for sustained arrhythmias.

Ventricular Tachycardia without Apparent Structural Heart Disease

- In patients with symptomatic outflow tract ventricular tachycardias in an otherwise normal heart for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient's preference
- Catheter ablation of fascicular ventricular tachycardia is indicated for patients with symptomatic VT when refractory to medical therapy or when the patient prefers catheter ablation over medical therapy
- Catheter ablation may be performed in patients with symptomatic papillary muscle ventricular tachycardia for whom antiarrhythmic medications are ineffective, not tolerated, or not the patient's preference

Ventricular Tachycardia with Structural Heart Disease

- In patients with ischemic heart disease and recurrent ventricular tachycardia with an ICD in place, catheter ablation may be performed after failure of antiarrhythmic therapy (i.e., treatment with amiodarone or sotalolol should be utilized to suppress recurrent VT prior to consideration of catheter ablation)
- With prior myocardial infarction and ICD shocks for sustained monomorphic VT or symptomatic sustained monomorphic VT that is recurrent and hemodynamically tolerated, catheter ablation as first-line therapy may be performed to reduce recurrent ventricular tachycardia
- Nonischemic cardiomyopathy and recurrent sustained monomorphic VT with failure or intolerance of antiarrhythmic medications, catheter ablation may be performed for reducing recurrent VT and ICD shocks
- In bundle branch reentrant ventricular tachycardia, catheter ablation may be performed for reducing the risk of recurrent VT

Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)

- Ablation is appropriate for:
 - Arrhythmogenic right ventricular cardiomyopathy (ARVC) patients who have experienced recurrent VT or ICD therapies (shocks or antitachycardia pacing), refractory to antiarrhythmic therapy
 - ARVC that has failed one or more attempts at catheter ablation of recurrent ventricular tachycardia, ablation using an epicardial approach is recommended
 - ARVC patients with recurrent VT that is symptomatic or requires ICD therapy who

prefer not to use antiarrhythmic drugs

CODING AND STANDARDS

Coding

CPT Codes

93462, 93654

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

With the exception of incessant rhythm disturbances and atrial fibrillation, most ablation procedures will be performed after (frequently immediately after) electrophysiology studies in which the mechanism of the dysrhythmia will have been elucidated. ⁽⁶⁾

Ablation of cardiac arrhythmias involves the use of multielectrode catheters introduced into the cardiac chambers, and typically positioned in the right atrium, right ventricle, region of the A-V Node and/or the Bundle of His, and frequently the coronary sinus. Several access sites are typically required, and may include the femoral vein(s), jugular vein(s), subclavian vein(s) and the brachial vein(s). When access to the left heart is required, an atrial transseptal puncture may be utilized, or a retrograde approach via the femoral artery and across the aortic valve; systemic anticoagulation is mandated in these cases. Sophisticated mapping systems are often utilized in ablation procedures to generate 3-dimensional representations of the cardiac chambers, characterizing the sequence of activation of myocardium during arrhythmia, the presence of scar tissue and areas of slow conduction of electrical impulses, and anatomic barriers that serve as targets to modify the substrate and eliminate or reduce arrhythmia recurrence. ⁽¹⁰⁾

Radiofrequency current is the most used energy source for ablation. Cryoablation is a useful alternative to radiofrequency ablation. Cryoablation has been shown to minimize injury to the AV node during ablation of specific arrhythmias, such as AVNRT, para-Hisian atrial tachycardia, and para-Hisian accessory pathways, especially in children and young adults. Selection of the energy source depends on operator experience, arrhythmia target location, and patient preference. Catheter ablation is typically performed using an endocardial approach. In selected cases, particularly in ventricular tachycardias in patients with

nonischemic cardiomyopathy, an epicardial approach accessing the pericardial space, may be required to reach target sites for ablation. ^(7,8,9)

Typical counterclockwise atrial flutter depends on a large reentrant circuit with a region of slow conduction in the cavo-tricuspid isthmus and has a characteristic appearance of the P waves on 12 lead ECG. Non-cavo-tricuspid isthmus-dependent flutters are generated by atrial scarring, which may develop after prior ablation procedures in the atrium (such as atrial fibrillation ablation), and after surgical interventions involving atriotomy. They require more extensive and complex mapping than typical atrial flutter. ⁽⁷⁾

Paroxysmal junctional tachycardia (aka junctional ectopic tachycardia is rare in adults) is seen most commonly in pediatric postoperative patients and after surgery for congenital heart disease in adults. Nonparoxysmal junctional tachycardia (aka accelerated junctional rhythm) is more common, typically benign, and usually responds well to pharmacological therapy. It is sometimes seen after slow pathway ablation for AVNRT and is usually self-limited. ⁽⁷⁾

Idiopathic monomorphic ventricular tachycardias in patients with structurally normal hearts are commonly the result of triggered activity or abnormal automaticity, while a few involve microreentry. They have a more benign clinical course than VT seen in association with structural heart disease, and often respond to calcium channel blockers and Type Ic antiarrhythmic drugs. Catheter ablation is appropriate for symptomatic patients who are either refractory to medical therapy or who prefer catheter ablation over medical treatment. ^(8,9)

Sustained ventricular tachycardia in patients with structural heart disease is usually treated with implantation of an ICD. Ablation is reserved for patients with frequent episodes of symptomatic VT that is refractory to therapy with antiarrhythmic drugs or in whom pharmacological therapy is not tolerated or contraindicated. Some patients have sustained VT which is hemodynamically well-tolerated, but often recurrent or incessant. In these cases, catheter ablation is recommended and often effective. ⁽⁸⁾

Bellhausen's idiopathic left ventricular tachycardia (fascicular VT) is caused by reentry involving a portion of the left ventricular Purkinje system, usually the left posterior fascicle as the retrograde limb of the circuit and a poorly defined segment of LV tissue as the anterograde limb. Parts of the circuit are often verapamil-sensitive. These VTs demonstrate a right bundle-branch block configuration with a superior axis and are amenable to catheter ablation with high rates of success. ^(8,9)

Bundle branch reentrant ventricular tachycardia is normally seen in patients with advanced left ventricular cardiomyopathy. The reentrant circuit incorporates the right bundle branch for anterograde conduction and the left bundle as the retrograde limb. Rates are usually more than 200 bpm and are poorly tolerated hemodynamically. Ablation of the right bundle branch can be curative. ⁽⁹⁾

Definitions

1. Frequent ventricular extrasystoles: >30 PVCs per hour on Holter or other extended monitoring system
2. Monomorphic ventricular extrasystoles: PVCs with a single, identical morphology in all the leads recorded on an ECG or heart monitor
3. Sustained tachycardia: tachycardias lasting 20 seconds or longer, or requiring cardioversion because of hemodynamic collapse or compromise

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ARVC: arrhythmogenic right ventricular cardiomyopathy

AT: atrial tachycardia

AUC: appropriate use criteria

AV: atrioventricular

AVNRT: atrioventricular nodal reentrant tachycardia

AVRT: atrioventricular reentrant tachycardia

ECG: electrocardiogram

EPS: electrophysiology study

ICD: implantable cardioverter-defibrillator

kg: kilogram

LVEF: left ventricular ejection fraction

NSVT: non-sustained ventricular tachycardia

PVC: premature ventricular contractions

SVT: supraventricular tachycardia

VT: ventricular tachycardia

WPW: Wolff-Parkinson-White syndrome

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1140 Cardio Policy EPS with Transseptal Left Heart Cath with Arrhythmia Induction and VT Ablation

LEGAL AND COMPLIANCE

Guideline Approval



Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Muresan L, Cismaru G, Martins R P, Bataglia A, Rosu R et al. Recommendations for the use of electrophysiological study: Update 2018. *Hellenic journal of cardiology*. 2019; 60: 82-100. 10.1016/j.hjc.2018.09.002.
7. Page R L, Joglar J A, Caldwell M A, Calkins H, Conti J B et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia. *Circulation*. 2016; 133: e471-505. 10.1161/CIR.0000000000000310.
8. Al-Khatib S M, Stevenson W G, Ackerman M J, Bryant W J, Callans D J et al. 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Journal of the American College of Cardiology*. 2018; 72: e91-e220. 10.1016/j.jacc.2017.10.054.
9. Cronin E M, Bogun F M, Maury P, Peichl P, Chen M et al. 2019 HRS/EHRA/APHRS/LAHR expert consensus statement on catheter ablation of ventricular arrhythmias. *Heart rhythm*. 2020; 17: e155-e205. 10.1016/j.hrthm.2019.03.014.
10. Haines D E, Beheiry S, Akar J G, Baker J L, Beinborn D et al. Heart Rythm Society expert consensus statement on electrophysiology laboratory standards: process, protocols, equipment, personnel, and safety. *Heart rhythm*. 2014; 11: e9-51. 10.1016/j.hrthm.2014.03.042.



Evolut Clinical Guideline 7285 for Abdominal Aortic Aneurysm Repair

Guideline Number: Evolut_CG_7285	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for repair of an abdominal aortic or iliac artery aneurysm.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

The choice of endovascular or open surgical repair for elective treatment of AAA or iliac artery aneurysm should be individualized with appropriate consideration of the following ⁽⁶⁾:

- Anatomic suitability for endovascular aneurysm repair (EVAR)
- Comorbidities and physical fitness
- Life expectancy
- Compliance with postoperative surveillance
- Patient preference

Abdominal Aortic Aneurysm (AAA)

Repair is indicated for **ANY** of the following:

- Ruptured AAA

- Abdominal aortic aneurysms (AAA) when maximal aneurysm diameter as measured by CTA (unless contraindicated) is ≥ 5.5 cm in men or ≥ 5.0 cm in women ^(6,7,8)
- AAA growth rate of ≥ 0.5 cm in 6 months
- In patients who have back or abdominal pain that can be attributed to the AAA
- Saccular AAA ⁽⁶⁾
- Inflammatory AAA ⁽⁸⁾
- Mycotic AAA ⁽⁸⁾
- Perianastomotic graft aneurysm ⁽⁸⁾
- Pseudoaneurysm or complicated penetrating aortic ulcer (PAU), isolated dissection, or intramural hematoma (IM) with ANY of the following ⁽⁸⁾:
 - Expansion
 - Co-existing peri-aortic or extra-aortic hematoma
 - Embolization
 - Recurrent pain
 - Malperfusion ⁽⁷⁾

Iliac Aneurysm

Includes: common iliac, internal iliac, external iliac, or any combination thereof as measured by CTA (unless contraindicated). Repair is indicated for **ANY** of the following:

- Aneurysm ≥ 40 mm ⁽⁸⁾
- Aneurysm ≥ 35 mm in a female patient may be reasonable ⁽⁸⁾
- Aneurysms < 40 mm in conjunction with repair of an AAA

Endoleak

Endovascular treatment should be the first line treatment for endoleak. Open surgery should be utilized when endovascular procedures have been unsuccessful. ⁽⁹⁾ Examples of endoleak that indicate repair include:

- Type I endoleak
- Type II endoleak with evidence of expansion
- Type III endoleak
- Unexplained aneurysm expansion following graft

Other Considerations

- Elective repair of AAA, by either endovascular or open surgical procedures, is not recommended in patients with a limited life expectancy ($< 2-3$ years) ⁽⁸⁾
- Open surgical repair of AAA is preferred over endovascular procedures in patients with long life expectancies ($> 10-15$ years) ⁽⁸⁾

Limitations

- When commercially-available grafts are used for endovascular repair of aortic aneurysms, implantation must follow the device’s specific instructions for use (IFU)
- Approval for outpatient treatment does not extend to outpatient endovascular repair of AAA

CODING AND STANDARDS

Coding

CPT Codes

34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34714, 34715, 34716, 34717, 34718, 34808, 34812, 34813, 34820, 34833, 34834, 34841, 34842, 34843, 34844, 34845, 34846, 34847, 34848, 35081, 35082, 35091, 35092, 35102, 35103, 35131, 35132

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

- An **aneurysm** is a ballooning of all the walls of the artery and occurs when the artery increases in size by 1.5 of its original size.
- **Pseudoaneurysm** involves blood outside the wall of the aneurysm but contained by surrounding structures.
- **Saccular aneurysm** is a ballooning of part of the wall of an artery. It accrues a greater risk of rupture.
- **Endovascular AAA** repair involves the placement of a stent graft within the affected blood vessel through an artery (usually the femoral artery), and which seals the aneurysm sac from within.
- **Endoleak** implies continuous filling of the aneurysm sac despite prior endograft. It is classified as Type I-IV depending on from where the endoleak arises.

- **Open Surgery** is used to sew in an aortic graft. It can be performed via a midline or retroperitoneal approach.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AAA: Abdominal aortic aneurysm

AUC: Appropriate use criteria

CTA: Computed tomographic Angiography

IFU: Instructions for use

IH: Intramural hematoma

IRB: Institutional Review Board

PAU: Penetrating aortic ulcer

TAAA: Thoracoabdominal aortic aneurysm

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline merges, and replaces, UM CARDIO_1162 for Endovascular Aortic and Iliac Artery Aneurysm Repair and UM CARDIO_1337 for Abdominal Aorta and Iliac Aneurysm Open Repair <ul style="list-style-type: none"> ○ Indications, CPT codes, and Applicable Lines of Business were merged and reconciled ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Rokosh R S, Starnes B W, Chaikof E L. Society for Vascular Surgery implementation of clinical practice guidelines for patients with an abdominal aortic aneurysm: Repair of an abdominal aortic aneurysm. *Journal of Vascular Surgery*. 2021; 73: 1485-1487. 10.1016/j.jvs.2020.12.103.
7. Isselbacher E, Preventza O, Hamilton Black J, Augoustides J, Beck A et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 146: e334-e482. 10.1161/CIR.0000000000001106.
8. Wanhainen A, Van Herzele I, Bastos Goncalves F, Bellmunt Montoya S, Berard X et al. European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms. *European Journal of Vascular and Endovascular Surgery*. 2024; 67: 192-331. 10.1016/j.ejvs.2023.11.002.
9. Chaikof E, Dalman R, Eskandari M, Jackson B, Lee W et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *Journal of Vascular Surgery*. 2018; 67: 2-77. 10.1016/j.jvs.2017.10.044.



Evolut Clinical Guideline 7286 for Endomyocardial Biopsy

Guideline Number: Evolut_CG_7286	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for endomyocardial biopsy.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Heart Transplant (HT) Recipients ⁽⁶⁾

Patients with no evidence of rejection:

Endomyocardial biopsy (EMB) may be used for routine monitoring of heart transplant patients on the following schedule:

- Periodically during the first 3-12 months postoperatively
- For continued surveillance of patients at high risk for rejection 1-5 years postoperatively
- Surveillance EMB > 5 years after HT at the discretion of the transplant service

Patients with known or suspected rejection:

- Signs and symptoms of acute rejection including:
 - sustained ventricular tachycardia

- new onset atrial arrhythmia
- new onset ventricular arrhythmia
- aborted sudden death
- 2-4 weeks after initiation of treatment for acute cellular rejection
- Surveillance of untreated asymptomatic moderate cellular rejection
- 1-4 weeks after initiation of treatment for antibody mediated rejection

Suspected Myocarditis (7,8,9)

EMB may be appropriate in patients for whom a histological diagnosis may inform treatment in the following circumstances:

- Suspected fulminant myocarditis. Signs may include:
 - unexplained acute heart failure (HF) and left ventricular (LV) dysfunction
 - cardiogenic shock or hemodynamic instability
 - ventricular arrhythmias and/or second- or third-degree heart block
- Hemodynamically stable patients with suspected myocarditis based upon new onset HF and associated signs of myocarditis such as ECG abnormalities and elevated biomarkers (i.e. troponin) in the absence of coronary artery disease

Cardiomyopathy/Heart Failure (8,9,10,11,12)

EMB may be appropriate in patients for whom a histological diagnosis may inform treatment in the following circumstances:

- Recent onset heart failure with dilated cardiomyopathy and moderate to severe LV dysfunction, refractory to standard therapy and after exclusion of specific etiologies.
- Second- or third-degree heart block, syncope and/or unexplained ventricular arrhythmias refractory to therapy without obvious cardiac abnormalities or with minimal cardiac structural abnormalities (possible sarcoidosis, arrhythmogenic right ventricular dysplasia (ARVD), etc.)
- Dilated cardiomyopathy of any duration with suspected hypersensitivity (i.e. allergic) reaction and/or eosinophilia
- Suspected immune checkpoint inhibitor (ICI)-mediated toxicity (i.e., acute HF early after drug initiation)
- HF associated with suspected anthracycline cardiomyopathy
- HF associated with unexplained restrictive or hypertrophic cardiomyopathy (possible amyloidosis or other infiltrative/depositional/storage disorder)
- Autoimmune disorders with worsening HF unresponsive to therapy
- Suspected idiopathic inflammatory myopathy (IIM) with cardiac involvement
- Cardiac tumors
- Unexplained cardiomyopathy in children
- Heart transplant candidates suspected of having an infiltrative or inflammatory

cardiomyopathy

CODING AND STANDARDS

Coding

CPT Codes

93505

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ARVD: Arrhythmogenic right ventricular dysplasia

EMB: Endomyocardial biopsy

HF: heart failure

ICI: Immune checkpoint inhibitor

IIM: Idiopathic inflammatory myopathy

LV: left ventricle

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM 1388 Endomyocardial Biopsy ● Updated references ● Revised heart transplant monitoring schedule to conform with new professional guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Velleca A, Shullo M, Dhital K, Azeka E, Colvin M et al. The International Society for Heart and Lung Transplantation (ISHLT) guidelines for the care of heart transplant recipients. *The Journal of Heart and Lung Transplantation*. 2023; 42: e1 - e141. 10.1016/j.healun.2022.10.015.
7. Schultheiss H, Escher F. Endomyocardial biopsy in fulminant myocarditis: need for early and accurate diagnosis to improve the outcome. *Eur Heart J*. 2023; 44: 5125 - 5127. 10.1093/eurheartj/ehad489.
8. Cooper L T, Baughman K L, Feldman A M, Frustaci A, Jessup M et al. The role of endomyocardial biopsy in the management of cardiovascular disease: a scientific statement from the American Heart Association, the American College of Cardiology, and the European Society of Cardiology. *Circulation*. 2007; 116: 2216-33.
9. Seferović P M, Tsutsui H, McNamara D M, Ristić A D, Basso C et al. Heart Failure Association of the ESC, Heart Failure Society of America and Japanese Heart Failure Society position statement on endomyocardial biopsy. *European journal of heart failure*. 2021; 23: 854-871.
10. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2022; 79: e263 - e421. <https://doi.org/10.1016/j.jacc.2021.12.012>.
11. Korthals D, Bietenbeck M, Könnemann H, Doldi F, Ventura D et al. Cardiac Sarcoidosis—Diagnostic and Therapeutic Challenges. 2024; 13: 10.3390/jcm13061694.
12. Sen G, Scully P, Gordon P, Sado D. Advances in the diagnosis of myocarditis in idiopathic inflammatory myopathies: an overview of diagnostic tests. *Rheumatology (Oxford)*. 2024; 63: 1825 - 1836. 10.1093/rheumatology/keae029.



Evolut Clinical Guideline 7287 for Endovascular Femoropopliteal Interventions

Guideline Number: Evolut_CG_7287	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Endovascular Femoropopliteal Interventions.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS

Stent

Primary stenting is medically necessary when percutaneous transluminal angioplasty alone is not expected to provide a durable result for patients. ⁽⁶⁾ Examples include:

- Arterial occlusions or highly irregular lesions that carry an elevated risk for distal embolization or rapid recurrence, **OR**
- Significantly calcified lesions, eccentric lesions, or lesions related to external compression, or ostial lesions

Claudication

When **ALL** the following requirements have been met:

- Impairment of activities of daily living and/or work ⁽⁷⁾
- Absence of other conditions that would limit exercise even if claudication is improved ⁽⁷⁾ (e.g. arthritis, angina, chronic respiratory disease)
- Member is on guideline-directed medical therapy (GDMT) ^(6,7,8)
- Inadequate response to a supervised or structured exercise program for 12 weeks ^(9,10)
- Proximal clinically significant aortoiliac disease is not present or successfully treated such that it is unlikely to be responsible for ongoing claudication ^(11,12)
- An Ankle Brachial Index (ABI) <0.9 or ≥1.4, **OR** TBI <0.7, **OR** 20% reduction in ankle pressure on exercise testing
 - If arteries are noncompressible making these tests unreliable, abnormal Doppler tracings or Pulse Volume Recordings (PVR) can be provided ^(12,13)
- Femoral or popliteal arteries with anatomically suitable lesion(s) for intervention with one of the following:
 - Documentation of lesion equal to or greater than 70% stenosis on angiography (e.g., CTA, invasive angiography, MRA) ⁽⁷⁾
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥300 cm/s or PSV ratio ≥4.0 and with monophasic flow pattern ⁽¹⁴⁾

Chronic Limb Threatening Ischemia

When the following requirements have been met:

- Gangrene or non-healing ischemic wounds present for more than two weeks despite provider directed and described wound care ^(11,15,16) **OR** wound Grade 1-3 based on The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wifl). ^(16,17) One of the following must also be present:
 - An ABI<0.8
 - Ankle pressure <100 mmHg
 - Toe pressures or TCPO₂ <60 mmHg
 - If ABI ≥1.4 then one of the following ^(16,18,19,20):
 - Toe pressures or TCPO₂ <60 mmHg, or
 - TBI <0.7 with Monophasic PVR or Doppler waveforms
- If no Gangrene or non-healing wounds but Rest Pain, then with ANY of the following ^(16,18,19,20):
 - ABI <0.4
 - If ankle pressure is unrecordable, toe pressure or TcPO₂ <30 mmHg
 - PVR amplitude or Doppler waveforms showing flat line or <5mm with absent dirotic notch

- Proximal clinically significant aortoiliac disease is not present or has been successfully treated such that it is unlikely to be responsible for ongoing CLTI, ^(11,12) OR will be treated concurrently with the tibial procedure
- Femoral or popliteal arteries with anatomically suitable lesion(s) for intervention (see **Definitions**) with one of the following:
 - Documentation of lesion $\geq 50\%$ stenosis on angiography (e.g., CTA, invasive angiography, MRA) ⁽⁶⁾
 - Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥ 250 cm/s or PSV ratio ≥ 2.0 ⁽²¹⁾

Other Indications

When at least one of the following requirements has been met:

- For the treatment of in-stent stenosis associated with new or recurrent rest pain, or new or persistent ulceration or gangrene, and at least one of the following ⁽⁷⁾:
 - A drop in ABI of $\geq 20\%$,
 - A peak systolic velocity of ≥ 300 cm/sec
 - A tripling of velocity across the stenosis
 - A translesional mean pressure gradient of ≥ 10 mmHg
 - A systolic gradient of ≥ 20 mmHg
- For the treatment of stenosis within a vein bypass graft in a member with new, progressive, or recurrent symptoms, or new, persistent, or lack of improvement in CLTI ⁽²²⁾
- For the treatment of stenosis within a vein bypass graft in an asymptomatic patient with concern for impending graft failure with one of the following ^(14,22):
 - Peak Systolic Velocity (PSV) of ≥ 180 cm/sec
 - A velocity ratio of ≥ 2.0
 - An end diastolic velocity of < 45 cm/sec
- For the treatment of stenosis within a prosthetic bypass graft with concern for impending graft failure **AND** an end diastolic velocity of < 45 cm/sec ⁽¹⁴⁾
- For the treatment of femoropopliteal aneurysms ≥ 20 mm, or < 20 mm with at least one of the following ⁽²³⁾:
 - Extensive thrombus ($\geq 50\%$ lumen involvement)
 - Evidence of distal embolization
 - Poor distal runoff
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but in and of itself not severe enough to warrant intervention; with ANY of the following ⁽¹⁶⁾:
 - An ABI < 0.8
 - Ankle pressure < 100 mmHg
 - Toe Pressure or TcPO₂ < 60 mmHg

- If ABI \geq 1.4 then one of the following:
 - Toe Pressure or TcPO₂ <60mmHg
 - Monophasic PVR or Doppler waveforms

Limitations

- Acute lower extremity ischemia is not considered in this policy
- IF a procedure is being requested for Claudication, there can be no assertion, directly or indirectly, that treatment is required to prevent amputation ⁽¹²⁾
- Endovascular intervention for PAD is not indicated in the absence of symptoms, ulceration, or gangrene regardless of hemodynamic measures or imaging findings demonstrating PAD ⁽¹²⁾
- Requests to perform a subsequent intervention on the same limb must have documentation detailing new symptoms or findings, or persistent (>12 weeks) clinical indications, supported by new physiologic (see **Definitions**) and imaging studies ⁽¹²⁾
- Requests to perform the *same* intervention on the same limb must have documentation detailing new symptoms or findings, or persistent (>12 weeks) clinical indications, and a discussion about why other alternative treatments have not been considered ^(11,12)
- Endovascular treatment of Common femoral PAD involving the bifurcation is approvable only for patients at high medical risk or at risk for local groin complications such as those with prior radiation, multiple prior surgeries, or infections ^(8,11,12,24)
- Atherectomy can only be requested for:
 - Lesions resistant to angioplasty
 - Heavily calcified lesions
 - Complete occlusions
 - Symptomatic in-stent stenosis as verified (see Indications Section) ^(6,7)

NOTE: Must include evidence that the member has been informed that there is no current definitive proof that atherectomy has added clinical benefit in comparison to PTA

CODING AND STANDARDS

Coding

CPT Codes

37224, 37225, 37226, 37227, 76937

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- An **anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success (> 2 years) based on accepted lesion classifications such as TASC II or GLASS. ^(7,8,19)
- **Ankle Brachial Index** is measured by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or posterior tibial artery. ⁽¹⁸⁾
- **Chronic Limb Threatening Ischemia (CLTI)** has replaced Critical Limb Ischemia (CLI) since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, “critical” implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of Rest Pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (WIfI) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ^(16,19,20)
- **Claudication** is a symptom complex of pain that begins with ambulation and that is relieved within a brief time by walking cessation. It is described by the intensity of discomfort, the distance walked, the duration of the walk and the impact that it has on quality of life (QOL) and activities of daily living (ADL). Claudication does not occur at rest. If left untreated, the natural history of claudication is slow progression, yet amputation is rare occurring in less than 5% of patients. ⁽⁸⁾
- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings
- **Endovascular intervention** is the treatment of peripheral arterial disease with angioplasty, atherectomy, intravascular lithotripsy, or stents. It is performed by opening the blood vessel with a device placed on a catheter inserted through a blood vessel. In some cases, drug elution is added to the device to prevent restenosis. Intravascular ultrasound and filters may assist the procedure. In some circumstances mechanical thrombectomy or drug infusion thrombolysis may be required. ⁽⁶⁾

- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks. ^(7,8,11)
- **Physiologic studies** include ABI, TBI, Toe pressures, TCPO₂, PVR or Doppler tracings
- **Rest Pain** is a distinct pain syndrome lasting more than 2 weeks, implying CLTI. It is defined as pain in the foot or toes aggravated by elevation and relieved by dependency. Nocturnal pain is not necessarily Rest Pain since there are other causes of pain at night. ^(11,12) Rest pain does not usually imply the same urgency for treatment as gangrene or nonhealing wounds.
- **Structured exercise program** is provider-directed and monitored. It involves walking to a pain threshold 3 times a week. Supervised exercise is performed under the guidance of a professional trained in exercise therapy and is reimbursed by the Carrier. ^(8,10,12)
- **Toe Brachial Index** is measured by dividing the highest brachial arm pressure by the pressure obtained from the first toe by any method. Unlike the ABI, the toe pressures are usually not affected by arterial calcification. ⁽²⁰⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABI: Ankle Brachial Index

AR: Authorization Request

AUC: Appropriate use criteria

CFA: Common femoral artery

CLI: Chronic limb ischemia

CLTI: Chronic limb threatening ischemia

CTO: Chronic total occlusion

CTA: Computed Tomography Angiography

DFA: Deep Femoral Artery

DSA: Digital Subtraction Angiography

EDV: End Diastolic Velocity

GDMT: Guideline directed medical therapy

GLASS: Global Anatomic Staging System
 ISR: In-stent restenosis
 PAD: Peripheral artery disease
 PTA: Percutaneous transluminal angioplasty
 PVR: Pulse Volume Recording
 SFA: Superficial Femoral Artery
 TASC: Trans-Atlantic Inter-Society Consensus
 TBI: Toe Brachial Index
 Wlfl Classification: Wound, Ischemia, and Foot Infection

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions. For PAD structured exercise and Cilostazol are added to the Guidelines. ⁽¹¹⁾

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1173 for Endovascular Femoropopliteal Interventions • Clinical indications updated and expanded per current guidance from major cardiovascular societies

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care



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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Klein A, Jaff M, Gray B, Aronow H, Bersin R et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. *Catheterization and Cardiovascular Interventions*. 2017; 90: E90-E110. 10.1002/ccd.27141.
7. Bailey S, Beckman J, Dao T, Misra S, Sobieszczyk P et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention. *Journal of the American College of Cardiology*. 2019; 73: 214-237. 10.1016/j.jacc.2018.10.002.
8. Woo K, Siracuse J, Klingbeil K, Kraiss L, Osborne N et al. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. *Journal of Vascular Surgery*. 2022; 76: 3-22. e1. 10.1016/j.jvs.2022.04.012.
9. Divakaran S, Carroll B, Chen S, Shen C, Bonaca M. Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease Among Medicare Beneficiaries Between 2017 and 2018: Participation Rates and Outcomes. *Circulation: Cardiovascular Quality and Outcomes*. 2021; 14: e007953. 10.1161/CIRCOUTCOMES.121.007953.
10. Lane R, Harwood A, Watson L, Leng G. Exercise for intermittent claudication. *Cochrane Database of Systematic Reviews*. 2017; 2017: CD000990. 10.1002/14651858.CD000990.pub4.
11. Gornik H, Aronow H, Goodney P, Arya S, Brewster L et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024; 149: e1313-e1410. 10.1161/CIR.0000000000001251.
12. Conte M, Pomposelli F, Clair D, Geraghty P, McKinsey J et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication. *Journal of Vascular Surgery*. 2015; 61: 2S-41S. 10.1016/j.jvs.2014.12.009.
13. Mohler E, Gornik H, Gerhard-Herman M, Misra S, Olin J. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing. *Journal of Vascular Surgery*. 2012; 56: e17-e51. 10.1016/j.jvs.2012.05.054.
14. Zierler R, Jordan W, Lal B, Mussa F, Leers S et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *Journal of Vascular Surgery*. 2018; 68: 256-284. 10.1016/j.jvs.2018.04.018.

15. Hawkins B, Li J, Wilkins L, Carman T, Reed A et al. SCAI/ACR/APMA/SCVS/SIR/SVM/SVS/VES Position Statement on Competencies for Endovascular Specialists Providing CLTI Care. *Vascular Medicine*. 2022; 27: 405-414. 10.1177/1358863X221095278.
16. Mills J, Conte M, Armstrong D, Pomposelli F, Schanzer A et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIFI). *Journal of Vascular Surgery*. 2014; 59: 220-234.e2. 10.1016/j.jvs.2013.08.003.
17. Smith M, Braet D, Albright J, Corriere M, Osborne N. Real-world application of wound, ischemia, and foot infection scores in peripheral arterial disease patients. *Journal of Vascular Surgery*. 2024; 80: 1216-1223. 10.1016/j.jvs.2024.04.071.
18. Paskiewicz A, Wang F, Yang C, Ballew S, Kalbaugh C et al. Ankle-Brachial Index and Subsequent Risk of Severe Ischemic Leg Outcomes: The ARIC Study. *Journal of the American Heart Association*. 2021; 10: e021801. 10.1161/JAHA.121.021801.
19. Conte M, Bradbury A, Kolh P, White J, Dick F et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *Journal of Vascular Surgery*. 2019; 69: 3S-125S. 10.1016/j.jvs.2019.02.016.
20. Aboyans V, Ricco J, Bartelink M, Björck M, Brodmann M et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *European Heart Journal*. 2018; 39: 763-816. 10.1093/eurheartj/ehx095.
21. Sidawy A, Perler B. Rutherford's Vascular Surgery and Endovascular Therapy, Book Chapter. 2022; 1: 253-264.
22. Abu Dabrh A, Mohammed K, Farah W, Haydour Q, Zierler R et al. Systematic review and meta-analysis of duplex ultrasound surveillance for infrainguinal vein bypass grafts. *Journal of Vascular Surgery*. 2017; 66: 1885-1891. 10.1016/j.jvs.2017.06.113.
23. Farber A, Angle N, Avgerinos E, Dubois L, Eslami M et al. The Society for Vascular Surgery clinical practice guidelines on popliteal artery aneurysms. *Journal of Vascular Surgery*. 2022; 75: 109S-120S. 10.1016/j.jvs.2021.04.040.
24. Feldman D, Armstrong E, Aronow H, Gigliotti O, Jaff M et al. SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions. *Catheterization and Cardiovascular Interventions*. 2018; 92: 124-140. 10.1002/ccd.27635.

Evolut Clinical Guideline 7288 for Endovascular Aortoiliac Interventions

Guideline Number: Evolut_CG_7288	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Endovascular Aortoiliac Interventions.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS

Stents

- Primary or provisional stenting can be approved for Aortoiliac lesions provided the indications listed below have been met

Claudication

When **ALL** the following requirements have been met:

- Impairment of activities of daily living and/or work ⁽⁶⁾
- Absence of other conditions that would limit exercise even if claudication is improved

- ⁽⁶⁾ (e.g., arthritis, angina, chronic respiratory disease)
- Member is on guideline-directed medical therapy (GDMT) ^(6,7,8)
 - Inadequate response to a supervised or structured exercise program for 12 weeks ^(9,10)
 - An Ankle Brachial Index (see **Definitions**) <0.9 or ≥ 1.4 , **OR** TBI <0.7 , **OR** 20% reduction in ankle pressure on exercise testing
 - If arteries are noncompressible making these tests unreliable, abnormal Doppler tracings or pulse volume recordings (PVR) can be provided ^(11,12)
 - Aortoiliac arteries with anatomically suitable lesion(s) (see **Definitions**) for intervention with one of the following:
 - Documentation of lesion $\geq 70\%$ stenosis on angiography (e.g., CTA, invasive angiography, MRA) ⁽⁶⁾
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥ 300 cm/s **OR** PSV ratio ≥ 4.0 and with monophasic flow pattern ⁽¹³⁾
 - Concurrent endovascular treatment of common femoral artery stenosis involving the bifurcation, only for patients at high medical risk, or at risk for local groin complications (such as those with prior radiation, multiple prior surgeries, or infections) ^(8,11,12,14)

Chronic Limb Threatening Ischemia

When the following requirements have been met:

- Gangrene or non-healing ischemic wounds present for more than two weeks despite provider directed and described wound care ^(12,15,16) **OR** wound Grade 1-3 based on The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wiffl). ^(16,17) One of the following must also be present:
 - ABI <0.8
 - Ankle pressure <100 mmHg
 - Toe pressures or TCPO₂ <60 mmHg
 - TBI <0.7
 - If ABI >1.3 , then one of the following ^(16,18,19,20):
 - Toe pressures or TCPO₂ <60 mmHg
 - TBI <0.7
 - Monophasic PVR or doppler waveforms
- If no Gangrene or non-healing wounds but Rest Pain, then with ANY of the following ^(16,18,19,20):
 - ABI <0.4
 - If ankle pressures unrecordable, toe pressure or TcPO₂ <30 mmHg
 - PVR amplitude or Doppler waveforms showing flat line or <5 mm with absent dirotic notch

- Aortoiliac arteries with anatomically suitable lesion(s) (see **Definitions**) for intervention with one of the following:
 - Documentation of lesion $\geq 50\%$ stenosis on angiography (e.g., CTA, invasive angiography, MRA) or resting mean or hyperemic translesional pressure gradient of ≥ 10 mmHg ⁽⁷⁾
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥ 200 cm/s or PSV ratio ≥ 2 and with biphasic or monophasic flow pattern distally ⁽²¹⁾
- Concurrent endovascular treatment of common femoral artery stenosis involving the bifurcation, only for patients at high medical risk, or at risk for local groin complications (such as those with prior radiation, multiple prior surgeries, or infections) ^(8,11,12,14)

Other Indications

When at least one of the following requirements have been met:

- To provide access for large bore devices required for treating pathology proximal to the abdominal aorta. Examples include:
 - Transaortic Valve Replacement (TAVR)
 - Extracorporeal Membrane Oxygenation (ECMO)
- To provide access for implanting endovascular devices for the treatment of Abdominal Aortic Aneurysms
- For the treatment of in-stent stenosis associated with new or recurrent rest pain, or new or persistent ulceration or gangrene, and at least one of the following criteria ⁽⁶⁾:
 - A drop in ABI of $\geq 20\%$
 - A peak systolic velocity of ≥ 300 cm/s
 - A tripling of velocity across the stenosis
 - A translesional mean pressure gradient of ≥ 10 mmHg
 - A systolic gradient of 20 mmHg
- For the treatment of symptomatic or asymptomatic covered in-stent stenosis confirmed by a drop in ABI of $\geq 20\%$, or one of the following criteria ⁽⁶⁾:
 - A peak systolic velocity of ≥ 300 cm/sec
 - A tripling of velocity across the stenosis,
 - A translesional mean pressure gradient of 10 mmHg
 - A systolic gradient of ≥ 20 mmHg
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but in and of itself not severe enough to warrant intervention; with ANY of the following ⁽¹⁶⁾:
 - An ABI < 0.8
 - Ankle pressure < 100 mmHg
 - Toe Pressure or TcPO₂ < 60 mmHg

- If ABI \geq 1.4, then one of the following:
 - Toe Pressure or TcPO₂ <60mmHg
 - Monophasic PVR or Doppler waveforms
- Internal iliac intervention may be appropriate for buttock claudication or vasculogenic impotence provided it is supported by noninvasive testing ⁽⁷⁾

Limitations

- Atherectomy of the aortoiliac arteries is not considered medically reasonable or necessary ⁽⁶⁾
- Invasive treatments for PAD cannot be authorized in the absence of symptoms, ulceration, or gangrene regardless of hemodynamic measures or imaging findings demonstrating PAD
- If a procedure is being requested for claudication there can be no assertion, directly or indirectly, that treatment is required to prevent amputation ⁽¹¹⁾
- Requests to perform a subsequent intervention on the same limb must have documentation detailing new symptoms or findings, or symptom persistence (>12 weeks) clinical indications, supported by new physiologic and imaging studies. ⁽¹¹⁾ A discussion about why other alternative treatments have not been considered is necessary. ^(11,12)

CODING AND STANDARDS

Coding

CPT Codes

37220, 37221, 37222, 37223

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
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BACKGROUND

Definitions

- An **anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success (> 2 years) based on accepted lesion classifications such as TASC II or GLASS. ^(6,8,19)
- **Ankle Brachial Index (ABI)** is measured by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or posterior tibial artery. ⁽¹⁸⁾
- **Chronic Limb Threatening Ischemia (CLTI)** has replaced Critical Limb Ischemia (CLI) since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, “critical” implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of Rest Pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (WIfI) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ^(16,19,20)
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- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings.
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- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks. ^(6,8,12)
- **Physiologic studies** include ABI, TBI, Toe pressures, TCPO₂, PVR or Doppler tracings
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- **Structured exercise program** is provider-directed and monitored. It involves walking to a pain threshold 3 times a week.
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AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

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Acronyms/Abbreviations

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AUC: Appropriate use criteria

CFA: Common femoral artery

CLTI: Chronic limb Threatening ischemia

CTA: Computed Tomography Angiography

CTO: Chronic Total Occlusion

DSA: Digital Subtraction Angiography

EIA: External iliac artery

ECMO: Extracorporeal membrane oxygenation

GDMT: Guideline directed medical therapy

GLASS: Global Anatomic Staging System

ISR: In-stent stenosis

PAD: Peripheral arterial disease

PSV: Peak systolic velocity

PTA: Percutaneous transluminal Angioplasty

PVR: Pulse Volume Recording

TASC: Trans-Atlantic Inter-Society Consensus

TAVR: Transaortic valve replacement

TBI: Toe brachial index

Wifl Classification: Wound, Ischemia, and Foot Infection

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions. For PAD, structured exercise and Cilostazol are added to the Guidelines.

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1172 for Endovascular Iliac Interventions <ul style="list-style-type: none"> ○ The guideline name has been changed to Endovascular Aortoiliac Interventions ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Bailey S, Beckman J, Dao T, Misra S, Sobieszczyk P et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention. *Journal of the American College of Cardiology*. 2019; 73: 214-237. 10.1016/j.jacc.2018.10.002.
7. Klein A, Jaff M, Gray B, Aronow H, Bersin R et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. *Catheterization and Cardiovascular Interventions*. 2017; 90: E90-E110. 10.1002/ccd.27141.
8. Woo K, Siracuse J, Klingbeil K, Kraiss L, Osborne N et al. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. *Journal of Vascular Surgery*. 2022; 76: 3-22.e1. 10.1016/j.jvs.2022.04.012.
9. Divakaran S, Carroll B, Chen S, Shen C, Bonaca M. Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease Among Medicare Beneficiaries Between 2017 and 2018: Participation Rates and Outcomes. *Circulation: Cardiovascular Quality and Outcomes*. 2021; 14: e007953. 10.1161/CIRCOUTCOMES.121.007953.
10. Lane R, Harwood A, Watson L, Leng G. Exercise for intermittent claudication. *Cochrane Database of Systematic Reviews*. 2017; 2017: CD000990. 10.1002/14651858.CD000990.pub4.
11. Conte M, Pomposelli F, Clair D, Geraghty P, McKinsey J et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication. *Journal of Vascular Surgery*. 2015; 61: 2S-41S. 10.1016/j.jvs.2014.12.009.
12. Gornik H, Aronow H, Goodney P, Arya S, Brewster L et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VES Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024; 149: e1313-e1410. 10.1161/CIR.0000000000001251.
13. Zierler R, Jordan W, Lal B, Mussa F, Leers S et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *Journal of Vascular Surgery*. 2018; 68: 256-284. 10.1016/j.jvs.2018.04.018.
14. Feldman D, Armstrong E, Aronow H, Gigliotti O, Jaff M et al. SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions. *Catheterization and Cardiovascular Interventions*. 2018; 92: 124-140. 10.1002/ccd.27635.

15. Hawkins B, Li J, Wilkins L, Carman T, Reed A et al. SCAI/ACR/APMA/SCVS/SIR/SVM/SVS/VES Position Statement on Competencies for Endovascular Specialists Providing CLTI Care. *Vascular Medicine*. 2022; 27: 405-414. 10.1177/1358863X221095278.
16. Mills J, Conte M, Armstrong D, Pomposelli F, Schanzer A et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIFI). *Journal of Vascular Surgery*. 2014; 59: 220-234.e2. 10.1016/j.jvs.2013.08.003.
17. Smith M, Braet D, Albright J, Corriere M, Osborne N. Real-world application of wound, ischemia, and foot infection scores in peripheral arterial disease patients. *Journal of Vascular Surgery*. 2024; 80: 1216-1223. 10.1016/j.jvs.2024.04.071.
18. Paskiewicz A, Wang F, Yang C, Ballew S, Kalbaugh C et al. Ankle-Brachial Index and Subsequent Risk of Severe Ischemic Leg Outcomes: The ARIC Study. *Journal of the American Heart Association*. 2021; 10: e021801. 10.1161/JAHA.121.021801.
19. Conte M, Bradbury A, Kolh P, White J, Dick F et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *Journal of Vascular Surgery*. 2019; 69: 3S-125S. 10.1016/j.jvs.2019.02.016.
20. Aboyans V, Ricco J, Bartelink M, Björck M, Brodmann M et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *European Heart Journal*. 2018; 39: 763-816. 10.1093/eurheartj/ehx095.
21. Sidawy A, Perler B. Rutherford's Vascular Surgery and Endovascular Therapy, Book Chapter. 2022; 1: 253-264.

Evolut Clinical Guideline 7289 for Endovascular Infrapopliteal (Tibioperoneal) Interventions

Guideline Number: Evolut_CG_7289	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Endovascular Infrapopliteal (Tibioperoneal) Interventions.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS

Stents

- Primary stenting tibial arteries is rarely appropriate. However, secondary stenting may be medically necessary for ⁽⁶⁾:
 - Arterial occlusions or highly irregular lesions that carry an elevated risk for distal embolization or rapid recurrence, **OR**
 - Lack of response to angioplasty despite maximal approvable inflation pressures

Claudication

Revascularization of infra-popliteal PAD is generally limited to those patients presenting with critical limb threatening ischemia (CLTI). ⁽⁶⁾ However, infrequently, intervention may be indicated when **ALL** the following requirements have been met:

- **Severe** Impairment of activities of daily living and/or work ⁽⁷⁾
- Absence of other conditions that would limit exercise even if claudication is improved ⁽⁷⁾ (e.g. arthritis, angina, chronic respiratory disease)
- Member is on guideline-directed medical therapy (GDMT) ^(6,7,8)
- Inadequate response to a supervised or structured exercise program for 12 weeks ^(9,10)
- Proximal clinically significant aortoiliac and/or femoropopliteal disease is not present or successfully treated such that it is unlikely to be responsible for ongoing claudication ^(11,12)
- An Ankle Brachial Index (see **Definitions**) <0.8, **OR** TBI <0.7, **OR** 20% reduction in ankle pressure during exercise testing
 - If ABI ≥1.4 due to arterial calcification, abnormal Doppler waveforms or pulse volume recordings (PVR) should be provided if available ^(11,13)

Revascularization of infra-popliteal PAD may also be considered when there is infrapopliteal disease with anatomically suitable lesion(s) (see **Definitions**) for intervention with documentation of **ALL** the following ⁽⁸⁾:

- Involvement of all three tibial arteries. Involvement of the tibioperoneal trunk will be regarded as involving two arteries (the posterior tibial and peroneal arteries)
- And one of the following:
 - ≥70% stenosis in all three tibial arteries on angiography (e.g., CTA, invasive angiography, MRA)
 - Duplex Doppler findings in the three tibial arteries with peak systolic velocities (PSV) ≥300 cm/s or PSV ratios ≥4.0 and with monophasic or absent flow patterns

NOTE: Authorization will be for the treatment of only one tibial artery

Chronic Limb Threatening Ischemia

When the following requirements have been met:

- Gangrene or non-healing ischemic wounds present for more than two weeks despite provider directed and described wound care ^(12,14,15) **OR** wound Grade 1-3 based on The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wiffl). ^(15,16) One of the following must also be present:
 - An ABI <0.8
 - Ankle pressure <100 mmHg
 - Toe pressures or TCPO₂ <60 mmHg
 - If ABI ≥1.4, then one of the following ^(15,17,18,19):
 - Toe pressures or TCPO₂ <60 mmHg, **OR**

- TBI <0.7 with Monophasic PVR or Doppler wave forms
- If no Gangrene or non-healing wounds but Rest Pain, then with ANY of the following ^(15,17,18,19):
 - ABI <0.4
 - If ankle pressures unrecordable, toe pressure or TcPO₂ <30 mmHg
 - PVR amplitude or Doppler waveforms showing flat line or <5 mm with absent dirotic notch
- Proximal clinically significant aortoiliac and/or femoropopliteal disease is not present or has been successfully treated such that it is unlikely to be responsible for ongoing CLTI, ^(11,12) **OR** will be treated concurrently with the tibial procedure
- Infrapopliteal disease in at least 2 tibial arteries (involvement of the tibioperoneal trunk will constitute two arteries; i.e., peroneal and posterior tibial arteries) with anatomically suitable lesion(s) (see **Definitions**) for intervention and documentation of any of the following:
 - Lesion ≥50% stenosis on angiography (e.g., CTA, invasive angiography, MRA) ⁽⁶⁾
 - Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥250 cm/s **OR** PSV ≥2.0 ⁽²⁰⁾

NOTE: Multiple tibial arteries may be treated, **OR** a single tibial artery supplying the angiosome associated with a non-healing ulcer or gangrene ⁽²¹⁾

NOTE: Inframalleolar procedures will be considered to treat continued poor healing only after a more proximal tibial intervention has not provided improvement ⁽²¹⁾

Other Indications

- For the treatment of in-stent stenosis associated with new or recurrent rest pain, or new or persistent ulceration or gangrene, and at least one of the following criteria ⁽⁷⁾:
 - A drop in ABI of ≥20%
 - A peak systolic velocity of ≥300 cm/s
 - A tripling of velocity across the stenosis
 - A translesional mean pressure gradient of ≥10 mmHg
 - A systolic gradient of ≥20 mmHg
- For the treatment of stenosis within a tibial vein bypass graft in a member with new, progressive, or recurrent symptoms, or new, persistent, or lack of improvement in CLTI ⁽²²⁾
- For the treatment of stenosis within a tibial vein bypass graft in an asymptomatic patient with concern for impending graft failure with peak systolic velocity (PSV) of >180 cm/s or a velocity ratio of >2.0 or an end diastolic velocity of <45 cm/s ^(22,23)
- For the treatment of stenosis within a tibial prosthetic bypass graft with concern for impending graft failure **AND** an end diastolic velocity of <45 cm/s ⁽²³⁾
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but in and of itself not severe enough to warrant intervention; with ANY of the following ⁽¹⁵⁾:

- An ABI <0.8
- Ankle pressure <100mmHg
- Toe Pressure or TcPO₂ <60mmHg
- If ABI ≥1.4, then one of the following:
 - Toe Pressure or TcPO₂ <60mmHg
 - Monophasic PVR or Doppler waveforms

Limitations

- Acute lower extremity ischemia is not considered in this policy
- Endovascular intervention for PAD is not indicated in the absence of symptoms, ulceration, or gangrene regardless of hemodynamic measures or imaging findings demonstrating PAD ⁽¹¹⁾
- Endovascular procedures are not indicated for non-ambulatory patients with a life expectancy <6 months and extensive lower extremity tissue necrosis. Such members should consider primary amputation at the lowest level possible to ensure healing of the surgical site
- If a procedure is being requested for Claudication, there can be no assertion, directly or indirectly, that treatment is required to prevent amputation ⁽¹¹⁾
- When tibial access is utilized to perform intervention on an artery proximal to that tibial artery, endovascular therapy of the transited artery is not indicated unless its treatment is required to revascularize a target distal to that transited tibial artery
- Inframalleolar interventions are not considered necessary for the management of rest pain or claudication.
- Requests to perform a subsequent intervention on the same limb must have documentation detailing new or worse symptoms or findings, or symptoms persistence (>12 weeks), supported by new physiologic (see **Definitions**) and imaging studies. ⁽¹¹⁾ A discussion about why other alternative treatments have not been considered is necessary. ^(11,12)
- Atherectomy can only be requested when at least one of the following apply:
 - Lesions resistant to angioplasty
 - Heavily calcified lesions
 - Complete occlusions
 - In-stent stenosis (see Indications section) ^(6,7)

NOTE: Must include a statement that the member has been informed that there is no current definitive proof that atherectomy has added clinical benefit in comparison to PTA

CODING AND STANDARDS

Coding

CPT Codes

37228, 37229, 37230, 37231, 37232, 37233, 37234, 37235

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- **Anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success (>2 years) based on accepted lesion classifications such as TASC II or GLASS. ^(7,8,18)
- **Ankle Brachial Index (ABI)** is measured by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or posterior tibial artery. ⁽¹⁷⁾
- **Chronic Limb Threatening Ischemia (CLTI)** has replaced Critical Limb Ischemia (CLI) since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, “critical” implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of Rest Pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wifl) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ^(15,18,19)
- **Claudication** is a symptom complex of pain that begins with ambulation and that is relieved within a brief time by walking cessation. It is described by the intensity of discomfort, the distance walked, the duration of the walk and the impact that it has on quality of life (QOL) and activities of daily living (ADL). Claudication does not occur at rest. If left untreated, the natural history of claudication is slow progression, yet amputation is rare occurring in less than 5% of patients. ⁽⁸⁾

- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings.
- **Endovascular intervention** is the treatment of peripheral arterial disease with angioplasty, atherectomy, intravascular lithotripsy, or stents. It is performed by opening the blood vessel with a device placed on a catheter inserted through a blood vessel. In some cases, drug elution is added to the device to prevent restenosis. Intravascular ultrasound and filters may assist the procedure. In some circumstances mechanical thrombectomy or drug infusion thrombolysis may be required. ⁽⁶⁾
- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks. ^(7,8,12)
- **Physiologic studies** include ABI, TBI, Toe pressures, TCPO₂, PVR or Doppler tracings
- **Rest Pain** is a distinct pain syndrome lasting more than 2 weeks, implying CLTI. It is defined as pain in the foot or toes aggravated by elevation and relieved by dependency. Nocturnal pain is not necessarily Rest Pain since there are other causes of pain at night. ^(11,12) Rest pain does not usually imply the same urgency for treatment as gangrene or nonhealing wounds.
- **Structured exercise program** is provider-directed and monitored. It involves walking to a pain threshold 3 times a week. Supervised exercise is performed under the guidance of a professional trained in exercise therapy and is reimbursed by the Carrier. ^(8,10,11)
- **Toe Brachial Index** is measured by dividing the highest brachial arm pressure by the pressure obtained from the first toe by any method. Unlike the ABI, the toe pressures are usually not affected by arterial calcification. ⁽¹⁹⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABI: Ankle Brachial Index

AR: Authorization Request

AUC: Appropriate use criteria

BMS: Bare metal stent

CFA: Common femoral artery

CLTI: Chronic limb Threatening ischemia

- CTO: Chronic total occlusion
- CTA: Computed Tomography Angiography
- DFA: Deep Femoral Artery
- DSA: Digital Subtraction Angiography
- GDMT: Guideline directed medical therapy
- GLASS: Global Anatomic Staging System
- ISR: In-stent restenosis
- PAD: Peripheral artery disease
- PTA: Percutaneous transluminal angioplasty
- PVR: Pulse Volume Recording
- SFA: Superficial Femoral Artery
- TASC: Trans-Atlantic Inter-Society Consensus
- TBI: Toe Brachial Index
- Wifl Classification: Wound, Ischemia, and Foot Infection

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POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1174 Endovascular Tibioperoneal Interventions <ul style="list-style-type: none"> ○ The name of the guideline has been changed to Endovascular Infrapopliteal (Tibioperoneal) Interventions ● Added CPT Codes 37232 and 37233 ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Klein A, Jaff M, Gray B, Aronow H, Bersin R et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. *Catheterization and Cardiovascular Interventions*. 2017; 90: E90-E110. 10.1002/ccd.27141.
7. Bailey S, Beckman J, Dao T, Misra S, Sobieszczyk P et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention. *Journal of the American College of Cardiology*. 2019; 73: 214-237. 10.1016/j.jacc.2018.10.002.
8. Woo K, Siracuse J, Klingbeil K, Kraiss L, Osborne N et al. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. *Journal of Vascular Surgery*. 2022; 76: 3-22. e1. 10.1016/j.jvs.2022.04.012.
9. Divakaran S, Carroll B, Chen S, Shen C, Bonaca M. Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease Among Medicare Beneficiaries Between 2017 and 2018: Participation Rates and Outcomes. *Circulation: Cardiovascular Quality and Outcomes*. 2021; 14: e007953. 10.1161/CIRCOUTCOMES.121.007953.
10. Lane R, Harwood A, Watson L, Leng G. Exercise for intermittent claudication. *Cochrane Database of Systematic Reviews*. 2017; 2017: CD000990. 10.1002/14651858.CD000990.pub4.
11. Conte M, Pomposelli F, Clair D, Geraghty P, McKinsey J et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication. *Journal of Vascular Surgery*. 2015; 61: 2S-41S. 10.1016/j.jvs.2014.12.009.
12. Gornik H, Aronow H, Goodney P, Arya S, Brewster L et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VES Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024; 149: e1313-e1410. 10.1161/CIR.0000000000001251.
13. Mohler E, Gornik H, Gerhard-Herman M, Misra S, Olin J. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing. *Journal of Vascular Surgery*. 2012; 56: e17-e51. 10.1016/j.jvs.2012.05.054.
14. Hawkins B, Li J, Wilkins L, Carman T, Reed A et al. SCAI/ACR/APMA/SCVS/SIR/SVM/SVS/VES Position Statement on Competencies for Endovascular Specialists Providing CLTI Care. *Vascular Medicine*. 2022; 27: 405-414. 10.1177/1358863X221095278.

15. Mills J, Conte M, Armstrong D, Pomposelli F, Schanzer A et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIFI). *Journal of Vascular Surgery*. 2014; 59: 220-234.e2. 10.1016/j.jvs.2013.08.003.
16. Smith M, Braet D, Albright J, Corriere M, Osborne N. Real-world application of wound, ischemia, and foot infection scores in peripheral arterial disease patients. *Journal of Vascular Surgery*. 2024; 80: 1216-1223. 10.1016/j.jvs.2024.04.071.
17. Paskiewicz A, Wang F, Yang C, Ballew S, Kalbaugh C et al. Ankle-Brachial Index and Subsequent Risk of Severe Ischemic Leg Outcomes: The ARIC Study. *Journal of the American Heart Association*. 2021; 10: e021801. 10.1161/JAHA.121.021801.
18. Conte M, Bradbury A, Kolh P, White J, Dick F et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *Journal of Vascular Surgery*. 2019; 69: 3S-125S. 10.1016/j.jvs.2019.02.016.
19. Aboyans V, Ricco J, Bartelink M, Björck M, Brodmann M et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *European Heart Journal*. 2018; 39: 763-816. 10.1093/eurheartj/ehx095.
20. Sidawy A, Perler B. Rutherford's Vascular Surgery and Endovascular Therapy, Book Chapter. 2022; 1: 253-264.
21. Dosluoglu H. Endovascular techniques for lower extremity revascularization. In: UpToDate, Wolters Kluwer. 2023.
22. Abu Dabrh A, Mohammed K, Farah W, Haydour Q, Zierler R et al. Systematic review and meta-analysis of duplex ultrasound surveillance for infrainguinal vein bypass grafts. *Journal of Vascular Surgery*. 2017; 66: 1885-1891. 10.1016/j.jvs.2017.06.113.
23. Zierler R, Jordan W, Lal B, Mussa F, Leers S et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *Journal of Vascular Surgery*. 2018; 68: 256-284. 10.1016/j.jvs.2018.04.018.



Evolut Clinical Guideline 7290 for Treatment of Varicose Veins

Guideline Number: Evolut _CG_7290	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

GENERAL

- Varicose veins can be treated by different methods depending on the anatomy of the vein, and surgeon or patient preference
 - Anatomical features that can determine treatment include:
 - Spider veins
 - Reticular veins
 - Individual varicosities or clusters of varicose veins
 - Perforator veins
 - Truncal veins which include the greater saphenous, small saphenous, anterior accessory saphenous, posterior accessory saphenous
 - Abnormalities of the deep veins do not constitute varicose veins, but may contribute to them
 - Treatment methods include:
 - Conservative measures including compression, ambulation, limb elevation, and avoiding prolonged sitting and standing
 - High ligation and stripping
 - Stab avulsion Phlebectomy (SAP) also known as mini- or micro-phlebectomy

- Cluster excision
- Transilluminated powered phlebectomy
- Sclerotherapy with polidocanol or sodium tetradecyl sulfate
- Thermal ablation of truncal veins using laser or radiofrequency
- Nonthermal ablation of truncal veins

INDICATIONS (6,7,8,9)

- Documentation of symptomatic venous disorders (see **Definitions**):
 - Any of the following with clinical issues attributed to venous reflux:
 - Axial reflux ≥ 500 ms and vein diameter ≥ 5 mm in the great saphenous vein or anterior accessory saphenous veins
 - Axial Reflux ≥ 500 ms and vein diameter ≥ 3 mm in the small saphenous vein
 - Axial Reflux >500 ms and vein diameter ≥ 5 mm in the posterior accessory vein provided all other axial reflux is absent, or successfully treated > 3 months previously, and patient has continued CEAP C2s or C4-C6
 - Perforator vein with reflux ≥ 500 milliseconds (ms) and diameter ≥ 3.5 mm **AND ANY** of the following:
 - It is located beneath an open venous ulcer and truncal reflux has been corrected or will be treated concurrently
 - It is Located beneath a healed venous ulcer and truncal reflux has been corrected
 - It lies directly beneath a symptomatic vein or cluster of veins with persistent or recurrent symptoms > 3 months after complete ablation of refluxing superficial truncal veins

Clinical issues attributed to venous reflux include **ANY** of the following:

- Leg or foot ulceration
- Hemorrhage or recurrent bleeding episodes from a ruptured varicosity or spider vein telangiectasia or reticular vein
- Superficial thrombophlebitis
- Severe and persistent pain and/or swelling that interferes with the quality of daily life (CEAP class C2s or greater) and persists despite 6 weeks of conservative measures (see Definition), unless contraindicated (e.g. suspected or proven peripheral arterial disease, severe peripheral neuropathy)
- Spider and reticular veins that have bled or in the elderly judged to be a substantial risk for hemorrhage with minimal trauma
- C6 with below the knee reflux in the great saphenous vein ≥ 500 ms and vein diameter ≥ 3 mm

A PLAN OF TREATMENT CAN BE PROVIDED FOR BOTH LEGS (6,7,8,9)

- The planned treatment/s must be completed within 90 days from the first treatment.
- When Truncal treatment is the primary treatment and Sclerotherapy or SAP is also being considered for that extremity, SAP should be performed with Truncal treatment unless:
 - There are extensive varicosities
 - There are circumferential limb varicosities requiring changing the patient's position from supine to decubitus
 - There is a need for general anesthesia or large amounts of local or tumescent anesthetic
- Ablation of two continuous saphenous segments accessed by a single or multiple access points is still considered a single ablation
- If both the AASV and great saphenous require treatment both should be treated concurrently unless a reason is specified
- A treatment plan that involves three truncal veins/leg must have detailed explanation and identify the proposed sequence of treatments

LIMITATIONS (6,7,8,9)

- Failure of ablation or recurrent venous reflux without other indications for treatment
- Bilateral leg edema (CEAP C3) unless other reasons for edema have been discussed and excluded
- Ultrasound guided foam sclerotherapy for truncal and varicose veins >6 mm
- Nonthermal techniques for truncal veins ≥ 10 mm
- Ablation by thermal or nonthermal techniques for venous aneurysms located within 3 cm of saphenofemoral junctions
- Isolated saphenofemoral junctional incompetence
- Isolated reflux in great saphenous vein segments, in the presence of competent segments proximally and distally
- Previous administration of sclerotherapy agent in the same vein less than 6 weeks prior
- The following are contradictions to intervention
 - Allergy to sclerotherapy agents
 - Pregnancy or within 3 months after delivery
 - Acute febrile illness
 - Local or general infection
 - Severe distal arterial occlusive disease (ankle brachial index < 0.4 arterial ulcer or

- gangrene)
- Obliteration of the deep venous system
 - Acute deep venous phlebitis
 - Prolonged immobility
 - Ultrasound guided foam sclerotherapy in a patient with symptomatic right to left shunt
 - Eminent requirement of the great or small saphenous vein for an arterial or coronary artery bypass

CODING AND STANDARDS

Coding

CPT Codes

36465, 36466, 36470, 36471, 36473, 36474, 36475, 36476, 36478, 36479, 36482, 36483, 37500, 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- Varicose veins: are abnormally dilated veins virtually always in the lower extremities, lower abdominal wall or pelvic region. They can be asymptomatic, cause cosmetic embarrassment, or may be symptomatic with a sense of discomfort, pressure, itching and heaviness.
- Venous reflux: is retrograde flow due to valvular incompetence
- Axial reflux: is defined as uninterrupted reflux from the junction of a truncal vein and the appropriate deep vein and extending distally at least to the knee or ankle
- Truncal veins are the great, small, anterior saphenous, and posterior accessory saphenous veins
- Perforating veins connect the deep and superficial system of veins

- Thermal ablation: involves heat and which is usually supplied by laser or radiofrequency applied to metal probes
- Nonthermal ablation implies ablation by any means other than thermal
- Conservative measures for treating varicose veins: include compression, ambulation, limb elevation, and avoiding prolonged sitting and standing

Venous Clinical Severity Score (VCSS) ⁽¹⁰⁾

Pain/Discomfort	None: 0	Mild: 1	Moderate: 2	Severe: 3
e.g., aching, fatigue, soreness, heaviness, burning		Occasional pain that does not restrict daily activities	Daily pain may interfere with regular daily activities (does not prevent)	Daily pain limiting most regular daily activities

Varicose Veins	None: 0	Mild: 1	Moderate: 2	Severe: 3
≥ 3 mm (diameter) in standing position		Few: scattered (varicosities confined to branch veins or clusters) Includes corona phlebectatica (ankle flare)	Multiple varicosities confined to the calf or the thigh	Multiple varicosities involves calf and thigh

Venous Edema	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin		Edema limited to the foot and ankle	Edema extends above the ankle but below the knee	Edema extends to the knee and above

Skin Pigmentation	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin Does not include focal pigmentation over varicose veins or due to other chronic diseases (e.g., vasculitis purpura)		Pigmentation is limited to perimalleolar area	Diffuse pigmentation that involves lower third of the calf	Wider distribution pigmentation above the lower third of the calf

Inflammation	None: 0	Mild: 1	Moderate: 2	Severe: 3
More than recent pigmentation (i.e., erythema, cellulitis, venous eczema, dermatitis)		Inflammation limited to perimalleolar area	Diffuse inflammation over lower third of calf	Wider distribution inflammation above lower third of calf

Induration	None: 0	Mild: 1	Moderate: 2	Severe: 3
Presumes venous origin of secondary skin & subcutaneous changes (e.g., chronic edema with fibrosis, hypodermatitis); includes white atrophy & Lipodermatosclerosis		Limited to perimalleolar area	Diffuse over lower third of calf	Wider distribution above lower third of calf

Active Ulcer Number	0	1	2	≥ 3
Active Ulcer Duration (longest active)	N/A	< 3 months	> 3 months but < 1 y	Not healed for > 1 y
Active Ulcer Size (largest active)	N/A	< 2 cm (diameter)	2-6 cm (diameter)	>6 cm (diameter)

Compression Therapy Use	0	1	2	3
	Not Used	Intermittent stocking use	Stocking use most days	Stocking use full compliance

CEAP Classification (Clinical Class, Etiology, Anatomy, Pathology) ⁽¹¹⁾

CEAP categories; Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)

Clinical (C) Classifications (C Classes present in Limb)

- C₀ – No visible or palpable signs of venous disease
- C₁ – Telangiectasias or reticular veins (< 3mm)
- C₂ – Simple varicose veins (≥ 3mm diameter)

- C_{2r} – Recurrent varicose veins
- C₃ – Ankle edema of venous origin (not foot edema)
- C₄ – Changes in skin and subcutaneous tissue secondary to CVD
 - C_{4a} – Pigmentation or eczema
 - C_{4b} – Lipodermatosclerosis or atrophie blanche
 - C_{4c} – Corona phlebectatica
- C₅ – Healed venous ulcer
- C₆ – Open venous ulcer
 - C_{6r} – Recurrent active venous ulcer

Subscripts of C Classes Indicating presence or absence of symptoms

- **S - Symptomatic**
 - Ache
 - Pain
 - Tightness
 - Skin irritation
 - Heaviness
 - Muscle cramps
 - Other complaints attributable to venous dysfunction
- **A – Asymptomatic**

Etiologic (E) Classification

- E_c – Congenital
- E_p – Primary
- E_s – Secondary
 - E_{si} – Secondary – intravenous
 - E_{se} – Secondary – extravenuous
- E_n – No cause identified

Anatomic (A) Classification

- A_s – Superficial veins
 - Telangiectasia
 - Reticular Veins
 - Great saphenous vein above knee
 - Great saphenous vein below knee
 - Small saphenous vein
 - Anterior accessory saphenous vein
 - Nonsaphenous vein

- A_p – Perforator veins
 - Thigh perforator vein
 - Calf perforator vein
- A_d – Deep veins
 - Inferior vena cava
 - Common iliac vein
 - Internal iliac vein
 - External iliac vein
 - Pelvic veins
 - Common femoral vein
 - Deep femoral vein
 - Femoral vein
 - Popliteal vein
 - Crural (tibial) vein
 - Peroneal vein
 - Anterior tibial vein
 - Posterior tibial vein
 - Muscular veins
 - Gastrocnemius vein
 - Soleal vein
- A_n – No venous anatomic location identified

Pathophysiologic (P) Classification

- P_r – Reflux
- P_o – Obstruction
- P_{r,o} – Reflux and obstruction
- P_n – No venous pathophysiology

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AASV: Anterior accessory saphenous vein (now known as the anterior saphenous vein)

AUC: Appropriate Use Criteria (Scores)

CEAP: Clinical (C), Etiology (e), Anatomical (A), and Pathophysiological (P)

PCF: Physician compounded foam

SAP: Stab avulsion phlebectomy

r-VCSS: Revised Venous Clinical Severity Score

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM 1252 Endovascular Venous Laser-Radiofrequency Ablation ● This guideline replaces UM 1253 Lower Extremity Venous Ligation/Stripping ● This guideline replaces UM 1254 Lower Extremity Venous Sclerotherapy ● This guideline replaces UM 1255 Lower Extremity Venous Stab Phlebectomy

LEGAL AND COMPLIANCE

Guideline Approval

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483-1502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA appropriateness method user's manual. RAND. 2001; 109.
3. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R, Patel M, Allen J, Min J, Shaw L et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: A report of the American college of cardiology foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-1317. 10.1016/j.jacc.2013.01.025.
5. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-1613. 10.1016/j.jacc.2005.08.030.
6. De Maeseneer M, Kakkos S, Aherne T, Baekgaard N, Black S et al. Editor's Choice – European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. *European Journal of Vascular and Endovascular Surgery*. 2022; 63: 184-267. 10.1016/j.ejvs.2021.12.024.
7. Gloviczki P, Lawrence P, Wasan S, Meissner M, Almeida J et al. The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II: Endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. 2024; 12: 10.1016/j.jvsv.2023.08.011.
8. Gloviczki P, Lawrence P, Wasan S, Meissner M, Almeida J et al. The 2022 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part I. Duplex Scanning and Treatment of Superficial Truncal Reflux: Endorsed by the Society for Vascular Medicine and the International Union of Phlebology. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. 2023; 11: 231-261.e6. 10.1016/j.jvsv.2022.09.004.
9. Masuda E, Ozsvath K, Vossler J, Woo K, Kistner R et al. The 2020 appropriate use criteria for chronic lower extremity venous disease of the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. 2020; 8: 505-525.e4. 10.1016/j.jvsv.2020.02.001.
10. Vasquez M, Rabe E, McLafferty R, Shortell C, Marston W et al. Revision of the venous clinical severity score: Venous outcomes consensus statement: Special communication of the American Venous Forum Ad Hoc Outcomes Working Group. *Journal of Vascular Surgery*. 2010; 52: 1387-1396. 10.1016/j.jvs.2010.06.161.
11. Lurie F, Passman M, Meisner M, Dalsing M, Masuda E et al. The 2020 update of the CEAP classification system and reporting standards. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. 2020; 8: 342-352. 10.1016/j.jvsv.2019.12.075.

Evolut Clinical Guideline 7291 for Enhanced External Counter Pulsation

Guideline Number: Evolut_CG_7291	<u>Applicable Codes</u>	
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Original Date: July 2011	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Enhanced External Counter Pulsation (EECP)

Special Note

- To review a request for medical necessity, the following items must be submitted for review:
 - Progress note that prompted request (including list of current medications)
 - Records from last EECP treatment (if applicable)
 - Most recent Echocardiogram, Stress test
 - Most recent cardiac catheterization report
- Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for Evolent and cannot be reviewed

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR ENHANCED EXTERNAL COUNTER PULSATION

An initial treatment course of 35 one-hour sessions, given 5 days per week will be considered for:

- Patients with chronic coronary disease, refractory angina pectoris, or with Class III or IV angina symptoms per New York Heart Association (NYHA) or Canadian Cardiovascular Society (CCS) and on maximally tolerated guideline-directed medical therapy (GDMT) ^(6,7)
- Patients who are not amenable for revascularization either percutaneously (PCI) or surgically (CABG) due to ⁽⁶⁾
 - Inoperative condition or high risk of operative complications or post-op failure
 - Recurrent angina pectoris despite multiple revascularization procedures
 - Unsuitable coronary anatomy
 - Additional co-morbid states which could create excessive risk
- Repeat courses of EECP will be considered on a case-by-case basis for patients with refractory angina pectoris if all the following criteria are met ⁽⁶⁾
- Patients meets medical necessity criteria for EECP **AND**
- Prior EECP has resulted in a sustained improvement in symptoms, with a significant (greater than 25%) reduction in frequency of angina symptoms
- Improvement by one or more angina classes (NYHA or CCS) **AND**
- Three or more months has elapsed from the prior EECP treatment

CONTRAINDICATIONS OF ENHANCED EXTERNAL COUNTER PULSATION ^(6,7)

- Decompensated heart failure
- Severe Aortic Regurgitation
- Severe Peripheral Artery Disease
- Recent myocardial infarction within the last 3 months
- Recent surgical intervention within the last 6 weeks
- Recent cardiac catheterization (1-2 weeks) or arterial femoral puncture
- Unstable angina pectoris
- Severe hypertension > 180/110 mm Hg
- Heart rate of <35 or >125 beats per minute
- Arrhythmias that interfere with EECP triggering
- Severe venous disease (thrombophlebitis, deep vein thrombosis, or pulmonary embolism)
- Severe lower extremity vaso-occlusive disease
- Presence of a documented aortic aneurysm requiring surgical repair

- Pregnancy

CODING AND STANDARDS

Coding

HCPCS Codes

G0166

ICD-10 Codes

I20.0, I20.1, I20.8, I20.9

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Enhanced External Counter pulsation is a nonsurgical outpatient treatment of angina pectoris and coronary artery disease (CAD) refractory to medical and/or surgical therapy. This therapy increases blood flow to the heart by compressing blood vessels in the lower extremities. The patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and deflate in synchronization with the patient's cardiac cycle.

Although EECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Non-coverage of hydraulic versions of these types of devices remains in force.

New York Heart Association Grading Scale for Heart Failure ⁽⁸⁾

- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)
- Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical

activity results in fatigue, palpitation, dyspnea, or chest pain

- Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or chest pain
- Class IV: Symptoms of heart failure at rest. Any physical activity causes further discomfort

Canadian Cardiovascular Society Grading Scale for Angina ⁽⁹⁾

- Class I: Ordinary physical activity does not cause angina, such as walking or climbing stairs. Angina occurs with strenuous, rapid or prolonged exertion
- Class II: Slight limitation of ordinary activity. Angina occurs only during vigorous physical activity, such as walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals in cold, wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions
- Class III: Marked limitation of ordinary physical activity. It is induced by walking one or two-level blocks and climbing one flight of stairs in normal conditions and at a normal pace
- Class IV: Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CABG: Coronary Artery Bypass Graft

CAD: Coronary Artery Disease

CCS: Canadian Cardiovascular Society

EECP: Enhanced External Counter Pulsation

FDA: Food and Drug Administration

GDMT: Guideline-Directed Medical Therapy

NYHA: New York Heart Association

PCI: Percutaneous Coronary Intervention

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> <li data-bbox="531 421 1362 488">This guideline replaces UM Cardio 1117 Enhanced External Counter Pulsation (EECP)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Caceres J, Atal P, Arora R, Yee D. Enhanced external counterpulsation: A unique treatment for the No-Option refractory angina patient. *Journal of clinical pharmacy and therapeutics*. 2021; 46: 295-303. 10.1111/jcpt.13330.
7. Fihn S D, Blankenship J C, Alexander K P, Bittl J A, Byrne J G et al. 2014 ACC/AHA/AATS/PCNA/SCAI/STS focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease. *Journal of the American College of Cardiology*. 2014; 64: 1929-49. 10.1016/j.jacc.2014.07.017.
8. New York Heart Association. New York Heart Association Functional Classification. American Heart Association (Online). 2023; Accessed: May 10, 2024. <https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure>.
9. Canadian Cardiovascular Society. Canadian Cardiovascular Society grading of angina pectoris. Canadian Cardiovascular Online. 2020; Accessed: May 10, 2024. https://ccs.ca/app/uploads/2020/12/Ang_Gui_1976.pdf.

Evolut Clinical Guideline 7292 for Infrainguinal Open Arterial Vascular Surgery

Guideline Number: Evolut_CG_7292	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for infrainguinal open arterial bypass surgery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

For this policy procedures will be considered if they involve the common, deep (profunda), superficial femoral, or popliteal arteries. Arteries below the popliteal artery may be referred to as “infrapopliteal” and include the tibioperoneal trunk, anterior tibial, posterior tibial, peroneal, plantar, dorsalis pedis, and tarsal arteries.

INDICATIONS

Claudication

When **ALL** the following requirements have been met:

- Impairment of activities of daily living and/or work ⁽⁶⁾
- Absence of other conditions that would limit exercise even if claudication is improved ⁽⁷⁾ (e.g. arthritis, angina, chronic respiratory disease)
- Member is on guideline directed medical therapy (GDMT) ^(6,8)
- Inadequate response to a supervised or structured exercise program for 12 weeks

(9,10)

- Proximal clinically significant aortoiliac disease is not present, or successfully treated such that it is unlikely to be responsible for ongoing claudication. If still present and clinically significant it will be treated concurrently with the infrainguinal procedure by open or endovascular techniques. ⁽⁶⁾
- An Ankle Brachial Index (ABI; see **Definitions**) <0.9 or ≥1.4, **OR** TBI <0.7, **OR** ≥20% reduction in ankle pressure on exercise testing.
 - If arteries are noncompressible, making these tests unreliable, abnormal Doppler tracings or pulse volume recordings (PVR) can be provided ⁽⁶⁾
- An anatomically suitable lesion with imaging demonstrating one of the following ⁽¹¹⁾:
 - ≥70% stenosis (CTA, MRA, invasive angiography)
 - Duplex ultrasound showing no flow or Doppler velocity in the stenosis with peak systolic velocity (PSV) ≥300 cm/s or PSV ratio ≥4.0 and with monophasic flow pattern
- A duplex scan of the ipsilateral great saphenous vein has been performed to evaluate suitability for use as a bypass graft (unless contraindicated or unavailable, the contralateral vein should be evaluated if the ipsilateral vein is absent or unusable. If bypass to a tibial artery is contemplated and leg vein is not available, arm vein should be evaluated) ^(6,12)

Chronic Limb Threatening Ischemia (CLTI)

When **ALL** the following requirements have been met:

- Gangrene or nonhealing ischemic wounds present for more than 2 weeks despite provider directed and described wound care ^(13,14) **OR** wound Grade 1-3 based on the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (Wiffl). ^(14,15) One of the following must be present:
 - An ABI <0.8
 - Ankle pressure <100 mmHg
 - Toe pressures or TCPO₂ <60 mmHg
 - If ABI ≥1.4, then one of the following ^(14,16,17,18):
 - Toe pressures or TCPO₂ <60 mmHg
 - TBI <0.7 with Monophasic PVR or Doppler waveforms
- If no Gangrene or non-healing wounds but Rest Pain, then with **ANY** of the following ^(14,16,17,18):
 - An ABI <0.4
 - If Ankle pressures unrecordable, Toe pressure or TcPO₂ <30 mmHg
 - PVR amplitude or Doppler waveforms showing flat line or <5mm with absent dirotic notch
- An anatomically suitable lesion with imaging demonstrating at least one of the following ^(8,19):
 - ≥50% stenosis, as shown by CTA, MRA, or invasive angiography

- Duplex ultrasonography with absent velocities **OR** peak systolic velocity (PSV) ≥ 250 cm/s **AND** PSV ratio of ≥ 2.0 across the stenosis with monophasic distal flow
- A duplex scan of the ipsilateral great saphenous vein has been performed to evaluate suitability for use as a bypass graft (unless contraindicated or unavailable, the contralateral vein should be evaluated if the ipsilateral vein is absent or unusable. If bypass to a tibial artery is contemplated and leg vein is not available, arm vein should be evaluated) ^(6,12)
- If a graft material other than autogenous vein will be used, the reason(s) for choosing that graft must be described in the notes provided since vein is the conduit of choice especially for bypass to the below knee popliteal or infrapopliteal arteries (see **Definitions**). ⁽⁸⁾

Other Indications or Specific Open Vascular Procedures

- For the treatment of femoral-popliteal aneurysms with **ANY** of the following:
 - ≥ 20 mm
 - < 20 mm with extensive thrombus involving $\geq 50\%$ of the lumen
 - Evidence of distal embolization
 - Poor distal runoff

NOTE: If a graft other than vein will be used, the reason(s) for that choice must be described in the notes provided since vein is the conduit of choice especially for bypass to the below knee popliteal or tibial arteries. ⁽²⁰⁾

- Common femoral endarterectomy to treat claudication or CLTI will follow the same policies listed above (but preoperative evaluation of the saphenous vein is not a requirement since often prosthetic patch is use instead). Common femoral endarterectomy can be performed as a standalone procedure.
- A patch (synthetic or vein) used as an add-on procedure where the provider places the patch (also known as a cuff) to the distal end of the graft to help maintain patency
- A patch (synthetic or vein) used for the treatment of stenosis within a vein bypass graft in a symptomatic or asymptomatic member with concern for impending graft failure and **ANY** one of the following ^(11,21):
 - Peak Systolic Velocity (PSV) of ≥ 180 cm/s
 - A velocity ratio of ≥ 2.0
 - An end diastolic velocity of < 45 cm/s
- To allow local podiatric or orthopedic interventions when circulation may be tenuous but in and of itself not severe enough to warrant intervention; with ANY of the following ⁽¹⁴⁾:
 - An ABI < 0.8 .
 - Ankle pressure < 100 mmHg
 - Toe Pressure or TcPO₂ < 60 mmHg
 - If ABI ≥ 1.4 then one of the following ⁽¹⁴⁾:
 - Toe Pressure or TcPO₂ < 60 mmHg

- Monophasic PVR or Doppler waveforms
- Embolectomy or Thrombectomy performed for acute ischemia

Limitations

- Femoral-tibial artery bypass with prosthetic or non-autogenous graft material should only be used if ALL possible autologous vein is not available and an endovascular alternative is not feasible or has been unsuccessful ⁽⁶⁾
- If a bypass is being requested for claudication there can be no assertion, directly or indirectly, that treatment is required to prevent amputation ⁽⁶⁾
- Common femoral endarterectomy cannot be requested concurrently with a bypass unless it involves the contralateral limb

CODING AND STANDARDS

Coding

CPT Codes

35302, 35303, 35304, 35306, 35351, 35355, 35361, 35363, 35371, 35372, 35539, 35540, 35556, 35558, 35560, 35563, 35565, 35566, 35570, 35571, 35572, 35583, 35585, 35587, 35646, 35647, 35650, 35654, 35656, 35661, 35663, 35665, 35666, 35671, 35681, 35682, 35683, 35685, 35700, 35701, 35702, 35703, 35721, 35741, 35860, 35879, 35881, 35883, 35884, 35903

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

- An **anatomically suitable lesion** is one where the appropriate intervention would have low risk, and a high probability of initial and long-term success based on accepted lesion classifications such as TASC II or GLASS. ^(7,8,17)
- **Ankle Brachial Index (ABI)** is measured by dividing the highest brachial blood pressure in either arm by the highest pressure obtained from the dorsalis pedis or

posterior tibial artery. ⁽¹⁶⁾

- **Chronic Limb Threatening Ischemia (CLTI)** has replaced **Critical Limb Ischemia (CLI)** since the threat to limb viability in patients with PAD is not only related to ischemia but other factors such as infection, neuropathy, and general patient morbidities. Further, “critical” implies that treatment is urgent to avoid limb loss, while some patients can keep their legs for extended periods of time even in the absence of revascularization. CLTI is defined clinically by the presence of Rest Pain, gangrene, a nonhealing wound or ulceration lasting more than 2 weeks despite appropriate wound care. Infection may make invasive treatment more urgent. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (WIfI) is helpful in defining CLTI and prognosticating indications for treatment and outcome. ^(14,17,18)
- **Claudication** is a symptom complex of pain that begins with ambulation and that is relieved within a brief time by walking cessation. It is described by the intensity of discomfort, the distance walked, the duration of the walk and the impact that it has on quality of life (QOL) and activities of daily living (ADL). Claudication does not occur at rest. If left untreated, the natural history of claudication is slow progression, yet amputation is rare occurring in less than 5% of patients. ⁽⁸⁾
- **Clinically significant disease** is such that it is likely causing ischemic symptoms or findings
- **Endovascular intervention** is the treatment of peripheral arterial disease with angioplasty, atherectomy, intravascular lithotripsy, or stents. It is performed by opening the blood vessel with a device placed on a catheter inserted through a blood vessel. In some cases, drug elution is added to the device to prevent restenosis. Intravascular ultrasound and filters may assist the procedure. In some circumstances mechanical thrombectomy or drug infusion thrombolysis may be required. ⁽²²⁾
- **Guideline Directed Medical Therapy (GDMT)** includes recommendations for antiplatelet therapy, cilostazol (unless contraindicated or not tolerated), statins, glycemic and hypertension control, structured exercise program, smoking cessation including planning, counseling, or behavior modification and pharmacotherapy if needed. Duration should be for at least 12 weeks. ^(7,8,13)
- **Rest Pain** is a distinct pain syndrome lasting more than 2 weeks, implying CLTI. It is defined as pain in the foot or toes aggravated by elevation and relieved by dependency. Nocturnal pain is not necessarily Rest Pain since there are other causes of pain at night. ^(6,13) Rest pain does not usually imply the same urgency for treatment as gangrene or nonhealing wounds.
- **Structured exercise program** is provider-directed and monitored. It involves walking to a pain threshold 3 times a week. Supervised exercise is performed under the guidance of a professional trained in exercise therapy and is reimbursed by the Carrier. ^(6,8,10)
- **Toe Brachial Index** is measured by dividing the highest brachial arm pressure by the pressure obtained from the First toe by any method. Unlike the ABI, the toe pressures are usually not affected by arterial calcification. ⁽¹⁸⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ABI: Ankle Brachial Index

AR: Authorization Request

AUC: Appropriate use criteria

CLTI: Chronic limb Threatening ischemia

CPT: Current Procedural Terminology

CTA: Computed Tomography Angiography

DSA: Digital Subtraction Angiography

GDMT: Guideline directed medical therapy

GLASS: Global Anatomic Staging System

PAD: Peripheral artery disease

PSV: Peak Systolic Velocity

PTA: Percutaneous transluminal angioplasty

PVR: Pulse Volume Recording

TASC: Trans-Atlantic Inter-Society Consensus

TBI: Toe Brachial Index

WIFI Classification: Wound, Ischemia, and Foot Infection

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions ⁽¹³⁾

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1164 for Femoral Popliteal Bypass Surgery <ul style="list-style-type: none"> ○ Guideline name changed to Infrainguinal Open Arterial Vascular Surgery ● Added CPT code 35685 ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACC/ACC/ACC/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC/AHA Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Conte M, Pomposelli F, Clair D, Geraghty P, McKinsey J et al. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication. *Journal of Vascular Surgery*. 2015; 61: 2S-41S. 10.1016/j.jvs.2014.12.009.
7. Bailey S, Beckman J, Dao T, Misra S, Sobieszczyk P et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention. *Journal of the American College of Cardiology*. 2019; 73: 214-237. 10.1016/j.jacc.2018.10.002.
8. Woo K, Siracuse J, Klingbeil K, Kraiss L, Osborne N et al. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. *Journal of Vascular Surgery*. 2022; 76: 3-22.e1. 10.1016/j.jvs.2022.04.012.
9. Divakaran S, Carroll B, Chen S, Shen C, Bonaca M. Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease Among Medicare Beneficiaries Between 2017 and 2018: Participation Rates and Outcomes. *Circulation: Cardiovascular Quality and Outcomes*. 2021; 14: e007953. 10.1161/CIRCOUTCOMES.121.007953.
10. Lane R, Harwood A, Watson L, Leng G. Exercise for intermittent claudication. *Cochrane Database of Systematic Reviews*. 2017; 2017: CD000990. 10.1002/14651858.CD000990.pub4.
11. Zierler R, Jordan W, Lal B, Mussa F, Leers S et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *Journal of Vascular Surgery*. 2018; 68: 256-284. 10.1016/j.jvs.2018.04.018.
12. Farber A, Menard M, Conte M, Kaufman J, Powell R et al. Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia. *New England Journal of Medicine*. 2022; 387: 2305-2316. 10.1056/NEJMoa2207899.
13. Gornik H, Aronow H, Goodney P, Arya S, Brewster L et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024; 149: e1313-e1410. 10.1161/CIR.0000000000001251.
14. Mills J, Conte M, Armstrong D, Pomposelli F, Schanzer A et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIFI). *Journal of Vascular Surgery*. 2014; 59: 220-234.e2. 10.1016/j.jvs.2013.08.003.

15. Smith M, Braet D, Albright J, Corriere M, Osborne N. Real-world application of wound, ischemia, and foot infection scores in peripheral arterial disease patients. *Journal of Vascular Surgery*. 2024; 80: 1216-1223. 10.1016/j.jvs.2024.04.071.
16. Paskiewicz A, Wang F, Yang C, Ballew S, Kalbaugh C et al. Ankle-Brachial Index and Subsequent Risk of Severe Ischemic Leg Outcomes: The ARIC Study. *Journal of the American Heart Association*. 2021; 10: e021801. 10.1161/JAHA.121.021801.
17. Conte M, Bradbury A, Kolh P, White J, Dick F et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *Journal of Vascular Surgery*. 2019; 69: 3S-125S. 10.1016/j.jvs.2019.02.016.
18. Aboyans V, Ricco J, Bartelink M, Björck M, Brodmann M et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *European Heart Journal*. 2018; 39: 763-816. 10.1093/eurheartj/ehx095.
19. Sidawy A, Perler B. Rutherford's Vascular Surgery and Endovascular Therapy, Book Chapter. 2022; 1: 253-264.
20. Farber A, Angle N, Avgerinos E, Dubois L, Eslami M et al. The Society for Vascular Surgery clinical practice guidelines on popliteal artery aneurysms. *Journal of Vascular Surgery*. 2022; 75: 109S-120S. 10.1016/j.jvs.2021.04.040.
21. Abu Dabrh A, Mohammed K, Farah W, Haydour Q, Zierler R et al. Systematic review and meta-analysis of duplex ultrasound surveillance for infrainguinal vein bypass grafts. *Journal of Vascular Surgery*. 2017; 66: 1885-1891. 10.1016/j.jvs.2017.06.113.
22. Klein A, Jaff M, Gray B, Aronow H, Bersin R et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. *Catheterization and Cardiovascular Interventions*. 2017; 90: E90-E110. 10.1002/ccd.27141.
23. Gerhard-Herman M, Gornik H, Barrett C, Barshes N, Corriere M et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease. *Journal of the American College of Cardiology*. 2017; 69: e71-e126. 10.1016/j.jacc.2016.11.007.
24. Hirsch A, Haskal Z, Hertzner N, Bakal C, Creager M et al. ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic). *Journal of the American College of Cardiology*. 2006; 47: 1239-1312. 10.1016/j.jacc.2005.10.009.
25. Gerhard-Herman M, Gornik H, Barrett C, Barshes N, Corriere M et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017; 135: e726-e779. 10.1161/CIR.0000000000000471.
26. Anderson J, Halperin J, Albert N, Bozkurt B, Brindis R et al. Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations). *Circulation*. 2013; 127: 1425-1443. 10.1161/CIR.0b013e31828b82aa.



Evolut Clinical Guideline 7293-01 for Fractional Flow Reserve CT

Guideline Number: Evolut_CG_7293-01	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Fractional flow reserve computed tomography (FFR_{CT}) is a technology that estimates the effect of coronary arterial narrowing on blood flow based upon the images acquired in the CCTA study. Its role is to provide information that can more appropriately select patients requiring invasive coronary angiography. ⁽¹⁾

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(2,3,4,5,6)

INDICATIONS FOR FRACTIONAL FLOW RESERVE CT

- Intermediate degrees of stenosis (40 - 90%) on coronary computerized tomographic angiography (CCTA) to guide decision making and help identify those patients who would benefit from revascularization ^(1,7,8,9) (**AUC 8**) ⁽¹⁰⁾
- Intermediate lesions in the above range and coronary calcification have made percentage stenosis interpretation difficult, thus could support approval of FFR_{CT}, in conjunction with the above criteria. ^(11,12)

Additional Information

The following clinical scenarios below do not apply for the use of FFR_{CT} ⁽¹¹⁾:

- Problematic artifacts, and/or clinical circumstances:
 - When patients have artifacts (heavy calcium) or body habitus (BMI > 35) that

could interfere with the examination, the suitability for FFR_{CT} is at the discretion of the vendor who provides the FFR_{CT} service

- Known ischemic coronary artery disease that has not been revascularized and there has been no change in patient status or in the CCTA images
- Recent myocardial infarction within 30 days ⁽¹³⁾
- Prior coronary artery bypass graft surgery
- Complex congenital heart disease or ventricular septal defect (VSD) with pulmonary-to-systemic flow ratio > 1.4
- Metallic stents ≤ 3.0 mm in diameter in the coronary system
- Coronary lesions with a vessel diameter < 1.8 mm ^(14,15)
- Severe wall motion abnormality on CCTA results
- Severe myocardial hypertrophy
- High risk indicators on stress test ⁽¹⁵⁾
- Coronary angiography within the past 90 days ⁽¹⁵⁾
- Marginal quality of the submitted imaging data, due to motion, blooming, misalignment, arrhythmia, etc.

CODING AND STANDARDS

Coding

CPT Codes

75580 Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional. Reported once per CCTA when done on the same day.

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

General Overview

Fractional flow reserve (FFR) is used to determine the functional significance of a coronary stenosis in angiographically “intermediate” or “indeterminant” lesions which allows the operator to decide when PCI may be beneficial or safely deferred. ⁽¹⁶⁾ During coronary catheterization, a catheter is inserted into the femoral (groin) or radial arteries (wrist) using a sheath and guidewire. FFR uses a small sensor (transducer) on the tip of the wire to measure pressure, temperature, and flow in order to determine the exact severity of the lesion during maximal blood flow (hyperemia). Hyperemia is induced by injecting products such as adenosine or papaverine. A pullback of the pressure wire is performed, and pressures are recorded across the vessel.

FFR is then calculated as the ratio of distal coronary pressure to aortic pressure measured during maximal hyperemia. A normal value for FFR is 1.0. $FFR \leq 0.80$ in an angiographically intermediate lesion (50-70% stenosis) is considered to be a significant coronary lesion (>70% stenosis). ⁽¹⁶⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

The Development of FFR-CT as a Technology ^(17,18,19,20,21)

Fractional Flow Reserve (FFR) is the ratio of baseline coronary flow to coronary flow during maximal hyperemia. Its use in the cardiac catheterization laboratory has successfully demonstrated utility in the quantitation of intracoronary flow dynamics secondary to lesional and microvasculature conditions. This technology has proven helpful in evaluating individual patients, with respect to prognostication of coronary artery disease and decisions regarding the appropriateness of coronary revascularization.

Definitions

- CCTA has shown utility in the evaluation of patients with stable chest pain, typically intermediate pretest probability, warranting non-invasive evaluation, ^(15,22,23) as well as in low-risk emergency department scenarios. ⁽²⁴⁾
- Fractional flow reserve using CCTA seeks to provide an estimation of FFR by non-invasive methodology. Following assessment of quality CCTA images, in the appropriate subsets of patients with coronary stenoses, the technology makes mathematical assumptions to simulate maximal hyperemia and calculates an estimation of FFR (fractional flow reserve) for those coronary vessels with lesions, based upon the principles of fluid mechanics inherent to the Navier-Stokes Theorem. ^(16,25)
- Quantitative estimation of coronary lesional hemodynamic severity using FFR_{CT}

might enable deferral of invasive coronary arteriography when values are above 0.80, since such lesions would not warrant revascularization. ⁽¹¹⁾

- FFR_{CT} measurements appear reproducible, ⁽²⁶⁾ with initial data demonstrating a strong correlation to invasive FFR, resulting in a high diagnostic performance. ⁽²⁷⁾ Invasive FFR has excellent reproducibility ⁽²⁸⁾ and a demonstrated track record of favorable outcomes when used in the selection of patients and vessels requiring PCI. ^(17,18,20) Evidence suggests that FFR_{CT} might be a better predictor of revascularization or adverse events than severe stenosis alone on CCTA ⁽²⁹⁾ and that a negative FFR_{CT} in the evaluation of chest pain results in lower revascularization rates and lower cardiovascular death and MI at 1 year follow-up. ⁽³⁰⁾
- The FFR_{CT} data to date provides no evidence showing that revascularization based upon FFR_{CT} improves clinical outcomes over invasive angiographic assessment.
- Current revascularization guidelines do not advocate FFR_{CT} as a surrogate for invasive FFR, although, those guidelines refer to FFR_{CT} as an “emerging technology”. ⁽³¹⁾

Acronyms / Abbreviations

BMI: Body Mass Index

CCTA: Coronary Computerized Tomographic Angiography

FFR: Fractional Flow Reserve

FFR_{CT}: Fractional Flow Reserve derived noninvasively from CCTA

ICA: Invasive Coronary Arteriography

MI: Myocardial Infarction

NPV: Negative Predictive Value

PCI: Percutaneous Coronary Intervention

VSD: Ventricular Septal Defect

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1457 for Fractional Flow Reserve CT
February 2024	<ul style="list-style-type: none"> ● Formatting change ● Addition of clinical reasoning statement with AUC scoring described ● AUC scores added to bullet points ● References updated
April 2023	<ul style="list-style-type: none"> ● Added statement on clinical indications not addressed in this guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Gulati M, Levy P, Mukherjee D, Amsterdam E, Bhatt D et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. Nov 30 2021; 78: e187-e285. 10.1016/j.jacc.2021.07.053.
2. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
3. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *J Am Coll Cardiol*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
4. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 1483-502. doi: 10.1161/CIR.0b013e31822935fc.
5. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User Manual. 2001;
6. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *J Am Coll Cardiol*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
7. Lawton J S, Tamis-Holland J E, Bangalore S, Bates E R, Beckie T M et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2022; 79: e21-e129. 10.1016/j.jacc.2021.09.006.
8. Mehta C R, Naeem A, Patel Y. Cardiac Computed Tomography Angiography in CAD Risk Stratification and Revascularization Planning. *Diagnostics (Basel)*. 2023; 13: 2902. 10.3390/diagnostics13182902.
9. Neumann F, Sousa-Uva M, Ahlsson A, Alfonso F, Banning A P et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. *Eur Heart J*. 2019; 40: 87-165. 10.1093/eurheartj/ehy394.
10. Winchester D E, Maron D J, Blankstein R, Chang I C, Kirtane A J et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *J Cardiovasc Magn Reson*. 2023; 25: 58. 10.1186/s12968-023-00958-5.
11. Chen J, Wetzell L H, Pope K L, Meek L J, Rosamond T. FFR(CT): Current Status. *AJR Am J Roentgenol*. 2021; 216: 640-648. 10.2214/AJR.20.23332.
12. Nørgaard B, Gaur S, Leipsic J, Ito H, Miyoshi T et al. Influence of Coronary Calcification on the Diagnostic Performance of CT Angiography Derived FFR in Coronary Artery Disease: A Substudy of the NXT Trial. *JACC Cardiovasc Imaging*. Sep 2015; 8: 1045-1055. 10.1016/j.jcmg.2015.06.003.
13. Gaur S, Taylor C, Jensen J, Bøtker H, Christiansen E et al. FFR Derived From Coronary CT Angiography in Nonculprit Lesions of Patients With Recent STEMI. *JACC Cardiovasc Imaging*. Apr 2017; 10: 424-433. 10.1016/j.jcmg.2016.05.019.
14. Douglas P, De Bruyne B, Pontone G, Patel M, Norgaard B et al. 1-Year Outcomes of FFRCT-Guided Care in Patients With Suspected Coronary Disease: The PLATFORM Study. *J Am Coll Cardiol*. 2016; 68: 435-445. 10.1016/j.jacc.2016.05.057.
15. Douglas P S, Pontone G, Hlatky M A, Patel M R, Norgaard B L et al. Clinical outcomes of fractional flow reserve by computed tomographic angiography-guided diagnostic strategies vs. usual

care in patients with suspected coronary artery disease: the prospective longitudinal trial of FFR(CT): outcome and resource impacts study. *Eur Heart J*. 2015; 36: 3359-67. 10.1093/eurheartj/ehv444..

16. Ball C, Pontone G, Rabbat M. Fractional Flow Reserve Derived from Coronary Computed Tomography Angiography Datasets: The Next Frontier in Noninvasive Assessment of Coronary Artery Disease. *Biomed Res Int*. 2018; 2018: 2680430. 10.1155/2018/2680430.

17. De Bruyne B, Fearon W, Pijls N, Barbato E, Tonino P et al. Fractional flow reserve-guided PCI for stable coronary artery disease. *N Engl J Med*. 2014; 371: 1208-17. 10.1056/NEJMoa1408758.

18. Xaplanteris P, Fournier S, Pijls N, Fearon W, Barbato E et al. Five-Year Outcomes with PCI Guided by Fractional Flow Reserve. *N Engl J Med*. 2018; 379: 250-259. 10.1056/NEJMoa1803538.

19. Zimmermann F M, Ferrara A, Johnson N P, van Nunen L X, Escaned J et al. Deferral vs. performance of percutaneous coronary intervention of functionally non-significant coronary stenosis: 15-year follow-up of the DEFER trial. *Eur Heart J*. 2015; 36: 3182-8. 10.1093/eurheartj/ehv452.

20. Zhang D, Lv S, Song X, Yuan F, Xu F et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention: a meta-analysis. *Heart*. 2015; 101: 455-62. 10.1136/heartjnl-2014-306578.

21. Terentes-Printzios D, Gkini K, Oikonomou D, Gardikioti V, Aznaouridis K et al. Prognostic Value of Post-PCI Angiography-Derived Fractional Flow Reserve: A Systematic Review and Meta-Analysis of Cohort Studies. *J Pers Med*. 2023; 13: 1251. 10.3390/jpm13081251.

22. Newby D, Williams M, Hunter A, Pawade T, Shah A et al. CT coronary angiography in patients with suspected angina due to coronary heart disease (SCOT-HEART): an open-label, parallel-group, multicentre trial. *Lancet*. 2015; 385: 2383-91. 10.1016/s0140-6736(15)60291-4.

23. Williams M, Hunter A, Shah A, Assi V, Lewis S et al. Use of Coronary Computed Tomographic Angiography to Guide Management of Patients With Coronary Disease. *J Am Coll Cardiol*. 2016; 67: 1759-1768. 10.1016/j.jacc.2016.02.026.

24. Barbosa M F, Canan A, Xi Y, Litt H, Diercks D B et al. Comparative Effectiveness of Coronary CT Angiography and Standard of Care for Evaluating Acute Chest Pain: A Living Systematic Review and Meta-Analysis. *Radiol Cardiothorac Imaging*. 2023; 5: e230022. 10.1148/ryct.230022.

25. Rajiah P, Cummings K W, Williamson E, Young P M. CT Fractional Flow Reserve: A Practical Guide to Application, Interpretation, and Problem Solving. 2. 2022; 42: 340-358. 10.1148/rg.210097.

26. Kumamaru K K, Angel E, Sommer K N, Iyer V, Wilson M F et al. Inter- and Intraoperator Variability in Measurement of On-Site CT-derived Fractional Flow Reserve Based on Structural and Fluid Analysis: A Comprehensive Analysis. *Radiology. Cardiothoracic imaging*. 2019; 1: e180012. 10.1148/ryct.2019180012.

27. Driessen R, Danad I, Stuijzand W, Raijmakers P, Schumacher S et al. Comparison of Coronary Computed Tomography Angiography, Fractional Flow Reserve, and Perfusion Imaging for Ischemia Diagnosis. *J Am Coll Cardiol*. 2019; 73: 161-173. 10.1016/j.jacc.2018.10.056.

28. Johnson N, Johnson D, Kirkeeide R, Berry C, De Bruyne B et al. Repeatability of Fractional Flow Reserve Despite Variations in Systemic and Coronary Hemodynamics. *JACC Cardiovasc Interv*. Jul 2015; 8: 1018-1027. 10.1016/j.jcin.2015.01.039.

29. Lu M, Ferencik M, Roberts R, Lee K, Ivanov A et al. Noninvasive FFR Derived From Coronary CT Angiography: Management and Outcomes in the PROMISE Trial. *JACC Cardiovasc Imaging*. Nov 2017; 10: 1350-1358. 10.1016/j.jcmg.2016.11.024.

30. Patel M, Nørgaard B, Fairbairn T, Nieman K, Akasaka T et al. 1-Year Impact on Medical Practice and Clinical Outcomes of FFR(CT): The ADVANCE Registry. *JACC Cardiovasc Imaging*. Jan 2020; 13: 97-105. 10.1016/j.jcmg.2019.03.003.

31. Patel M, Calhoun J, Dehmer G, Grantham J, Maddox T et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery,



American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. J Am Coll Cardiol. 2017; 69: 2212-2241. 10.1016/j.jacc.2017.02.001.

Evolut Clinical Guideline 7294-01 for Heart (Cardiac) PET

Guideline Number: Evolut_CG_7294-01	<u>Applicable Codes</u>	
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Original Date: July 1999	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Special Note

Indications for determining medical necessity for myocardial perfusion imaging (MPI) with appropriate preference for suitable alternatives, such as stress echocardiography (SE), when more suitable, unless otherwise stated (see **Definitions** section).

Indicated when all the criteria for MPI are met **AND** there is likely to be equivocal imaging results because of BMI, large breasts or implants, mastectomy, chest wall deformity, pleural or pericardial effusion, or prior thoracic surgery or results of a prior MPI. ^(1,2) **(AUC Score 7)** ⁽³⁾

See Legislative Language for specific mandates in **Washington**.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(4,5,6,7,8)

INDICATIONS FOR HEART PET ^(9,10,11)

Suspected CAD

When neither SE nor MPI have provided or are expected to provide optimal imaging

- **Symptomatic patients without known CAD** (use **Diamond Forrester Table** ^(41,42)) **(AUC Score 9)** ⁽³⁾
 - Low or intermediate pretest probability and unable to exercise
 - High pretest probability

- Repeat testing in a patient with new or worsening symptoms and negative result at least one year ago **AND** meets one of the criteria above
- **Asymptomatic patients without known CAD**
 - Previously unevaluated ECG evidence of possible myocardial ischemia including substantial ischemic ST segment or T wave abnormalities (see **Background** section)
 - Previously unevaluated pathologic Q waves (see **Background** section)
 - Unevaluated complete left bundle branch block (**AUC Score 8**)⁽³⁾

Abnormal Calcium Scores (CAC) (9,12,13,14,15)

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior MPI done within the last 12 months⁽¹⁶⁾
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior MPI done within the last 12 months⁽¹⁶⁾
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior MPI done within the last 12 months

Inconclusive CAD Evaluation and Obstructive CAD remain a Concern

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- Exercise stress ECG with low-risk Duke treadmill score (≥ 5) (see **Background** section) but patient's current symptoms indicate an intermediate or high pretest probability
- Exercise stress ECG with an intermediate Duke treadmill score (**AUC Score 8**)⁽³⁾
- Inconclusive/borderline coronary computed tomography angiography (CCTA) or SPECT nuclear stress testing (e.g., 40 - 70% lesions) (**AUC Score 9**)⁽³⁾
- Cardiac PET stress-rest perfusion and metabolic activity study (with ¹⁸F-FDG PET) is appropriate in patients with ischemic cardiomyopathy to determine myocardial viability prior to revascularization following an inconclusive SPECT^(9,17) (**AUC Score 9**)⁽³⁾
- Non-diagnostic exercise stress test with physical inability to achieve target heart rate (THR)
- An intermediate evaluation by prior stress imaging
- Coronary stenosis of unclear significance on previous coronary angiography⁽⁹⁾ (**AUC Score 8**)⁽³⁾

Follow-Up Of Patient's Post Coronary Revascularization (PCI or CABG)

When neither SE nor MPI have provided, or are expected to provide, optimal imaging⁽⁹⁾

- **Asymptomatic, follow-up stress imaging** at a minimum of 2 years post coronary

artery bypass grafting (CABG), or percutaneous coronary intervention (PCI), (whichever is later), is appropriate only for patients with:

- High risk: diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
- a history of silent ischemia or
- a history of a prior left main stent

OR

- For patients with high occupational risk (e.g., associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters)

New, recurrent, or worsening symptoms post coronary revascularization are an indication for stress imaging, if it will alter management

Follow-Up Of Known CAD ⁽⁹⁾

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- **Follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or $FFR \leq 0.80$ or significant stenosis in a major vessel ($\geq 50\%$ left main coronary artery or $\geq 70\%$ LAD, LCX or RCA)), over two years ago, without intervening coronary revascularization is an appropriate indication for stress imaging in patients if it will alter management

Special Diagnostic Conditions Requiring Coronary Evaluation

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- **Unevaluated ACS**
 - Prior acute coronary syndrome (as documented in MD notes), without subsequent invasive or non-invasive coronary evaluation within the last 12 months
 - Has ventricular wall motion abnormality demonstrated by another imaging modality and myocardial perfusion imaging is being performed to determine if the patient has myocardial ischemia. No imaging stress test within the last 12 months
- **Heart Failure**
 - Newly diagnosed systolic heart failure or diastolic heart failure, with *reasonable suspicion of cardiac ischemia (prior events, risk factors)*, unless invasive coronary angiography is immediately planned or adequate stress imaging has been done within the last 12 months ^(10,18,19) **(AUC Score 9)** ⁽³⁾
- **Viability**
 - Reduced LVEF $\leq 50\%$ requiring myocardial viability assessment to assist with decisions regarding coronary revascularization. (Diversion from PET not required when LVEF less than or equal to 40%) ^(18,19,20) **(AUC Score 9)** ⁽³⁾
- **Ischemia and Nonobstructive Coronary Artery Disease (INOCA)**

- To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA), as documented in provider notes (*no MPI diversion required*).
- **Arrhythmias**
 - Ventricular arrhythmias
 - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography is not the immediately planned test ⁽²¹⁾
 - Non-sustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVC's (defined as greater than or equal to 30/hour on remote monitoring) without known cause or associated cardiac pathology, when an exercise ECG cannot be performed
- **Anti-arrhythmic Drug Therapy**
 - Class IC antiarrhythmic drug
 - In the intermediate and high global risk patient prior to initiation of Class IC antiarrhythmic drug initiation (Propafenone or Flecainide)
 - Annually for intermediate and high global risk patients taking Class IC antiarrhythmic drug (Propafenone or Flecainide) ⁽²²⁾ **(AUC Score 7)** ⁽³⁾
- **Coronary Anomaly and Aneurism**
 - Assessment of hemodynamic significance of one of the following documented conditions: ⁽²³⁾
 - Anomalous coronary arteries ⁽²⁴⁾
 - Muscle bridging of coronary artery ^(9,25)
 - Coronary aneurysms in Kawasaki's disease ⁽²⁶⁾ or due to atherosclerosis
- **Radiation**
 - Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter ⁽²⁷⁾
- **Cardiac Sarcoidosis** ^(28,29,30)
 - May be approved as a combination study with MPI for the evaluation and treatment of sarcoidosis ⁽³¹⁾
 - Evaluation and therapy monitoring in patients with sarcoidosis, after documentation of suspected cardiac involvement by echo or ECG, when CMR has not been performed
 - Evaluation of suspected cardiac sarcoid, after CMR has shown equivocal or negative findings in the setting of a high clinical suspicion ⁽³⁰⁾
 - Evaluation of CMR findings showing highly probable cardiac sarcoidosis, when PET could serve to identify inflammation and the consequent potential role for immunosuppressive therapy ⁽³⁰⁾ **(AUC Score 9)** ⁽³⁾
 - Initial and follow-up PET in monitoring therapy for cardiac sarcoid with immunosuppressive therapy, typically about 4 times over 2 years

- **Infective Endocarditis**
 - In suspected infective endocarditis with moderate to high probability (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inconclusive with respect to diagnosis of infective endocarditis or characterization of paravalvular invasive complications ^(32,33)
- **Aortitis**
 - For diagnosis and surveillance of Aortitis, PET/CT or PET/MRI[‡] hybrid imaging ⁽³⁴⁾
 - **‡NOTE:** If PET/MR study is requested, there is no specific CPT Code for this imaging study and a Health Plan review will be required.

Prior To Elective Non-Cardiac Surgery

When neither SE nor MPI have provided or are expected to provide optimal imaging

- An intermediate or high-risk surgery with of one or more risk factors (see below), **AND** documentation of an inability to walk (or < 4 METs) **AND** there has not been an imaging stress test within 1 year ^(35,36,37)
 - **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine > 2.0 mg/dL.
 - **Surgical Risk:**
 - **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
 - **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
 - **Low risk surgery:** Endoscopic procedures, superficial procedure, cataract surgery, breast surgery
- Planning for any organ or stem cell transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service ⁽³⁸⁾

Post Cardiac Transplant

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography ⁽³⁹⁾

LEGISLATIVE LANGUAGE

Washington

20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease ⁽⁴⁰⁾

Number and coverage topic:

20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease

HTCC coverage determination:

Noninvasive cardiac imaging is a **covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage: The following noninvasive cardiac imaging technologies are **covered with conditions**:

- Stress echocardiography for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of Coronary Artery Disease (CAD), or
 - Adult patients with known CAD who have new or worsening symptoms.
- Single Positron Emission Tomography (SPECT) for:
 - Patients under the same conditions as stress echocardiography when stress echocardiography is not technically feasible or clinically appropriate.
- Positron Emission Tomography (PET) for:
 - Patients under the same conditions as SPECT, when SPECT is not technically feasible or clinically appropriate.
- Coronary Computed Tomographic Angiography (CCTA) for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of CAD, or
 - Adult patients with known CAD who have new or worsening symptoms.
- CCTA with Fractional Flow Reserve (FFR) for:
 - Patients under the same conditions as CCTA, when further investigation of functional significance of stenoses is clinically indicated.

Non-covered indicators:

N/A

Notes:

- Out of scope/data not reviewed for this decision:
 - Asymptomatic individuals, follow up of prior abnormal cardiac imaging studies, myocardial viability, preoperative evaluation
 - Patients presenting for evaluation of cardiac pathologies other than CAD
- This determination supersedes the following previous determinations:
 - Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease (20081114A)
 - Cardiac Nuclear Imaging (20130920A)

CODING AND STANDARDS

Coding

CPT Codes

+78434, 78459, 78472, 78491, 78492, 93015, 93016, 93017, 93018, A9555

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

General Overview (1,2)

A PET study is a diagnostic test used to evaluate blood flow to the heart. During the test, a small amount of radioactive tracer is injected into a vein. A special camera, called a gamma camera, detects the radiation released by the tracer to produce computer images of the heart. Combined with a medication, the test can help determine if there is adequate blood flow to the heart during activity versus at rest. The medication simulates exercise for patients unable to exercise on a treadmill or stationary cycle.

PET perfusion studies illustrate myocardial blood flow by demonstrating tracer uptake. PET metabolic evaluation studies are used to demonstrate inflammation produced by infiltrative disease such as sarcoidosis, but also enhance the detection of viable (hibernating) myocardium. Hybrid PET-CT scanning combines anatomical information with blood flow assessment and is useful for assessing viable myocardium, especially in CHF patients with global ischemia, or in patients with multivessel diffuse coronary artery disease as opposed to focal stenotic lesions.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. (4)

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Definitions

- Stable patients without known CAD fall into 2 categories ^(9,10,11):
 - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section).
 - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant CAD (below):
- The THREE Types of Chest Pain or Discomfort
 - **Typical Angina (Definite)** is defined as including all **3** characteristics:
 - Substernal chest pain or discomfort with characteristic quality and duration
 - Provoked by exertion or emotional stress
 - Relieved by rest and/or nitroglycerine
 - **Atypical Angina (Probable)** has only **2** of the above characteristics
 - **Nonanginal Chest Pain/Discomfort** has only **0 - 1** of the above characteristics
- The medical record should provide enough detail to establish the type of chest pain. From those details, the pretest probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability ^(9,10,11):

Diamond Forrester Table ^(41,42)

Age (Years)	Gender	Typical/ Definite Angina Pectoris	Atypical/ Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40-49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50-59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Very low: < 5% pretest probability of CAD, usually not requiring stress evaluation

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

High: > 90% pretest probability of CAD

- An uninterpretable baseline ECG includes ⁽¹⁰⁾:
 - ST segment depression 1 mm or more; (not for non-specific ST- T wave changes)
 - Ischemic looking T waves; at least 2.5 mm inversions (excluding V1 and V2)
 - Bundle Branch Blocks
 - LBBB
 - RBBB or IVCD, either containing ST or T wave abnormalities (see above)
 - LVH with repolarization abnormalities
 - Ventricular paced rhythm
 - Digitalis use with associated ST segment abnormalities
 - Resting HR under 50 bpm on a medication, such as beta-blockers or calcium channel blockers, that is required for patient's treatment and cannot be stopped, with an anticipated suboptimal workload
- Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
 - 40 ms (1 mm) wide
 - 2 mm deep
 - 25% of depth of QRS complex
- ECG Stress Test Alone versus Stress Testing with Imaging
 - Prominent scenarios suitable for an ECG stress test **WITHOUT** imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise ⁽⁹⁾:
 - The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG ⁽⁹⁾
 - The patient who is under evaluation for exercise-induced arrhythmia
 - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
 - For the evaluation of syncope or presyncope during exertion ⁽⁴³⁾
- Duke Exercise ECG Treadmill Score ⁽⁴⁴⁾
 - Calculates risk from ECG treadmill alone:
 - The equation for calculating the Duke treadmill score (DTS) is: $DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score})$, with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting
 - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of $\geq + 5$), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of $\leq - 11$) categories
- Coronary application of PET includes evaluation of stable patients without known CAD, who fall into two categories ^(9,10,11)

- **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section).
- **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant ($\geq 50\%$) CAD (below)
- An uninterpretable baseline ECG includes ⁽¹⁰⁾:
 - ST segment depression 1 mm or more (not for non-specific ST- T wave changes)
 - Ischemic-looking T waves; at least 2.5 mm inversions (excluding V1 and V2)
 - LVH with repolarization abnormalities, pre-excitation pattern such as WPW, ventricular paced rhythm, or left bundle branch block
 - Digitalis use with associated ST segment abnormalities
- Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
 - > 40 ms (1 mm) wide
 - > 2 mm deep
 - > 25% of depth of QRS complex
- Global Risk of Cardiovascular Disease
 - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. **High global risk by itself generally lacks scientific support as an indication for stress imaging.** There are rare exceptions, such as patients requiring IC antiarrhythmic drugs who might require coronary risk stratification prior to initiation of the drug.
 - **CAD Risk—Low**
 - 10-year absolute coronary or cardiovascular risk less than 10%
 - **CAD Risk—Moderate**
 - 10-year absolute coronary or cardiovascular risk between 10% and 20%
 - **CAD Risk—High**
 - 10-year absolute coronary or cardiovascular risk of greater than 20%

Websites for Global Cardiovascular Risk Calculators* (45,46,47,48,49)

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk

Risk Calculator	Websites for Online Calculator
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clinicalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

- Definitions of Coronary Artery Disease ^(10,11,14)
 - Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
 - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into global risk can be achieved by using the MESA risk calculator.
 - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; intermediate lesions are 50 – 69%
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ or minimum lumen cross-sectional area on IVUS ≤ 6 square mm ^(10,50)
 - FFR (fractional flow reserve) ≤ 0.80 for a major vessel ⁽⁵⁰⁾
 - Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
 - A major vessel would be a coronary vessel that would be amenable to revascularization if indicated. This assessment is made based on the

diameter of the vessel and/or the extent of myocardial territory served by the vessel.

- FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
- Newer technology that estimates FFR from CCTA image is covered under the Evolent Clinical Guideline 7293 for Fractional Flow Reserve CT.
- Anginal Equivalent ^(10,43)
 - Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data, such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Most syncope per se is not an anginal equivalent.

Acronyms/Abbreviations

ADLs: Activities of daily living

BMI: Body mass index

CABG: Coronary artery bypass grafting

CAC: Coronary artery calcium

CAD: Coronary artery disease

CCTA: Coronary computed tomography angiography

CMR: Cardiac magnetic resonance imaging

CT(A): Computed tomography (angiography)

DTS: Duke Treadmill Score

ECG: Electrocardiogram

FFR: Fractional flow reserve

IVUS: Intravascular ultrasound

LBBB: Left bundle-branch block

LVEF: Left ventricular ejection fraction

LVH: Left ventricular hypertrophy

MESA: Multi-Ethnic Study of Atherosclerosis

MET: Estimated metabolic equivalent of exercise

MI: Myocardial infarction

MPI: Myocardial perfusion imaging

MR(I): Magnetic resonance (imaging)

PCI: Percutaneous coronary intervention
 PET: Positron emission tomography
 PFT: Pulmonary function test
 PVCs: Premature ventricular contractions
 SE: Stress echocardiography
 TEE: Transesophageal echocardiography
 THR: Target heart rate
 TTE: Transthoracic echocardiography
 VF: Ventricular fibrillation
 VT: Ventricular tachycardia
 WPW: Wolff-Parkinson-White

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> Removed “SE diversion not required”
November 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1124 Positron Emission Tomography (PET) Myocardial Imaging

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bateman T, Dilsizian V, Beanlands R, DePuey E, Heller G. American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. *J Nucl Med.* Oct 2016; 57: 1654-1656. 10.2967/jnumed.116.180448.
2. Fazel R, Dilsizian V, Einstein A, Ficaro E, Henzlova M. Strategies for defining an optimal risk-benefit ratio for stress myocardial perfusion SPECT. *J Nucl Cardiol.* May 2011; 18: 385-92. 10.1007/s12350-011-9353-4.
3. Schindler T H, Bateman T M, Berman D S, Chareonthaitawee P, De Blanche L E et al. Appropriate Use Criteria for PET Myocardial Perfusion Imaging. *J Nucl Med.* 2020; 61: 1221-1265. 10.2967/jnumed.120.246280.
4. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *J Am Coll Cardiol.* 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
5. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *J Am Coll Cardiol.* 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
6. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation.* 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
7. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. 2001.
8. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *J Am Coll Cardiol.* 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
9. Winchester D E, Maron D J, Blankstein R, Chang I C, Kirtane A J et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *J Cardiovasc Magn Reson.* 2023; 25: 58. 10.1186/s12968-023-00958-5.
10. Fihn S, Gardin J, Abrams J, Berra K, Blankenship J et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation.* Dec 18, 2012; 126: e354-471. 10.1161/CIR.0b013e318277d6a0.
11. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J.* Oct 2013; 34: 2949-3003. 10.1093/eurheartj/eh296.
12. Budoff M, Raggi P, Beller G, Berman D, Druz R et al. Noninvasive Cardiovascular Risk Assessment of the Asymptomatic Diabetic Patient: The Imaging Council of the American College of Cardiology. *JACC Cardiovasc Imaging.* Feb 2016; 9: 176-92. 10.1016/j.jcmg.2015.11.011.
13. Gulati M, Levy P, Mukherjee D, Amsterdam E, Bhatt D et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* Nov 30, 2021; 78: e187-e285. 10.1016/j.jacc.2021.07.053.

14. Patel M, Calhoun J, Dehmer G, Grantham J, Maddox T et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. May 2, 2017; 69: 2212-2241. 10.1016/j.jacc.2017.02.001.
15. Guzmán A, Navarro E, Obando L, Pacheco J, Quirós K et al. Effectiveness of interventions for the reversal of a metabolic syndrome diagnosis: An update of a meta-analysis of mixed treatment comparison studies. *Biomedica*. 2019; 39: 647-662. 10.7705/biomedica.4684.
16. Brindis R G, Douglas P S, Hendel R C, Peterson E D, Wolk M J et al. ACCF/ASNC appropriateness criteria for single-photon emission computed tomography myocardial perfusion imaging (SPECT MPI): a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group and the American Society of Nuclear Cardiology endorsed by the American Heart Association. *J Am Coll Cardiol*. 2005; 46: 1587-605. 10.1016/j.jacc.2005.08.029.
17. Truong Q A, Gewirtz H. Cardiac PET-CT for monitoring medical and interventional therapy in patients with CAD: PET alone versus hybrid PET-CT? *Curr Cardiol Rep*. 2014; 16: 460. 10.1007/s11886-013-0460-5.
18. Patel M, White R, Abbara S, Bluemke D, Herfkens R et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR appropriate utilization of cardiovascular imaging in heart failure: a joint report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. May 28, 2013; 61: 2207-31. 10.1016/j.jacc.2013.02.005.
19. Yancy C, Jessup M, Bozkurt B, Butler J, Casey D J et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. Oct 15, 2013; 62: e147-239. 10.1016/j.jacc.2013.05.019.
20. Xu J, Cai F, Geng C, Wang Z, Tang X. Diagnostic Performance of CMR, SPECT, and PET Imaging for the Identification of Coronary Artery Disease: A Meta-Analysis. *Front Cardiovasc Med*. 2021; 8: 621389. 10.3389/fcvm.2021.621389.
21. Al-Khatib S, Stevenson W, Ackerman M, Bryant W, Callans D et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Oct 2, 2018; 72: e91-e220. 10.1016/j.jacc.2017.10.054.
22. Reiffel J, Camm A, Belardinelli L, Zeng D, Karwatowska-Prokopczuk E et al. The HARMONY Trial: Combined Ranolazine and Dronedarone in the Management of Paroxysmal Atrial Fibrillation: Mechanistic and Therapeutic Synergism. *Circ Arrhythm Electrophysiol*. Oct 2015; 8: 1048-56. 10.1161/circep.115.002856.
23. Anagnostopoulos C, Harbinson M, Kelion A, Kundley K, Loong C et al. Procedure guidelines for radionuclide myocardial perfusion imaging. *Heart (British Cardiac Society)*. 2004; 90 Suppl 1: i1-i10. 10.1136/heart.90.suppl_1.i1.
24. Gräni C, Bigler M R, Kwong R Y. Noninvasive Multimodality Imaging for the Assessment of Anomalous Coronary Artery. *Curr Cardiol Rep*. 2023; 25: 1233-1246. 10.1007/s11886-023-01948-w.
25. Evbayekha E O, Nwogwugwu E, Olawoye A, Bolaji K, Adeosun A A et al. A Comprehensive Review of Myocardial Bridging: Exploring Diagnostic and Treatment Modalities. *Cureus*. 2023; 15: e43132. 10.7759/cureus.43132.
26. McCrindle B, Rowley A, Newburger J, Burns J, Bolger A et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the

American Heart Association. *Circulation*. Apr 25, 2017; 135: e927-e999. 10.1161/cir.0000000000000484.

27. Lancellotti P, Nkomo V, Badano L, Bergler-Klein J, Bogaert J et al. Expert consensus for multi-modality imaging evaluation of cardiovascular complications of radiotherapy in adults: a report from the European Association of Cardiovascular Imaging and the American Society of Echocardiography. *Eur Heart J Cardiovasc Imaging*. Aug 2013; 14: 721-40. 10.1093/ehjci/jet123.

28. Birnie D, Nery P, Ha A, Beanlands R. Cardiac Sarcoidosis. *J Am Coll Cardiol*. Jul 26, 2016; 68: 411-21. 10.1016/j.jacc.2016.03.605.

29. Blankstein R, Waller A. Evaluation of Known or Suspected Cardiac Sarcoidosis. *Circ Cardiovasc Imaging*. Mar 2016; 9: e000867. 10.1161/circimaging.113.000867.

30. Vita T, Okada D, Veillet-Chowdhury M, Bravo P, Mullins E et al. Complementary Value of Cardiac Magnetic Resonance Imaging and Positron Emission Tomography/Computed Tomography in the Assessment of Cardiac Sarcoidosis. *Circ Cardiovasc Imaging*. Jan 2018; 11: e007030. 10.1161/circimaging.117.007030.

31. Tersalvi G, Beltrani V, Grüber M R, Molteni A, Cristoforetti Y et al. Positron Emission Tomography in Heart Failure: From Pathophysiology to Clinical Application. *J Cardiovasc Dev Dis*. 2023; 10: 220. 10.3390/jcdd10050220.

32. Habib G, Lancellotti P, Antunes M, Bongiorni M, Casalta J et al. 2015 ESC Guidelines for the management of infective endocarditis: The Task Force for the Management of Infective Endocarditis of the European Society of Cardiology (ESC). Endorsed by: European Association for Cardio-Thoracic Surgery (EACTS), the European Association of Nuclear Medicine (EANM). *Eur Heart J*. Nov 21, 2015; 36: 3075-3128. 10.1093/eurheartj/ehv319.

33. Doherty J, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. Sep 26, 2017; 70: 1647-1672. 10.1016/j.jacc.2017.07.732.

34. Isselbacher E, Preventza O, Hamilton Black J 3, Augoustides J, Beck A et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. Dec 13, 2022; 146: e334-e482. 10.1161/cir.0000000000001106.

35. Kristensen S, Knuuti J, Saraste A, Anker S, Bøtker H et al. 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management: The Joint Task Force on non-cardiac surgery: cardiovascular assessment and management of the European Society of Cardiology (ESC) and the European Society of Anaesthesiology (ESA). *Eur Heart J*. Sep 14, 2014; 35: 2383-431. 10.1093/eurheartj/ehu282.

36. Fleisher L, Fleischmann K, Auerbach A, Barnason S, Beckman J et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *J Am Coll Cardiol*. Dec 09, 2014; 64: e77-137. 10.1016/j.jacc.2014.07.944.

37. Velasco A, Reyes E, Hage F. Guidelines in review: Comparison of the 2014 ACC/AHA guidelines on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery and the 2014 ESC/ESA guidelines on noncardiac surgery: Cardiovascular assessment and management. *J Nucl Cardiol*. 02 2017; 24: 165-170. 10.1007/s12350-016-0643-8.

38. Lentine K, Costa S, Weir M, Robb J, Fleisher L et al. Cardiac disease evaluation and management among kidney and liver transplantation candidates: a scientific statement from the American Heart Association and the American College of Cardiology Foundation. *J Am Coll Cardiol*. Jul 31, 2012; 60: 434-80. 10.1016/j.jacc.2012.05.008.

39. Mc Ardle B, Dowsley T, deKemp R, Wells G, Beanlands R. Does rubidium-82 PET have superior accuracy to SPECT perfusion imaging for the diagnosis of obstructive coronary disease? A systematic review and meta-analysis. *J Am Coll Cardiol.* Oct 30, 2012; 60: 1828-37. 10.1016/j.jacc.2012.07.038.
40. Washington State Health Care Authority. WSHCA Health Technology Clinical Committee: 20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease. [Final Adoption: March 18, 2022].
41. Wolk M J, Bailey S R, Doherty J U, Douglas P S, Hendel R C et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2014; 63: 380-406. 10.1016/j.jacc.2013.11.009.
42. Diamond G A, Forrester J S. Analysis of probability as an aid in the clinical diagnosis of coronary-artery disease. *N Engl J Med.* 1979; 300: 1350-8. 10.1056/NEJM197906143002402.
43. Shen W, Sheldon R, Benditt D, Cohen M, Forman D et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol.* Aug 1, 2017; 70: 620-663. 10.1016/j.jacc.2017.03.002.
44. Shaw L J, Peterson E D, Shaw L K, Kesler K L, DeLong E R et al. Use of a prognostic treadmill score in identifying diagnostic coronary disease subgroups. *Circulation.* 1998; 98: 1622-30. 10.1161/01.cir.98.16.1622.
45. Arnett D, Blumenthal R, Albert M, Buroker A, Goldberger Z et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* Sep 10, 2019; 74: e177-e232. 10.1016/j.jacc.2019.03.010.
46. D'Agostino R S, Vasan R, Pencina M, Wolf P, Cobain M et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation.* Feb 12, 2008; 117: 743-53. 10.1161/circulationaha.107.699579.
47. Goff D J, Lloyd-Jones D, Bennett G, Coady S, D'Agostino R S et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* Jul 1, 2014; 63: 2935-2959. 10.1016/j.jacc.2013.11.005.
48. McClelland R, Jorgensen N, Budoff M, Blaha M, Post W et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *J Am Coll Cardiol.* Oct 13, 2015; 66: 1643-53. 10.1016/j.jacc.2015.08.035.
49. Ridker P, Buring J, Rifai N, Cook N. Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *Jama.* Feb 14, 2007; 297: 611-9. 10.1001/jama.297.6.611.
50. Lotfi A, Davies J, Fearon W, Grines C, Kern M. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society of cardiac angiography and interventions. *Catheter Cardiovasc Interv.* Aug 1, 2018; 92: 336-347. 10.1002/ccd.27672.



Evolut Clinical Guideline 7295-01 for Heart Catheterization

Guideline Number: Evolut_CG_7295-01	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Heart catheterization is an invasive angiographic procedure used to evaluate the presence and extent of coronary artery disease (CAD).

In addition to angiography, it can also include ventriculography, aortography, acquisition of hemodynamic data, measurement of cardiac output, detection and quantification of shunts and flows, intravascular ultrasound (IVUS), and fractional flow reserve (FFR)/instantaneous wave free ratio (iFR) for determination of a lesion's hemodynamic severity. CAD stenosis $\geq 70\%$ ($\geq 50\%$ in the left main coronary artery) is considered clinically significant or obstructive CAD. ^(1,2,3,4)

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(5,6,7,8,9)

INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY ^(1,10,11,12)

General

- Typical angina with new onset or evolving ischemic EKG changes
- Prinzmetal's or variant angina (pain experienced at rest with ST elevation) on GDMT
- New onset or worsening of the patient's previously known anginal symptoms in a patient with a history of CABG or PCI (**AUC Score 7**) ⁽⁴⁾

- Symptomatic patients with a high pretest probability (**AUC Score 7**)⁽⁴⁾
- Unheralded syncope (not near syncope), where the etiology is unclear
- Patient with CAD and symptoms of angina with intermediate or high-risk findings on non-invasive imaging stress test including stress induced LV dysfunction.

Stable Ischemic Heart Disease

- Exercise electrocardiogram (ECG) stress test with high-risk findings, such as Duke Score ≤ -11 , ST segment elevation, hypotension, exercise-induced ventricular tachycardia (VT), or greater than 1.0 mm persistent ST depression in multiple leads into recovery for 5 minutes or greater⁽¹¹⁾
- Ischemia at low threshold on stress-testing with or without an abnormal decrease in normal systolic blood pressure response during exercise.
- Stress imaging with high-risk findings (see **Definitions**)
- Stress imaging with intermediate risk findings (see **Background** section) in a patient with one of the following:
 - Symptoms consistent with ischemia unresponsive to guideline directed medical therapy (GDMT)⁽¹¹⁾
 - Unsatisfactory quality of life due to angina; interfering with the patient's occupation or the ability to perform usual activities⁽¹⁾
 - Ejection fraction (EF) $< 50\%$ ⁽¹⁾
- Non-invasive test with low-risk findings with new, worsening, or limiting symptoms with reasonable suspicion of cardiac origin despite optimal medical therapy (GDMT) or inability to tolerate GDMT^(1,10,11)
- New, worsening, or limiting symptoms, with known unrevascularized obstructive coronary artery disease (CAD), in a patient eligible for revascularization^(1,10)
- Post STEMI with "culprit only" revascularization and plan for further PCI of non-culprit lesion⁽¹³⁾
- Before high-risk non-cardiac surgery in patients who have evidence of ischemia by non-invasive testing.
- Discordant, equivocal, or inconclusive non-invasive evaluation in patients with suspected symptomatic stable ischemic heart disease, including the following^(3,4,11):
 - Low risk stress imaging with high-risk stress ECG response or stress induced typical angina⁽¹¹⁾
 - Equivocal, uninterpretable, or inconclusive stress imaging due to issues of attenuation or other problems with interpretability^(1,11)

CCTA Abnormalities

- Symptomatic patient with one of the following:^(1,11,12)
 - One vessel with $\geq 50\%$ stenosis (**AUC Score 7**)⁽⁴⁾
 - A stenosis of 40-90% and FFR-CT ≤ 0.8 ⁽¹⁴⁾ (**AUC Score 8**)⁽⁴⁾
 - $\geq 50\%$ left main stenosis, **even if asymptomatic**

Heart Failure with Left Ventricular Dysfunction

- New heart failure, cardiomyopathy, or wall motion abnormality in patients who are candidates for coronary revascularization; including one of the following ^(1,11,15,16) (**AUC Score 8**) ⁽⁴⁾:
 - Newly recognized heart failure in patients with known or suspected CAD
 - Symptomatic heart failure or ischemia with new, unexplained wall motion abnormality ^(1,11)
 - Structural abnormality (severe mitral regurgitation or ventricular septal defect) with reason to suspect ischemic origin
 - Deterioration in clinical status of heart failure or cardiomyopathy requiring invasive evaluation for guidance or alteration in therapy
 - Clarification of the diagnosis of myocarditis versus acute coronary syndrome ⁽¹⁷⁾

Ventricular Arrhythmias

- Ventricular arrhythmias, without identified non-cardiac cause:
 - Following recovery from unexplained sudden cardiac arrest ⁽¹⁸⁾
 - Sustained VT or VF (**AUC Score 7**) ^(4,11)
 - Exercise-induced VT (**AUC Score 7**) ^(4,11)

Prior to Non-Coronary Intervention and Cardiac Surgery

- Evaluation of coronary anatomy, with consideration of coronary revascularization, prior to cardiac surgery in patients with any of the following ^(19,20,21,22):
 - Symptoms of angina
 - Stress imaging with evidence of ischemia
 - Decreased LV systolic function (EF < 50%)
 - History of CAD
 - Coronary risk factors, including men > 40 and postmenopausal women
 - Non-invasive data that is inconclusive
 - Severe valve disease
 - Requirement for detailed assessment of coronary artery anatomy prior to aortic valve homograft surgery, pulmonary autograft (Ross procedure), or aortic root procedure
 - Patients undergoing transcatheter aortic valve replacement (TAVR) or other transcatheter valve procedures
 - Can be done pre-organ transplant when required by transplant center protocol in place of, but not in addition to an imaging study

Hypertrophic Cardiomyopathy

- Patients with HCM, who are candidates for SRT, and for whom there is uncertainty of LVOT obstruction on noninvasive imaging studies, invasive hemodynamic

assessment with cardiac catheterization is recommended ⁽²³⁾

- In patients with symptoms or evidence of myocardial ischemia (CCTA also allowed)
- Prior to surgical myectomy in HCM patients who are at risk for coronary atherosclerosis (CCTA also allowed)

Post Cardiac Transplantation

- Assessment for allograft vasculopathy annually ⁽²⁴⁾

Hemodynamic Assessment

- Indications for angiographic and/or hemodynamic assessment of valvular function or shunt physiology ^(11,19,25)
 - Assessment of bioprosthetic valve when transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) were inadequate, and cardiac magnetic resonance (CMR) or cardiac computed tomography (CCT) are not available
 - Assessment of mechanical valve prostheses when TTE and TEE are inadequate and CCTA is not available
 - Discordance between non-invasive data and clinical impression of severity of valvular disease
 - Evaluation of indeterminate shunt anatomy or shunt flows/ratio
- Indications for hemodynamic assessment only ^(11,25)
 - Assessment of constrictive and restrictive physiology
 - Assessment of pulmonary hypertension when non-invasive data provides inadequate information for management, or to evaluate response to intravenous drug therapy
 - Assessment of hemodynamics in heart failure, cardiomyopathy, or adult congenital heart disease, when
 - Non-invasive data is discordant or conflicts with the clinical presentation
 - Non-invasive data is inadequate for clinical management

INDICATIONS FOR ASCENDING AORTOGRAPHY (19,21,22)

- Evaluation of aortic root dilatation in patients with severe aortic stenosis and regurgitation prior to valve surgery
- Evaluation of aortic root, ascending aortic aneurysm prior to repair
- Evaluation central shunts, coarctation and great vessels
- Bypass graft identification at the time of left heart catheterization
- Disease affecting the aorta and coronary arteritis in which coronary artery involvement is suspected.

CODING AND STANDARDS

Coding

CPT Codes

93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, +93462, +93463, +93464, 93531, 93532, 93533, 93563, 93564, +93565, +93566, +93567, +93568, 93573, 93574, 93595, 93596, 93597, 93598

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Heart catheterization is the passage of a thin flexible tube (catheter) into the left or right heart systems via arteries or veins, respectively, for the purposes of hemodynamic measurements, acquisition of blood samples from specific locations, and/or the injection of radiopaque medium for the purposes of visualizing vascular anatomy. Coronary angiography is the passage of a catheter into the left side of the heart to diagnose or treat blockages of coronary arteries.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁵⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Definitions

- Stable Patients without Known CAD fall into 2 categories ^(1,3,4):
 - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Global Cardiovascular Risk Calculators section)
 - **Symptomatic**, for whom the pretest probability that chest-related symptoms are

due to clinically significant CAD is estimated

- The Three Types of Chest Pain or Discomfort and Pretest Probability of CAD
 - **Typical Angina (Definite)** is defined as including all 3 characteristics:
 - Substernal chest pain or discomfort with characteristic quality and duration
 - Provoked by exertion or emotional stress
 - Relieved by rest and/or nitroglycerine
 - **Atypical Angina (Probable)** has only 2 of the above characteristics
 - **Non-anginal Chest Pain/Discomfort** has only 0 - 1 of the above characteristics
- The medical record should provide enough detail to establish the type of chest pain. From those details, the pretest probability of obstructive CAD is estimated from the Diamond Forrester Table below, recognizing that in some cases multiple additional coronary risk factors could increase pretest probability. ^(1,4)

Diamond Forrester Table ^(26,27)

Age (Years)	Gender	Typical/ Definite Angina Pectoris	Atypical/ Probable Angina Pectoris	Non-anginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

High: > 90% pretest probability of CAD

- Coronary Risk Categories Derived from Non-invasive Testing ^(1,12)
 - **High risk (> 3% annual death or MI)**
 - Severe resting left ventricular (LV) dysfunction (LVEF < 35%) not readily explained by non-coronary causes
 - Resting perfusion abnormalities ≥ 10% of the myocardium in patients without prior history or evidence of myocardial infarction (MI)
 - Stress ECG findings including ≥ 2 mm of ST-segment depression at low workload or persisting into recovery, exercise-induced ST-segment elevation,

- or exercise-induced ventricular tachycardia (VT)/ventricular fibrillation (VF)
 - Severe stress-induced left ventricular (LV) dysfunction (peak exercise EF < 45% or drop in EF with stress \geq 10%)
 - Stress-induced perfusion abnormalities involving \geq 10% myocardium or stress segmental scores indicating multiple abnormal vascular territories
 - Stress-induced LV dilation. Transient ischemic dilation (TID) is the ratio of left ventricular area immediately post-exercise divided by the area of the 4-hour redistribution image, with an abnormal ratio defined as > 1.12 ⁽²⁸⁾
 - Inducible wall motion abnormality (involving \geq 2 segments or \geq 2 vascular territories)
 - Wall motion abnormality developing at low dose of dobutamine (\leq 10 mg/kg/min) or at a low heart rate ($<$ 120 beats/min)
 - Multivessel obstructive CAD (\geq 70% stenosis) or left main stenosis (\geq 50% stenosis) on CCTA
- **Intermediate risk (1% to 3% annual death or MI)**
 - Mild or moderate resting LV dysfunction (EF 35% to 49%) not readily explained by non-coronary causes
 - Resting perfusion abnormalities in 5% to 9.9% of the myocardium in patients without a history or prior evidence of MI
 - \geq 1 mm of ST-segment depression occurring with exertional symptoms
 - Stress-induced perfusion abnormalities involving 5% to 9.9% of the myocardium or stress segmental scores (in multiple segments) indicating 1 vascular territory with abnormalities but without LV dilation
 - Inducible wall motion abnormality involving 1 segment or 1 vascular territory
 - CAC score 100 to 399 Agatston units (only for use in primary prevention, not for heart catheterization decision making) ^(1,3,11,29)
 - One vessel CAD with \geq 70% stenosis or moderate CAD stenosis (50% to 69% stenosis) in \geq 2 arteries on CCTA
- **Low risk (< 1% annual death or MI)**
 - Low-risk treadmill score (score \geq 5) or no new ST segment changes or exercise-induced chest pain symptoms, when achieving maximal levels of exercise
 - Normal or small myocardial perfusion defect at rest or with stress involving $<$ 5% of the myocardium
 - Normal stress or no change of baseline wall motion abnormalities during stress
 - CAC score $<$ 100 Agatston units (only for use in primary prevention, not for heart catheterization decision making) ^(1,3,11,29)
 - No coronary stenosis $>$ 50% on CCTA
- Global Risk of Cardiovascular Disease
 - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without

known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years.

- **CAD Risk—Low**
 - 10-year absolute coronary or cardiovascular risk less than 10%
- **CAD Risk—Moderate**
 - 10-year absolute coronary or cardiovascular risk between 10% and 20%
- **CAD Risk—High**
 - 10-year absolute coronary or cardiovascular risk of greater than 20%
- **NOTE:** High global risk by itself generally lacks scientific support as an indication for stress imaging. ⁽³⁰⁾ There are rare exemptions, such as patients requiring I-C antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug, when global risk is moderate or high.

Websites for Global Cardiovascular Risk Calculators* (29,31,32,33,34)

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clinicalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/

Risk Calculator	Websites for Online Calculator
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

- Definitions of Coronary Artery Disease ^(1,3,12,35)
 - Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
 - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a risk stratification tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.
 - Ischemia-producing disease (also called hemodynamically or functionally significant disease, or obstructive coronary disease for which revascularization might be appropriate) implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; intermediate lesions are 50 – 69% ⁽¹¹⁾
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ or minimum luminal cross-sectional area on IVUS ≤ 6 square mm ^(1,2,35)
 - FFR (fractional flow reserve) ≤ 0.80 for a major vessel ^(2,35)
 - iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel ^(2,36,37,38)
 - A major vessel would be a coronary vessel that would be amenable to revascularization, if indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
 - FFR is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
 - Instantaneous wave-free ratio (iFR) measures the ratio of distal coronary to aortic pressure during the wave free period of diastole, with a value ≤ 0.89 considered hemodynamically significant. ^(36,37,38)
- Anginal Equivalent ^(1,39,40)
 - Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry,

lung exam, etc. (as well as D-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

- Optimal Medical Therapy (OMT)
 - In general, a trial of OMT includes
 - Anti-platelet therapy
 - Lipid-lowering therapy
 - Beta blocker
 - Angiotensin converting enzyme (ACE) inhibitor

Acronyms/Abbreviations

CABG: Coronary artery bypass grafting surgery

CAC: Coronary artery calcium

CAD: Coronary artery disease

CCT: Cardiac computed tomography

CCTA: Coronary computed tomographic angiography

CMR: Cardiac magnetic resonance

CT(A): Computed tomography (angiography)

ECG: Electrocardiogram

EF: Ejection fraction

FFR: Fractional flow reserve

FFR-CT: Fractional flow reserve – computed tomography

HCM: Hypertrophic cardiomyopathy

iFR: Instantaneous wave-free ratio

IVUS: Intravascular ultrasound

LV: Left ventricular

LVEF: Left ventricular ejection fraction

LVOT: Left ventricular outflow tract

MESA: Multi-Ethnic Study of Atherosclerosis

MI: Myocardial infarction

MR: Mitral regurgitation

OMT: Optimal medical therapy

PCI: Percutaneous coronary intervention

PFT: Pulmonary function test

SRT: Septal reduction therapy

TAVR: Transcatheter aortic valve replacement

TID: Transient ischemic dilation

TTE: Transthoracic echocardiography
 TEE: Transesophageal echocardiography
 VT: Ventricular tachycardia
 VF: Ventricular fibrillation

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1127 Diagnostic Heart Catheterization ● Removed erroneous CPT code 93547

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Fihn S, Gardin J, Abrams J, Berra K, Blankenship J et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation*. Dec 18, 2012; 126: e354-471. 10.1161/CIR.0b013e318277d6a0.
2. Lotfi A, Davies J, Fearon W, Grines C, Kern M. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society of cardiac angiography and interventions. *Catheter Cardiovasc Interv*. Aug 1, 2018; 92: 336-347. 10.1002/ccd.27672.
3. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J*. Oct 2013; 34: 2949-3003. 10.1093/eurheartj/eh296.
4. Winchester D E, Maron D J, Blankstein R, Chang I C, Kirtane A J et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *J Cardiovasc Magn Reson*. 2023; 25: 58. 10.1186/s12968-023-00958-5.
5. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
6. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *J Am Coll Cardiol*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
7. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
8. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
9. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User Manual. 2001.
10. Fihn S, Blankenship J, Alexander K, Bittl J, Byrne J et al. 2014 ACC/AHA/AATS/PCNA/SCAI/STS focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, and the American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. Nov 4, 2014; 64: 1929-49. 10.1016/j.jacc.2014.07.017.

11. Patel M, Bailey S, Bonow R, Chambers C, Chan P et al. ACCF/SCAI/AATS/AHA/ASE/ASNC/HFSA/HRS/SCCM/SCCT/SCMR/STS 2012 appropriate use criteria for diagnostic catheterization: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society of Critical Care Medicine, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. May 29, 2012; 59: 1995-2027. 10.1016/j.jacc.2012.03.003.
12. Patel M, Calhoun J, Dehmer G, Grantham J, Maddox T et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. May 2, 2017; 69: 2212-2241. 10.1016/j.jacc.2017.02.001.
13. Mehta C R, Naeem A, Patel Y. Cardiac Computed Tomography Angiography in CAD Risk Stratification and. *Diagnostics (Basel, Switzerland)*. 2023; 13:
14. Gulati M, Levy P, Mukherjee D, Amsterdam E, Bhatt D et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. Nov 30, 2021; 78: e187-e285. 10.1016/j.jacc.2021.07.053.
15. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. May 3, 2022; 145: e876-e894. 10.1161/cir.0000000000001062.
16. Patel M, White R, Abbara S, Bluemke D, Herfkens R et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR appropriate utilization of cardiovascular imaging in heart failure: a joint report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. May 28, 2013; 61: 2207-31. 10.1016/j.jacc.2013.02.005.
17. Lasica R, Djukanovic L, Savic L, Krljanac G, Zdravkovic M et al. Update on Myocarditis: From Etiology and Clinical Picture to Modern Diagnostics and Methods of Treatment. *Diagnostics (Basel, Switzerland)*. 2023; 13:
18. Al-Khatib S, Stevenson W, Ackerman M, Bryant W, Callans D et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Oct 2, 2018; 72: e91-e220. 10.1016/j.jacc.2017.10.054.
19. Doherty J, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. Sep 26, 2017; 70: 1647-1672. 10.1016/j.jacc.2017.07.732.
20. Ramee S, Anwaruddin S, Kumar G, Piana R, Babaliaros V et al. The Rationale for Performance of Coronary Angiography and Stenting Before Transcatheter Aortic Valve Replacement: From the Interventional Section Leadership Council of the American College of Cardiology. *JACC Cardiovasc Interv*. Dec 12, 2016; 9: 2371-2375. 10.1016/j.jcin.2016.09.024.

21. Svensson L, Adams D, Bonow R, Kouchoukos N, Miller D et al. Aortic valve and ascending aorta guidelines for management and quality measures. *Ann Thorac Surg.* Jun 2013; 95: S1-66. 10.1016/j.athoracsur.2013.01.083.
22. Otto C M, Nishimura R A, Bonow R O, Carabello B A, Erwin J P 3 et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2021; 143: e72-e227.
23. Ommen S, Mital S, Burke M, Day S, Deswal A et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* Dec 22, 2020; 76: 3022-3055. 10.1016/j.jacc.2020.08.044.
24. Costanzo M, Dipchand A, Starling R, Anderson A, Chan M et al. The International Society of Heart and Lung Transplantation Guidelines for the care of heart transplant recipients. *J Heart Lung Transplant.* Aug 2010; 29: 914-56. 10.1016/j.healun.2010.05.034.
25. Stout K, Daniels C, Aboulhosn J, Bozkurt B, Broberg C et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* Apr 2, 2019; 73: e81-e192. 10.1016/j.jacc.2018.08.1029.
26. Diamond G A, Forrester J S. Analysis of probability as an aid in the clinical diagnosis of coronary-artery disease. *N Engl J Med.* 1979; 300: 1350-8. 10.1056/NEJM197906143002402.
27. Wolk M J, Bailey S R, Doherty J U, Douglas P S, Hendel R C et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2014; 63: 380-406. 10.1016/j.jacc.2013.11.009.
28. Weiss A, Berman D, Lew A, Nielsen J, Potkin B et al. Transient ischemic dilation of the left ventricle on stress thallium-201 scintigraphy: a marker of severe and extensive coronary artery disease. *J Am Coll Cardiol.* Apr 1987; 9: 752-9. 10.1016/s0735-1097(87)80228-0.
29. Goff D J, Lloyd-Jones D, Bennett G, Coady S, D'Agostino R S et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* Jul 1, 2014; 63: 2935-2959. 10.1016/j.jacc.2013.11.005.
30. Douglas P, De Bruyne B, Pontone G, Patel M, Norgaard B et al. 1-Year Outcomes of FFRCT-Guided Care in Patients With Suspected Coronary Disease: The PLATFORM Study. *J Am Coll Cardiol.* Aug 2, 2016; 68: 435-445. 10.1016/j.jacc.2016.05.057.
31. Ridker P, Buring J, Rifai N, Cook N. Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *Jama.* Feb 14, 2007; 297: 611-9. 10.1001/jama.297.6.611.
32. McClelland R, Jorgensen N, Budoff M, Blaha M, Post W et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *J Am Coll Cardiol.* Oct 13, 2015; 66: 1643-53. 10.1016/j.jacc.2015.08.035.
33. D'Agostino R S, Vasan R, Pencina M, Wolf P, Cobain M et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation.* Feb 12, 2008; 117: 743-53. 10.1161/circulationaha.107.699579.

34. Arnett D, Blumenthal R, Albert M, Buroker A, Goldberger Z et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. Sep 10, 2019; 74: e177-e232. 10.1016/j.jacc.2019.03.010.
35. Shlofmitz E, Ali Z A, Maehara A, Mintz G S, Shlofmitz R. Intravascular Imaging-Guided Percutaneous Coronary Intervention: A Universal. *Circ Cardiovasc Interv*. 2020; 13: e008686. 10.1161/CIRCINTERVENTIONS.120.008686.
36. Götberg M, Christiansen E, Gudmundsdottir I, Sandhall L, Danielewicz M et al. Instantaneous Wave-free Ratio versus Fractional Flow Reserve to Guide PCI. *N Engl J Med*. May 11, 2017; 376: 1813-1823. 10.1056/NEJMoa1616540.
37. Verdoia M, Rognoni A. Coronary Physiology: Modern Concepts for the Guidance of Percutaneous Coronary Interventions and Medical Therapy. *J Clin Med*. 2023; 12: 2274. 10.3390/jcm12062274.
38. Davies J, Sen S, Dehbi H, Al-Lamee R, Petraco R et al. Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI. *N Engl J Med*. May 11, 2017; 376: 1824-1834. 10.1056/NEJMoa1700445.
39. Shen W, Sheldon R, Benditt D, Cohen M, Forman D et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Aug 1, 2017; 70: 620-663. 10.1016/j.jacc.2017.03.002.
40. Brignole M, Moya A, de Lange F J, Deharo J, Elliott P M et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J*. 2018; 39: 1883-1948. 10.1093/eurheartj/ehy037.



Evolut Clinical Guideline 7296-01 for Heart CT

Guideline Number: Evolut_CG_7296-01	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for non-contrast cardiac computed tomography.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR HEART CT

Congenital Heart Disease (6,7)

For all indications below, either CT or CMR can be performed:

- All congenital lesions: prior to planned repair and for change in clinical status and/or new concerning signs or symptoms

Patent Ductus Arteriosus

- Routine surveillance (1-2 years) in a patient with postprocedural aortic obstruction (AUC 7)

Aortic Dilation

- Routine surveillance (6-12 months) in a child with aortic sinus and/or ascending aortic dilation with increasing size (AUC 7)

Aortic Coarctation and Interrupted Aortic Arch

- Routine surveillance (3–5 years) in a child or adult with mild aortic coarctation (**AUC 7**)
- Post procedure (surgical or catheter-based) routine surveillance (3–5 years) in an asymptomatic patient to evaluate for aortic arch aneurysms, in-stent stenosis, stent fracture, or endoleak (**AUC 8**)

Tetralogy of Fallot

- Post procedure routine surveillance (2–3 years) in a patient with valvular or ventricular dysfunction, right ventricular outflow tract obstruction, branch pulmonary artery stenosis, arrhythmias, or presence of an RV-to-PA conduit (**AUC 7**)

D-Loop Transposition of the Great Arteries

- Post procedure routine surveillance (3–5 years) in an asymptomatic patient (**AUC 7**)
- Post procedure routine surveillance (1–2 years) in a patient with dilated aortic root with increasing size, or aortic regurgitation (**AUC 7**)
- Post procedure routine surveillance (3–12 months) in a patient with \geq moderate systemic AV valve regurgitation, systemic RV dysfunction, LVOT obstruction, or arrhythmias (**AUC 7**)

Congenitally Corrected Transposition of the Great Arteries

- Unrepaired: routine surveillance (3–5 years) in an asymptomatic patient (**AUC 7**)
- Postoperative: routine surveillance (3–5 years) in an asymptomatic patient (**AUC 7**)
- Postoperative anatomic repair: routine surveillance (6–12 months) in a patient with valvular or ventricular dysfunction, right or left ventricular outflow tract obstruction, or presence of an RV-to-PA conduit (**AUC 7**)
- Postoperative physiological repair with VSD closure and/or LV-to-PA conduit: routine surveillance (3–12 months) in a patient with \geq moderate systemic AV valve regurgitation, systemic RV dysfunction, and/or LV-to-PA conduit dysfunction (**AUC 7**)

Truncus Arteriosus

- Routine surveillance (1–2 years) in an asymptomatic child or adult with \geq moderate truncal stenosis and/or regurgitation (**AUC 7**)
- Single-Ventricle Heart Disease (includes hypoplastic left heart syndrome, double-inlet LV, double-inlet RV, mitral atresia, tricuspid atresia, unbalanced A-V septal defect): postoperative routine surveillance (3–5 years) in an asymptomatic patient (**AUC 7**)

Cardiomyopathy ⁽⁸⁾

- Quantification of myocardial (muscle) mass (CMR or CT) ^(9,10,11)
- Assessment of left ventricular systolic dysfunction when prior noninvasive imaging has been inadequate (**AUC 7**)
- Assessment of right ventricular morphology in suspected arrhythmogenic right

ventricular cardiomyopathy (**AUC 7**), ⁽¹²⁾ based upon other findings such as ⁽⁹⁾:

- Nonsustained VT
- Unexplained syncope
- ECG abnormalities ⁽¹¹⁾
- First-degree relative with positive genotype of ARVC (either, but CMR is superior to CT) ^(9,11)

Valvular Heart Disease ^(13,14)

- Characterization of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE, TEE, and/or fluoroscopy have been inadequate (**AUC 7**)
- Evaluation of RV systolic function in severe TR, including systolic and diastolic volumes, when TTE images are inadequate and CMR is not readily available
- Pulmonary hypertension in the absence of severe valvular disease ⁽¹⁵⁾
- Evaluation of suspected infective endocarditis with moderate to high pretest probability (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inadequate
- Evaluation of suspected paravalvular infections when the anatomy cannot be clearly delineated by TTE and TEE

Evaluation of Intra- and Extra-cardiac Structures ⁽⁸⁾

- Evaluation of cardiac mass, suspected tumor or thrombus, or cardiac source of emboli, when imaging with TTE and TEE have been inadequate (**AUC 7**)
- Re-evaluation of prior findings for interval change (i.e., reduction or resolution of atrial thrombus after anticoagulation (**AUC 8**), when a change in therapy is anticipated (**AUC 7**) ^(8,16)
- Evaluation of pericardial anatomy (**AUC 8**), when TTE and/or TEE are inadequate or for better tissue characterization of a mass and detection of metastasis [CMR superior for physiologic assessment (constrictive versus restrictive) and tissue characterization, CT superior for calcium assessment] ^(9,17,18)

Electrophysiologic Procedure Planning ^(9,12)

- Evaluation of pulmonary venous anatomy prior to radiofrequency ablation of atrial fibrillation and for follow-up when needed for evaluation of pulmonary vein stenosis (**AUC 8**)
- Non-invasive coronary vein mapping prior to placement of biventricular pacing leads (**AUC 8**)

Transcatheter Structural Intervention Planning

- Evaluation for transcatheter aortic valve replacement (TAVR) (**AUC 9**) ^(13,19)
- When TTE and TEE cannot provide adequate imaging, CT imaging can be used for planning: robotic mitral valve repair, atrial septal defect closure, left atrial appendage

closure, ventricular septal defect closure, endovascular grafts, and percutaneous pulmonic valve implantation ⁽²⁰⁾

- Evaluation for suitability of transcatheter mitral valve procedures, alone or in addition to TEE ⁽²¹⁾

Aortic Pathology (8,13,16,22,23)

- CT, MR, or echo can be used for screening and follow-up, with CT and MR preferred for imaging beyond the proximal ascending thoracic aorta in the following scenarios:
 - Evaluation of dilated aortic sinuses or ascending aorta identified by TTE (**AUC 8**)
 - Suspected acute aortic pathology, such as dissection (**AUC 9**)
 - Re-evaluation of known aortic dilation or aortic dissection with a change in clinical status or cardiac examination or when findings would alter management (**AUC 8**)
 - Screening first-degree relatives of individuals with a history of thoracic aortic aneurysm or dissection, or an associated high-risk mutation for thoracic aneurysm in common (**AUC 7**)
 - Screening second-degree relative of a patient with thoracic aortic aneurysm, when the first-degree relative has aortic dilation, aneurysm, or dissection
 - Six-month follow-up after initial finding of a dilated thoracic aorta, for assessment of rate of change (**AUC 8**)
 - Annual follow-up of enlarged thoracic aorta with size up to 4.4 cm
 - Biannual (twice/year) follow-up of enlarged aortic root ≥ 4.5 cm or showing growth rate ≥ 0.5 cm/year
- Patients with Marfan syndrome may undergo annual imaging with CT, MRI or TTE, with increase to biannual (twice-yearly) when diameter ≥ 4.5 cm or when expansions is > 0.5 cm/year (**AUC 8**)
- Patient with Turner syndrome should undergo initial imaging with CT, MRI, or TTE for evidence of dilatation of the ascending thoracic aorta. If imaging is normal and there are no risk factors for aortic dissection, repeat imaging should be performed every 5 - 10 years, or if otherwise indicated. If the aorta is enlarged, appropriate follow-up imaging should be done according to size, as above
- Evaluation of the aorta in the setting of a known or suspected connective tissue disease or genetic condition that predisposes to aortic aneurysm or dissection (i.e., Loeys-Dietz, Ehlers-Danlos), with re-evaluation at 6 months for rate of expansion. Complete evaluation with CMR from the cerebrovascular circulation to the pelvis is recommended with Loeys-Dietz syndrome.

Combination Studies

Chest MRA and Heart CT

- When medical necessity criteria indications are met for each Chest MRA (see Evolent Clinical Guideline 022-2 for Chest MRA and Heart MRI (see Evolent Clinical Guideline 7297 for Heart MRI) or CT (such as for certain congenital malformations when evaluation of extra cardiac and cardiac structures are needed)

CODING AND STANDARDS

Coding

CPT Codes

75572, 75573

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

General Overview

- Cardiac computed tomography (Heart CT) images the cardiac chambers, great vessels, valves, myocardium, and pericardium to assess cardiac structure and function, particularly when echocardiography (transthoracic echocardiography and transesophageal echocardiography) cannot provide adequate information
- CT imaging can be used for assessment of:
 - Structures of the heart (e.g., chambers, valves, great vessels, masses), as in this guideline
 - Quantitative level of calcium in the walls of the coronary arteries, in the separate coronary artery calcium (CAC) scoring guideline

Acronyms / Abbreviations

ARVD/C: Arrhythmogenic right ventricular dysplasia/cardiomyopathy

CABG: Coronary artery bypass grafting surgery

CAD: Coronary artery disease

CCS: Coronary calcium score

CCT: Cardiac (heart) CT

CHD: Coronary heart disease

CMR: Cardiac magnetic resonance (imaging)

CT: Computed tomography

CTA: Computed tomography angiography
 ECG: Electrocardiogram
 EF: Ejection fraction
 HF: Heart failure
 LVOT: Left ventricular outflow tract
 MI: Myocardial infarction
 MPI: Myocardial perfusion Imaging or cardiac nuclear imaging
 MR(I): Magnetic resonance (imaging)
 PA: Pulmonary artery
 PCI: Percutaneous coronary intervention
 PVML: Paravalvular mitral leak
 RV: Right ventricle
 SE: Stress echocardiogram
 TAVR: Transcatheter aortic valve replacement
 TMVR: Transcatheter mitral valve replacement
 TR: Tricuspid regurgitation
 TEE: Transesophageal echocardiography
 TTE: Transthoracic echocardiography
 VT: Ventricular tachycardia

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1459 for CT Heart CT Heart Congenital (Not Including Coronary Arteries) ● Updated the names of other Evolent Clinical Guidelines that are referenced in this document
June 2024	<ul style="list-style-type: none"> ● Formatting change ● Addition of clinical reasoning statement with AUC scoring described ● AUC scores added to bullet points ● References updated ● Combination Studies section added
April 2023	<ul style="list-style-type: none"> ● Added statement on clinical indications not addressed in this guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483-1502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R, Patel M, Allen J, Min J, Shaw L et al. Appropriate Use of Cardiovascular Technology. *Journal of the American College of Cardiology*. 2013; 61: 1305-1317. 10.1016/j.jacc.2013.01.025.
5. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF Proposed Method for Evaluating the Appropriateness of Cardiovascular Imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-1613. 10.1016/j.jacc.2005.08.030.
6. Sachdeva R, Valente A M, Armstrong A K, Cook S C, Han B K et al. ACC/AHA/ASE/HRS/ISACHD/SCAI/SCCT/SCMR/SOPE 2020 Appropriate Use Criteria for Multimodality Imaging During the Follow-Up Care of Patients With Congenital Heart Disease: A Report of the American College of Cardiology Solution Set Oversight Committee and Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Pediatric Echocardiography. *J Am Coll Cardiol*. 2020; 75: 657-703. 10.1016/j.jacc.2019.10.002.
7. Stout K, Daniels C, Aboulhosn J, Bozkurt B, Broberg C et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019; 73: e81-e192. 10.1016/j.jacc.2018.08.1029.
8. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and the Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2019; 73: 488-516. 10.1016/j.jacc.2018.10.038.
9. Conte E, Mushtaq S, Muscogiuri G, Formenti A, Annoni A et al. The Potential Role of Cardiac CT in the Evaluation of Patients With Known or Suspected Cardiomyopathy: From Traditional Indications to Novel Clinical Applications.. *Front Cardiovasc Med*. 2021; 8: 709124. 10.3389/fcvm.2021.709124.
10. Ommen S, Mital S, Burke M, Day S, Deswal A et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2020; 76: e159-e240. 10.1016/j.jacc.2020.08.045.
11. Te Riele A, Tandri H, Sanborn D M, Bluemke D A. Noninvasive Multimodality Imaging in ARVD/C. *JACC Cardiovasc Imaging*. 2015; 8: 597-611. 10.1016/j.jcmg.2015.02.007.
12. Taylor A J, Cerqueira M, Hodgson J M, Mark D, Min J et al. ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 appropriate use criteria for cardiac computed tomography. A report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the American

Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic Resonance. *J Am Coll Cardiol.* 2010; 56: 1864-94. 10.1016/j.jacc.2010.07.005.

13. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2017; 70: 1647-1672. 10.1016/j.jacc.2017.07.732.

14. Otto C, Nishimura R, Bonow R, Carabello B, Erwin 3rd J et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2021; 77: e25-e197. 10.1016/j.jacc.2020.11.018.

15. Ascha M, Renapurkar R, Tonelli A. A review of imaging modalities in pulmonary hypertension. *Ann Thorac Med.* 2017; 12: 61-73. 10.4103/1817-1737.203742.

16. Baumgartner H, Falk V, Bax J J, De Bonis M, Hamm C et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J.* 2017; 38: 2739-2791. 10.1093/eurheartj/ehx391.

17. Cosyns B, Plein S, Nihoyanopoulos P, Smiseth O, Achenbach S et al. European Association of Cardiovascular Imaging (EACVI) position paper: Multimodality imaging in pericardial disease. *Eur Heart J Cardiovasc Imaging.* 2015; 16: 12-31. 10.1093/ehjci/jeu128.

18. Klein A L, Abbara S, Agler D A, Appleton C P, Asher C R et al. American Society of Echocardiography clinical recommendations for multimodality cardiovascular imaging of patients with pericardial disease: endorsed by the Society for Cardiovascular Magnetic Resonance and Society of Cardiovascular Computed Tomography. *J Am Soc Echocardiogr.* 2013; 26: 965-1012.e15. 10.1016/j.echo.2013.06.023.

19. Otto C M, Kumbhani D J, Alexander K P, Calhoun J H, Desai M Y et al. 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol.* 2017; 69: 1313-1346. 10.1016/j.jacc.2016.12.006.

20. Pison L, Potpara T S, Chen J, Larsen T B, Bongioni M G. Left atrial appendage closure- indications, techniques, and outcomes: results of the European Heart Rhythm Association Survey. *Europace.* 2015; 17: 642-6. 10.1093/europace/euv069.

21. Wunderlich N C, Beigel R, Ho S Y, Nietlispach F, Cheng R et al. Imaging for Mitral Interventions: Methods and Efficacy. *JACC Cardiovasc Imaging.* 2018; 11: 872-901. 10.1016/j.jcmg.2018.02.024.

22. Erbel R, Aboyans V, Boileau C, Bossone E, Bartolomeo R D et al. 2014 ESC Guidelines on the diagnosis and treatment of aortic diseases: Document covering acute and chronic aortic diseases of the thoracic and abdominal aorta of the adult. The Task Force for the Diagnosis and Treatment of Aortic Diseases of the European Society of Cardiology (ESC). *Eur Heart J.* 2014; 35: 2873-926. 10.1093/eurheartj/ehu281.

23. Isselbacher E M, Preventza O, Black 3rd J, Augoustides J G, Beck A W et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022; 146: e334-e482. 10.1161/cir.0000000000001106.

Evolut Clinical Guideline 7297-01 for Heart MRI

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

CMR is an imaging modality used to assess cardiac or vascular anatomy, function, perfusion, and tissue characteristics in a single examination. In lesions affecting the right heart, CMR provides excellent visualization and volume determination regardless of RV shape. This is particularly useful in patients with congenital heart disease.

Special Note

Since many cardiac patients have cardiac implanted electrical devices, the risk of CMR to the patient and the device must be weighed against the benefit to the patient in terms of clinical value in optimal management ^(1,2,3,4).

See legislative language for specific mandates in Washington State

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

In instances where an AUC has not been established through prior publication, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(5,6,7,8,9)

INDICATIONS FOR CARDIAC MAGNETIC RESONANCE

Cardiomyopathy & Heart Failure ^(10,11,12)

- To assess systolic and diastolic function in the evaluation of a newly diagnosed cardiomyopathy (**AUC 7**) ⁽¹⁰⁾
- Suspected infiltrative disease such as amyloidosis, sarcoidosis ⁽¹³⁾, hemochromatosis, or endomyocardial fibrosis if PET has not been performed (**AUC**

- 8) ⁽¹⁰⁾
- Suspected inherited or acquired cardiomyopathy (**AUC 7**) ⁽¹⁰⁾
 - Diagnosis of acute myocarditis, with suspicion based upon new, unexplained findings such as:
 - Rise in troponin not clearly due to acute myocardial infarction
 - Change in ECG suggesting acute myocardial injury or pericarditis, without evident myocardial infarction
 - Assessment of hypertrophic cardiomyopathy ⁽¹⁴⁾ (**AUC 8**) ⁽¹⁰⁾
 - When TTE is inadequate for diagnosis, management, or operative planning, or when tissue characterization (degree of fibrosis) will impact indications for ICD
 - For patients with LVH when there is a suspicion of alternative diagnoses, including infiltrative or storage disease as well as athlete's heart
 - For patients with obstructive HCM in whom the autonomic mechanism of obstruction is inconclusive on echocardiography, CMR is indicated for selection and planning of SRT (septal reduction therapy)
 - For patients with HCM, repeat imaging on a periodic basis (every 3-5 years) for the purpose of SCD risk stratification to evaluate changes in LGE, EF, development of apical aneurysm or LV wall thickness
 - Arrhythmogenic right ventricular cardiomyopathy to aid in identification and diagnosis (assessment of myocardial fat, fibrosis, and RV tissue characteristics), based upon reason for suspicion, such as:
 - Nonsustained ventricular tachycardia (VT)
 - Unexplained syncope
 - ECG abnormalities
 - First-degree relatives with positive genotype for ARVD
 - Noncompaction cardiomyopathy to aid in the diagnosis (measurement of compacted to noncompacted myocardium) when TTE is suggestive
 - Viability assessment when SPECT, PET or Dobutamine Echo has provided "equivocal or indeterminate" results
 - Clinical symptoms and signs consistent with a cardiac diagnosis known to cause presyncope/syncope (including, but not limited to, hypertrophic cardiomyopathy) (**AUC 7**) ⁽¹⁰⁾
 - Pulmonary hypertension in the absence of severe valvular disease (**AUC 7**) ⁽¹⁰⁾
 - Cardiomyopathy
 - Hemosiderosis
 - Restrictive cardiomyopathy (**AUC 7**) ⁽¹⁰⁾
 - Cardio toxic chemotherapy

Valvular Heart Disease

- Evaluation of valvular stenosis, regurgitation, or valvular masses when transthoracic

echocardiography (TTE) is inadequate (**AUC 7**)⁽¹⁵⁾

- Pre-TAVR assessment if the patient has not undergone cardiac CT⁽¹⁶⁾
- Prior to transcatheter mitral valve intervention, when TTE and TEE result in uncertain assessment of the severity of mitral regurgitation^(17,18)
- Suspected clinically significant bioprosthetic valvular dysfunction and inadequate images from TTE and TEE (**AUC 7**)⁽¹⁵⁾

Evaluation of Intra- and Extra-Cardiac Structures

- Initial evaluation of cardiac mass, suspected tumor or thrombus, or potential cardiac source of emboli (**AUC 7**)⁽¹⁰⁾
- Re-evaluation of intracardiac mass when findings would change therapy; no prior imaging in the last three months (**AUC 7**)⁽¹⁰⁾
- Evaluation of pericardial disease to provide structural and functional assessment and differentiate constrictive vs restrictive physiology (**AUC 8**)⁽¹⁰⁾
- Assessment of left ventricular pseudoaneurysm, when TTE was inadequate
- Identification and characteristics of coronary aneurysms or anomalous coronary arteries (**AUC 7**)⁽¹⁰⁾

Pre-procedure Evaluation for Closure of ASD or PFO (**AUC 7**)⁽¹⁰⁾

- For assessment of atrial septal anatomy and atrial septal aneurysm
- For assessment of suitability for percutaneous device closure

Assessment Following LAA Occlusion

- For surveillance at 45 days or FDA guidance, if TEE or Heart CT was not done, to assess:
 - Device stability
 - Device leaks
 - To exclude device migration

Pre-Ablation Planning

- Evaluation of left atrium and pulmonary veins prior to radiofrequency ablation for atrial fibrillation, if cardiac CT has not been done

Aortic Pathology

- CT, MR, or echocardiogram can be used for screening and follow-up, with CT and MR preferred for imaging beyond the proximal ascending thoracic aorta (**AUC 8**)⁽¹⁰⁾
- Screening of first-degree relatives with a history of thoracic aortic aneurysm or dissection (**AUC 7**)⁽¹⁰⁾
- Six-month follow-up after initial diagnosis of thoracic aortic aneurysm to measure rate

of change

- Annual follow-up for an enlarged thoracic aortic aneurysm (usually defined as > 4.4.cm)
- Biannual (2x/year) follow-up of enlarged aortic root or showing growth rate ≥ 0.5 cm/year
- Screening of first-degree relative with a bicuspid aortic valve
- Re-evaluation (<1 y) of the size and morphology of the aortic sinuses and ascending aorta in patients with a bicuspid AV and an ascending aortic diameter > 4 cm with 1 of the following:
 - Aortic diameter > 4.5 cm
 - Rapid rate of change in aortic diameter
 - Family history (first-degree relative) of aortic dissection
- Patients with Turner's syndrome annually if an abnormality exists; if initial study normal, can have imaging every 5 - 10 years ⁽¹⁹⁾
- Evaluation in patients with known or suspected connective tissue disease or genetic condition that predispose to aortic aneurysm or dissection, such as Marfan syndrome, Ehlers-Danlos or Loeys-Dietz syndrome (at the time of diagnosis and 6 months thereafter), followed by annual imaging (can be done more frequently if > 4.5 cm or rate of growth > 0.5 cm/year- up to twice per year) **(AUC 8)** ⁽¹⁰⁾

Congenital Heart Disease

For all indications below, either CT or CMR can be done:

- All lesions: evaluation prior to planned repair and evaluation for change in clinical status and/or new concerning signs or symptoms
- Patent Ductus Arteriosus: routine surveillance (1-2 years) in a patient with postprocedural aortic obstruction **(AUC 7)** ⁽²⁰⁾
- In the absence of prior imaging documenting congenital heart disease, a cardiac MRI is appropriate for anomalous pulmonary venous drainage and pulmonary outflow tract obstruction
- Eisenmenger Syndrome and Pulmonary Hypertension associated with congenital heart disease (CHD) **(AUC 7)** ⁽²⁰⁾
 - Evaluation due to change in pulmonary arterial hypertension-targeted therapy
 - Initial evaluation with suspicion of pulmonary hypertension following CHD surgery
- Aortic Stenosis or Regurgitation:
 - Routine surveillance (6-12 months) in a child with aortic sinus and/or ascending aortic dilation with increasing size **(AUC 8)** ⁽²⁰⁾
 - Routine surveillance (2–3 years) in a child with aortic sinus and/or ascending aortic dilation with stable size (CMR only) **(AUC 7)** ⁽²⁰⁾
- Aortic Coarctation and Interrupted Aortic Arch: **(AUC 8)** ⁽²⁰⁾
 - In the absence of prior imaging documenting congenital heart disease, a cardiac MRI is appropriate for suspected Coarctation **(AUC 8)** ⁽²⁰⁾

- Routine surveillance (3–5 years) in a child or adult with mild aortic coarctation
- Post procedure (surgical or catheter-based) routine surveillance (3–5 years) in an asymptomatic patient to evaluate for aortic arch aneurysms, in-stent stenosis, stent fracture, or endoleak
- Coronary anomalies
- Tetralogy of Fallot:
 - Postoperative routine surveillance (2–3 years) in a patient with pulmonary regurgitation and preserved ventricular function (CMR only) **(AUC 7)** ⁽²⁰⁾
 - Routine surveillance (2–3 years) in an asymptomatic patient with no or mild sequelae (CMR only) **(AUC 7)** ⁽²⁰⁾
 - Routine surveillance (2–3 years) in a patient with valvular or ventricular dysfunction, right ventricular outflow tract obstruction, branch pulmonary artery stenosis, arrhythmias, or presence of an RV-to-PA conduit **(AUC 8)** ⁽²⁰⁾
- Double Outlet Right Ventricle: Routine surveillance (3–5 years) in an asymptomatic patient with no or mild sequelae (CMR only)
- D-Loop Transposition of the Great Arteries (postoperative):
 - Routine surveillance (3–5 years) in an asymptomatic patient **(AUC 7)**
 - Routine surveillance (1–2 years) in a patient with dilated aortic root with increasing size, or aortic regurgitation **(AUC 8)**
 - Routine surveillance (3–12 months) in a patient with \geq moderate systemic AV valve regurgitation, systemic RV dysfunction, LVOT obstruction, or arrhythmias
- Congenitally Corrected Transposition of the Great Arteries: **(AUC 7)** ⁽²⁰⁾
 - Unrepaired: routine surveillance (3–5 years) in an asymptomatic patient
 - Postoperative: routine surveillance (3–5 years) in an asymptomatic patient
 - Postoperative anatomic repair: routine surveillance (6–12 months) in a patient with valvular or ventricular dysfunction, right or left ventricular outflow tract obstruction, or presence of an RV-to-PA conduit
 - Postoperative physiological repair with VSD closure and/or LV-to-PA conduit: routine surveillance (3–12 months) in a patient with \geq moderate systemic AV valve regurgitation, systemic RV dysfunction, and/or LV-to-PA conduit dysfunction
- Truncus Arteriosus: routine surveillance (1–2 years) in an asymptomatic child or adult with \geq moderate truncal stenosis and/or regurgitation **(AUC 7)** ⁽²⁰⁾
- Single-Ventricle Heart Disease:
 - Postoperative routine surveillance (1–2 years) in an asymptomatic patient
 - Routine surveillance (1–2 years) in an asymptomatic adult postoperative Stage 2 palliation (CMR only) **(AUC 7)** ⁽²⁰⁾
- Ebstein’s anomaly and Tricuspid Valve dysplasia (only CMR indicated):
 - Evaluation prior to planned repair and evaluation for change in clinical status and/or new concerning signs or symptoms **(AUC 7)** ⁽²⁰⁾
- Pulmonary Stenosis (only CMR indicated) **(AUC 7)** ⁽²⁰⁾

- Unrepaired: routine surveillance (3–5 years) in an asymptomatic adult with PS and pulmonary artery dilation
- Postprocedural (surgical or catheter-based): routine surveillance (1–3 years) in an asymptomatic adult with moderate or severe sequelae
- Pulmonary Atresia (postprocedural complete repair): routine surveillance (1–3 years) in an asymptomatic adult with ≥ moderate sequelae (**AUC 7**)⁽²⁰⁾

Coronary Artery Disease Evaluation

CMR, which is done pharmacologically, is used for the assessment of coronary artery disease, and can be performed if the patient would otherwise be a candidate for a pharmacologic MPI.

- If the patient can walk and is having an MPI for another reason (LBBB, CABG, etc.), MPI is chosen over CMR
- Assessment of LV wall motion to identify patients with akinetic segments that would benefit from coronary revascularization
- To identify the extent and location of myocardial necrosis in patients with chronic or acute ischemic heart disease
- Follow-up of known CAD
 - Coronary stenosis of unclear significance on previous coronary angiography^(12,21)
- To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA) as documented in provider notes (no MPI diversion required).⁽²²⁾

Combination Studies

Chest MRA and Heart MRI

- When medical necessity criteria indications are met for each Chest MRA (see Evolent Clinical Guideline 022-2 for Chest MRA) and Heart MRI or CT (see Evolent Clinical Guideline 7296 for Heart CT) (such as for certain congenital malformations when evaluation of extra cardiac and cardiac structures are needed)

LEGISLATIVE LANGUAGE

Washington

20211119A – Use of Cardiac Magnetic Resonance Angiography (CMRA) in Adults and Children⁽²³⁾

Washington State Health Care Authority Technology Assessment

HTCC coverage determination:

CMRA is a **covered benefit** for adults or children with known or suspected coronary vessel anomalies or congenital heart disease

CMRA is a **covered benefit with conditions** for stable symptomatic adults with known or suspected coronary artery disease (CAD)

HTCC reimbursement determination:

Limitations of coverage: CMRA should not be a first line diagnostic tool in patients with stable symptoms consistent with CAD. CMRA is covered with conditions for stable symptomatic adults with known or suspected CAD when the following conditions are met:

- In consultation with a cardiologist, and
- The patient is unable to tolerate or safely participate in other noninvasive anatomic or functional testing.

CMRA is not a covered service in coronary artery bypass graft (CABG) patients without CAD symptoms, or in those requiring cardiac lead placement unless cardiac vascular anomalies are suspected.

Non-covered indicators:

N/A

Notes:

Out of scope/data not reviewed for this decision:

- Cardiac stress MRI

CODING AND STANDARDS

Coding

CPT Codes

75557, 75559, 75561, 75563, +75565

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

General Overview ⁽²⁴⁾

- CMR in CAD ^(21,25,26) is often required when transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) provide inadequate imaging data.
- Stress CMR for assessment of coronary artery disease (CAD) is performed

pharmacologically either as a vasodilator perfusion imaging with gadolinium contrast or dobutamine inotropic wall motion (ventriculography).

- With respect to CAD evaluation, since CMR is only pharmacologic (non-exercise stress), and stress echocardiography (SE) or myocardial perfusion imaging (MPI) provide similar information about CAD:
 - Requests for stress CMR require diversion to exercise SE first, and to exercise MPI second.
 - Exemptions for the diversion to SE or exercise MPI:
 - If body habitus or marked obesity (e.g., BMI ≥ 40) would interfere significantly with imaging with SE and MPI ⁽²⁷⁾
 - Evaluation of young (< 55 years old) patients with documented complex CAD, who are likely to need frequent non-invasive coronary ischemia evaluation and/or frequent radiation exposure from other testing ⁽²⁸⁾
- Heart magnetic resonance imaging (MRI) is an imaging method that uses powerful magnets and radio waves to create pictures of the heart. It does not use radiation (x-rays).

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁵⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Definitions

- Stable patients without known CAD fall into 2 categories ^(21,25,26):
 - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online
 - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant ($\geq 50\%$) CAD (below):
- The THREE Types of Chest Pain or Discomfort
 - **Typical Angina (Definite)** is defined as including all **3** characteristics:
 - Substernal chest pain or discomfort with characteristic quality and duration
 - Provoked by exertion or emotional stress
 - Relieved by rest and/or nitroglycerine
 - **Atypical Angina (Probable)** has only **2** of the above characteristics
 - **Nonanginal Chest Pain/Discomfort** has only **0 - 1** of the above characteristics
- The medical record should provide enough detail to establish the type of chest pain. From those details, the pretest probability of obstructive CAD is estimated from the **Diamond Forrester Table** below, recognizing that in some cases multiple additional

coronary risk factors could increase pretest probability ⁽²¹⁾:

Diamond Forrester Table ^(29,30)

Age (Years)	Gender	Typical/ Definite Angina Pectoris	Atypical/ Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Very low: < 5% pretest probability of CAD, usually not requiring stress evaluation

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

High: > 90% pretest probability of CA

- For additional information on stress imaging, please refer to Evolent Clinical Guideline 024 for Myocardial Perfusion Imaging.

Acronyms/Abbreviations

ARVD/C: Arrhythmogenic right ventricular dysplasia/cardiomyopathy

ASD: Atrial septal defect

CABG: Coronary artery bypass grafting surgery

CAD: Coronary artery disease

CMR: Cardiac magnetic resonance (imaging)

CT: Computed tomography

ECG: Electrocardiogram

EF: Ejection fraction

HCM: Hypertrophic cardiomyopathy

ICD: Implantable cardioverter-defibrillator

LAA: Left atrial appendage

LBBB: Left bundle-branch block

LGE: Late gadolinium enhancement

LV: Left ventricle
 LVH: Left ventricular hypertrophy
 LVOT: Left ventricular outflow
 MPI: Myocardial perfusion imaging
 MR: Mitral regurgitation
 MR(I): Magnetic resonance (imaging)
 PA: Pulmonary artery
 PET: Positron emission tomography
 PFO: Patent foramen ovale
 PS: Pulmonary stenosis
 RV: Right ventricle
 SCD: Sudden cardiac death
 SE: Stress echocardiography
 SRT: Septal reduction therapy
 TAVR: Transcatheter Aortic Valve Replacement
 TTE: Transthoracic Echo
 TEE: Transesophageal Echo
 VT: Ventricular tachycardia

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> <li data-bbox="531 1379 1342 1447">This guideline replaces UM Cardio 1113 Cardiac Magnetic Resonance Imaging (MRI)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Brignole M, Auricchio A, Baron-Esquivias G, Bordachar P, Boriani G et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). *Eur Heart J*. Aug 2013; 34: 2281-329. 10.1093/eurheartj/ehs150.
2. Indik J, Gimbel J, Abe H, Alkmmim-Teixeira R, Birgersdotter-Green U et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. *Heart Rhythm*. Jul 2017; 14: e97-e153. 10.1016/j.hrthm.2017.04.025.
3. Nazarian S, Hansford R, Rahsepar A, Weltin V, McVeigh D et al. Safety of Magnetic Resonance Imaging in Patients with Cardiac Devices. *N Engl J Med*. Dec 28, 2017; 377: 2555-2564. 10.1056/NEJMoa1604267.
4. Russo R, Costa H, Silva P, Anderson J, Arshad A et al. Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator. *N Engl J Med*. Feb 23, 2017; 376: 755-764. 10.1056/NEJMoa1603265.
5. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
6. Hendel R, Patel M, Allen J, Min J, Shaw L et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF Appropriate Use Criteria Methodology Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. 2013; 61: 1305 - 1317. 10.1016/j.jacc.2013.01.025.
7. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *J Am Coll Cardiol*. 2011; 58: 1517-38. 10.1016/j.jacc.2011.07.007.
8. Fitch K, Bernstein S, Aguilar M, Burnand B, LaCalle J et al. The RAND/UCLA Appropriateness Method User's Manual. 2001;
9. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *J Am Coll Cardiol*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
10. Doherty J, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and the Society of Thoracic Surgeons. *J Am Coll Cardiol*. Feb 5, 2019; 73: 488-516. 10.1016/j.jacc.2018.10.038.
11. Patel M, White R, Abbara S, Bluemke D, Herfkens R et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR appropriate utilization of cardiovascular imaging in heart failure: a joint report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. May 28, 2013; 61: 2207-31. 10.1016/j.jacc.2013.02.005.
12. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145: e876-e894. 10.1161/CIR.0000000000001062.

13. Birnie D, Nery P, Ha A, Beanlands R. Cardiac Sarcoidosis. *J Am Coll Cardiol.* 2016; 68: 411-21. 10.1016/j.jacc.2016.03.605.
14. Ommen S, Mital S, Burke M, Day S, Deswal A et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* Dec 22, 2020; 76: e159-e240. 10.1016/j.jacc.2020.08.045.
15. Doherty J, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* Sep 26, 2017; 70: 1647-1672. 10.1016/j.jacc.2017.07.732.
16. Otto C, Kumbhani D, Alexander K, Calhoun J, Desai M et al. 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol.* Mar 14, 2017; 69: 1313-1346. 10.1016/j.jacc.2016.12.006.
17. Bonow R, O'Gara P, Adams D, Badhwar V, Bavaria J et al. 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol.* May 5 2020; 75: 2236-2270. 10.1016/j.jacc.2020.02.005.
18. Agricola E, Ingallina G, Ancona F, Biondi F, Margonato D et al. Evolution of interventional imaging in structural heart disease. *Eur Heart J Suppl.* 2023; 25: C189 - C199. 10.1093/eurheartjsupp/suad044.
19. Isselbacher E M, Preventza O, Black J H, Augoustides J G, Beck A W et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022; 146: e334-e482. doi:10.1161/CIR.0000000000001106.
20. Sachdeva R, Valente A, Armstrong A, Cook S, Han B et al. ACC/AHA/ASE/HRS/ISACHD/SCAI/SCCT/SCMR/SOPE 2020 Appropriate Use Criteria for Multimodality Imaging During the Follow-Up Care of Patients With Congenital Heart Disease: A Report of the American College of Cardiology Solution Set Oversight Committee and Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Pediatric Echocardiography. *J Am Coll Cardiol.* Feb 18, 2020; 75: 657-703. 10.1016/j.jacc.2019.10.002.
21. Winchester D, Maron D, Blankstein R, Chang I, Kirtane A et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *J Cardiovasc Magn Reson.* 2023; 25: 58. 10.1186/s12968-023-00958-5.
22. Gulati M, Levy P, Mukherjee D, Amsterdam E, Bhatt D et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* Nov 30, 2021; 78: e187-e285. 10.1016/j.jacc.2021.07.053.
23. Washington State Health Care Authority. Health Technology Clinical Committee: 20211119A – Use of Cardiac Magnetic Resonance Angiography (CMRA) in Adults and Children. [Final Adoption: 20211119A – Use of Cardiac Magnetic Resonance Angiography (CMRA) in Adults and Children: [Final Adoption: March 18, 2022]. 2022; <https://www.hca.wa.gov/assets/program/cmra-final-findings-and-decision-2022-03-18.pdf>.

24. Pennell D. Cardiovascular magnetic resonance. *Circulation*. Feb 9, 2010; 121: 692-705. 10.1161/circulationaha.108.811547.
25. Fihn S, Gardin J, Abrams J, Berra K, Blankenship J et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation*. Dec 18 2012; 126: e354-471. 10.1161/CIR.0b013e318277d6a0.
26. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J*. Oct 2013; 34: 2949-3003. 10.1093/eurheartj/eh296.
27. Cortez R, Okoshi M, K O. A Review of the Roles and Limitations of Noninvasive Imaging Methods for Investigating Cardiovascular Disease in Individuals with Obesity. *Med Sci Monit*. 2022; 28: e937362. 10.12659/MSM.937362.
28. Hirshfeld J J, Ferrari V, Bengel F, Bergersen L, Chambers C et al. 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging-Best Practices for Safety and Effectiveness, Part 1: Radiation Physics and Radiation Biology: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways Developed in Collaboration With Mended Hearts. *Catheter Cardiovasc Interv*. Aug 1, 2018; 92: 203-221. 10.1002/ccd.27660.
29. Diamond G, Forrester J. Analysis of probability as an aid in the clinical diagnosis of coronary-artery disease. *N Engl J Med*. 1979; 300: 1350-8. 10.1056/NEJM197906143002402.
30. Wolk M, Bailey S, Doherty J, Douglas P, Hendel R et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. Feb 4, 2014; 63: 380-406. 10.1016/j.jacc.2013.11.009.



Evolut Clinical Guideline 7298-01 for Heart PET with CT for Attenuation

Guideline Number: Evolut_CG_7298-01	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Special Note

A Heart PET scan for Ischemic evaluation is indicated when all the criteria for MPI are met **AND** there is likely to be equivocal imaging results because of BMI, large breasts or implants, mastectomy, chest wall deformity, pleural or pericardial effusion, or prior thoracic surgery or results of a prior MPI. ^(1,2) **(AUC 7)** ⁽³⁾

Cardiac PET scanning, when used in conjunction with CT attenuation, includes evaluation of perfusion, function, viability, inflammation, anatomy, and risk stratification for cardiac-related events such as myocardial infarction and death. Maximum diagnostic accuracy of cardiac PET/CT is achieved when images are interpreted in conjunction with other relevant imaging, clinical information, and laboratory data.

See **Legislative Language** for specific mandates in Washington State.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(4,5,6,7,8)

INDICATIONS FOR HEART PET WITH CT FOR ATTENUATION ^(9,10,11)

Suspected CAD

When neither SE nor MPI have provided or are expected to provide optimal imaging

- **Symptomatic patients without known CAD. No imaging stress test within the last 12 months.** The terms "typical," "atypical," and "non-anginal symptoms" can still

be observed in medical records (consult the Diamond Forrester table in the Definitions section). However, the ACC has simplified its terminology to "Less likely anginal symptoms" and "Likely anginal symptoms" (refer to **Definitions** section) and utilized below.

- Less-likely anginal symptoms (**AUC 4-6**)
 - When a patient cannot walk a treadmill
 - When baseline EKG makes standard exercise test inaccurate (see Definitions section).
 - When a noncardiac explanation is provided for symptoms, no testing is required (**AUC 8**)
- Likely Anginal Symptoms (typical angina)
 - < 50 years old with \leq one risk factor if an ECG treadmill test cannot be done. **AUC scores for this bullet point are identical for MPI, stress echo, and ETT (**AUC 7**). Although the ACC guideline does not specify youth and gender, decisions should be guided by best medical judgment, considering factors such as safety and radiation exposure.
 - \geq 50 years old (**AUC 8**)
- Repeat testing in a patient with new or worsening symptoms and negative result at least one year ago **AND** meets one of the criteria above
- **Asymptomatic patients without known CAD**
 - Previously unevaluated ECG evidence of possible myocardial ischemia including substantial ischemic ST segment or T wave abnormalities (see **Background** section)
 - Previously unevaluated pathologic Q waves (see **Background** section)
 - Unevaluated complete left bundle branch block (**AUC 8**)⁽³⁾

Abnormal Calcium Scores (CAC) (9,12,13,14,15)

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of > 100. No prior MPI done within the last 12 months⁽¹⁶⁾
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of > 100. No prior MPI done within the last 12 months⁽¹⁶⁾
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior MPI done within the last 12 months

Inconclusive CAD Evaluation and Obstructive CAD remain a Concern

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- Exercise stress ECG with low-risk Duke treadmill score (\geq 5) (see **Background** section) but patient's current symptoms indicate increasing likelihood of disease
- Exercise stress ECG with an intermediate Duke treadmill score (**AUC 8**)⁽³⁾

- Inconclusive/borderline coronary computed tomography angiography (CCTA) or SPECT nuclear stress testing (e.g., 40 - 70% lesions) (**AUC 9**)⁽³⁾
- Cardiac PET stress-rest perfusion and metabolic activity study (with ¹⁸F-FDG PET) is appropriate in patients with ischemic cardiomyopathy to determine myocardial viability prior to revascularization following an inconclusive SPECT^(9,17) (**AUC 9**)⁽³⁾
- Non-diagnostic exercise stress test with physical inability to achieve target heart rate (THR)
- An intermediate evaluation by prior stress imaging
- Coronary stenosis of unclear significance on previous coronary angiography⁽⁹⁾ (**AUC 8**)⁽³⁾

Follow-Up Of Patient's Post Coronary Revascularization (PCI or CABG)

When neither SE nor MPI have provided, or are expected to provide, optimal imaging⁽⁹⁾

- **Asymptomatic, follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG), or percutaneous coronary intervention (PCI), (whichever is later), is appropriate only for patients with:
 - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
 - a history of silent ischemia or
 - a history of a prior left main stent

OR

- For patients with high occupational risk (e.g., associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, and firefighters)

New, recurrent, or worsening symptoms post coronary revascularization treated medically or by revascularization is an indication for stress imaging, if it will alter management for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization if no imaging stress test within the last 12 months. (**AUC 8**)

Follow-Up Of Known CAD⁽⁹⁾

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- **Follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or FFR \leq 0.80 or significant stenosis in a major vessel (\geq 50% left main coronary artery or \geq 70% LAD, LCX or RCA)), over two years ago, without intervening coronary revascularization is an appropriate indication for stress imaging in patients if it will alter management

Special Diagnostic Conditions Requiring Coronary Evaluation

When neither SE nor MPI have provided, or are expected to provide, optimal imaging

- **Unevaluated ACS**
 - Prior acute coronary syndrome (as documented in MD notes), without subsequent invasive or non-invasive coronary evaluation within the last 12 months
 - Has ventricular wall motion abnormality demonstrated by another imaging modality and myocardial perfusion imaging is being performed to determine if the patient has myocardial ischemia. No imaging stress test within the last 12 months
 - The addition of Coronary CTA to the PETCT study may be considered for patients facing complex coronary interventions, suspected global myocardial ischemia, necessitating correlation between anatomy and perfusion ⁽¹⁷⁾ **(AUC 7)**
- **Heart Failure**
 - Newly diagnosed systolic heart failure or diastolic heart failure, with *reasonable suspicion of cardiac ischemia (prior events, risk factors)*, unless invasive coronary angiography is immediately planned or adequate stress imaging has been done within the last 12 months ^(10,18,19) **(AUC 9)** ⁽³⁾
- **Suboptimal Revascularization**
 - To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA), as documented in provider notes (no MPI diversion required) ⁽¹³⁾.
- **Viability**
 - Reduced LVEF $\leq 50\%$ requiring myocardial viability assessment to assist with decisions regarding coronary revascularization. (Diversion from PET not required when LVEF less than or equal to 40%) ^(18,19,20) **(AUC 9)** ⁽³⁾
- **Ischemia and Nonobstructive Coronary Artery Disease (INOCA)**
 - To diagnose microvascular dysfunction in patients with persistent stable anginal chest pain with suspected ischemia and nonobstructive coronary artery disease (INOCA), as documented in provider notes (*no MPI diversion required*).
- **Arrhythmias**
 - Ventricular arrhythmias
 - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography is not the immediately planned test ⁽²¹⁾
 - Non-sustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVC's (defined as greater than or equal to 30/hour on remote monitoring) without known cause or associated cardiac pathology, when an exercise ECG cannot be performed
- **Anti-arrhythmic Drug Therapy**
 - Class IC antiarrhythmic drug
 - In the intermediate and high global risk patient prior to initiation of Class IC antiarrhythmic drug initiation (Propafenone or Flecainide)
 - Annually for intermediate and high global risk patients taking Class IC antiarrhythmic drug (Propafenone or Flecainide) ⁽²²⁾ **(AUC 7)** ⁽³⁾

- **Coronary Anomaly and Aneurism**
 - Assessment of hemodynamic significance of one of the following documented conditions ⁽²³⁾:
 - Anomalous coronary arteries ⁽²⁴⁾
 - Muscle bridging of coronary artery ^(9,25)
 - Coronary aneurysms in Kawasaki's disease ⁽²⁶⁾ or due to atherosclerosis
- **Radiation**
 - Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter ⁽²⁷⁾
- **Cardiac Sarcoidosis** ^(28,29,30)
 - May be approved as a combination study with MPI for the evaluation and treatment of sarcoidosis ⁽³¹⁾
 - Evaluation and therapy monitoring in patients with sarcoidosis, after documentation of suspected cardiac involvement by echo or ECG, when CMR has not been performed
 - Evaluation of suspected cardiac sarcoid, after CMR has shown equivocal or negative findings in the setting of a high clinical suspicion ⁽³⁰⁾
 - Evaluation of CMR findings showing highly probable cardiac sarcoidosis, when PET could serve to identify inflammation and the consequent potential role for immunosuppressive therapy ⁽³⁰⁾ **(AUC 9)** ⁽³⁾
 - Initial and follow-up PET in monitoring therapy for cardiac sarcoid with immunosuppressive therapy, typically about 4 times over 2 years
- **Infective Endocarditis**
 - In suspected infective endocarditis with moderate to high probability (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inconclusive with respect to diagnosis of infective endocarditis or characterization of paravalvular invasive complications ^(32,33,34)
- **Aortitis**
 - For diagnosis and surveillance of Aortitis, PET/CT or PET/MRI[‡] hybrid imaging ⁽³⁵⁾
 - **‡NOTE:** If PET/MR study is requested, there is no specific CPT Code for this imaging study and a Health Plan review will be required.

Prior To Elective Non-Cardiac Surgery

When neither SE nor MPI have provided or are expected to provide optimal imaging

- An intermediate or high-risk surgery with of one or more risk factors (see below), **AND** documentation of an inability to walk (or < 4 METs) **AND** there has not been an imaging stress test within 1 year ^(36,37,38)
 - **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine > 2.0 mg/dL.
 - **Surgical Risk:**

- **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
- **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
- **Low risk surgery:** Endoscopic procedures, superficial procedure, cataract surgery, breast surgery
- Planning for any organ or stem cell transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service ⁽³⁹⁾

Post Cardiac Transplant

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

LEGISLATIVE REQUIREMENTS

State of Washington

Health Technology Clinical Committee 20211105A ⁽⁴⁰⁾

Number and coverage topic:

20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease

HTCC coverage determination:

Noninvasive cardiac imaging is a **covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage: The following noninvasive cardiac imaging technologies are **covered with conditions**:

- Stress echocardiography for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of Coronary Artery Disease (CAD), or
 - Adult patients with known CAD who have new or worsening symptoms.
- Single Positron Emission Tomography (SPECT) for:
 - Patients under the same conditions as stress echocardiography when stress echocardiography is not technically feasible or clinically appropriate.
- Positron Emission Tomography (PET) for:
 - Patients under the same conditions as SPECT, when SPECT is not technically feasible or clinically appropriate.
- Coronary Computed Tomographic Angiography (CCTA) for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of

CAD, or

- Adult patients with known CAD who have new or worsening symptoms.
- CCTA with Fractional Flow Reserve (FFR) for:
 - Patients under the same conditions as CCTA, when further investigation of functional significance of stenoses is clinically indicated.

Non-covered indicators:

N/A

Notes:

- Out of scope/data not reviewed for this decision:
 - Asymptomatic individuals, follow up of prior abnormal cardiac imaging studies, myocardial viability, preoperative evaluation
 - Patients presenting for evaluation of cardiac pathologies other than CAD
- This determination supersedes the following previous determinations:
 - Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease (20081114A)
 - Cardiac Nuclear Imaging (20130920A)

CODING AND STANDARDS

Coding

CPT Codes

78429, 78430, 78431, 78432, 78433, 78459, 78472, 78491, 78492, 93015, 93016, 93017, 93018, A9555

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

General Overview (1,41)

A PET study is a diagnostic test used to evaluate blood flow to the heart. During the test, a small amount of radioactive tracer is injected into a vein. A special camera, called a gamma camera, detects the radiation released by the tracer to produce computer images of the heart. Combined with a medication, the test can help determine if there is adequate blood flow to the heart during activity versus at rest. The medication simulates exercise for patients unable to exercise on a treadmill or stationary cycle.

PET perfusion studies illustrate myocardial blood flow by demonstrating tracer uptake. PET metabolic evaluation studies are used to demonstrate inflammation produced by infiltrative disease such as sarcoidosis, but also enhance the detection of viable (hibernating) myocardium. Hybrid PET-CT scanning combines anatomical information with blood flow assessment and is useful for assessing viable myocardium, especially in CHF patients with global ischemia, or in patients with multivessel diffuse coronary artery disease as opposed to focal stenotic lesions.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Definitions

- Coronary application of PET includes evaluation of stable patients without known CAD, who fall into two categories ^(9,10,11)
 - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see Websites for Global Cardiovascular Risk Calculators section).
 - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant ($\geq 50\%$) CAD (below)
- The medical record should provide enough detail to establish the type of chest pain:
 - **Likely Anginal symptoms** encompass chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort occurring with exertion or emotional stress and relieved by rest, nitroglycerine or both.
 - **Less-Likely Anginal symptoms** include dyspnea, or fatigue not relieved by rest/nitroglycerin, as well as generalized fatigue or chest discomfort with a time course not indicative of angina (e.g., resolving spontaneously within seconds or lasting for an extended period unrelated to exertion).
- **Risk Factors for Coronary disease include (but not limited to):** diabetes mellitus, smoking, family history of premature CAD (men age less than 55, females less than 65), hypertension, dyslipidemia.

- Beginning 2023, the classification terms for angina were updated within the ACC’s Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease to **Less Likely Anginal Symptoms** and **Likely Anginal Symptoms**. Previously, the document referred to “Typical Angina”, “Atypical Angina” and “Non-Anginal” symptoms, defined by the Diamond Forrester Table. We still provide this information for your reference ^(9,10,11):

Diamond Forrester Table ^(42,43)

Age (Years)	Gender	Typical/ Definite Angina Pectoris	Atypical/ Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40-49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50-59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Very low: < 5% pretest probability of CAD, usually not requiring stress evaluation

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

High: > 90% pretest probability of CAD

- ECG Stress Test Alone versus Stress Testing with Imaging
 - Prominent scenarios suitable for an ECG stress test **WITHOUT** imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise: ⁽⁹⁾
 - The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG ⁽⁹⁾
 - The patient who is under evaluation for exercise-induced arrhythmia
 - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
 - For the evaluation of syncope or presyncope during exertion ⁽⁴⁴⁾
 - When exercise cannot be performed, pharmacologic stress can be considered.
 - Duke Exercise ECG Treadmill Score ⁽⁴⁵⁾
 - Calculates risk from ECG treadmill alone:

- The equation for calculating the Duke treadmill score (DTS) is: $DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score})$, with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting
 - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of $\geq + 5$), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of $\leq - 11$) categories
- An uninterpretable baseline ECG includes: ⁽¹⁰⁾
 - ST segment depression 1 mm or more; (not for non-specific ST- T wave changes)
 - Ischemic-looking T waves; at least 2.5 mm inversions (excluding V1 and V2)
 - LVH with repolarization abnormalities, pre-excitation pattern such as WPW, ventricular paced rhythm, or left bundle branch block
 - Digitalis use with associated ST segment abnormalities
- Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
 - > 40 ms (1 mm) wide
 - > 2 mm deep
 - > 25% of depth of QRS complex
- Global Risk of Cardiovascular Disease
 - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. **High global risk by itself generally lacks scientific support as an indication for stress imaging.** There are rare exceptions, such as patients requiring IC antiarrhythmic drugs who might require coronary risk stratification prior to initiation of the drug.
 - **CAD Risk—Low**
 - 10-year absolute coronary or cardiovascular risk less than 10%
 - **CAD Risk—Moderate**
 - 10-year absolute coronary or cardiovascular risk between 10% and 20%
 - **CAD Risk—High**
 - 10-year absolute coronary or cardiovascular risk of greater than 20%

Websites for Global Cardiovascular Risk Calculators* (46,47,48,49,50)

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clinicalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

- Definitions of Coronary Artery Disease ^(10,11,14)
 - Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
 - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into global risk can be achieved by using the MESA risk calculator.
 - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; intermediate lesions are 50 – 69% ⁽⁹⁾
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ or minimum lumen cross-sectional area on IVUS ≤ 6 square mm ^(10,51)

- FFR (fractional flow reserve) ≤ 0.80 for a major vessel ⁽⁵¹⁾
- Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
- A major vessel would be a coronary vessel that would be amenable to revascularization if indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
- FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
- Newer technology that estimates FFR from CCTA image is covered under the Evolent Clinical Guideline 062-1 for Fractional Flow Reserve CT.
- Anginal Equivalent ^(10,44)
 - Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data, such as respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Most syncope per se is not an anginal equivalent.

Acronyms / Abbreviations

ADLs: Activities of daily living

BMI: Body mass index

CABG: Coronary artery bypass grafting

CAC: Coronary artery calcium

CAD: Coronary artery disease

CCTA: Coronary computed tomography angiography

CMR: Cardiac magnetic resonance imaging

CT(A): Computed tomography (angiography)

DTS: Duke Treadmill Score

ECG: Electrocardiogram

FFR: Fractional flow reserve

IVUS: Intravascular ultrasound

LBBB: Left bundle-branch block

LVEF: Left ventricular ejection fraction

LVH: Left ventricular hypertrophy

MESA: Multi-Ethnic Study of Atherosclerosis

MET: Estimated metabolic equivalent of exercise

MI: Myocardial infarction

MPI: Myocardial perfusion imaging

MR(I): Magnetic resonance (imaging)

PCI: Percutaneous coronary intervention

PET: Positron emission tomography

PFT: Pulmonary function test

PVCs: Premature ventricular contractions

SE: Stress echocardiography

TEE: Transesophageal echocardiography

THR: Target heart rate

TTE: Transthoracic echocardiography

VF: Ventricular fibrillation

VT: Ventricular tachycardia

WPW: Wolff-Parkinson-White

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> Removed the following language and reference from the Indications section for post-cardiac transplant “SE diversion not required ⁽⁴⁰⁾”
November 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1461 Cardiac PET with CT for Attenuation
July 2024	<ul style="list-style-type: none"> Formatting change Addition of clinical reasoning statement with AUC scoring described AUC scores added to bullet points Change in definition to symptomatic patients as per ACC AUC guidelines including likely and less likely anginal symptoms Calcium score – asymptomatic patient with high global risk statement added References updated WA legislative requirement added
May 2023	<ul style="list-style-type: none"> Removed time limitation “within past two years” for further evaluation inconclusive prior CAD evaluation

Date	Summary
	<ul style="list-style-type: none"> ● Added coronary stenosis of unclear significance on previous coronary angiography ● Added indication for evaluation of ischemia and nonobstructive coronary artery disease (INOCA) ● Clarified indication for PET/MPI combination study for evaluation of cardiac sarcoidosis ● Added statement on clinical indications not addressed in this guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bateman T, Dilsizian V, Beanlands R, DePuey E, Heller G. American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. *J Nucl Med.* Oct 2016; 57: 1654-1656. 10.2967/jnumed.116.180448.
2. Fazel R, Dilsizian V, Einstein A J, Ficaro E P, Henzlova M. Strategies for defining an optimal risk-benefit ratio for stress myocardial perfusion SPECT. *J Nucl Cardiol.* 2011; 18: 385-92. 10.1007/s12350-011-9353-4.
3. Schindler T H, Bateman T M, Berman D S, Chareonthaitawee P, De Blanche L E et al. Appropriate Use Criteria for PET Myocardial Perfusion Imaging. *J Nucl Med.* 2020; 61: 1221-1265. 10.2967/jnumed.120.246280.
4. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *J Am Coll Cardiol.* 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
5. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *J Am Coll Cardiol.* 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
6. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation.* 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
7. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User Manual. 2001;
8. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *J Am Coll Cardiol.* 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
9. Winchester D E, Maron D J, Blankstein R, Chang I C, Kirtane A J et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *J Cardiovasc Magn Reson.* 2023; 25: 58. 10.1186/s12968-023-00958-5.
10. Fihn S, Gardin J, Abrams J, Berra K, Blankenship J et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation.* Dec 18 2012; 126: e354-471. 10.1161/CIR.0b013e318277d6a0.
11. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J.* Oct 2013; 34: 2949-3003. 10.1093/eurheartj/eh296.
12. Budoff M, Raggi P, Beller G, Berman D, Druz R et al. Noninvasive Cardiovascular Risk Assessment of the Asymptomatic Diabetic Patient: The Imaging Council of the American College of Cardiology. *JACC Cardiovasc Imaging.* Feb 2016; 9: 176-92. 10.1016/j.jcmg.2015.11.011.
13. Gulati M, Levy P, Mukherjee D, Amsterdam E, Bhatt D et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* Nov 30 2021; 78: e187-e285. 10.1016/j.jacc.2021.07.053.

14. Patel M, Calhoun J, Dehmer G, Grantham J, Maddox T et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. May 2 2017; 69: 2212-2241. 10.1016/j.jacc.2017.02.001.
15. Guzmán A, Navarro E, Obando L, Pacheco J, Quirós K et al. Effectiveness of interventions for the reversal of a metabolic syndrome diagnosis: An update of a meta-analysis of mixed treatment comparison studies. *Biomedica*. 2019; 39: 647-662. 10.7705/biomedica.4684.
16. Brindis R G, Douglas P S, Hendel R C, Peterson E D, Wolk M J et al. ACCF/ASNC appropriateness criteria for single-photon emission computed tomography myocardial perfusion imaging (SPECT MPI): a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group and the American Society of Nuclear Cardiology endorsed by the American Heart Association. *J Am Coll Cardiol*. 2005; 46: 1587-605. 10.1016/j.jacc.2005.08.029.
17. Truong Q A, Gewirtz H. Cardiac PET-CT for monitoring medical and interventional therapy in patients with CAD: PET alone versus hybrid PET-CT?. *Curr Cardiol Rep*. 2014; 16: 460. 10.1007/s11886-013-0460-5.
18. Patel M, White R, Abbara S, Bluemke D, Herfkens R et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR appropriate utilization of cardiovascular imaging in heart failure: a joint report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. May 28 2013; 61: 2207-31. 10.1016/j.jacc.2013.02.005.
19. Heidenreich P A, Bozkurt B, Aguilar D, Allen L A, Byun J J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145: e876-e894. 10.1161/CIR.0000000000001062.
20. Xu J, Cai F, Geng C, Wang Z, Tang X. Diagnostic Performance of CMR, SPECT, and PET Imaging for the Identification of Coronary Artery Disease: A Meta-Analysis. *Front Cardiovasc Med*. 2021; 8: 621389. 10.3389/fcvm.2021.621389.
21. Al-Khatib S, Stevenson W, Ackerman M, Bryant W, Callans D et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Oct 2 2018; 72: e91-e220. 10.1016/j.jacc.2017.10.054.
22. Reiffel J, Camm A, Belardinelli L, Zeng D, Karwatowska-Prokopczuk E et al. The HARMONY Trial: Combined Ranolazine and Dronedarone in the Management of Paroxysmal Atrial Fibrillation: Mechanistic and Therapeutic Synergism. *Circ Arrhythm Electrophysiol*. Oct 2015; 8: 1048-56. 10.1161/circep.115.002856.
23. Anagnostopoulos C, Harbinson M, Kelion A, Kundley K, Loong C et al. Procedure guidelines for radionuclide myocardial perfusion imaging. *Heart (British Cardiac Society)*. 2004; 90 Suppl 1: i1-i10. 10.1136/heart.90.suppl_1.i1.
24. Gräni C, Bigler M R, Kwong R Y. Noninvasive Multimodality Imaging for the Assessment of Anomalous Coronary Artery. *Curr Cardiol Rep*. 2023; 25: 1233-1246. 10.1007/s11886-023-01948-w.
25. Evbayekha E O, Nwogwugwu E, Olawoye A, Bolaji K, Adeosun A A et al. A Comprehensive Review of Myocardial Bridging: Exploring Diagnostic and Treatment Modalities. *Cureus*. 2023; 15: e43132. 10.7759/cureus.43132.
26. McCrindle B, Rowley A, Newburger J, Burns J, Bolger A et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the

American Heart Association. *Circulation*. Apr 25 2017; 135: e927-e999. 10.1161/cir.0000000000000484.

27. Lancellotti P, Nkomo V, Badano L, Bergler-Klein J, Bogaert J et al. Expert consensus for multimodality imaging evaluation of cardiovascular complications of radiotherapy in adults: a report from the European Association of Cardiovascular Imaging and the American Society of Echocardiography. *Eur Heart J Cardiovasc Imaging*. Aug 2013; 14: 721-40. 10.1093/ehjci/jet123.

28. Birnie D, Nery P, Ha A, Beanlands R. Cardiac Sarcoidosis. *J Am Coll Cardiol*. Jul 26 2016; 68: 411-21. 10.1016/j.jacc.2016.03.605.

29. Blankstein R, Waller A. Evaluation of Known or Suspected Cardiac Sarcoidosis. *Circ Cardiovasc Imaging*. Mar 2016; 9: e000867. 10.1161/circimaging.113.000867.

30. Vita T, Okada D, Veillet-Chowdhury M, Bravo P, Mullins E et al. Complementary Value of Cardiac Magnetic Resonance Imaging and Positron Emission Tomography/Computed Tomography in the Assessment of Cardiac Sarcoidosis. *Circ Cardiovasc Imaging*. Jan 2018; 11: e007030. 10.1161/circimaging.117.007030.

31. Tersalvi G, Beltrani V, Grüber M R, Molteni A, Cristoforetti Y et al. Positron Emission Tomography in Heart Failure: From Pathophysiology to Clinical Application. *J Cardiovasc Dev Dis*. 2023; 10: 220. 10.3390/jcdd10050220.

32. Doherty J, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. Sep 26 2017; 70: 1647-1672. 10.1016/j.jacc.2017.07.732.

33. Habib G, Lancellotti P, Antunes M, Bongiorni M, Casalta J et al. 2015 ESC Guidelines for the management of infective endocarditis: The Task Force for the Management of Infective Endocarditis of the European Society of Cardiology (ESC). Endorsed by: European Association for Cardio-Thoracic Surgery (EACTS), the European Association of Nuclear Medicine (EANM). *Eur Heart J*. Nov 21 2015; 36: 3075-3128. 10.1093/eurheartj/ehv319.

34. Baddour L M, Wilson W R, Bayer A S, Fowler V G J, Tleyjeh I M et al. Infective Endocarditis in Adults: Diagnosis, Antimicrobial Therapy, and Management of Complications: A Scientific Statement for Healthcare Professionals From the American Heart Association. *Circulation*. 2015; 132: 1435-86. 10.1161/CIR.0000000000000296.

35. Isselbacher E, Preventza O, Hamilton Black J 3, Augoustides J, Beck A et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. Dec 13 2022; 146: e334-e482. 10.1161/cir.0000000000001106.

36. Kristensen S, Knutti J, Saraste A, Anker S, Bøtker H et al. 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management: The Joint Task Force on non-cardiac surgery: cardiovascular assessment and management of the European Society of Cardiology (ESC) and the European Society of Anaesthesiology (ESA). *Eur Heart J*. Sep 14 2014; 35: 2383-431. 10.1093/eurheartj/ehu282.

37. Fleisher L, Fleischmann K, Auerbach A, Barnason S, Beckman J et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *J Am Coll Cardiol*. Dec 09 2014; 64: e77-137. 10.1016/j.jacc.2014.07.944.

38. Velasco A, Reyes E, Hage F. Guidelines in review: Comparison of the 2014 ACC/AHA guidelines on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery and the 2014 ESC/ESA guidelines on noncardiac surgery: Cardiovascular assessment and management. *J Nucl Cardiol*. 02 2017; 24: 165-170. 10.1007/s12350-016-0643-8.

39. Lentine K, Costa S, Weir M, Robb J, Fleisher L et al. Cardiac disease evaluation and management among kidney and liver transplantation candidates: a scientific statement from the American Heart Association and the American College of Cardiology Foundation. *J Am Coll Cardiol*. Jul 31 2012; 60: 434-80. 10.1016/j.jacc.2012.05.008.
40. Washington State Health Care Authority. WSHCA Health Technology Clinical Committee: 20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease. [Final Adoption: March 18, 2022]. 2022; <https://www.hca.wa.gov/assets/program/noninvasive-cardiac-imaging-final-findings-and-decision-2022-03-18.pdf>.
41. Fazel R, Dilsizian V, Einstein A, Ficaro E, Henzlova M. Strategies for defining an optimal risk-benefit ratio for stress myocardial perfusion SPECT. *J Nucl Cardiol*. May 2011; 18: 385-92. 10.1007/s12350-011-9353-4.
42. Wolk M J, Bailey S R, Doherty J U, Douglas P S, Hendel R C et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2014; 63: 380-406. 10.1016/j.jacc.2013.11.009.
43. Diamond G A, Forrester J S. Analysis of probability as an aid in the clinical diagnosis of coronary-artery disease. *N Engl J Med*. 1979; 300: 1350-8. 10.1056/NEJM197906143002402.
44. Shen W, Sheldon R, Benditt D, Cohen M, Forman D et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Aug 1 2017; 70: 620-663. 10.1016/j.jacc.2017.03.002.
45. Shaw L J, Peterson E D, Shaw L K, Kesler K L, DeLong E R et al. Use of a prognostic treadmill score in identifying diagnostic coronary disease subgroups. *Circulation*. 1998; 98: 1622-30. 10.1161/01.cir.98.16.1622.
46. Arnett D, Blumenthal R, Albert M, Buroker A, Goldberger Z et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. Sep 10 2019; 74: e177-e232. 10.1016/j.jacc.2019.03.010.
47. D'Agostino R S, Vasan R, Pencina M, Wolf P, Cobain M et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation*. Feb 12 2008; 117: 743-53. 10.1161/circulationaha.107.699579.
48. Goff D J, Lloyd-Jones D, Bennett G, Coady S, D'Agostino R S et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. Jul 1 2014; 63: 2935-2959. 10.1016/j.jacc.2013.11.005.
49. McClelland R, Jorgensen N, Budoff M, Blaha M, Post W et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *J Am Coll Cardiol*. Oct 13 2015; 66: 1643-53. 10.1016/j.jacc.2015.08.035.
50. Ridker P, Buring J, Rifai N, Cook N. Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *Jama*. Feb 14 2007; 297: 611-9. 10.1001/jama.297.6.611.
51. Lotfi A, Davies J, Fearon W, Grines C, Kern M. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society



of cardiac angiography and interventions. Catheter Cardiovasc Interv. Aug 1 2018; 92: 336-347.
10.1002/ccd.27672.



Evolut Clinical Guideline 7299 for Hemodialysis Access Creation

Guideline Number: Evolut_CG_7299	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Hemodialysis Access Creation.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

- Hemodialysis access can be achieved via a central venous catheter (CVC) or via creation of an arteriovenous fistula (AVF) or arteriovenous graft (AVG). For the most part, CVC(s) should be regarded as temporary procedures and avoided whenever possible. Except in rare circumstances a CVC should always be tunneled (CVTC) (see **Definitions**).
- If there is sufficient time for permanent access to be created an AV fistula is generally preferred over an AV graft assuming suitable anatomy, local limb conditions and patient preference. The previous “fistula first” initiative is no longer appropriate.
- Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS ⁽⁶⁾

Central Venous Catheters

- Short Term indications include ANY of the following:
 - An AVF or AVG has been created but is not ready for use
 - Acute indication for hemodialysis such as acute transplant rejection
 - Peritoneal dialysis patients requiring a time limited period of rest or resolution of a complication.
 - Complications of an AVF or AVG that result in temporary non-use until the problem is resolved
 - Living donor confirmed within the next 90 days but dialysis required in the interim
- Long term indications include ANY of the following:
 - Multiple prior failed AV access with no available options
 - Limited life expectancy
 - Valid patient preference whereby use of an AV access will severely limit quality of life or achievement of life goals, and after the patient has been properly informed of patient specific risks and benefits of other potential and reasonable access options for that patient (if available)
 - Absence of an AV access creation option due to severe arterial inflow disease or outflow venous obstruction, or adverse local limb conditions
 - Diminutive patients or children with prohibitively small vessels

AV Fistula or AV Graft

- Dialysis-dependent renal failure expected to be of long-term duration

Limitations

- A CDC should not be inserted if dialysis can be delayed long enough for a functional AVF or AVG to be created
- An AVF should not be created in a terminally ill patient with life expectancy of less than 6 months unless specifically requested by the patient

CODING AND STANDARDS

Coding

CPT Codes

36005, 36010, 36011, 36800, 36810, 36815, 36818, 36819, 36820, 36821, 36825, 36830, 36835, 36836, 36837, 75820, 75822

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Hemodialysis is a process of purifying the blood of a person whose kidneys are not working normally (renal failure). Hemodialysis requires vascular access to obtain blood for purifying in the dialysis machine and then to return blood to the body. This can be achieved via a centrally placed venous catheter (CVC) or an arteriovenous (AV) fistula (AVF) or AV graft. CVC are preferably tunneled from the insertion site to another site from which it is inserted into a central vein (Central vein tunneled catheter (CVTC))

An **arteriovenous fistula (AV fistula)** is a surgical or endovenous (minimally invasive radiologic) procedure where a vein is connected to an artery. This artificial connection allows the vein to become larger and for the walls of the vein to thicken, a process termed maturation. A mature fistula makes it easier for the vein to be punctured repeatedly for dialysis. Maturation typically takes three to six months to occur. An arteriovenous fistula is the preferred type of vascular access due to lower rate of infection and clot formation, resulting in greater longevity than other types of vascular access. However, not everyone is a good candidate for an arteriovenous fistula, particularly older patients, and patients with small veins.

An **AV Graft** is considered if the patient is not a suitable candidate for an AVF. An arteriovenous graft is an artificial tubing that is surgically attached on one end to an artery, and on the other end to a vein. The tube is placed entirely under the skin. AVG are more prone to infection and clotting than AVF.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms

AV: Arteriovenous

AVF: Arteriovenous fistula

AVG: Arteriovenous graft

CPT: Customary Procedural Terminology

CVC: Central venous catheter

CVTC: Central venous tunneled catheter

endoAVF: AV fistula constructed using minimally invasive technology and X-ray visualization

PTFE: Polytetrafluoroethylene

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1165 for Hemodialysis Access Creation ● Added CPT codes 36836 and 36837 ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Lok C, Huber T, Lee T, Shenoy S, Yevzlin A et al. KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. *American Journal of Kidney Diseases*. 2020; 75: S1-S164. 10.1053/j.ajkd.2019.12.001.



Evolut Clinical Guideline 7300 for Hemodialysis Access Maintenance

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General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for hemodialysis maintenance using angiography, endovascular, or open surgical procedures.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

General Considerations

- For this Policy, the specific endovascular (e.g. angioplasty or stent) or surgical methods (e.g. interposition graft, transposition, or DRIL procedure) that may be utilized should not be considered when determining whether a procedure can be approved or denied
- Providers must involve patients in a shared decision-making process involving reason(s) for, as well as the type of procedure(s) that could be used including their potential outcomes. This process should be reflected in notes provided.

INDICATIONS FOR DIAGNOSTIC FISTULOGRAM ^(6,7)

See also **Definitions - Interventions**. Indications for diagnostic fistulogram include any of the following:

- ANY change in physical examination of the dialysis access or limb such as:
 - Decreased or absent thrill or bruit

- Increased pulsatility
- Ipsilateral limb swelling
- Development of new superficial collateral venous channels consistent with venous outflow stenosis or obstruction
- Distal steal syndrome
- Ischemic monomelic neuropathy
- Aneurysm(s) or pseudoaneurysm(s)
- Clinical evidence of high flow e.g. high output cardiac failure
- ANY abnormality encountered during dialysis such as:
 - AV access thrombosis
 - Aspiration of clots
 - Persistent or new difficulty in cannulation
 - Elevated venous pressures recorded during hemodialysis (static and dynamic pressures) or measured within the vascular access during a diagnostic study (static pressures)
 - Increased bleeding from the needle puncture sites, *usually for 3 consecutive dialysis sessions*
 - Evidence of decreased flow (Qa)
 - Inadequate dialysis
 - Low Kt/V on a constant dialysis prescription without prolongation of dialysis duration
- ANY abnormality encountered by duplex ultrasound such as:
 - Increased pulsatility
 - Decreased flow volume
 - Fistula size <3mm
 - Severe tortuosity
 - Aneurysm and pseudoaneurysm
 - Depth of the AVF or graft that would make cannulation difficult

INDICATIONS FOR THERAPEUTIC INTERVENTION ON THE AV ACCESS CIRCUIT ⁽⁶⁾

- ANY of the following
 - Autogenous fistulae that have failed to mature after 4 to 6 weeks as expected
 - Symptomatic or complicated Aneurysm(s) or Pseudo aneurysm(s) (see **Limitations**)
 - AV access infection
 - High flow complications

- Erosion of the skin overlying the AV access
- Severe tortuosity or depth of the AV access that would make cannulation difficult
- ANY finding(s) during an *indicated* diagnostic fistulogram confirming reason(s) for decreased dialysis function, steal or other access related complication(s) such as thrombosis or:
 - Anastomotic stenosis
 - At the arterial anastomosis of an AV fistula or AV graft
 - At the venous anastomosis of an AV graft
 - Proximal Inflow arterial stenosis unrelated to the arterial anastomosis
 - Venous outflow stenosis or obstruction distal to the AV fistula or AV graft
 - Intraluminal high-grade stenosis
 - Aberrant veins draining flow away from the main AV fistula
- Covered intraluminal stents can be utilized to manage AV access aneurysms or pseudoaneurysms but should be reserved for patient contraindications to surgery, lack of a surgical option, or as a temporizing measure for patients with active bleeding
- Symptoms or conditions warranting intervention on aneurysms include any of the following:
 - Pain
 - Access flow dysfunction
 - Thrombus
 - Limited cannulation sites
 - High output congestive heart failure
 - Unacceptable cosmetic disfigurement
 - Rapid enlargement

NOTE: Aneurysm size alone is likely not an indication for treatment in the absence of symptoms of threatened skin.

Limitations ⁽⁶⁾

- A diagnostic fistulogram should not be performed without new clinical findings. Routine fistulogram for “surveillance” is not appropriate
- Preemptive endovascular intervention to improve patency of an AV fistula or AV graft with stenosis, not associated with clinical indicators, is not appropriate

CODING AND STANDARDS

Coding

CPT Codes

36901, 36902, 36903, 36904, 36905, 36906, 36907, 36908, 36909, 36831, 36832, 36833, 37607

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions ⁽⁶⁾

- **Interventions on Arteriovenous (AV) dialysis graft/fistula** are intended to restore and/or maintain functional patency of the AV access circuit. However, occasionally interventions may be necessary to move, alter, add to or close the access circuit. Access related procedures encompass endovascular percutaneous or open surgical procedures. They are utilized to treat thrombotic or non-thrombotic flow-related complications or dysfunction, infection, aneurysm, or pseudoaneurysm. In most, but not all cases, a diagnostic fistulogram is performed first. If identified during the fistulogram, culprit lesion(s) should be concurrently treated by an endovascular procedure if appropriate, or soon thereafter by open or hybrid procedures. Open surgical procedures are usually reserved for recurrent stenotic lesions, aneurysms and pseudoaneurysms, AV access infections, steal, ischemic monomelic neuropathy, or difficult access due vein size, tortuosity, or depth.
- **Dialysis access circuit** is the continuing from the heart and the arterial inflow through the AV access to the venous outflow back to the heart. For coding purposes, the hemodialysis circuit is comprised of a peripheral segment and a central segment. The peripheral segment begins at the arterial anastomosis and extends to the central segment. In the upper extremity the peripheral segment extends up to and includes the axillary vein and entire cephalic vein including the cephalic arch. In the lower extremity, the peripheral segment extends up to and includes the common femoral vein. In the upper extremity, the central segment includes the subclavian and innominate veins through the superior vena cava. In the lower extremity the central segment includes the external iliac and common iliac veins through the inferior vena cava

- **Arteriovenous access** allows for dialysis and includes arteriovenous fistula (AV fistula) or arteriovenous graft (AV graft)
- **Diagnostic Fistulogram** is the diagnostic angiography of the entire AV access circuit from the arterial anastomosis through the central vena cava is performed to identify the area or areas of narrowing or occlusion that are creating flow problems for, or related to, the AV access. It is performed through the AV access or via a remote artery
- **Endovascular fistula (endoAVF)** is an autologous fistula created by endovascular techniques
- **Endovascular interventions** are procedures performed percutaneously utilizing angioplasty, stents, thrombectomy, or thrombolysis. Thrombolysis involves the use of pharmaceuticals that are infused or injected directly into the thrombosed access and which dissolve clot. Mechanical thrombectomy devices may also be utilized to percutaneously remove clots. Thrombectomy can also be performed surgically
- **Open surgical therapy** utilizes direct open access to the conduit and contiguous vessels. Residual vascular stenosis or obstructive lesions are removed and corrected using standard vascular surgical techniques. Angiography is adjunctively employed, when appropriate and medically necessary, to assess the functional integrity of afferent and efferent vessels remote from the surgical field.
- **Vessel superficialization or Transposition** is a procedure where the vessel used for dialysis needs to be moved closer to the surface or away from the neural structures for it to be safely punctured for dialysis
- **DRIL procedure** is a surgical procedure to treat steal and involve distal revascularization and interval ligation of an AV fistula or graft
- **Kt/V** is a number used to quantify hemodialysis treatment (where K = dialyzer clearance of urea, t = dialysis time, and V = volume of distribution of urea approximately equal to the patient's total body water)
- **Failure to mature** an AV fistula that cannot be used successfully for dialysis despite at least 4 weeks of observation since creation, or 6 months despite endovascular or surgical attempts to allow successful cannulation and dialysis
- **Pseudoaneurysm** implies a hole through the vessel or graft with accumulation of flowing blood outside of that vessel but contained by the surrounding tissues.
- **Aneurysm** implies dilatation of all 3 layers of a fistula, vein or artery beyond what would be normally expected following creation of a fistula. Aneurysms can develop anywhere along the course of the AV access circuit including the inflow artery, but typically occur in the outflow vein. By definition, aneurysms do not occur in grafts, but a ballooning of a collagen biologic graft should still be considered an aneurysm
- **Steal** occurs when creation of an AV access results in distal ischemic complications usually related to decreased distal blood flow. Clinically it presents as a cool extremity with few symptoms, progressing to intermittent symptoms during dialysis, limb claudication, ischemic rest pain and tissue loss. Left untreated Steal can result in limb deformity or amputation.
- **Ischemic monomelic neuropathy** is a poorly understood syndrome that occurs soon after creation of an AV access usually at the elbow. It is diagnosed by acute onset of severe forearm pain, numbness and paresthesia usually without hemodynamic evidence of ischemia and requires immediate ligation of the AV

access

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate use criteria

AV: Arteriovenous

AVF: Arteriovenous fistula

AVG: Arteriovenous graft

CVC: Central venous catheter

endoAVF: Endovascular arteriovenous fistula

ESKD: End-stage kidney disease

URR: Urea reduction ratio

Qa: Intra-access blood flow

Qb: Blood pump flow delivered to the dialyzer

UDM: ultrasound dilution method

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1339 for Hemodialysis Access Maintenance • Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee



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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Lok C, Huber T, Lee T, Shenoy S, Yevzlin A et al. KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. *American Journal of Kidney Diseases*. 2020; 75: S1-S164. 10.1053/j.ajkd.2019.12.001.
7. Higgins M C, Diamond M, Mauro D M, Kapoor B S, Steigner M L et al. ACR Appropriateness Criteria® Dialysis Fistula Malfunction. *Journal of the American College of Radiology*. 2023; 20: S382-S412. 10.1016/j.jacr.2023.08.016.

Evolut Clinical Guideline 7301-01 for Implantable Cardioverter Defibrillator

Guideline Number: Evolut_CG_7301-01	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for an implantable cardiac defibrillator (ICD). Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. All indications are predicated on a meaningful life expectancy of greater than one year if the ICD is implanted.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR ICD INSERTION

Ischemic Heart Disease (CAD) ^(6,7,8)

Primary Prevention of SCD/Prophylactic ICD Implantation

- LVEF \leq 35% due to nonischemic or ischemic heart disease and **NYHA** class II or III, despite **GDMT**, and at least 40 days post-MI (**AUC 9**)
- LVEF \leq 30% due to ischemic heart disease, **NYHA** class I, **GDMT**, and at least 40 days post-MI (**AUC 8**)
- LVEF \leq 40% with prior MI, NSVT, and inducible sustained VT or VF at electrophysiological testing

Secondary Prevention of SCD

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes (**AUC 9**)
- Syncope of undetermined origin, with inducible VF or sustained VT at electrophysiological study (**AUC 9**)
- Syncope of undetermined origin, with EF \leq 35% (**AUC 8-9**)

Nonischemic Cardiomyopathy (NICM) ⁽⁶⁾

Primary Prevention of SCD/Prophylactic ICD Implantation

- Lamin A/C gene mutation, with \geq 2 risk factors from the following: NSVT, LVEF < 45%, male sex, missense mutation
- LVEF \leq 35% and **NYHA** functional Class II or III, despite at least 3 months of **GDMT**

NOTE: LVEF \leq 35% and **NYHA** functional Class I despite at least 3 months of **GDMT** may be considered

Secondary Prevention of SCD

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes
- LVEF \leq 50% with unexplained syncope presumed to be due to VA who do not meet indications for primary prevention ICD implantation

Advanced Heart Failure & Transplantation ^(6,7,8)

- In non-hospitalized patients with **NYHA** class IV who are candidates for cardiac transplantation or left ventricular assist device (LVAD)
- In a patient with an LVAD, sustained ventricular arrhythmias
- In **NYHA** ambulatory class IV, with appropriate indications for CRT

Myocardial Diseases

Hypertrophic Cardiomyopathy (HCM) ^(6,8,9,10,11)

- Previously documented cardiac arrest or sustained VT
- Adult patients with HCM with at least 1 risk factor for SCD as follows:
 - Sudden death attributable to HCM in at least 1 first-degree relative who is \leq 50 years of age
 - LVH \geq 30 mm
 - At least 1 recent (within 5 years) episode of syncope suspected by history to be arrhythmic (unlikely neurocardiogenic (vasovagal), especially occurring within 6 months of evaluation
 - LV apical aneurysm
 - LV systolic dysfunction (EF < 50%)

- Pediatric patients with HCM with at least 1 risk factor for SCD as follows:
 - Unexplained syncope
 - LVH \geq 30 mm
 - Nonsustained VT
 - Family history of HCM-related SCD

Cardiac Sarcoidosis

With one of the following ^(6,8,9):

- Cardiac arrest or documented sustained VT
- LVEF \leq 35% (**AUC 8**)
- LVEF $>$ 35% with inducible sustained VA at electrophysiological testing
- Syncope and/or scar on CMR or PET
- Requires a permanent pacemaker

Neuromuscular Disorders

Including but not limited to Duchenne, Becker, Limb-girdle type 1B, Limb-girdle type 2C-2F, Limb-girdle type 2I, Myotonic type 1, Myotonic type 2, Emery-Dreifuss, or Facioscapulohumeral Muscular Dystrophy with one of the following ^(6,8):

- Primary and secondary prevention, with same indications as for NICM
- Emery-Dreifuss or limb-girdle type I-B muscular dystrophy with progressive cardiac involvement

Arrhythmogenic Right Ventricular Cardiomyopathy

With at least one of the following risk factors for SCD ^(6,9,10):

- Resuscitated sudden cardiac arrest
- Sustained VT
- Right or left ventricular systolic dysfunction with an EF \leq 35%
- Syncope with documented or presumed ventricular arrhythmia

Channelopathies

Congenital Long QT Syndrome

With one of the following (**AUC 9**) ^(6,8,10):

- Sudden cardiac arrest
- Sustained VT or recurrent syncope when beta blocker is ineffective or not tolerated
- QTc $>$ 500 ms on a beta blocker
- Strong family history of SCD
- High risk genotype

Brugada Syndrome and Spontaneous Type 1 Brugada Echocardiographic Pattern

With one of the following (AUC 9) ^(6,8,10):

- Cardiac arrest
- Documented sustained VA
- Syncope presumed to be due to VA

Catecholaminergic Polymorphic VT

With one of the following (AUC 9) ^(6,7,10):

- Sudden cardiac arrest
- Syncope or sustained VT
- Inducible VT or VF

Early Repolarization ("J-wave Syndrome") or Short QT Syndrome

With one of the following (AUC 9) ^(6,8):

- Cardiac arrest
- Sustained VA

Idiopathic Polymorphic VT/VF ⁽⁶⁾

- Cardiac arrest due to polymorphic VT or VF

Adult & Pediatric Congenital Heart Disease (CHD) ^(6,7,8,9,11)

- Cardiac arrest due to VF or VT, or unstable VT, after exclusion of a reversible etiology
- Systemic LVEF \leq 35%, biventricular physiology, and NYHA class II or III on GDMT
- Tetralogy of Fallot with one of the following:
 - Spontaneous sustained VT
 - Inducible VF or sustained VT
 - \geq 1 risk from the following list:
 - Prior palliative systemic to pulmonary shunts
 - Unexplained syncope
 - Frequent PVCs (Premature Ventricular Contractions)
 - Atrial tachycardia
 - Left ventricular dysfunction or diastolic dysfunction
 - NSVT
 - QRS duration \geq 180 ms
 - Dilated right ventricle

- Residual pulmonary regurgitation or stenosis
- RV Hypertension
- Single or systemic RVEF < 35%, in the presence of an additional risk factor such as:
 - NSVT
 - Unexplained syncope
 - NYHA class II or III, despite GDMT
 - QRS duration ≥ 140 ms
 - Severe systemic AV valve regurgitation
- Syncope of unknown origin in the presence of either at least moderate ventricular dysfunction or marked hypertrophy or inducible sustained VT or VF
- Syncope and moderate or severe complexity CHD, with high clinical suspicion of VA
- Non-hospitalized patients with CHD awaiting heart transplant
- Left ventricular non-compaction that meets same indications as NICM, including a familial history of SCD

ICD With an Appropriate Pacing Modality in Special Situations ^(6,7,12)

NOTE: With these ICD indications, CRT would sometimes be the appropriate pacing modality. CRT is likely to be the appropriate modality with anticipated requirement for significant (> 40%) ventricular pacing

- ICD criteria met, and elevated troponin is deemed not due to a myocardial infarction
- ICD criteria met, except for myocardial infarction within 40 days or revascularization within 3 months, but a non-elective permanent pacemaker (new or replacement) is required, and recovery of left ventricular function to LVEF > 35% is uncertain or not expected *
- ICD criteria met, except NICM or ischemic cardiomyopathy has not had 3 months' time for LVEF to improve on medical therapy, a non-elective permanent pacemaker is required, and recovery of LVEF is uncertain or not expected*
- Patient met primary prevention criteria for an ICD prior to coronary revascularization, and it is unlikely that LVEF will recover to > 35% despite a 90-day wait

*** These indications avoid a second implantation procedure within less than 3 months**

CODING AND STANDARDS

Coding

CPT Codes

33216, 33217, 33230, 33231, 33240, 33249, 93640, 93641

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

The implantable cardioverter defibrillator (ICD) has become valuable in the management of patients with ventricular arrhythmias (VA) capable of causing syncope, cardiac arrest, and sudden cardiac death (SCD). An ICD system includes a pulse generator and one or more leads. ICDs are indicated both for patients who have survived life threatening rhythm disturbances (secondary prevention) and for those who are at risk for them (primary prevention).

Patient eligibility for an ICD presumes all the following:

- Anticipated reasonable quality of life for \geq 1-year post implantation
- Patient’s ability to live with a shock-delivering device that requires management
- Absence of a completely reversible cause that led to VA for which an ICD is being considered
- Completion of \geq 3 months of guideline-directed medical therapy (GDMT) for heart failure (HF), unless an intervening indication for pacemaker implantation arises
- ICD indications are present in most scenarios in which cardiac resynchronization therapy (CRT) is appropriate

Guidelines for the pediatric population are extrapolated from the adult population due to a lack of relevant trials.

NYHA Class Definitions ^(7,13)

- Class I: No limitation of functional activity. Ordinary physical activity does not cause symptoms of HF
- Class II: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF
- Class III: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF
- Class IV: Unable to continue any physical activity without symptoms of HF, or symptoms of HF at rest

Guideline Directed (or Optimal) Medical Therapy in Heart Failure ⁽¹⁴⁾

- Angiotensin converting enzyme inhibitor (ACE-I), angiotensin receptor blocker (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker

Other Options/Considerations for GDMT

- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans, NYHA class III-IV
- Addition of an aldosterone antagonist, provided eGFR is ≥ 30 ml/min/1.73m² and K⁺ < 5.0, NYHA class II-IV
- Normal serum sodium and potassium
- Not required for consideration of ICD: Ivabradine for NYHA class II – III, when a beta blocker has failed to reduce a sinus rate to < 70 bpm. Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of Ivabradine.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. ⁽³⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Acronyms/Abbreviations

ACE-I: Angiotensin converting enzyme inhibitor

ARNI: Combined angiotensin receptor inhibitor and neprilysin inhibitor

ARVD/C: Arrhythmogenic right ventricular dysplasia/cardiomyopathy

AV: Atrioventricular

CAD: Coronary artery disease, same as ischemic heart disease

CHD: Congenital heart disease

CHF: Congestive heart failure

CRT: Cardiac resynchronization therapy

CRT-D: Cardiac resynchronization therapy ICD system

DCM: Dilated cardiomyopathy

ECG: Electrocardiogram

EF: Ejection fraction

EPS: Electrophysiologic Study
 GDMT: Guideline-Directed Medical Therapy
 HCM: Hypertrophic cardiomyopathy
 HF: Heart failure
 HV: His-ventricle
 ICD: Implantable cardioverter-defibrillator
 LBBB: Left bundle-branch block
 LV: Left ventricular/left ventricle
 LVAD: Left ventricular assist device, mechanical heart
 LVEF: Left ventricular ejection fraction
 LVH: Left ventricular hypertrophy
 MI: Myocardial infarction
 ms: Milliseconds
 NICM: Nonischemic cardiomyopathy
 NSVT: Nonsustained ventricular tachycardia
 NYHA: New York Heart Association
 PET: Positron emission tomography
 PVC: Premature Ventricular Contraction
 RV: Right ventricular/right ventricle
 RVEF: Right ventricular ejection fraction
 SCD: Sudden Cardiac Death
 STEMI: ST-elevation myocardial infarction
 SND: Sinus node dysfunction
 VT: Ventricular tachycardia
 VF: Ventricular fibrillation

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> <li data-bbox="531 1727 1246 1794">This guideline replaces UM Cardio 1080 Automatic Implantable Cardioverter Defibrillator (ICD)

LEGAL AND COMPLIANCE

Guideline Approval



Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483 - 1502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. 2001.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF Appropriate Use Criteria Methodology Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2013; 61: 1305 - 1317. 10.1016/j.jacc.2013.01.025.
5. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. doi:10.1016/j.jacc.2005.08.030.
6. Al-Khatib S, Stevenson W, Ackerman M, Bryant W, Callans D et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Oct 2, 2018; 72: e91-e220. 10.1016/j.jacc.2017.10.054.
7. Russo A M, Stainback R F, Bailey S R, Epstein A E, Heidenreich P A et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy. *J Am Coll Cardiol*. 2013; 61: 1318-68. 10.1016/j.jacc.2012.12.017.
8. Priori S, Blomström-Lundqvist C, Mazzanti A, Blom N, Borggrefe M et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). *Eur Heart J*. Nov 1, 2015; 36: 2793-2867. 10.1093/eurheartj/ehv316.
9. Shen W, Sheldon R, Benditt D, Cohen M, Forman D et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Aug 1, 2017; 70: e39-e110. 10.1016/j.jacc.2017.03.003.
10. Epstein A, DiMarco J, Ellenbogen K, Estes N 3, Freedman R et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation*. Jan 22, 2013; 127: e283-352. 10.1161/CIR.0b013e318276ce9b.
11. Brugada J, Blom N, Sarquella-Brugada G, Blomstrom-Lundqvist C, Deanfield J et al. Pharmacological and non-pharmacological therapy for arrhythmias in the pediatric population: EHRA and AEPC-Arrhythmia Working Group joint consensus statement. *Europace*. Sep 2013; 15: 1337-82. 10.1093/europace/eut082.
12. Kusumoto F, Calkins H, Boehmer J, Buxton A, Chung M et al. HRS/ACC/AHA expert consensus statement on the use of implantable cardioverter-defibrillator therapy in patients who are not included or not well represented in clinical trials. *Heart Rhythm*. Jul 2014; 11: 1271-303. 10.1016/j.hrthm.2014.03.041.

13. Goldman L, Hashimoto B, Cook E, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. *Circulation*. Dec 1981; 64: 1227-34. 10.1161/01.cir.64.6.1227.

14. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. May 3, 2022; 145: e876-e894. 10.1161/cir.0000000000001062.

Evolut Clinical Guideline 7303 for Interventions for Adults with Congenital Heart Defects

Guideline Number: Evolut_CG_7303	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for percutaneous and surgical therapeutic interventions for adults with congenital heart disease.

Special Note

In order to review a request for medical necessity, the following items must be submitted for review

- Progress notes from the cardiologist and (if indicated) cardiovascular surgeon
- Reports from trans-thoracic and/or trans-esophageal echocardiograms, coronary/cardiac CTA, invasive cardiac catheterization, and CMR as applicable

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Shunt Lesions

Atrial Septal Defects (ASD) ^(6,7)

This section refers only to isolated ASD and not ASD associated with complex congenital heart disease (CHD).

- Primum ASD, sinus venosus defect (SVD) or coronary sinus defect (note: due to

increased association between SVD and anomalous pulmonary venous connection (APVC), imaging to exclude APVC is necessary prior to intervention) ⁽⁸⁾:

- Surgical repair for patients with defects causing:
 - symptoms (i.e., impaired functional capacity) AND
 - right atrial and/or RV enlargement AND
 - net left-to-right shunt AND
 - hemodynamically significant shunt (pulmonary to systemic blood flow ratio (Qp:Qs) $\geq 1.5:1$) AND
 - no cyanosis at rest or during exercise AND
 - systolic pulmonary artery pressure (SPAP) $\leq \frac{2}{3}$ systolic systemic pressure and pulmonary vascular resistance (PVR) $\leq \frac{2}{3}$ systemic vascular resistance (SVR)
- Secundum ASD ^(6,7)
 - Percutaneous or surgical repair for symptomatic or asymptomatic patients with defects causing:
 - right atrial and/or RV enlargement, AND
 - net left-to-right shunt AND
 - Qp:Qs $\geq 1.5:1$ AND
 - no cyanosis at rest or during exercise AND
 - SPAP $\leq \frac{2}{3}$ systolic systemic pressure and pulmonary vascular resistance (PVR) $\leq \frac{2}{3}$ systemic vascular resistance (SVR)
- Suspected Paradoxical Embolism
 - Surgical or percutaneous closure in patients with ASD (regardless of size) and no other identified source of embolism, in the absence of pulmonary artery hypertension and left ventricular dysfunction ⁽⁶⁾

Ventricular Septal Defect (VSD) ^(6,7)

- Surgical or percutaneous closure for patients with defects causing:
 - left ventricular volume overload AND
 - Qp:Qs $\geq 1.5:1$ AND
 - net left-to-right shunt AND
 - SPAP $\leq \frac{2}{3}$ systolic systemic pressure and pulmonary vascular resistance (PVR) $\leq \frac{2}{3}$ systemic vascular resistance (SVR)
- Surgical closure with history of infective endocarditis caused by VSD
- Surgical closure of perimembranous or supracristal VSD with worsening aortic regurgitation (AR) caused by VSD

Anomalous Pulmonary Venous Connections (APVC) ⁽⁷⁾

- Partial APVC surgical repair for patients with:

- Evidence of RV volume overload AND
- Qp:Qs \geq 1.5:1 AND
- SPAP $<$ 50% systolic systemic pressure and pulmonary vascular resistance (PVR) $<$ $\frac{1}{3}$ systemic vascular resistance (SVR)
- Scimitar vein (connection of right pulmonary vein(s) to the inferior vena cava) surgical repair for patients with
 - Evidence of RV volume overload AND
 - Qp:Qs \geq 1.5:1
- Repair of partial anomalous pulmonary venous connection is recommended at the time of closure of a sinus venosus defect or ASD

Atrioventricular Septal Defect (AVSD) (6,7,9,10,11)

- Primary surgical repair of AVSD or repair of residual shunts after AVSD repair with:
 - net left-to-right shunt AND
 - Qp:Qs \geq 1.5:1 AND
 - SPAP \leq $\frac{2}{3}$ systolic systemic pressure and pulmonary vascular resistance (PVR) \leq $\frac{2}{3}$ systemic vascular resistance (SVR)
- Surgical repair for ASVD with discrete LVOT obstruction and:
 - maximum gradient of \geq 50 mmHg OR
 - gradient $<$ 50 mmHg in presence of heart failure (HF) symptoms OR
 - concomitant moderate-to-severe mitral or aortic valve regurgitation
- Surgical repair for severe left atrioventricular valve regurgitation per guideline directed indications for mitral regurgitation:
 - Acute severe MR
 - Symptomatic chronic severe MR regardless of LV systolic function
 - Asymptomatic Patients:
 - Severe MR with LV dysfunction (LVEF \leq 60% and/or LVESD \geq 40 mm)
 - Severe MR with preserved LV function (LVEF $>$ 60%, LVESD $<$ 40 mm) and
 - AF secondary to MR **or**
 - Pulmonary hypertension (SPAP at rest $>$ 50 mmHg)
 - Surgical MV **repair** can be considered in severe MR with preserved LV function (LVEF $>$ 60%, LVESD $<$ 40 mm) and
 - 95% likelihood of successful and durable repair without residual regurgitation **and**
 - Mortality $<$ 1%
 - Severe MR with preserved LV function (LVEF $>$ 60 %, LVESD $<$ 40%) but with progressive increase in LV size or decrease in LVEF on at least 3 serial imaging studies, irrespective of likelihood of successful repair

Patent Ductus Arteriosus (PDA) ^(6,7)

- Surgical or percutaneous closure for patients with PDA when:
 - left atrial or LV enlargement present and attributable to PDA AND
 - net left-to-right shunt
 - SPAP $\leq \frac{2}{3}$ systolic systemic pressure and pulmonary vascular resistance (PVR) $\leq \frac{2}{3}$ systemic vascular resistance (SVR)

Left-Sided Obstructive Lesions

Cor Triatriatum Sinister (membrane dividing left atrium) ⁽⁷⁾

- Surgical repair for patients with:
 - symptoms attributable to the obstruction OR
 - significant gradient (e.g., mean gradient ≥ 8 mmHg) across the membrane

Congenital Mitral Stenosis (MS) ⁽⁹⁾

- Surgical valve replacement for patients with symptomatic severe MS (mitral valve area (MVA) ≤ 1.5 cm²)

Subaortic Stenosis ^(6,7)

- Surgical repair for patients with:
 - symptoms attributable to the obstruction and maximum gradient ≥ 50 mmHg OR
 - symptoms/signs of heart failure (HF) or ischemia with maximum gradient < 50 mmHg OR
 - asymptomatic with a maximum gradient ≥ 50 mmHg and at least mild aortic regurgitation (to prevent progression of AR)

Valvular Aortic Stenosis (AS) ^(7 9)

Note: Includes bicuspid aortic valve (BAV), unicuspid aortic valve and hypoplastic aortic annulus and intervention may require annular enlargement and other surgical techniques not typically used in valvular aortic stenosis.

See **Definitions** section for information on AS severity based on valve hemodynamics.

- Aortic valve replacement (or balloon valvuloplasty for noncalcified BAV stenosis with \leq mild aortic regurgitation) for patients with:
 - Symptomatic severe high-gradient AS (see Definitions section)
 - Symptomatic low-flow, low gradient severe AS with reduced left ventricular ejection fraction (LVEF, $< 50\%$)
 - Symptomatic low-flow, low-gradient severe AS with normal LVEF ($\geq 50\%$) if AS is most likely cause of symptoms
 - Asymptomatic severe AS with LVEF $< 50\%$
 - Apparently asymptomatic severe AS and low surgical risk when exercise treadmill test demonstrates decreased exercise capacity or a ≥ 10 mm Hg fall in

systolic blood pressure from baseline to peak exercise

- Apparently asymptomatic severe AS with low surgical risk (see Definitions sections) and B-type natriuretic protein (BNP) > 3 times normal
- Asymptomatic high-gradient severe AS with low surgical risk when serial testing shows an increase in aortic velocity ≥ 0.3 m/s per year
- Asymptomatic high-gradient severe AS and progressive decrease in LVEF to <60% on at least 3 serial imaging studies
- Asymptomatic with very severe AS and low surgical risk
 - Asymptomatic moderate or severe AS undergoing cardiac surgery for other indications

Supravalvular Aortic Stenosis ^(6,7)

- Surgical repair for patients with:
 - symptoms or decreased LV systolic function secondary to aortic obstruction
- Coronary artery revascularization for patients with:
 - symptoms and coronary ostial stenosis

Turner Syndrome ^(7,12)

- Prophylactic replacement of the aortic root or ascending aorta in patients who are:
 - asymptomatic with aortic size index (ASI) is ≥ 2.5 cm/m²
- in pregnancy, a rapid increase in diameter (>3 mm) justifies intervention prior to delivery

Coarctation of the Aorta ^(6,7)

- Surgical or percutaneous repair for patients with hypertension and significant native or recurring coarctation as defined by:
 - ≥ 20 mmHg peak-peak gradient between upper and lower extremities by invasive measurement OR
 - $\geq 50\%$ stenosis relative to the aortic diameter at the diaphragm

Right-Sided Lesions

Valvular Pulmonary Stenosis (PS) ^(6,7)

(see **Definitions** section)

- Balloon valvuloplasty (with surgical repair if balloon valvuloplasty has failed or is not feasible) for:
 - \geq Moderate PS and
 - otherwise unexplained symptoms of HF OR
 - cyanosis from interatrial right-to-left communication OR
 - exercise intolerance

- Percutaneous or surgical repair
 - Asymptomatic severe PS

Pulmonary Regurgitation (PR) After Repair of PS ⁽⁷⁾

- Symptomatic patients with:
 - ≥ moderate PR AND
 - right ventricular (RV) dilation/dysfunction
- Asymptomatic patients with:
 - ≥ moderate PR AND
 - progressive RV dilatation/dysfunction

Branch and Peripheral Pulmonary Artery Stenosis ^(6,7)

- Percutaneous dilatation and stenting for patients with ANY of the following:
 - symptoms of reduced pulmonary blood flow (i.e., dyspnea, reduced functional capacity)
 - >50% stenosis
 - reduced lung perfusion
 - right ventricular systolic pressure (RVSP) > 50 mm Hg

Double-Chamber Right Ventricle ⁽⁷⁾

- Surgical repair for patients with:
 - ≥ moderate outflow obstruction (see Definitions section) AND otherwise unexplained symptoms of HF, cyanosis, or exercise limitation
 - severe outflow obstruction (including asymptomatic patients)

Ebstein Anomaly ^(6,7)

- Surgical repair of tricuspid valve (TV) for patients with severe TR and one or more of the following:
 - HF symptoms
 - objective evidence of worsening exercise capacity
 - progressive RV dilatation or reduction of systolic function
 - systemic desaturation from right-to-left atrial shunt
 - paradoxical embolism
 - atrial tachyarrhythmias
- Electrophysiological (EP) study with catheter ablation (as needed) for patients with:
 - symptomatic arrhythmias
 - ventricular preexcitation without supraventricular tachycardia (SVT)
 - high-risk pathway conduction

- multiple accessory pathways
- prior to planned TV surgical repair (even in the absence of preexcitation or SVT)

Tetralogy of Fallot (TOF) ^(6,7,13)

- Surgical or percutaneous pulmonary valve replacement for repaired TOF and:
 - ≥ moderate PR with cardiovascular symptoms (i.e. dyspnea, chest discomfort, and/or exercise intolerance) not otherwise explained
 - asymptomatic patients with ≥ moderate PR and ventricular tachyarrhythmias
 - asymptomatic patients with ≥ moderate PR with other lesions requiring surgical intervention
 - asymptomatic patients with ≥ moderate PR and ≥2 of the following:
 - mild or moderate LV or RV systolic dysfunction
 - LVEF <55% and/or RVEF <47%
 - severe RV enlargement
 - Right ventricular end diastolic volume index (RVEDVi) >150 ml/m² OR
 - Right ventricular end systolic volume index (RVESVi) >80 ml/m²
 - QRS duration on electrocardiogram (ECG) >160 ms
 - SPAP ≥²/₃ systemic pressure due to right ventricular outflow tract (RVOT) obstruction
 - severe AR
 - ≥ moderate TR
 - severe branch pulmonary artery stenosis
 - large RVOT aneurysm

Right Ventricle (RV) to Pulmonary Artery (PA) Conduit Intervention ⁽⁷⁾

Includes percutaneous conduit stenting or surgical replacement, and/or transcatheter valve replacement (TPVR) for failing RV to PA conduit in patients with:

- ≥ moderate conduit regurgitation and/or stenosis (see Definitions section) AND
 - reduced exercise capacity OR
 - arrhythmias
- Asymptomatic patients with severe conduit stenosis and/or regurgitation AND
 - Reduced RV function OR
 - RV dilatation

Complex Lesions

Transposition of the Great Arteries (TGA or d-TGA) ⁽⁶⁾

- Following atrial switch procedure, **percutaneous intervention** for:

- Asymptomatic or symptomatic patients with baffle stenosis
- patients with baffle leaks AND
 - cyanosis at rest or with exercise OR
 - strong suspicion of paradoxical emboli OR
 - left to right shunt associated with symptoms or signs (e.g., ventricular volume overload) OR
 - prior to placement of pacemaker (PM) or implantable cardioverter defibrillator (ICD)
- Following atrial switch procedure, **surgical intervention** for:
 - symptomatic patients with pulmonary venous atrial obstruction (catheter intervention rarely possible) OR
 - symptomatic patients with baffle stenosis not amenable to catheter intervention (surgical intervention not indicated for asymptomatic patients with baffle stenosis) OR
 - symptomatic patients with baffle leaks not amenable to percutaneous intervention OR
 - tricuspid valve repair or replacement for severe tricuspid regurgitation (TR) without ventricular systolic dysfunction (EF >40%), regardless of symptoms

Congenitally Corrected Transposition of the Great Arteries (ccTGA) (6,7)

- Tricuspid valve replacement for patients with ccTGA and:
 - Symptomatic with severe (TR) and preserved or mildly depressed systemic ventricular function (EF ≤ 40%) OR
 - Asymptomatic severe TR and dilatation or mild dysfunction of the systemic ventricle

Intervention Following Fontan Surgery

- Catheter ablation for intra-atrial reentrant tachycardia or focal atrial tachycardia
 - Fontan revision surgery, and arrhythmia surgery as indicated, in patients with atrio-pulmonary connections and recurrent atrial tachyarrhythmias refractory to pharmacological and catheter ablation in patients with:
 - normal ventricular function OR
 - severe atrial dilatation
- Reoperation or intervention for repair of structural or anatomic abnormalities in patients with:
 - symptoms (i.e., exercise limitation) or with failure of Fontan circulation

Coronary Artery Anomalies (6,7)

- Surgical intervention for patients with:
 - left coronary artery originating from the right sinus

- with or without symptoms or signs of ischemia
- right coronary artery originating from the left sinus
 - with symptoms of ischemia OR
 - with ventricular arrhythmias
- left coronary artery originating from the pulmonary artery
 - with or without symptoms or signs of ischemia
- right coronary artery originating from the pulmonary artery
 - with symptoms attributed to the anomalous artery OR
 - with ventricular dysfunction or myocardial ischemia attributed to the anomalous artery
- coronary artery fistula
 - surgical repair or embolization as determined by knowledgeable team

CODING AND STANDARDS

Coding

CPT Codes

33414, 33415, 33416, 33417, 33470, 33471, 33474, 33475, 33476, 33477, 33478, 33500, 33501, 33502, 33503, 33504, 33505, 33506, 33507, 33641, 33645, 33647, 33660, 33665, 33670, 33675, 33676, 33677, 33681, 33684, 33724, 33726, 33730, 33732, 33820, 33822, 33824, 33840, 33845, 33881, 33917, 33920, 33922, 33924, 33925, 33926, 37236, 37237, 92986, 92990, 93580, 93581, 93582

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Hemodynamically significant shunt ⁽⁷⁾

- Pulmonary-systemic blood flow ratio (Qp:Qs) ≥1.5:1

- Chamber enlargement distal to shunt

Aortic Stenosis (AS) ⁽⁹⁾

- Severity
 - Severe AS: aortic peak velocity (V_{max}) ≥ 4 meters/second or mean gradient ≥ 40 mm Hg. Aortic valve area (AVA) typically is ≤ 1.0 cm² (or valve index (AVAI) 0.6 cm²/m²) but not required to define severe AS ⁽⁶⁾
 - Very severe AS: aortic $V_{max} \geq 5$ m/s or mean gradient ≥ 60 mm Hg ⁽⁶⁾
 - Low flow/low gradient severe AS: defined by a mismatch between reduced aortic valve area (AVA, < 1 cm²) and a non-severe increase mean valve pressure gradient (i.e., < 40 mmHg) with an impaired left ventricular stroke volume (volume of blood pumped by the heart with each beat, similar to LVEF) at rest. This creates a diagnostic and therapeutic dilemma: choosing between aortic valve replacement (AVR) and medical therapy vs optimal medical therapy alone. Low dose dobutamine stress echo (DSE) is recommended as a means of increasing stroke volume with a simultaneous reassessment of aortic valve indices. **Flow reserve** is defined as a 20% increase in stroke volume demonstrated by DSE. DSE can yield three possible results in this situation:
 - Truly severe AS: significant increase in stroke volume (i.e. flow reserve is demonstrated) and mean valve gradient (> 40 mmHg). Aortic valve is severely stenotic, and the low gradient measured at rest is a consequence of the LV contractile dysfunction.
 - Pseudo-severe AS: significant increase in stroke volume and persistent low mean valve gradient (< 40 mmHg) and AS does not meet the hemodynamic criteria to be defined as severe.
 - Undetermined AS severity: Absence of significant increase in stroke volume and mean valve gradient (< 40 mmHg): In this case, DSE fails to demonstrate an increase in stroke volume (lack of flow reserve) and the AS severity grade remains undetermined. In this situation clinicians have to rely on the morphologic features of the valve on imaging (such as cardiac CT). ⁽¹³⁾
- Moderate AS: aortic V_{max} 3.0-3.9 m/s or mean gradient 20-39 mm Hg

STS-PROM (Society of Thoracic Surgeons predicted risk of surgical mortality) ^(9, 14)

- Low risk: STS score $< 3\%$
- Intermediate: 3 to 8%
- High: STS score $> 8\%$ to $< 15\%$
- Extreme: $\geq 15\%$

STS Risk Calculator **STS ACSD Operative Risk Calculator**

Severity of Right Ventricular Outflow Obstruction (including pulmonary valve stenosis) ⁽⁷⁾

- Mild: peak gradient (PG) < 36 mmHg
- Moderate: PG 36-64 mmHg
- Severe PG > 64 mmHg or mean gradient (MG) > 35 mmHg

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

APVC: anomalous pulmonary venous connections

AR: aortic regurgitation

AS: aortic stenosis

ASD: atrial septal defect

AVSD: atrioventricular septal defect

BAV: bicuspid aortic valve

BNP: B-type natriuretic protein

ccTGA: congenitally corrected transposition of the great arteries

CHD: congenital heart disease

ECG: electrocardiogram

HF: heart failure

ICD: implantable cardioverter defibrillator

LV: left ventricle

LVEF: left ventricular ejection fraction

MG: mean gradient

MS: mitral stenosis

PA: pulmonary artery

PG: peak gradient

PDA: patent ductus arteriosus

PM: pacemaker

PR: pulmonic regurgitation

PS: pulmonic stenosis

PVR: pulmonary vascular resistance

RV: right ventricle

RVEDVi: right ventricular end diastolic volume index

RVESVi: right ventricular end systolic volume index

RVOT: right ventricular outflow tract

RVSP: right ventricular systolic pressure
 SPAP: systolic pulmonary artery pressure
 SVD: sinus venosus defect
 SVR: systemic vascular resistance
 SVT: supraventricular tachycardia
 TGA: transposition of the great arteries
 TOF: Tetralogy of Fallot
 TPVR: transcatheter pulmonary valve replacement
 TR: Tricuspid regurgitation
 TV: tricuspid valve
 VSD: ventricular septal defect

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM 1418 Interventions for Adults with Congenital Heart Defects ● Added suspected paradoxical embolism as indication for ASD repair ● Added indication for VSD repair related to endocarditis, worsening aortic regurgitation related to the VSD ● Added indication for repair of subaortic stenosis to prevent worsening of aortic regurgitation ● Added indication for coronary revascularization in symptomatic patients with supraaortic stenosis and ostial coronary artery stenosis ● Added indications for intervention in patients with Turner syndrome ● Added indication for intervention in coarctation of aorta for stenosis $\geq 50\%$ at diaphragm ● Added indications for intervention in asymptomatic patients with severe pulmonary valve stenosis ● Added indications for intervention for Ebstein anomaly related to the presence of shunting, paradoxical embolism and arrhythmia ● Added indications for pulmonary valve replacement in tetralogy of Fallot related to the presence of ventricular arrhythmia, ECG abnormalities, significant disease involving other cardiac valves, branch pulmonary stenosis and RVOT

	<p>aneurysm</p> <ul style="list-style-type: none"> ● Added indications for intervention for RV to PA conduit dysfunction ● Added section on intervention for sequelae related to prior surgical procedures (TGA repair and Fontan palliation) ● Added indication for intervention for coronary fistulae ● Added definitions and abbreviations
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LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Baumgartner H, De Backer J, Babu-Narayan S, Budts W, Chessa M et al. 2020 ESC Guidelines for the management of adult congenital heart disease: The Task Force for the management of adult congenital heart disease of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Adult Congenital Heart Disease (ISACHD). *Eur Heart J*. 2021; 42: 563 - 645. 10.1093/eurheartj/ehaa554.
7. Stout K, Daniels C, Aboulhosn J, Bozkurt B, Broberg C et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2019; 73: e81 - e192. <https://doi.org/10.1016/j.jacc.2018.08.1029>.
8. Pascoe RD, Oh JK, Warnes CA, Danielson GK, Tajik AJ, Seward JB. Diagnosis of sinus venosus atrial septal defect with transesophageal echocardiography. *Circulation*. 1996 Sep 1;94(5):1049-55. doi: 10.1161/01.cir.94.5.1049. PMID: 8790045
9. Otto C M, Nishimura R A, Bonow R O et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. *Journal of the American College of Cardiology*. 2021; 77: e25-e197.
10. Bonow R, O'Gara P, Adams D, Badhwar V, Bavaria J et al. 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. *Journal of the American College of Cardiology*. 2020; 75: 2236 - 2270. <https://doi.org/10.1016/j.jacc.2020.02.005>.
11. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease: Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2022; 43: 561 - 632. 10.1093/eurheartj/ehab395.
12. Silberbach M, Roos-Hesselink J W, Anderson N H et al. Cardiovascular health in Turner Syndrome: A scientific Statement from the American Heart Association. *Circ Genom Precis med*. 2018; 11 (10): e000048.
13. Moore J, Trivedi M, Samad S et al. Clinical Practice Algorithm For the Follow-Up of Unrepaired and Repaired Tetralogy of Fallot. *American College of Cardiology*. 2024; <https://www.acc.org/latest-in-cardiology/articles/2024/10/30/13/20/clinical-practice-algorithm-for-the-follow-up-of-unrepaired-and-repaired-tof>

14. Bonow R, Brown A, Gillam L et al. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients with Severe Aortic Stenosis. *Journal of the American College of Cardiology*. 2017; 70(20).



Evolut Clinical Guideline 7304 for Intra Cardiac Echocardiography (ICE)

Guideline Number: Evolut_CG_7304	<u>Applicable Codes</u>	
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Original Date: June 2019	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Intracardiac Echocardiography (ICE).

Special Note

In order to review a request for medical necessity, the following items must be submitted for review:

- Cardiologist or Electrophysiologist note that prompted request

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Intracardiac echocardiography (ICE) is indicated for:

- ICE is the preferred imaging modality during percutaneous closure of patent foramen ovale (PFO) or atrial septal defect (ASD) **(AUC Score 8)** ⁽⁶⁾
- Intraprocedural guidance for a left atrial appendage occlusion device **(AUC Score 6)** ⁽⁶⁾
- Preprocedural screening before intracardiac percutaneous interventions to detect emboli that may become dislodged during the procedure ⁽⁷⁾
- As an alternative imaging module when TEE is infeasible ^(8,9) or conscious sedation is

desired ⁽⁹⁾

- **Other medically appropriate applications of ICE may also include:**
- Transseptal puncture and catheterization ^(10,11,12)
- Endomyocardial biopsy ^(10,11,12)
- Mitral and aortic valvuloplasty ^(10,11,12)
- Ablation of atrial ⁽¹⁰⁾ or ventricular ⁽¹¹⁾ arrhythmias
- For positioning of left atrial appendage occlusive devices ^(10,11,12)

CODING AND STANDARDS

Coding

CPT Codes

93662

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Intracardiac echocardiography (ICE) is a unique imaging modality able to provide high-resolution real time visualization of cardiac structures, continuous monitoring of catheter location within the heart, and early recognition of procedural complications, such as pericardial effusion or thrombus formation.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6

- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ASD: Atrial septal defect

AUC: Appropriate use criteria

ICE: Intra cardiac echocardiography

PFD: Patent foramen ovale

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1358 for Intra Cardiac Echocardiography (ICE)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Doherty J, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease. *Journal of the American Society of Echocardiography*. 2019; 32: 553-579. 10.1016/j.echo.2019.01.008.
7. Saric M, Armour A, Arnaout M, Chaudhry F, Grimm R et al. Guidelines for the Use of Echocardiography in the Evaluation of a Cardiac Source of Embolism. *Journal of the American Society of Echocardiography*. 2016; 29: 1-42. 10.1016/j.echo.2015.09.011.
8. Otto C, Kumbhani D, Alexander K, Calhoun J, Desai M et al. 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis. *Journal of the American College of Cardiology*. 2017; 69: 1313-1346. 10.1016/j.jacc.2016.12.006.
9. Wunderlich N, Beigel R, Ho S, Nietlispach F, Cheng R et al. Imaging for Mitral Interventions. *JACC: Cardiovascular Imaging*. 2018; 11: 872-901. 10.1016/j.jcmg.2018.02.024.
10. Silvestry F, Kerber R, Brook M, Carroll J, Eberman K et al. Echocardiography-Guided Interventions. *Journal of the American Society of Echocardiography*. 2009; 22: 213-231. 10.1016/j.echo.2008.12.013.
11. Enriquez A, Saenz L, Rosso R, Silvestry F, Callans D et al. Use of Intracardiac Echocardiography in Interventional Cardiology. *Circulation*. 2018; 137: 2278-2294. 10.1161/CIRCULATIONAHA.117.031343.
12. Alkhouli M, Hijazi Z, Holmes D, Rihal C, Wiegers S. Intracardiac Echocardiography in Structural Heart Disease Interventions. *JACC: Cardiovascular Interventions*. 2018; 11: 2133-2147. 10.1016/j.jcin.2018.06.056.



Evolut Clinical Guideline 7305 for Introduction of Inferior Vena Cava Filter Device

Guideline Number: Evolut_CG_7305	<u>Applicable Codes</u>	
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Original Date: September 2011	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for introduction and removal of Inferior Vena Cava (IVC) Filter Device.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR INFERIOR VENA CAVA FILTER DEVICE

- Presence of DVT or PE with any of the following conditions:
 - Failure or major complication of anticoagulation, or contraindication to anticoagulation ^(6,7)
 - Recurrent PE despite anticoagulation ⁽⁶⁾
 - Poor compliance with anticoagulation ⁽⁸⁾
 - Massive PE with residual DVT in a patient at risk for further PE ⁽⁸⁾
 - PE and limited cardiac reserve
- For patients at high risk of developing a clinically significant procedure-related PE
 - Prophylactic in patients with severe trauma, spinal cord injury, or paraplegia ⁽⁶⁾
 - As prophylaxis before surgery (in patients with DVT) ⁽⁷⁾

- Protection during DVT thrombolysis ^(6,7)

*Indications for removal and repositioning of IVC filter needs to be documented in provider notes

LIMITATIONS FOR INFERIOR VENA CAVA FILTER DEVICE

- Absolute contraindications for Insertion of IVC filter:
 - Lack of access into IVC
- Relative contraindications for Insertion of IVC filter:
 - Bleeding Diathesis
 - Total thrombosis of IVC
 - Bacteremia, sepsis, or both
 - Caval diameter less than 15 mm

CODING AND STANDARDS

Coding

CPT Codes

37191, 37192, 37193

Place of Service Codes

Inpatient hospital (21)

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

An inferior vena cava filter, also IVC filter is a type of vascular filter. This device is implanted into the inferior vena cava to prevent fatal pulmonary emboli.

Placing a filter in the inferior vena cava (IVC) is an important way to prevent significant pulmonary embolism (PE) arising from a deep vein thrombosis (DVT). This procedure is currently performed under radiological guidance via femoral vein or jugular vein access.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

DVT: Deep vein thrombosis

IVC: Inferior vena cava

PE: Pulmonary embolism

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none">● This guideline replaces UM CARDIO_1168 Introduction of Inferior Vena Cava Filter Device

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001 Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Minocha J, Smith A M, Kapoor B S, Fidelman N, Cain T R et al. ACR Appropriateness Criteria® Radiologic Management of Venous Thromboembolism-Inferior Vena Cava Filters. *Journal of the American College of Radiology*. 2019; 16: S214-S226.
7. Kaufman J A, Barnes G D, Chaer R A, Cuschieri J, Eberhardt R T et al. Society of Interventional Radiology Clinical Practice Guideline for Inferior Vena Cava Filters in the Treatment of Patients with Venous Thromboembolic Disease: Developed in collaboration with the American College of Cardiology, American College of Chest Physicians, American College of Surgeons Committee on Trauma, American Heart Association, Society for Vascular Surgery, and Society for Vascular Medicine. *Journal of vascular and interventional radiology*. 2020; 31: 1529-1544.
8. DeYoung E, Minocha J. Inferior Vena Cava Filters: Guidelines, Best Practice, and Expanding Indications. *Seminars in interventional radiology*. 2016; 33: 65-70.



Evolut Clinical Guideline 7309 for Microvolt T-Wave Alternans

Guideline Number: Evolut_CG_7309	<u>Applicable Codes</u>	
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Original Date: August 2011	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Microvolt T-Wave Alternans testing.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR MICROVOLT T-WAVE ALTERNANS

The non-invasive Microvolt T-Wave Alternans is not recommended for risk stratification of patients with ventricular arrhythmias or who are at risk for developing life threatening arrhythmias. ⁽⁶⁾ Data on the use of Microvolt T-Wave Alternans is inconclusive and not routinely used in clinical practice. ⁽⁷⁾

CODING AND STANDARDS

Coding

CPT Codes

93025

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- Electrocardiogram (ECG): is a recording of the heart’s electrical activity to review the electrical conduction system of the heart
- Sudden Cardiac Death (SCD): sudden or unexpected death due to a cardiovascular cause and occurs within an hour of onset of symptoms
- Ventricular Arrhythmias: abnormal heart rhythm affecting the ventricular chambers of the heart
 - Premature Ventricular Complexes (PVCs)
 - Nonsustained Ventricular Tachycardia (NSVT)
 - Ventricular Tachycardia (VT)
 - Torsades de pointes
 - Ventricular Flutter
 - Ventricular Fibrillation

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ECG: Electrocardiogram

MTWA: Microvolt T-Wave Alternans

NSVT: Nonsustained Ventricular Tachycardia

PVC: Premature Atrial Contractions

SCD: Sudden Cardiac Death

VT: Ventricular Tachycardia

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> <li data-bbox="555 636 1321 696">• This guideline replaces UM CARDIO_1158 Microvolt T-Wave Alternans

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Priori S G, Blomström-Lundqvist C, Mazzanti A, Blom N, Borggrefe M et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). *European heart journal*. 2015; 36: 2793-2867.
7. Al-Khatib S M, Stevenson W G, Ackerman M J, Bryant W J, Callans D J et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*. 2018; 72: e91-e220.



Evolut Clinical Guideline 7310 for Mitral Valve Surgery

Guideline Number: Evolut_CG_7310	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Mitral Valve Surgery, which includes open-procedure repair or replacement of a mitral valve.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR MITRAL VALVE REPAIR OR REPLACEMENT

Mitral Regurgitation (MR)

Primary MR

- Acute severe MR ⁽⁶⁾
- Symptomatic chronic severe MR regardless of LV systolic function ⁽⁶⁾
- Asymptomatic Patients ^(6,7,8)
 - Severe MR with LV dysfunction (LVEF \leq 60% and/or LVESD \geq 40 mm)
 - Severe MR with preserved LV function (LVEF $>$ 60%, LVESD $<$ 40 mm) and
 - Atrial fibrillation (AF) secondary to MR **or**
 - Pulmonary hypertension (SPAP at rest $>$ 50 mmHg)

- Surgical MV **repair** can be considered in severe MR with preserved LV function (LVEF >60%, LVESD <40 mm) and
 - > 95% likelihood of successful and durable repair without residual regurgitation **and**
 - Mortality < 1%
- Severe MR with preserved LV function (LVEF >60 %, LVESD <40%) but with progressive increase in LV size or decrease in LVEF on at least 3 serial imaging studies, irrespective of likelihood of successful repair

Secondary MR ^(6,8)

Chronic secondary mitral regurgitation typically develops because of LV systolic dysfunction. Therefore, GDMT for heart failure, including standard medication (and, as indicated, coronary revascularization and biventricular pacing) should be the foundation of treatment. Surgical or transcatheter therapies should only be contemplated in those patients who are genuinely refractory to full GDMT.

- Chronic severe MR with LV systolic dysfunction (LVEF < 50%) with persistent severe symptoms (NYHA class III or IV) despite GDMT for HF
- Chronic severe MR in patients undergoing another cardiac surgery such as CABG
- Chronic severe MR from annular dilatation with preserved LVEF (>= 50%) with persistent severe symptoms (NYHA class III or IV) despite therapy for HF and therapy for AF or other comorbidities

Mitral Stenosis (MS)

Rheumatic MS ^(6,8)

- Severely symptomatic (NYHA class III or IV) severe MS with any of the following:
 - not a candidate for Percutaneous Mitral Balloon Commissurotomy (PMBC)
 - failed previous PMBC
 - no access to PMBC
 - undergoing another cardiac surgery

Non-rheumatic (calcific) MS ⁽⁶⁾

- Intervention for severe calcific MS may be considered in severely symptomatic patients (NYHA class III or IV) only after shared decision making regarding high procedural risk (see **Background** section)

CODING AND STANDARDS

Coding

CPT Codes

33422, 33425, 33426, 33427, 33430, 33530

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Calcific Mitral Stenosis

Calcific (or degenerative) MS is a distinct condition that differs from rheumatic mitral stenosis. It results from calcification of the mitral annulus extending into the leaflet bases, causing narrowing of the annulus and rigidity of the leaflets. These patients are usually elderly and may have co-morbidities, including disease of other valves, making surgical intervention high-risk. Intervention for severe mitral annular calcification also presents technical challenges due to the difficulty in securely attaching the prosthetic valve, and the valve may further narrow the orifice. Therefore, intervention should be delayed until symptoms are severely limiting and are refractory to aggressive medical therapy.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AF: Atrial fibrillation

CABG: Coronary artery bypass graft

EF: Ejection fraction

GDMT: Guideline-directed medical therapy

HF: Heart failure

LV: Left ventricle

LVEF: Left ventricular ejection fraction

LVESD: Left ventricular end-systolic dimension

MR: Mitral regurgitation

MS: Mitral stenosis

NYHA: New York Heart Association

PMBC: Percutaneous mitral balloon commissurotomy

SPAP: Systolic pulmonary artery pressure

TEE: transesophageal echocardiogram

TTE: Transthoracic echocardiogram

TEER: transcatheter edge-to-edge repair

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM 1099 Mitral Valve Surgery ● Updated references ● Removed redundant indications ● Re-organized indications by condition

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Otto C, Nishimura R, Bonow R, Blase C, John E et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. *Journal of the American College of Cardiology*. 2021; 77: e25 - e197. 10.1016/j.jacc.2020.11.018.
7. Bonow R, O'Gara P, Adams D, Badhwar V, Bavaria J et al. 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. *Journal of the American College of Cardiology*. 2020; 75: 2236 - 2270. <https://doi.org/10.1016/j.jacc.2020.02.005>.
8. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease: Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2022; 43: 561 - 632. 10.1093/eurheartj/ehab395.



Evolut Clinical Guideline 7311-01 for Multiple Gated Acquisition Scan

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose (1,2,3,4)

Multiple-gated acquisition (MUGA) scanning uses radiolabeled red blood cells to scan right and left ventricular images in a cine loop format that is synchronized with the electrocardiogram.

A prior MUGA scan is not an indication for repeat MUGA (if another modality would be suitable, i.e., TTE).

Special Note

See legislative language for specific mandates in Washington State

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(5,6,7,8,9)

INDICATIONS FOR MULTIPLE GATED ACQUISITION (MUGA) SCAN ⁽¹⁰⁾

- To evaluate left ventricular function in a patient with coronary artery disease, valvular heart disease, myocardial disease, or congenital heart disease, in any of the following scenarios:
 - When ventricular function is required for management, and transthoracic echocardiography (TTE) or other imaging has proven inadequate ^(1,11)
 - Radionuclide ventriculography is being performed for assessment of RV function

with no prior MUGA done within the last 3 months

- In the course of treatment with cardiotoxic medication when TTE images are inadequate to evaluate left ventricular systolic function ^(1,11,12,13,14):
 - Baseline assessment prior to initiation of therapy
 - Monitoring during therapy. The frequency of testing should be left to the discretion of the ordering provider but in the absence of new abnormal findings, generally no more often than every 6 weeks while on active therapy
 - Long term surveillance after completion of therapy may be required, especially for those who have been exposed to anthracycline medication. The frequency of testing is generally every 6-12 months, or at the discretion of the provider

LEGISLATIVE LANGUAGE

Washington

20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease ⁽¹⁵⁾

Washington State Health Care Authority Technology Assessment

HTCC coverage determination:

Noninvasive cardiac imaging is a **covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage: The following noninvasive cardiac imaging technologies are **covered with conditions**:

- Stress echocardiography for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of Coronary Artery Disease (CAD), or
 - Adult patients with known CAD who have new or worsening symptoms.
- Single Positron Emission Tomography (SPECT) for:
 - Patients under the same conditions as stress echocardiography when stress echocardiography is not technically feasible or clinically appropriate.
- Positron Emission Tomography (PET) for:
 - Patients under the same conditions as SPECT, when SPECT is not technically feasible or clinically appropriate.
- Coronary Computed Tomographic Angiography (CCTA) for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of CAD, or
 - Adult patients with known CAD who have new or worsening symptoms.
- CCTA with Fractional Flow Reserve (FFR) for:
 - Patients under the same conditions as CCTA, when further investigation of functional significance of stenoses is clinically indicated.

Non-covered indicators:

N/A

Notes:

- Out of scope/data not reviewed for this decision:
 - Asymptomatic individuals, follow up of prior abnormal cardiac imaging studies, myocardial viability, preoperative evaluation
 - Patients presenting for evaluation of cardiac pathologies other than CAD
- This determination supersedes the following previous determinations:
 - Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease (20081114A)
 - Cardiac Nuclear Imaging (20130920A)

CODING AND STANDARDS

Coding

CPT Codes

78472, 78473, 78494, +78496, A9560/A9512

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

The two types of radionuclide studies commonly used for cardiac evaluation are myocardial perfusion imaging and ventriculography. Myocardial perfusion imaging is used primarily for the evaluation of coronary artery disease. Ventriculography is sometimes referred to as multiple gated acquisition scanning (MUGA) and is primarily used to evaluate valvular disease and cardiomyopathies. Either type of study may be obtained at rest or stress.

Radionuclide Ventriculography is a medical imaging test used to determine a patient's cardiac function in the right, or more typically, left ventricle. Cardiac ventriculography involves injecting a radioisotope into the heart's ventricle(s) through a peripheral vein to measure the volume of blood pumped. Both regional and global left ventricular function (ejection fraction) as well as left ventricular size is measured.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. ⁽⁸⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Acronyms / Abbreviations

EF: Ejection fraction

MUGA: Multiple gated acquisition (nuclear scan of ventricular function)

TTE: Transthoracic echocardiography

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> • This guideline replaces UM Cardio 1120 Radionuclide Angiography / (MUGA SCAN)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Patel M, White R, Abbara S, Bluemke D, Herfkens R et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR appropriate utilization of cardiovascular imaging in heart failure: a joint report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. May 28, 2013; 61: 2207-31. 10.1016/j.jacc.2013.02.005.
2. Friedman J, Berman D, Borges-Neto S, Hayes S, Johnson L et al. First-pass radionuclide angiography. *J Nucl Cardiol*. Nov 2006; 13: e42-55. 10.1016/j.nuclcard.2006.08.006.
3. Mitra D, Basu S. Equilibrium radionuclide angiocardiology: Its usefulness in current practice and potential future applications. *World J Radiol*. Oct 28, 2012; 4: 421-30. 10.4329/wjr.v4.i10.421.
4. Ritchie J, Bateman T, Bonow R, Crawford M, Gibbons R et al. Guidelines for clinical use of cardiac radionuclide imaging. Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Radionuclide Imaging), developed in collaboration with the American Society of Nuclear Cardiology. *J Am Coll Cardiol*. Feb 1995; 25: 521-47. 10.1016/0735-1097(95)90027-6.
5. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483 - 1502. 10.1161/CIR.0b013e31822935fc.
6. Fitch K, Bernstein S, Aguilar M, Burnand B, LaCalle J et al. The RAND/UCLA Appropriateness Method User's Manual. 2001;
7. Hendel R, Patel M, Allen J, Min J, Shaw L et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF Appropriate Use Criteria Methodology Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2013; 61: 1305 - 1317. <https://doi.org/10.1016/j.jacc.2013.01.025>.
8. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. <https://doi.org/10.1016/j.jacc.2018.01.007>.
9. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular . *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
10. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and the Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2019; 73: 488-516. 10.1016/j.jacc.2018.10.038.
11. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. May 3, 2022; 145: e876-e894. 10.1161/cir.0000000000001062.
12. Plana J, Galderisi M, Barac A, Ewer M, Ky B et al. Expert consensus for multimodality imaging evaluation of adult patients during and after cancer therapy: a report from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. *J Am Soc Echocardiogr*. Sep 2014; 27: 911-39. 10.1016/j.echo.2014.07.012.
13. Zamorano J, Lancellotti P, Rodriguez Muñoz D, Aboyans V, Asteggiano R et al. 2016 ESC Position Paper on cancer treatments and cardiovascular toxicity developed under the auspices of the

ESC Committee for Practice Guidelines: The Task Force for cancer treatments and cardiovascular toxicity of the European Society of Cardiology (ESC). Eur Heart J. Sep 21, 2016; 37: 2768-2801. 10.1093/eurheartj/ehw211.

14. Baldassarre L, Ganatra S, Lopez-Mattei J, Yang E, Zaha V et al. Advances in Multimodality Imaging in Cardio-Oncology: JACC State-of-the-Art Review. J Am Coll Cardiol. Oct 18, 2022; 80: 1560-1578. 10.1016/j.jacc.2022.08.743.

15. Washington State Health Care Authority. WSHCA Health Technology Clinical Committee: 20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease. [Final Adoption: March 18, 2022]. 2022; <https://www.hca.wa.gov/assets/program/noninvasive-cardiac-imaging-final-findings-and-decision-2022-03-18.pdf>.

Evolut Clinical Guideline 7312-01 for Myocardial Perfusion Imaging

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Special Note

Medical necessity for myocardial perfusion imaging (MPI) will consider the preference for appropriate alternatives, such as stress echocardiography (SE), when deemed more suitable, unless contraindications are present (see **DEFINITIONS** section). Preference toward stress echocardiography will be denoted by 

See legislative language for specific mandates in **Washington** State.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR MPI (6,7,8,9,10)

Suspected Coronary Artery Disease (CAD)

- **Symptomatic patients without known CAD. No imaging stress test within the last 12 months.** *The terms "typical," "atypical," and "non-anginal symptoms" can still be observed in medical records (consult the **Diamond Forrester table** in the **Definitions** section). However, the ACC has simplified its terminology to "Less likely anginal symptoms" and "Likely anginal symptoms" (refer to definitions) and utilized below.*
 - **Less likely anginal symptoms (AUC 4-6)**
 - When a patient cannot walk a treadmill
 - When baseline EKG makes standard exercise test inaccurate (see

Definitions section).^(SE)

- When a noncardiac explanation is provided for symptoms, no testing is required (**AUC 8**)
- Likely Anginal Symptoms (typical angina)
 - < 50 years old with ≤ one risk factor if an ECG treadmill test cannot be done. **AUC scores for this bullet point are identical for MPI, stress echo, and ETT (**AUC = 7**). Although the ACC guideline does not specify youth and gender, decisions should be guided by best medical judgment, considering factors such as safety and radiation exposure.
 - ≥ 50 years old (**AUC 8**)
- Repeat testing in a patient with new or worsening symptoms **AND** negative result at least one year prior **AND** meets one of the criteria above^(SE)
- **Asymptomatic patients without known CAD AUC Score = 7**
 - A pharmacologic MPI is indicated for those unable to exercise with previously unevaluated ECG evidence of possible myocardial ischemia including ischemic ST segment or T wave abnormalities (see DEFINITIONS section).
 - Previously unevaluated pathologic Q waves (see DEFINITIONS section)
 - Previously unevaluated complete left bundle branch block

Abnormal Calcium Scores (9,11,12,13,14)

AUC Score = 7

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months ⁽⁶⁾ ^(SE)
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months ⁽⁶⁾ ^(SE)
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior stress imaging done within the last 12 months ^(SE)

Inconclusive CAD Evaluation and Obstructive CAD

REMAINS A CONCERN:

- Exercise stress ECG with low-risk Duke treadmill score (≥5), (see DEFINITIONS section) but patient's current symptoms indicate increasing likelihood of disease **AUC score = 8**
- Exercise stress ECG with an intermediate Duke treadmill score ^(SE) (*of note, SE diversion is not required for symptoms consistent with likely anginal symptoms*)
- Intermediate coronary computed tomography angiography (CCTA) (40 - 70% lesions) performed less than 90 days ago. (**AUC Score = 7**)
- Non-diagnostic exercise stress test with inability to achieve target heart rate (THR) defined as greater than 85% age predicted maximal heart rate by physiologic exercise). **AUC Score = 8**

- An indeterminate (equivocal, borderline, or discordant) evaluation by prior stress imaging (SE or CMR) within the last 12 months
- Coronary stenosis of unclear significance on previous coronary angiography not previously evaluated ⁽⁹⁾

Follow-Up of Patient's Post Coronary Revascularization (PCI or CABG) ⁽⁹⁾

- **Asymptomatic follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) (whichever is later) is appropriate for patients with: **(AUC = 6)** ^{SE} (*of note, SE diversion is not required for post CABG patients*)
 - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
 - A history of silent ischemia or
 - A history of a prior left main stent

OR

- For patients with high occupational risk, associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers and firefighters ^{SE} (*of note, SE diversion not required for post-CABG patients*)
- **New, recurrent, or worsening symptoms, treated medically or by revascularization** is an indication for stress imaging, if it will alter management for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization if no imaging stress test within the last 12 months. **(AUC Score 8)** ⁽⁶⁾

Follow-Up of Known CAD

- **Follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or $FFR \leq 0.80$ or significant stenosis in a major vessel ($\geq 50\%$ left main coronary artery or $\geq 70\%$ LAD, LCX, RCA)), over two years ago, without intervening coronary revascularization is an appropriate indication for stress imaging in patients if it will alter management. ^{SE}

Special Diagnostic Conditions Requiring Coronary Evaluation

AUC Score = 8

Unevaluated ACS

- Prior acute coronary syndrome (with documentation in MD notes), without invasive or non-invasive coronary evaluation within last 12 months
- Has ventricular wall motion abnormality demonstrated by another imaging modality and myocardial perfusion imaging is being performed to determine if the patient has

myocardial ischemia. No imaging stress test within the last 12 months

Heart Failure

- Newly diagnosed systolic heart failure or diastolic heart failure, *with reasonable suspicion of cardiac ischemia (prior events, risk factors)*, unless invasive coronary angiography is immediately planned. ^(7,15,16,17) No imaging stress test done within the last 12 months.

Viability

- LVEF requiring myocardial viability assessment to assist with decisions regarding coronary revascularization **(AUC Score 9)** ^(6,9)

Suboptimal Revascularization

- MPI is being done to evaluate the effectiveness of the intervention in a high-risk patient who has undergone cardiovascular re-perfusion (CABG or Percutaneous Coronary Intervention, PCI) with suboptimal and/or incomplete revascularization results. No imaging stress test has been done within the last 12 months. **(AUC Score 7)** ^(6,9)

Arrhythmias

- Ventricular arrhythmias **(AUC Score = 7)**
 - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography is not immediately planned ⁽¹⁸⁾
 - Non-sustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, or frequent PVCs (defined as greater than or equal to 30/hour on remote monitoring) without known cause or associated cardiac pathology, when an exercise ECG cannot be performed ⁽¹⁹⁾

Anti-Arrhythmic Drug Therapy

- Class IC antiarrhythmic drug
 - In the intermediate and high global risk patient prior to initiation of Class IC antiarrhythmic drug initiation (Propafenone or Flecainide)
 - Annually in intermediate and high global risk patients taking Class IC antiarrhythmic drug (Propafenone or Flecainide) ⁽²⁰⁾

Coronary Anomaly and Aneurism

- Assessment of hemodynamic significance of one of the following documented conditions:
 - Anomalous coronary arteries ⁽²¹⁾
 - Myocardial bridging of coronary artery
- Coronary aneurysms in Kawasaki's disease ⁽²²⁾ or due to atherosclerosis

Radiation and Chemotherapy

- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter ⁽²³⁾

Sarcoidosis and Amyloidosis (PYP study)

- Cardiac sarcoidosis: as a combination study with Heart PET for the evaluation and treatment of cardiac sarcoidosis ⁽²⁴⁾
- Cardiac amyloidosis: for the diagnosis of cardiac transthyretin amyloidosis (ATTR)

***Not** to be used for the diagnosis of cardiac light chain amyloidosis (AL) ⁽²⁵⁾

Prior To Elective Non-Cardiac Surgery In Asymptomatic Patient

AUC score = 8

- An intermediate or high risk surgery with of one or more risk factors (see below), AND documentation of an inability to walk (or <4 METs) AND there has not been an imaging stress test within 1 year ^(26,27,28)
 - **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine >2.0 mg/dL
 - **Surgical Risk:**
 - **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
 - **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
 - **Low risk surgery:** Endoscopic procedures, superficial procedure, cataract surgery, breast surgery
- Planning for any organ or stem cell transplantation is an indication for preoperative MPI, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service. ^(8,29)

Post Cardiac Transplant (SE Diversion Not Required)

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

LEGISLATIVE LANGUAGE

Washington

20211105A - Noninvasive Cardiac Imaging for Coronary Artery Disease ⁽³⁰⁾

Washington State Health Care Authority Technology Assessment

HTCC coverage determination:

Noninvasive cardiac imaging is a **covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage: The following noninvasive cardiac imaging technologies are **covered with conditions**:

- Stress echocardiography for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of Coronary Artery Disease (CAD), or
 - Adult patients with known CAD who have new or worsening symptoms.
- Single Positron Emission Tomography (SPECT) for:
 - Patients under the same conditions as stress echocardiography when stress echocardiography is not technically feasible or clinically appropriate.
- Positron Emission Tomography (PET) for:
 - Patients under the same conditions as SPECT, when SPECT is not technically feasible or clinically appropriate.
- Coronary Computed Tomographic Angiography (CCTA) for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of CAD, or
 - Adult patients with known CAD who have new or worsening symptoms.
- CCTA with Fractional Flow Reserve (FFR) for:
 - Patients under the same conditions as CCTA, when further investigation of functional significance of stenoses is clinically indicated.

Non-covered indicators:

N/A

Notes:

- Out of scope/data not reviewed for this decision:
 - Asymptomatic individuals, follow up of prior abnormal cardiac imaging studies, myocardial viability, preoperative evaluation
 - Patients presenting for evaluation of cardiac pathologies other than CAD
- This determination supersedes the following previous determinations:
 - Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease (20081114A)
 - Cardiac Nuclear Imaging (20130920A)

CODING AND STANDARDS

Coding

CPT Codes

78451, 78452, 78453, 78454, 78466, 78468, 78469, 78481, 78483, 93015, 93016, 93017, 93018, A9500, A9502, A9505, J0153, J1245, J2785

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Myocardial perfusion imaging is used primarily for the evaluation of coronary artery disease and determining prognosis. Myocardial perfusion imaging is a cardiac radionuclide imaging procedure that evaluates blood flow to the cardiac muscle during rest or stress. Stress may be provided by exercise or with pharmacologic agents. A variety of radionuclides may be used, including Technetium tc-99M sestamibi, thallium201 and Technetiumtc-99M tetrofosmin.

For those patients who are unable to complete the exercise protocol without achieving >85% of predicted maximal heart rate, a pharmacological nuclear stress test is recommended. This testing method uses a drug to mimic the response of the cardiovascular system to exercise. Adenosine, Persantine, Dobutamine, or Regadenoson are vasodilators used in pharmacological nuclear stress testing. A gamma camera is used to record images in planar or tomographic (single photon emission computed tomography, SPECT) projections.

High global CAD risk is defined as 10-year CAD risk of >20%. CAD equivalents (e.g., DM, PAD) can also define high risk.

10 year CAD risk (%) is defined based on the risk factors- Sex, Age, Race, Total Cholesterol, HDL Cholesterol, Systolic Blood Pressure, and Treatment for High Blood Pressure, Diabetes Mellitus, and Smoker.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. ⁽³⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Definitions

- Stable patients without known CAD fall into 2 categories ^(7,8,9):
 - **Asymptomatic**, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online (see **Websites for Global Cardiovascular Risk Calculators** section).
 - **Symptomatic**, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant CAD (below):
- The medical record should provide enough detail to establish the type of chest pain:
 - **Likely Anginal symptoms** encompass chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort occurring with exertion or emotional stress and relieved by rest, nitroglycerine or both.
 - **Less-Likely Anginal symptoms** include dyspnea, or fatigue not relieved by rest/nitroglycerin, as well as generalized fatigue or chest discomfort with a time course not indicative of angina (e.g., resolving spontaneously within seconds or lasting for an extended period unrelated to exertion).
- **Risk Factors for Coronary disease include (but not limited to)**: diabetes mellitus, smoking, family history of premature CAD (men age less than 55, females less than 65), hypertension, dyslipidemia.
- Beginning 2023, the classification terms for angina were updated within the ACC's Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease to **Less Likely Anginal Symptoms** and **Likely Anginal Symptoms** as in #2. Previously, the document referred to "Typical Angina", "Atypical Angina" and "Non-Anginal" symptoms, defined by the **Diamond Forrester Table**. We still provide this information for your reference ^(7,8,9):

Diamond Forrester Table ^(31,32)

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40-49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50-59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Very low: < 5%pretest probability of CAD, usually not requiring stress evaluation; **Low:** 5 - 10% pretest probability of CAD; **Intermediate:** 10% - 90% pretest probability of CAD; **High:** > 90% pretest probability of CAD

- An uninterpretable baseline ECG includes ⁽⁷⁾:
 - ST segment depression is considered significant when there is 1 mm or more, not for non-specific ST - T wave changes
 - Ischemic looking T waves are considered significant when there are at least 2.5 mm inversions (excluding V1 and V2)
 - Bundle Branch Blocks
 - LBBB
 - RBBB or IVCD, containing ST or T wave abnormalities
 - LVH with repolarization abnormalities
 - Ventricular paced rhythm
 - Digitalis use with associated ST segment abnormalities
 - Resting HR under 50 bpm on a medication, such as beta-blockers or calcium channel blockers, that is required for patient's treatment and cannot be stopped, with an anticipated suboptimal workload
- Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
 - 40 ms (1 mm) wide
 - 2 mm deep
 - 25% of depth of QRS complex
- ECG Stress Test Alone versus Stress Testing with Imaging
- Prominent scenarios suitable for an ECG stress test WITHOUT imaging (i.e., exercise treadmill ECG test) require that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise ⁽⁹⁾:
 - The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG ⁽⁹⁾
 - The patient who is under evaluation for exercise-induced arrhythmia
 - The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription
 - For the evaluation of syncope or presyncope during exertion ⁽³³⁾
 - When exercise cannot be performed, pharmacologic stress can be considered.
- Duke Exercise ECG Treadmill Score ⁽³⁴⁾
- Calculates risk from ECG treadmill alone:
 - The equation for calculating the Duke treadmill score (DTS) is: $DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score})$, with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting
 - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of $\geq + 5$), intermediate risk (with scores ranging from - 10 to + 4),

and high-risk (with a score of ≤ -11) categories

- MPI may be performed without diversion to a SE in any of the following ^(9,35):
 - Inability to Exercise
 - Physical limitations precluding ability to exercise for at least 3 full minutes of Bruce protocol
 - Limited functional capacity (< 4 METS) **such as one** of the following:
 - Unable to take care of their ADLs or ambulate
 - Unable to walk 2 blocks on level ground
 - Unable to climb 1 flight of stairs
 - Other Comorbidities
 - Severe chronic obstructive pulmonary disease (COPD) with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
 - Poorly controlled hypertension, with systolic BP > 180 or diastolic BP > 120 (and clinical urgency not to delay MPI)
 - ECG and Echo-Related Baseline Findings
 - Prior cardiac surgery (coronary artery bypass graft or valvular)
 - Documented poor acoustic imaging window
 - Left ventricular ejection fraction $\leq 40\%$
 - Pacemaker or ICD
 - Persistent atrial fibrillation
 - Resting wall motion abnormalities that would make SE interpretation difficult
 - Complete left bundle branch block (LBBB)
 - Risk-Related scenarios
 - High pretest probability in suspected CAD
 - Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs (prior to initiation of therapy and annually)
 - Arrhythmia risk with exercise
 - Previously unevaluated pathologic Q waves (in two contiguous leads)
- Global Risk of Cardiovascular Disease
 - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years.
 - **CAD Risk—Low**
10-year absolute coronary or cardiovascular risk less than 10%.
 - **CAD Risk—Moderate**
10-year absolute coronary or cardiovascular risk between 10% and 20%.

■ **CAD Risk—High**

10-year absolute coronary or cardiovascular risk of greater than 20%.

Websites for Global Cardiovascular Risk Calculators* (36,37,38,39,40)

Risk Calculator	Websites for Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have already manifested cardiovascular disease are already at high global risk and are not applicable to the calculators.

- Definitions of Coronary Artery Disease (7,8,13,41)
- Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).
 - Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into global risk can be achieved by using the MESA risk calculator.
 - Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; intermediate lesions are 50 – 69% (9)
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ (7,41,42)

- FFR (fractional flow reserve) ≤ 0.80 for a major vessel ^(41,42)
- Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree
- FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion. Less than or equal to 0.80 is considered a significant reduction in coronary flow.
- Anginal Equivalent ^(7,33)
- Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia). This may include respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

Acronyms / Abbreviations

ADLs: Activities of daily living

BSA: Body surface area in square meters

CABG: Coronary artery bypass grafting

CAD: Coronary artery disease

CMR: Cardiac magnetic resonance imaging

CTA: Computed tomography angiography

ECG: Electrocardiogram

FFR: Fractional flow reserve

IVUS: Intravascular ultrasound

LBBS: Left bundle-branch block

LVEF: Left ventricular ejection fraction

LVH: Left ventricular hypertrophy

MI: Myocardial infarction

MET: Estimated metabolic equivalent of exercise

MPI: Myocardial perfusion imaging

PCI: Percutaneous coronary intervention

PFT: Pulmonary function test

PVCs: Premature ventricular contractions

SE: Stress echocardiography

THR: Target heart rate

VT: Ventricular tachycardia

VF: Ventricular fibrillation

WPW: Wolf Parkinson White

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> <li data-bbox="533 539 1334 607">This guideline replaces UM Cardio 1119 Pharmacological Nuclear Stress Test / Myocardial Perfusion Imaging (MPI)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483 - 1502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. 2001.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF Appropriate Use Criteria Methodology Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2013; 61: 1305 - 1317. 10.1016/j.jacc.2013.01.025.
5. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. doi:10.1016/j.jacc.2005.08.030.
6. Brindis R G, Douglas P S, Hendel R C, Peterson E D, Wolk M J et al. ACCF/ASNC Appropriateness Criteria for Single-Photon Emission Computed Tomography Myocardial Perfusion Imaging (SPECT MPI). *Journal of the American College of Cardiology*. 2005; 46: 1587 - 1605. 10.1016/j.jacc.2005.08.029.
7. Fihn S, Gardin J, Abrams J, Berra K, Blankenship J et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation*. Dec 18, 2012; 126: e354-471. 10.1161/CIR.0b013e318277d6a0.
8. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J*. Oct 2013; 34: 2949-3003. 10.1093/eurheartj/eh296.
9. Winchester D E, Maron D J, Blankstein R, Chang I C, Kirtane A J et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *Journal of Cardiovascular Magnetic Resonance*. 2023; 25: true. <https://doi.org/10.1186/s12968-023-00958-5>.
10. Bandettini W P, Kwong R Y, Patel A R, Plein S, S f C M R. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 multi-modality appropriate use criteria for the detection and risk assessment of chronic coronary disease. *Journal of Cardiovascular Magnetic Resonance*. 2023; 25: <https://doi.org/10.1186/s12968-023-00959-4>.
11. Budoff M, Raggi P, Beller G, Berman D, Druz R et al. Noninvasive Cardiovascular Risk Assessment of the Asymptomatic Diabetic Patient: The Imaging Council of the American College of Cardiology. *JACC Cardiovasc Imaging*. Feb 2016; 9: 176-92. 10.1016/j.jcmg.2015.11.011.
12. Gulati M, Levy P, Mukherjee D, Amsterdam E, Bhatt D et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Cardiovasc Comput Tomogr*. Dec 01, 2021; 10.1016/j.jcct.2021.11.009.
13. Patel M, Calhoun J, Dehmer G, Grantham J, Maddox T et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary

Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. May 2 2017; 69: 2212-2241. 10.1016/j.jacc.2017.02.001.

14. Guzman A, Navarro E, Obando L, Pacheco J, Quiros K et al. Effectiveness of interventions to reverse the diagnosis of metabolic syndrome: update of a mixed treatment comparison meta-analysis. *Biomedica*. 2019; 39: 647-662. <https://doi.org/10.7705/biomedica.4684>.

15. Patel M, White R, Abbara S, Bluemke D, Herfkens R et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR appropriate utilization of cardiovascular imaging in heart failure: a joint report of the American College of Radiology Appropriateness Criteria Committee and the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *J Am Coll Cardiol*. May 28, 2013; 61: 2207-31. 10.1016/j.jacc.2013.02.005.

16. Yancy C, Jessup M, Bozkurt B, Butler J, Casey D J et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. Oct 15, 2013; 62: e147-239. 10.1016/j.jacc.2013.05.019.

17. Doherty John U, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease. *Journal of the American College of Cardiology*. 2019/02/05; 73: 488-516. 10.1016/j.jacc.2018.10.038.

18. Lasica R, Djukanovic L, Savic L, Krljanac G, Zdravkovic M et al. Update on Myocarditis: From Etiology and Clinical Picture to Modern Diagnostics and Methods of Treatment. 2023; 13: 10.3390/diagnostics13193073.

19. Zimetbaum PJ, Wylie JV. Nonsustained ventricular tachycardia: Clinical manifestations, evaluation, and management. *UpToDate*. August 26, 2022; 2023:

20. Reiffel J, Camm A, Belardinelli L, Zeng D, Karwatowska-Prokopczuk E et al. The HARMONY Trial: Combined Ranolazine and Dronedarone in the Management of Paroxysmal Atrial Fibrillation: Mechanistic and Therapeutic Synergism. *Circ Arrhythm Electrophysiol*. Oct 2015; 8: 1048-56. 10.1161/circep.115.002856.

21. Gräni C, Bigler M R, Kwong R Y. Noninvasive Multimodality Imaging for the Assessment of Anomalous Coronary Artery. *Current Cardiology Reports*. 2023; 25: 1233 - 1246. 10.1007/s11886-023-01948-w.

22. Newburger J, Takahashi M, Burns J. Kawasaki Disease. *J Am Coll Cardiol*. Apr 12 2016; 67: 1738-49. 10.1016/j.jacc.2015.12.073.

23. Lancellotti P, Nkomo V, Badano L, Bergler-Klein J, Bogaert J et al. Expert consensus for multimodality imaging evaluation of cardiovascular complications of radiotherapy in adults: a report from the European Association of Cardiovascular Imaging and the American Society of Echocardiography. *Eur Heart J Cardiovasc Imaging*. Aug 2013; 14: 721-40. 10.1093/ehjci/jet123.

24. Tersalvi G, Beltrani V, Grüber M R, Molteni A, Cristoforetti Y et al. Positron Emission Tomography in Heart Failure: From Pathophysiology to Clinical Application. 2023; 10: 10.3390/jcdd10050220.

25. Tahara N, Lairez O, Endo J, Okada A, Ueda M et al. 99mTechnetium-pyrophosphate scintigraphy: a practical guide for early diagnosis of transthyretin amyloid cardiomyopathy. *ESC Heart Failure*. 2022; 9: 251 - 262. <https://doi.org/10.1002/ehf2.13693>.

26. Fleisher L, Fleischmann K, Auerbach A, Barnason S, Beckman J et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *J Am Coll Cardiol*. Dec 09, 2014; 64: e77-137. 10.1016/j.jacc.2014.07.944.

27. Kristensen S, Knuuti J, Saraste A, Anker S, Bøtker H et al. 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management: The Joint Task Force on non-cardiac surgery: cardiovascular assessment and management of the European Society of Cardiology (ESC) and the European Society of Anaesthesiology (ESA). *Eur Heart J*. Sep 14, 2014; 35: 2383-431. 10.1093/eurheartj/ehu282.
28. Velasco A, Reyes E, Hage F. Guidelines in review: Comparison of the 2014 ACC/AHA guidelines on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery and the 2014 ESC/ESA guidelines on noncardiac surgery: Cardiovascular assessment and management. *J Nucl Cardiol*. 02 2017; 24: 165-170. 10.1007/s12350-016-0643-8.
29. Lentine K, Costa S, Weir M, Robb J, Fleisher L et al. Cardiac disease evaluation and management among kidney and liver transplantation candidates: a scientific statement from the American Heart Association and the American College of Cardiology Foundation. *J Am Coll Cardiol*. Jul 31, 2012; 60: 434-80. 10.1016/j.jacc.2012.05.008.
30. Washington State Health Care Authority. WSHCA Health Technology Clinical Committee: 20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease. [Final Adoption: March 18, 2022]. 2022.
31. Diamond G, Forrester J. Analysis of probability as an aid in the clinical diagnosis of coronary-artery disease. *The New England journal of medicine*. 1979; 300: 1350 - 1358. 10.1056/nejm197906143002402.
32. Wolk M, Bailey S, Doherty J, Douglas P, Hendel R et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. Feb 4, 2014; 63: 380-406. 10.1016/j.jacc.2013.11.009.
33. Shen W, Sheldon R, Benditt D, Cohen M, Forman D et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Aug 1, 2017; 70: 620-663. 10.1016/j.jacc.2017.03.002.
34. Shaw L, Peterson E, Shaw L, Kesler K, DeLong E et al. Use of a prognostic treadmill score in identifying diagnostic coronary disease. *Circulation*. 1998; 98: 1622-30. doi:10.1161/01.cir.98.16.1622.
35. Henzlova M, Duvall W, Einstein A, Travin M, Verberne H. ASNC imaging guidelines for SPECT nuclear cardiology procedures: Stress, protocols, and tracers. *J Nucl Cardiol*. Jun 2016; 23: 606-39. 10.1007/s12350-015-0387-x.
36. Arnett D, Blumenthal R, Albert M, Buroker A, Goldberger Z et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. Sep 10, 2019; 74: e177-e232. 10.1016/j.jacc.2019.03.010.
37. D'Agostino R S, Vasan R, Pencina M, Wolf P, Cobain M et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation*. Feb 12, 2008; 117: 743-53. 10.1161/circulationaha.107.699579.
38. Goff D J, Lloyd-Jones D, Bennett G, Coady S, D'Agostino R et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. Jun 24, 2014; 129: S49-73. 10.1161/01.cir.0000437741.48606.98.
39. McClelland R, Jorgensen N, Budoff M, Blaha M, Post W et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA

(Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study). *J Am Coll Cardiol*. Oct 13, 2015; 66: 1643-53. 10.1016/j.jacc.2015.08.035.

40. Ridker P, Buring J, Rifai N, Cook N. Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *Jama*. Feb 14, 2007; 297: 611-9. 10.1001/jama.297.6.611.

41. Shlofmitz E, Ali Z A, Maehara A, Mintz G S, Shlofmitz R. Intravascular Imaging-Guided Percutaneous Coronary Intervention. *Circulation: Cardiovascular Interventions*. 2020; 13: 10.1161/CIRCINTERVENTIONS.120.008686.

42. Lotfi A, Davies J, Fearon W, Grines C, Kern M. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society of cardiac angiography and interventions. *Catheter Cardiovasc Interv*. Aug 1, 2018; 92: 336-347. 10.1002/ccd.27672.



Evolent Clinical Guideline 7315-01 for Pacemaker Implantation

Guideline Number: Evolut_CG_7315-01	<u>Applicable Codes</u>	
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Original Date: February 2013	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

This guideline is not intended to specify the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines. Pacemaker implantation generally serves to address bradycardia, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR PACEMAKERS IN ADULTS

Excludes conditions that are expected to resolve.

Sinus Node Dysfunction (SND)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses ^(6,7)
- Symptomatic chronotropic incompetence (broadly defined as an inability to increase heart rate commensurate with activity or demand), documented by stress test or cardiac monitoring data (Holter/MCOT/Electrocardiography (ECG)) recording data ^(6,7)
- Symptomatic sinus bradycardia that results from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment ^(6,7)
- Heart rate less than 40 while awake, even without definite association with significant

symptoms consistent with bradycardia ⁽⁶⁾

- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia ^(7,8)
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS) ⁽⁶⁾

Acquired Atrioventricular (AV) Block

First-Degree AV Block

- Marked first-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block ⁽⁷⁾
- First-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise ⁽⁷⁾

Second Degree AV Block (Mobitz Types I and II)

- Marked second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block ^(6,7)
- Second-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise ⁽⁶⁾
- Second-degree Mobitz Type II AV block regardless of symptoms ^(6,7)
- Advanced second-degree AV block ⁽⁶⁾
- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction ⁽⁶⁾
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II ⁽⁶⁾

Third-Degree/Complete AV Block

- Third-degree (complete) AV block, intermittent or persistent, regardless of symptoms ⁽⁶⁾
- High-grade AV block, regardless of symptoms ⁽⁷⁾

AF/Other

- Atrial fibrillation while awake, with pauses ≥ 5 seconds, or symptomatic bradycardia ⁽⁶⁾
- In sinus rhythm (with AV block) while awake, pauses ≥ 3 seconds or heart rates less than 40 beats per minute or an escape rhythm below the AV node ⁽⁶⁾
- Following catheter ablation of the AV junction ⁽⁶⁾
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment ^(6,7)
- Exercise-induced second- or third-degree AV block without myocardial ischemia ^(6,7)

Neuromuscular Disorders

- Marked first-degree or higher AV block, or an H-V interval ≥ 70 ms, associated with neuromuscular diseases, such as myotonic muscular dystrophy, Erb's dystrophy, Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms^(6,7)

Chronic Fascicular (Including Any of RBBB, LBBB, LAHB, LPHB) Block

- Alternating bundle-branch block^(6,7)
- Syncope of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia⁽⁶⁾
- Syncope and bundle branch block with an HV interval ≥ 70 ms, or evidence of infranodal block at EPS⁽⁷⁾
- Incidental findings at EPS study of an H-V interval ≥ 100 milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients⁽⁶⁾

Hypersensitive Carotid Sinus Syndrome And Neurocardiogenic Syncope

- Recurrent syncope due to spontaneously occurring carotid sinus stimulation AND carotid sinus pressure induced ventricular asystole ≥ 3 seconds⁽⁶⁾, or AV block, or ≥ 50 mmHg drop in systolic BP
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) ≥ 3 seconds⁽⁶⁾
- Recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by ECG recording data^(9,10)

Pacing to Terminate or Prevent Tachycardia

- Symptomatic recurrent supraventricular tachycardia documented to be terminated by pacing in the setting of failed catheter ablation and/or drug treatment⁽⁶⁾
- Prevention of pause-dependent ventricular tachycardia (VT)⁽⁶⁾

Recommendations for Permanent Pacing in Patients with Hypertrophic Cardiomyopathy (HCM)

- Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction

Recommendations for Leadless Pacemaker Include^(11,12)

- Patients with bradycardia and need only single chamber (RV) pacing in VVI or VVIR mode:
 - Symptomatic paroxysmal or permanent high-grade AV block in the presence of atrial fibrillation (AF).

- Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
- Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity

INDICATIONS FOR CONGENITAL HEART DISEASE PACING (PEDIATRIC AND ADULT)

Children, Adolescents (<19 Years), and Adult Patients with Congenital Heart Disease (CHD)

Sinus Node Dysfunction

- SND with symptomatic age- and activity-inappropriate bradycardia ⁽⁷⁾
- Sinus bradycardia with complex CHD AND a resting heart rate < 40 bpm **OR** pauses in ventricular rate > 3 seconds ⁽¹³⁾
- CHD and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony
- Asymptomatic sinus bradycardia following repair of CHD with an awake resting heart rate < --40 bpm or pauses in ventricular rate > 3 seconds
- CHD and SND or junctional bradycardia, for the prevention of recurrent episodes of intra-atrial reentrant tachycardia

AV Block

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output ⁽⁸⁾
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction ⁽⁷⁾
- Congenital third-degree AV block in the infant with a ventricular rate < 55 bpm or with congenital heart disease and a ventricular rate < 70 bpm
- Congenital third-degree AV block after 1 year of age with an average heart rate < 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence ⁽⁷⁾
- Adults with congenital complete AV block with symptomatic bradycardia, wide QRS escape rhythm, mean daytime heart rate < 50 bpm, complex ventricular ectopy, or ventricular dysfunction ^(7,8)
- Adults with congenital complete AV block, regardless of symptoms ⁽⁷⁾
- Unexplained syncope after prior congenital heart surgery complicated by transient complete heart block, with residual fascicular block after excluding other causes of

syncope

- Congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS, and normal ventricular function

SCENARIOS IN WHICH PACEMAKERS ARE NOT INDICATED ^(8,14)

- SND in patients that are asymptomatic, or symptoms occur without documented bradycardia
- Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS
- Asymptomatic fascicular block (Including any of RBBB, LBBB, LAHB, LPHB)
- Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB where a higher degree of heart block has not been demonstrated
- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms
- Asymptomatic bifascicular block (RBBB/LAHB or RBBB/LPHB) with or without first-degree AVB after surgery for CHD without prior transient complete AV block

CODING AND STANDARDS

Coding

CPT Codes

33206, 33207, 33208, 33212, 33213, 33215, 33216, 33217, 33218, 33220, 33274, 33275

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

A pacemaker system is composed of a pulse generator and one or more leads. The pulse generator is implanted under the skin, usually below one of the collarbones (clavicles). It

contains a battery, a microprocessor that governs timing and function, and a radio antenna to allow for noninvasive interrogation and reprogramming. The leads are insulated cables that conduct electricity from the pulse generator to the heart. Leads are most commonly inserted into a vein and then advanced under fluoroscopy (x-ray guidance) to within one or more heart chambers. The leads are fastened within the chambers to the heart muscle using either hooks or retractable/extendable screws, which are built into their tips. Timed electrical impulses are delivered from the pulse generator via the leads to the heart, where stimulation results in heart muscle contraction.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost effective manner. ⁽⁴⁾

- *Appropriate Care - Median Score 7-9*
- *May be Appropriate Care - Median Score 4-6*
- *Rarely Appropriate Care - Median Score 1-3*

Heart Block Definitions ⁽⁶⁾

- First-Degree: All sinus or atrial beats are conducted to the ventricles, but with a delay (PR interval of > 200 ms)
- Second-Degree: Intermittent failure of conduction of single beats from atrium to ventricles
 - (Mobitz) Type I: Conducted beats have variable conduction times from atrium to ventricles
 - (Mobitz) Type II: Conducted beats have uniform conduction times from atrium to ventricles
 - Advanced or high degree: Two or more consecutive non-conducted sinus or (non-premature) atrial beats with some conducted beats
- Third-Degree: No atrial beats are conducted from atrium to ventricle

Acronyms / Abbreviations

AV: Atrioventricular

CHF: Congestive heart failure

CRT: Cardiac resynchronization therapy (same as biventricular pacing)

ECG: Electrocardiogram

EPS: Electrophysiologic Study

GDMT: Guideline-Directed Medical Therapy

HV: His-ventricular

ICD: Implantable cardioverter-defibrillator

LAHB: Left Anterior Hemiblock

LBBB: Left bundle-branch block

LPHB: Left Posterior Hemiblock
 LV: Left ventricular/left ventricle
 LVEF: Left ventricular ejection fraction
 MI: Myocardial infarction
 ms: Milliseconds
 RBBB: Right Bundle Branch Block
 s: Seconds
 STEMI: ST-elevation Myocardial Infarction
 SND: Sinus node dysfunction
 VT: Ventricular tachycardia

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> This guideline replaces UM 1147 Pacemaker Implantation
March 2024	<ul style="list-style-type: none"> Added AUC Scoring to Cardiac Guidelines from published Societies. When an AUC score was not published by a Society, we assigned an AUC score of 6 based upon AUC scoring standards – this has been explained in Clinical Reasoning

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483 - 1502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. 2001.
3. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
4. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
5. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate Use of Cardiovascular Technology. *Journal of the American College of Cardiology*. 2013; 61: 1305 - 1317. 10.1016/j.jacc.2013.01.025.
6. Epstein A, DiMarco J, Ellenbogen K, Estes N 3, Freedman R et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation*. Jan 22 2013; 127: e283-352. 10.1161/CIR.0b013e318276ce9b.
7. Kusumoto F, Schoenfeld M, Barrett C, Edgerton J, Ellenbogen K et al. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Aug 20 2019; 74: e51-e156. 10.1016/j.jacc.2018.10.044.
8. Hernández-Madrid A, Paul T, Abrams D, Aziz P F, Blom N A et al. Arrhythmias in congenital heart disease: a position paper of the European Heart Rhythm Association (EHRA), Association for European Paediatric and Congenital Cardiology (AEPC), and the European Society of Cardiology (ESC) Working Group on Grown-up Congenital heart disease, endorsed by HRS, PACES, APHRS, and SOLAECE. *Europace*. 2018; 20: 1719 - 1753. 10.1093/europace/eux380.
9. Varosy P, Chen L, Miller A, Noseworthy P, Slotwiner D. Pacing as a Treatment for Reflex-Mediated (Vasovagal, Situational, or Carotid Sinus Hypersensitivity) Syncope: A Systematic Review for the 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. Aug 1 2017; 136: e123-e135. 10.1161/cir.0000000000000500.
10. Sutton R, Ungar A, Sgobino P, Russo V, Massa R et al. Cardiac pacing in patients with neurally mediated syncope and documented asystole: effectiveness analysis from the Third International Study on Syncope of Uncertain Etiology (ISSUE-3) Registry. *Europace*. 2014; 16: 595 - 599. 10.1093/europace/eut323.
11. Ngo L, Nour D, Denman R A, Walters T E, Haqqani H M et al. Safety and Efficacy of Leadless Pacemakers: A Systematic Review and Meta-Analysis. *Journal of the American Heart Association*. 2021; 10: 10.1161/JAHA.120.019212.
12. Tjong F V, Reddy V Y. Permanent Leadless Cardiac Pacemaker Therapy. *Circulation*. 2017; 135: 1458 - 1470. 10.1161/CIRCULATIONAHA.116.025037.
13. Brugada J, Blom N, Sarquella-Brugada G, Blomstrom-Lundqvist C, Deanfield J et al. Pharmacological and non-pharmacological therapy for arrhythmias in the pediatric population: EHRA and AEPC-Arrhythmia Working Group joint consensus statement. *Europace*. Sep 2013; 15: 1337-82. 10.1093/europace/eut082.

14. Glikson M, Nielsen J, Kronborg M, Michowitz Y, Auricchio A et al. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) With the special contribution of the European Heart Rhythm Association (EHRA). *European Heart Journal*. 2021; 42: 3427-3520. [10.1093/eurheartj/ehab364](https://doi.org/10.1093/eurheartj/ehab364).



Evolent Clinical Guideline 7317 for Percutaneous Closure of Patent Foramen Ovale (PFO)

Guideline Number: Evolent_CG_7317	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for percutaneous closure of patent foramen ovale (PFO) for the secondary prevention of neurologic events.

Special Note

To review a request for medical necessity, the following items must be submitted for review:

- Medical notes from a Cardiologist and a Neurologist that indicate the need for the procedure and document that no other obvious etiology for the neurologic event has been discovered
- A TEE report that documents the presence of the defect and addresses the suitability of the anatomy for the device placement
- Results of diagnostic testing performed to rule out other causes of neurologic event, i.e. vascular disease, hypercoagulable state, occult atrial fibrillation, and consisting of at least a carotid duplex or CTA/MRA report, evidence of hematological workup, and evidence of heart rhythm monitoring

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR PERCUTANEOUS CLOSURE OF A PATENT FORAMEN OVALE

Percutaneous PFO closure is appropriate for patients with all of the following ^(6,7):

- A prior history of cryptogenic stroke or TIA
- ≤ 60 years of age
- TEE evidence of interatrial communication that is amenable to percutaneous closure

Limitations

- The existence of other stroke risk factors that would not be affected by device closure, such as but not limited to a cardiac source of embolism apart from PFO, rheumatic mitral stenosis, significant atherosclerosis of the carotid and intracranial circulation, protruding or mobile aortic plaque, coagulopathy, atrial fibrillation or flutter, or vasculitis involving the carotid circulation
- Presence of an inferior vena cava filter
- Elevated bleeding risk or coagulopathy that would prevent the use of dual anti-platelet therapy for six months, and aspirin indefinitely thereafter

CODING AND STANDARDS

Coding

CPT Codes

93580

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

PFO is a congenital heart defect that allows for unnatural communication between the left and right sides of the heart at the level of the atria. One possible complication of this is that

blood clots forming in the venous system have the opportunity to travel from the right side of the heart into the systemic circulation resulting in a paradoxical embolism that can cause neurologic events such as transient ischemic attack (TIA) and ischemic cerebrovascular accident (CVA or stroke) should it enter the cerebral circulation.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

CTA: Computed tomographic angiography

MRA: Magnetic resonance angiography

PFO: Patent foramen ovale

TEE: Transesophageal echocardiography/cardiograph

TIA: Transient ischemic attack

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1417 for Percutaneous Closure of Patent Foramen Ovale (PFO)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a



covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACCF Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Collado F, Poulin M, Murphy J, Jneid H, Kavinsky C. Patent Foramen Ovale Closure for Stroke Prevention and Other Disorders. *Journal of the American Heart Association*. 2018; 7: e004152. 10.1161/JAHA.117.007146.
7. Wiktor D, Carroll J. The Case for Selective Patent Foramen Ovale Closure After Cryptogenic Stroke. *Circulation: Cardiovascular Interventions*. 2018; 11: 10.1161/CIRCINTERVENTIONS.117.004152.

Evolut Clinical Guideline 7318 for Percutaneous Coronary Interventions

Guideline Number: Evolut_CG_7318	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: January 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

This guideline addresses Percutaneous Coronary Interventions for stable coronary artery disease. **This guideline does NOT cover acute coronary syndromes including ST segment elevation myocardial infarction and non-ST segment elevation myocardial infarction.**

Coronary Artery Stenosis

- The severity of coronary artery stenoses may be defined by either cardiac catheterization or CT Angiography by the following:
 - A diameter stenosis by visual estimation of $\geq 70\%$ for non-left main disease and $\geq 50\%$ for left main disease are considered significant stenoses to guide revascularization.
 - Intermediate coronary stenoses are defined as a diameter stenosis of 40% to 69% and may be candidates for further evaluation to assess the physiologic or anatomic significance.
 - Fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) can be used to assess physiological lesion significance, with cutoffs of ≤ 0.80 and ≤ 0.89 , respectively.
 - Intravascular ultrasound (IVUS) for left main disease is considered significant for a minimal luminal area $\leq 6.0 \text{ mm}^2$, while a smaller value may be more appropriate in patients of Asian descent ($4.5 - 4.8 \text{ mm}^2$). Lower values are advocated outside of the left main coronary artery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated

risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR PERCUTANEOUS CORONARY INTERVENTION (PCI)

Refractory Angina ⁽⁶⁾

- Patients with stable ischemic heart disease (SIHD), refractory angina (despite medical therapy), and significant coronary artery stenosis in a lesion amenable to PCI

Multivessel Coronary Artery Disease (CAD) ⁽⁶⁾

- Patients with SIHD and the following:
 - Normal ejection fraction
 - Significant stenosis in 3 major coronary arteries (with or without proximal LAD)
 - Anatomy is suitable for PCI

Stenosis in Proximal Left Anterior Descending (LAD) artery ⁽⁶⁾

- Patients with SIHD and the following:
 - Normal left ventricular ejection fraction
 - Significant stenosis in the proximal LAD

Left Main CAD ⁽⁶⁾

A diameter stenosis by visual estimation of $\geq 50\%$ for left main disease are considered significant stenoses to guide revascularization.

- Selected patients with SIHD and significant left main stenosis in whom PCI can provide equivalent revascularization as CABG

Diabetes Mellitus and Multivessel Coronary Artery Disease (CAD) ⁽⁶⁾

- Patients with Diabetes and multivessel CAD with any of the following:
 - Involvement of the LAD and are not appropriate candidates for coronary artery bypass graft (CABG)
 - Poor candidates for surgery
 - Left main stenosis and low- or intermediate- complexity CAD in rest of the coronary anatomy

Previous CABG ⁽⁶⁾

- Patients with a previous CABG and all of the following:
 - Patent LIMA to the LAD
 - Clinical indication for revascularization
 - Lesion amenable to PCI

Cardiac Allograft Vasculopathy ⁽⁶⁾

- Cardiac Allograft Vasculopathy
 - Patients with cardiac allograft vasculopathy with severe, proximal, discrete coronary lesions

Revascularization Prior to Percutaneous Valve Procedures

- Patients with significant left main or proximal CAD with/without angina ^(6,7)

CODING AND STANDARDS

Coding

CPT Codes

92920, 92921, 92924, 92925, 92928, 92929, 92933, 92934, 92937, 92938, 92943, 92944

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Angina Classification

Canadian Cardiovascular Society grading of angina pectoris ⁽⁸⁾

Grade	Description
Grade I	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation
Grade II	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions
Grade III	Marked limitation of ordinary physical activity. Walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace
Grade IV	Inability to carry on any physical activity without discomfort, anginal syndrome may be present at rest

Guideline Directed Medical Therapy

Guideline directed medical therapy (GDMT) is outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

Guideline-directed medical therapy (GDMT) is a part of management of patients with stable ischemic heart disease (SIHD) regardless if revascularization is performed. GDMT for patients with coronary artery disease is synonymous with secondary prevention and consists of pharmacologic therapy with an antiplatelet agent, risk factor modification, and lifestyle interventions. In patients with chronic coronary disease and angina, two antianginals are recommended for relief on angina. ⁽⁹⁾

In patients with refractory angina despite medical therapy and with significant coronary artery stenoses amenable to revascularization, revascularization is recommended to improve symptoms.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6

- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
January 2024	<ul style="list-style-type: none"> ● This guideline replaces UM Cardio 1094 Percutaneous Coronary Interventions

LEGAL AND COMPLIANCE

Guideline Approval

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483-1502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA appropriateness method user's manual. *RAND*. 2001; 109. Accessed: 09/10/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: A report of the American college of cardiology foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-1317. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-1613. 10.1016/j.jacc.2005.08.030.
6. Lawton J S, Tamis-Holland J E, Bangalore S, Bates E R, Beckie T M et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2022; 79: 197-215. 10.1016/j.jacc.2021.09.005.
7. Otto C M, Nishimura R A, Bonow R O, Carabello B A, Erwin J P et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2021; 77: e25-e197. 10.1016/j.jacc.2020.11.018.
8. Campeau L. Grading of angina pectoris. *Circulation*. 1976; 54: 522-523.
9. Virani S, Newby L, Arnold S, Bittner V, Brewer L et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2023; 148: E9-E119. 10.1161/CIR.0000000000001168.



Evolut Clinical Guideline 7319 for Percutaneous Iliocaval Interventions

Guideline Number: Evolut_CG_7319	<u>Applicable Codes</u>	
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Original Date: September 2019	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Percutaneous Iliocaval Intervention.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

- Acute iliocaval thrombophlebitis:
 - Can be treated by lytic therapy, mechanical thrombectomy, a combination of both, surgical thrombectomy or bypass. If an underlying lesion is encountered, it may be stented. Angioplasty alone is not sufficient ⁽⁶⁾
- When both of the following criteria are met:
 - Patients have undergone at least 3 months of conservative treatment (including pain management, compression stockings and wound care if ulceration is present) ⁽⁷⁾
 - Results from a diagnostic venogram and intravascular ultrasound performed in the AP and multiplanar positions, with at least one in the left lateral decubitus, demonstrate either of the following ⁽⁸⁾:
 - Iliocaval compression related to external compression from malignancy, bone spurs, arterial grafts, or other causes of external compression not due to arterial compression syndromes

- A fixed (Non-dynamic (see **Definitions**)) iliofemoral venous stenosis/occlusion with a $\geq 50\%$ area or $\geq 61\%$ diameter reduction (7,8,9,10,11)

Limitations (7,8,9,10)

- Incidentally identified venous stenosis of the iliac veins or inferior vena cava on imaging performed for other reasons
- Prophylactic stent placement for NIVL in asymptomatic patients to prevent possible future venous thromboembolism events
- Dynamic lesions, where the severity of stenosis varies with factors that include hydration, respiration, position, Valsalva maneuvers, phasicity, or variation in intra-abdominal pressure
- NILV in a patient with mild symptoms or findings e.g. CEAP1-2 or C3 where swelling is limited to the calf and is controlled with stockings
- NILV in the presence of bilateral leg swelling in patients with other reasons for edema
- NILV in patients 80 years or older with recent onset of bilateral leg swelling
- NILV in non-ambulatory individuals
- Post thrombotic iliac vein lesions for C3 disease in non-ambulatory individuals

Contraindications (7,8)

- Active Infection: Presence of systemic or local infections at the planned intervention site
- Severe Comorbidities: Conditions that significantly increase procedural risk or limit life expectancy
- Uncorrected Coagulopathy: Bleeding disorders that cannot be managed appropriately

CODING AND STANDARDS

Coding

CPT Codes

37238 - Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein

37239 - Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein; add on code

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- **Chronic iliofemoral venous obstruction** is a medical condition related to chronic narrowing or occlusion of the iliac or common femoral veins usually as a result of a prior deep vein thrombophlebitis but also non-thrombotic iliac vein lesions
- **Non-thrombotic iliac vein lesions** are related to external compression of the iliac veins usually by iliac arteries
- **May Thurner or Crockett syndrome** involves left iliac vein stenosis as a result of the left iliac vein being crossed by the right iliac artery
- A **fixed Non-Dynamic iliac vein stenosis/occlusion** is a stenosis which does not vary dependent on the patient’s position, state of hydration, breathing, or changes in intra-abdominal pressure. It is usually a result of a post thrombotic event but can also be due to an NILV. It is generally considered safer to stent a fixed non-dynamic lesion since stent migration is less likely and it is more likely that the lesion will be responsible for symptoms.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate use criteria

CVI: Chronic venous insufficiency

CEAP: Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)

DVT: Deep vein thrombophlebitis

NILV: Non thrombotic iliac vein lesion/s

PTS: Post thrombotic Syndrome

CT: Computed Tomography

MR: Magnetic Resonance

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1368 for Percutaneous Iliocaval Interventions ● Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Farsad K, Kapoor B, Fidelman N, Cain T, Caplin D et al. ACR Appropriateness Criteria® Radiologic Management of Iliofemoral Venous Thrombosis. *Journal of the American College of Radiology*. 2020; 17: S255-S264. 10.1016/j.jacr.2020.01.035.
7. De Maeseneer M, Kakkos S, Aherne T, Baekgaard N, Black S et al. European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. *European Journal of Vascular and Endovascular Surgery*. 2022; 63: 184-267. 10.1016/j.ejvs.2021.12.024.
8. Vedantham S, Weinberg I, Desai K, Winokur R, Kolli K et al. Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents. *Journal of Vascular and Interventional Radiology*. 2023; 34: 1643-1657. 10.1016/j.jvir.2023.06.013.
9. Desai K, Sabri S, Elias S, Gagne P, Garcia M et al. Consensus Statement on the Management of Nonthrombotic Iliac Vein Lesions From the VIVA Foundation, the American Venous Forum, and the American Vein and Lymphatic Society. *Circulation: Cardiovascular Interventions*. 2024; 17: e014160. 10.1161/CIRCINTERVENTIONS.124.014160.
10. Mahnken A, Thomson K, de Haan M, O'Sullivan G. CIRSE Standards of Practice Guidelines on Iliocaval Stenting. *Cardiovascular and Interventional Radiology*. 2014; 37: 889-897. 10.1007/s00270-014-0875-4.
11. Birn J, Vedantham S. May–Thurner syndrome and other obstructive iliac vein lesions: Meaning, myth, and mystery. *Vascular Medicine*. 2015; 20: 74-83. 10.1177/1358863X14560429.

Evolut Clinical Guideline 7320 for Percutaneous Left Atrial Appendage Closure

Guideline Number: Evolut_CG_7320	<u>Applicable Codes</u>	
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Original Date: July 2017	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Percutaneous Left Atrial Appendage Closure.

Special Note

In order to review a request for medical necessity, the following items must be submitted for review:

- Progress note that prompted request from Electrophysiologist/Interventional Cardiologist/Cardiologist

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Transcatheter left atrial appendage closure (LAAC) is appropriate for patients with nonvalvular atrial fibrillation (AF) with high thromboembolic risk who meet the following criteria ⁽⁶⁾:

- Have an increased risk of stroke, defined as CHA₂DS₂-VASc of ≥ 2 (men) or ≥ 3 (women)
- Have adequate life expectancy (minimum >1 year) and quality of life to benefit from LAAC

- Have an increased bleeding risk (High HAS-BLED score ≥ 3), or are not suited for long-term oral anticoagulation (OAC), including but not limited to:
 - Prior bleeding
 - Fall risk
 - Uncontrolled hypertension
 - Renal or liver failure
 - Alcohol use
 - Concomitant antiplatelet or nonsteroidal agents
 - High-risk occupations
 - Noncompliance
 - Labile international normalized ratio
 - OAC intolerance/allergy
 - Drug interactions
- Do not have another absolute requirement for the continuation of long-term anticoagulant therapy, such as mechanical heart valve.

CODING AND STANDARDS

Coding

CPT Codes

33340

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Patients with atrial fibrillation (AF), an irregular heartbeat, are at an increased risk of stroke. The left atrial appendage (LAA) is a tubular structure that opens into the left atrium and has

been shown to be one potential source for blood clots that can cause strokes. While thinning the blood with anticoagulant medications has been proven to prevent strokes, percutaneous LAA closure (LAAC) has been studied as a non-pharmacologic alternative for patients with AF.

The CHA₂DS₂-VASc score is widely used for evaluating thromboembolic risk in those with nonvalvular AF.⁽⁷⁾ A score > 2 is considered an indication for anticoagulation in patients with AF and for left atrial appendage closure (LAAC) in men. Because the procedure is associated with a greater incidence of major complications in women, a score >3 is required for women.

CHA₂DS₂-VASc score is calculated as follows (criterion/points given):

- Age: <60/0; 60+/1; >75/+2
- Gender: Male 0; Female +1
- CHF history: No 0; Yes +1
- HTN history: No 0; Yes +1
- Stroke/TIA/thromboembolism history: No 0; Yes +2
- Vascular disease (including prior MI, PAD, aortic plaque: No 0; Yes +1
- Diabetes history: No 0; Yes +1

HAS-BLED Score for Major Bleeding Risk is calculated as follows (criterion/points given):

- Uncontrolled hypertension (systolic pressure >160): No 0; Yes +1
- Renal disease (kidney transplant or creatinine >2.26 mg/dl): No 0; Yes +1
- Liver disease (cirrhosis or bilirubin > 2x normal with AST/ALT/AP > 3x normal): No 0; Yes +1
- Stroke history: No 0; Yes +1
- Labile INR on warfarin (time in therapeutic range < 60%): No 0; Yes +1
- Age > 65: No 0; Yes +1
- Other medications predisposing to bleeding (NSAIDs, ASA, clopidogrel): No: 0; Yes +1
- Alcohol use (8 or more drink/week): No 0; Yes +1

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner.⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AF: Atrial fibrillation

AUC: Appropriate use criteria

LAA: Left atrial appendage

LAAC: Left atrial appendage closure

OAC: Oral anticoagulant therapy

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1320 for Percutaneous Left Atrial Appendage Closure ● Updated references and rewrote the Indications section based upon guidance from a recent consensus statement ● Clarified CHA2DS2-VASC and HAS-BLED scoring in the Background

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Saw J, Holmes D R, Cavalcante J L, Freeman J V, Goldsweig A M et al. SCAI/HRS Expert Consensus Statement on Transcatheter Left Atrial Appendage Closure. *JACC: Cardiovascular Interventions*. 2023; 16: 1384-1400. 10.1016/j.jcin.2023.01.011.
7. Zhu W, Xiong Q, Hong K. Meta-Analysis of CHADS2 versus CHA2DS2-VASc for Predicting Stroke and Thromboembolism in Atrial Fibrillation Patients Independent of Anticoagulation. *Texas Heart Institute Journal*. 2015; 42: 6-15. 10.14503/THIJ-14-4353.

Evolut Clinical Guideline 7321 for Pericardial Disease Interventions

Guideline Number: Evolut_CG_7321	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Pericardial Disease Interventions.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Pericardiocentesis

- Pericardial effusion with one or more of the following:
 - cardiac tamponade
 - symptomatic moderate to large effusion non-responsive to medical therapy ⁽⁶⁾
 - pericarditis, when bacterial or neoplastic etiology suspected ^(6,7)
 - large, idiopathic chronic effusion (> 3 months) not responsive to conventional therapy ^(6,7)
 - large, idiopathic subacute effusion (4-6 weeks) not responsive to medical therapy with signs of right-sided chamber collapse on echocardiogram ⁽⁶⁾
 - tuberculous pericarditis (diagnosis and treatment) ⁽⁶⁾
 - purulent pericarditis (diagnosis and treatment) ⁽⁶⁾
 - pericarditis in renal failure not responding to dialysis ⁽⁶⁾

- Pericardial cyst (symptomatic) and one or more of the following ⁽⁶⁾:
 - congenital
 - inflammatory

Pericardial Window

- Cardiac tamponade with one or more of the following characteristics: ⁽⁷⁾
 - recurrent
 - loculated
 - neoplastic
- Pericardial effusion with one or more of the following characteristics: ⁽⁶⁾
 - recurrent
 - biopsy material needed
 - not amenable to pericardiocentesis (i.e., loculated and/or posterior location)

Intrapericardial Treatment

- Intrapericardial instillation of medications for one or more of the following:
 - tuberculous pericarditis, to reduce risk of constriction ⁽⁶⁾
 - treatment of neoplastic effusions (i.e., cytostatic or sclerosing agents) ^(6,7)
 - treatment of uremic pericardial effusion (in addition to dialysis) ⁽⁶⁾
 - purulent pericarditis, to reduce the risk of recurrence, tamponade and constriction ^(6,7)
 - treatment of autoreactive/lymphocytic effusion ⁽⁶⁾

Pericardiectomy

- Recurrent pericarditis or pericardial effusion not responsive to medical therapy ^(6,7)
- Chronic constrictive pericarditis with persistent and prominent symptoms (i.e., NYHA class III or IV) ^(6,7)
- Constrictive tuberculous pericarditis that has not improved or has deteriorated after 4-8 weeks of antituberculosis therapy ⁽⁶⁾
- Purulent pericarditis with one or more of the following ⁽⁶⁾:
 - dense adhesions
 - loculated or thick effusion
 - recurrent tamponade
 - persistent infection
 - progression to constriction
- Chylopericardium ⁽⁶⁾

Pericardioscopy

As an alternative to a surgical approach, to allow for one or more of the following ⁽⁶⁾:

- pericardial biopsy and acquisition of fluid samples when the etiology of pericardial disease is in question
- pericardial drainage
- instillation of medication into the pericardiac sac

CODING AND STANDARDS

Coding

CPT Codes

32601, 32604, 32658, 32659, 32661, 33016, 33017, 33018, 33019, 33020, 33025, 33030, 33031, 33050

Applicable Lines of Business

☒	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Pericardiocentesis - It is a procedure done to remove fluid that has built up in the sac around the heart (pericardium) using a needle and small catheter to drain excess fluid either fluoroscopy or echocardiography guided.

Pericardioscopy - This procedure permits visualization and biopsy of the pericardial sac with its epicardial and pericardial layers.

Intrapericardial treatment - This procedure involves introduction of antineoplastic treatment in patients with neoplastic pericardial effusion in setting of metastatic malignancy.

Pericardial window - A pericardial window is a cardiac surgical procedure to create a communication, or 'window', from the pericardial space to the pleural cavity. The purpose of the window is to allow a pericardial effusion (usually malignant) to drain from the space surrounding the heart into the chest cavity in order to prevent a large pericardial effusion and

cardiac tamponade. A pericardial window may be created by video-assisted thoracoscopy or balloon pericardiotomy by a percutaneous intervention.

Pericardiectomy - It is the surgical removal of a portion or all of the pericardium. It is also called pericardial stripping. The pericardium is a double-walled, membrane sac that surrounds the heart.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

NYHA: New York Heart Association

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This policy replaces UM 1369 Pericardial Disease Interventions

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Adler Y, Charron P, Imazio M, Badano L, Barón-Esquivias G et al. 2015 ESC Guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC) Endorsed by: The European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2015; 36: 2921 - 2964. 10.1093/eurheartj/ehv318.
7. Tuck B, Townsley M. Clinical Update in Pericardial Diseases. *Journal of Cardiothoracic and Vascular Anesthesia*. 2019; 33: 184 - 199. 10.1053/j.jvca.2018.04.003.

Evolent Clinical Guideline 7323 Peripheral Intravascular Arterial and Venous Ultrasound

Guideline Number: Evolent_CG_7323	<u>Applicable Codes</u>	
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Original Date: October 2018	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for peripheral (non-coronary) intravascular arterial and venous ultrasound (IVUS).

Special Note

In order to review a request for medical necessity, the following items must be submitted for review:

- Progress note that prompted request
- Prior diagnostic peripheral angiogram/venogram
- Non-invasive vascular/venous testing

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

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INDICATIONS

Intravascular ultrasound is primarily indicated in the lower extremities. However, approval and AUC Scores vary depending on the vessel being investigated.

Iliac Artery ⁽⁶⁾

- Preintervention Scenarios

- Occlusion **(AUC Score 6)**
- Plaque morphology **(AUC Score 6)**
- Ambiguous lesion/severity **(AUC Score 7)**
- Filling defects **(AUC Score 6)**
- Vessel sizing **(AUC Score 7)**
- Minimizing contrast **(AUC Score 8)**
- Intraprocedural Scenarios
 - Location of crossing track **(AUC Score 9)**
 - Determination of next therapeutic step **(AUC Score 8)**
 - Vessel sizing for device **(AUC Score 6)**
- Postintervention optimization scenarios
 - Residual stenosis/plaque after debulking **(AUC Score 7)**
 - Stent optimization/postdilation **(AUC Score 6)**
 - Dissection detection **(AUC Score 8)**

Femoropopliteal Artery ⁽⁶⁾

- Preintervention Scenarios
 - Occlusion **(AUC Score 6)**
 - Plaque morphology **(AUC Score 6)**
 - Ambiguous lesion/severity **(AUC Score 8)**
 - Filling defects **(AUC Score 8)**
 - Vessel sizing **(AUC Score 8)**
 - Minimizing contrast **(AUC Score 8)**
- Intraprocedural Scenarios
 - Location of crossing track **(AUC Score 8)**
 - Determination of next therapeutic step **(AUC Score 9)**
 - Vessel sizing for device **(AUC Score 7)**
- Postintervention optimization scenarios
 - Residual stenosis/plaque after debulking **(AUC Score 7)**
 - Stent optimization/postdilation **(AUC Score 7)**
 - Dissection detection **(AUC Score 8)**

Tibial Artery ⁽⁶⁾

- Preintervention Scenarios
 - Occlusion **(AUC Score 8)**
 - Plaque morphology **(AUC Score 8)**

- Ambiguous lesion/severity **(AUC Score 7)**
- Filling defects **(AUC Score 8)**
- Vessel sizing **(AUC Score 8)**
- Minimizing contrast **(AUC Score 9)**
- Intraprocedural Scenarios **(AUC Score 8)**
 - Location of crossing track
 - Determination of next therapeutic step
 - Vessel sizing for device
- Postintervention optimization scenarios
 - Residual stenosis/plaque after debulking **(AUC Score 7)**
 - Stent optimization/postdilation **(AUC Score 8)**
 - Dissection detection **(AUC Score 8)**

Iliofemoral Vein ⁽⁶⁾

- Preintervention Scenarios
 - Lesion characteristics **(AUC Score 8)**
 - Lesion severity **(AUC Score 9)**
 - Filling defects **(AUC Score 9)**
 - Vessel sizing **(AUC Score 9)**
 - Minimizing contrast **(AUC Score 9)**
- Intraprocedural Scenarios **(AUC Score 9)**
 - Determination of next therapeutic step
 - Vessel sizing for device
- Postintervention optimization scenarios **(AUC Score 9)**
 - Stent optimization/postdilation

Other Indications

- Guiding of endovascular procedures for iliac vein outflow obstruction ⁽⁷⁾
- Assessment or guiding of treatment for aortic dissections or aneurysms ⁽⁸⁾
- Assessment of renal infarct etiology to evaluate secondary treatment options ⁽⁸⁾
- IVUS may be reasonable during peripheral arterial interventional procedures for complicated ilio-femoro-popliteal arterial lesions-TASC II class, longer lesion length, and narrower reference diameter, to aid in decision of treatment strategy including size and length of stent. ⁽⁹⁾

Limitations

IVUS is not appropriate for routine evaluation of peripheral artery disease when revascularization is not being contemplated based on angiographic results.

CODING AND STANDARDS

Coding

CPT Codes

37252, 37253

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Intravascular ultrasound (IVUS) is an invasive imaging modality that uses a specially designed catheter with a miniaturized ultrasound probe attached to the distal end of the catheter, which allows ultrasound imaging to be performed from within the lumen of the blood vessel. IVUS can be used to assess vessel/lumen diameter, lesion length, help determine the amount of plaque buildup in a vessel and its composition and check to ensure stents have been properly placed and fully deployed.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate use criteria

IVUS: Intravascular ultrasound

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none">• This guideline replaces UM 1318 Peripheral Intravascular Arterial and Venous Ultrasound

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Secemsky E, Mosarla R, Rosenfield K, Kohi M, Lichtenberg M et al. Appropriate Use of Intravascular Ultrasound During Arterial and Venous Lower Extremity Interventions. *JACC: Cardiovascular Interventions*. 2022; 15: 1558 - 1568. <https://doi.org/10.1016/j.jcin.2022.04.034>.
7. De Maeseneer M G, Kakkos S K, Aherne T, Baekgaard N, Black S et al. Editor's Choice 2013; European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. *European Journal of Vascular and Endovascular Surgery*. 2022; 63: 184 - 267. 10.1016/j.ejvs.2021.12.024.
8. Secemsky E, Aronow H, Kwolek C, Meissner M, Muck P et al. Intravascular Ultrasound Use in Peripheral Arterial and Deep Venous Interventions: Multidisciplinary Expert Opinion From SCAI/AVF/AVLS/SIR/SVM/SVS. *Journal of the Society for Cardiovascular Angiography & Interventions*. 2024; 3: 10.1016/j.jscai.2023.101205.
9. Iida O, Takahara M, Soga Y, Suzuki K, Hirano K et al. Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease with TASC II Class A to C Lesions. *Journal of Endovascular Therapy*. 2014; 21: 485 - 492. 10.1583/14-4721R.1.

Evolut Clinical Guideline 7324 for Renal Angiography

Guideline Number: Evolut_CG_7324	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Renal Angiography.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR RENAL ANGIOGRAPHY

Renal Artery Stenosis

- Hypertension:
 - Uncontrolled arterial hypertension (> 140/90 mm Hg) ⁽⁶⁾ despite being on maximal tolerated guideline-directed medical therapy (≥ 3 antihypertensive medications), defined as resistant hypertension ^(7,8)
 - Accelerated (defined as sudden and persistent worsening of controlled hypertension) and malignant hypertension (defined as hypertension with evidence of acute end-organ damage) ⁽⁷⁾
 - Onset of hypertension at < 30 years old ^(7,8)
 - Onset of severe hypertension at > 55 years old, with evidence of CKD (chronic kidney disease) and cardiac failure ^(7,8)
- Renal Dysfunction
 - New azotemia or worsening renal function after administration of an ACE inhibitor

- or ARB agent ^(7,8)
- Unexplained atrophic kidney (7 to 8 cm) or size discrepancy greater than 1.5 cm between kidneys ^(7,8)
- Unexplained renal dysfunction, including individuals starting renal replacement therapy (dialysis or renal transplantation) ^(7,8)
- Sudden and unexplained pulmonary edema, especially in azotemic patients ^(7,8)
- Multivessel coronary artery disease with no evidence of PAD at the time of arteriography ⁽⁷⁾
- Unexplained congestive heart failure or refractory angina ⁽⁷⁾

Note: 2013 ACCF/AHA ⁽⁷⁾ and 2024 ESC ⁽⁸⁾ recommend noninvasive DUS (duplex ultrasonography) as the first-line imaging, followed by CTA (eGFR is ≥ 60 mL/min) and/or MRA (eGFR is ≥ 30 mL/min) to establish the diagnosis of renal artery stenosis (RAS). When the clinical index of suspicion is high and the results of noninvasive studies are inconclusive, 2013 ACC/AHA recommends catheter angiography, while 2017 ESC ⁽⁹⁾ recommends DSA (digital subtraction angiography).

Fibromuscular Dysplasia ⁽¹⁰⁾

- Onset of hypertension less than 30 years of age, especially women
- Accelerated, malignant, or grade 3 (> 180/110 mm Hg) hypertension
- Drug-resistant hypertension despite being on maximal tolerated GDMT (blood pressure target not achieved despite 3 drug-therapy at optimal doses including a diuretic)
- Unilateral small kidney without a causative urological abnormality
- Abdominal bruit in the absence of atherosclerotic disease or risk factors for atherosclerosis
- Suspected renal artery dissection or infarction
- Presence of FMD in at least one other vascular territory

Note: CTA is the first-line imaging for suspected FMD for accurate differentiation of FMD from atherosclerotic renal artery stenosis. Contrast-enhanced magnetic resonance angiography (MRA) is the next option if CTA is contraindicated. When the results of CTA or MRA confirm the diagnosis of FMD, or when a clinical index of suspicion is high despite negative findings on CTA or MRA, catheter angiography should be considered for angioplasty and gradient obliteration assessment. Translesional pressure gradient measurement is also recommended for assessment of hemodynamic significance of stenosis, particularly in multifocal FMD, as well as post-angioplasty in both focal and multifocal FMD. ^(10,11)

CODING AND STANDARDS

Coding

CPT Codes

36251, 36252, 75726

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Renal angiography is X-ray study of blood vessels to the kidney. X-rays are taken while contrast dye is injected into a catheter (a tiny tube) that has been placed into the blood vessels of the kidneys to detect any signs of blockage, narrowing, or other abnormalities affecting the blood supply to the kidneys.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ACE: Angiotensin-converting enzyme

ARB: Angiotensin II receptor blockers

CKD: Chronic kidney disease

DUS: Duplex ultrasonography

DSA: Digital subtraction angiography

eGFR: Estimated glomerular filtration rate

FMD: Fibromuscular dysplasia
 GDMT: Guideline-directed medical therapy
 PAD: Peripheral artery disease
 RAS: Renal Artery Stenosis

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1293 Renal Angiography ● Updated clinical indication for Renal Angiography ● Removed limitation and special note sections

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; Accessed: 08/12/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Klein A, Jaff M, Gray B, Aronow H, Bersin R et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. *Catheter Cardiovasc Interv*. 2017; 90: E90-E110.
7. Anderson J, Halperin J, Albert N, Bozkurt B, Brindis R et al. Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*. 2013; 61: 1555 - 1570. 10.1016/j.jacc.2013.01.004.
8. Mazzolai L, Teixido-Tura G, Lanzi S, Boc V, Bossone E et al. 2024 ESC Guidelines for the management of peripheral arterial and aortic diseases. *European heart journal*. 2024.
9. Aboyans V, Ricco J, Bartelink M E L, Björck M, Brodmann M et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *European heart journal*. 2018; 39: 763-816.
10. Gornik H, Persu A, Adlam D, Aparicio L, Azizi M et al. First International Consensus on the diagnosis and management of fibromuscular dysplasia. *Vascular medicine (London, England)*. 2019; 24: 164-189.
11. Bhalla V, Textor S, Beckman J, Casanegra A, Cooper C et al. Revascularization for Renovascular Disease: A Scientific Statement From the American Heart Association. *Hypertension (Dallas, Tex.: 1979)*. 2022; 79: e128-e143.



Evolut Clinical Guideline 7325 for Renal Artery Intervention

Guideline Number: Evolut_CG_7325	<u>Applicable Codes</u>	
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Original Date: May 2016	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Renal Artery Intervention.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR RENAL ARTERY INTERVENTION

- Cardiac Disturbance Syndromes
 - Hemodynamically significant RAS and recurrent, unexplained congestive heart failure or sudden, unexplained pulmonary edema ⁽⁶⁾
 - Hemodynamically significant RAS and unstable angina ⁽⁶⁾
 - Flash pulmonary edema or acute coronary syndrome with hypertension and moderate RAS with resting translesional mean gradient of ≥ 10 mm Hg and/or severe RAS. **(AUC Score 9)** ⁽⁷⁾
 - Recurrent congestive heart failure with unilateral moderate RAS with resting translesional mean gradient of ≥ 10 mm Hg **(AUC Score 5)** ⁽⁷⁾
- Hypertension
 - Hemodynamically significant RAS and accelerated/resistant/malignant hypertension, or hypertension with an unexplained unilateral small kidney, or hypertension with intolerance to medication ⁽⁶⁾
 - Fibromuscular Dysplasia with early onset of accelerated/malignant/resistant

hypertension ⁽⁸⁾

- Resistant hypertension (uncontrolled arterial hypertension despite being on maximal (≥ 3) tolerated medical therapy including diuretic) with evidence of bilateral or solitary severe RAS (**AUC Score 7**) ⁽⁷⁾
- Resistant hypertension with evidence of unilateral severe RAS (**AUC Score 6**) ⁽⁷⁾
- Resistant hypertension severe unilateral RAS and high-risk lesion or complex anatomy (**AUC Score 4**) ⁽⁷⁾
- Nonproteinuric hypertension with unilateral renal artery disease ⁽⁸⁾
- Kidney Dysfunction
 - Progressive chronic kidney disease with bilateral ($>70\%$) RAS or a RAS in a solitary kidney ^(6,9)
 - Chronic renal insufficiency with unilateral RAS ($>70\%$) ^(6,9)
 - CKD Stage 4 with bilateral moderate RAS and resting mean translesion gradient of ≥ 10 mm Hg with kidney size > 7 cm in pole-pole length. (**AUC Score 8**) ⁽⁷⁾
 - CKD Stage 4 and global renal ischemia (unilateral severe RAS with solitary kidney or bilateral severe RAS) without other explanation. (**AUC Score 7**) ⁽⁷⁾
 - CKD class II with bilateral severe RAS (**AUC Score 5**) ⁽⁷⁾
 - CKD class III, stable for one year, with bilateral severe RAS (**AUC Score 5**) ⁽⁷⁾
- Hypertension and/or signs of renal dysfunction due to RAS caused by fibromuscular dysplasia ⁽⁹⁾
- Evidence of progressive renal artery occlusion ⁽⁸⁾
- Identifiable activation of renin-angiotensin system with hyperreninemia or with unilateral renal artery stenosis, lateralization of renal vein renin ⁽⁸⁾
- Angiotensin-dependent glomerular filtration rate ⁽⁸⁾
- Renal artery dissection; renal artery aneurysm and renal artery atherosclerosis greater than 50% in a transplanted kidney
- Special Populations ⁽⁸⁾:
 - Transplant renal artery stenosis with or without calcineurin inhibitors
 - Episodic, circulatory congestion with bilateral atherosclerotic renovascular disease
 - Progressive loss of glomerular filtration rate with occlusive atherosclerotic renovascular disease and no other kidney disease (ischemic nephropathy)
 - Aortic disease with renovascular protection as part of endovascular repair
 - Left-ventricular assist device
 - Radiation-induced renovascular disease with clinical syndromes
 - Other diseases: eg, Takayasu arteritis, extrinsic vascular compression
 - Pediatric patients with mid aortic syndrome or fibromuscular variants

Note: Atherosclerotic renovascular disease with **hemodynamically insignificant stenosis** do **not** benefit from vascular intervention when treated with optimal guideline-directed

medical therapy. Symptomatic FMD-related renovascular disease is warranted for consideration for renal ballon angioplasty procedure, followed by stenting in dissection management or balloon angioplasty failure. ^(8,10)

LIMITATIONS FOR RENAL ARTERY INTERVENTION (7)

- Resistant hypertension and unilateral moderate RAS with a mean translesional gradient of < 10 mm Hg
- Progressive CKD stage 3 to stage 4 over six months with solitary or unilateral, severe RAS, with kidney size < 7 cm in pole-to-pole length
- Resistant hypertension with unilateral chronic total occlusion of the renal artery
- BP ≥ 150/100 mm Hg on two medications (one diuretic) with severe unilateral RAS
- BP ≥ 150/100 mm Hg on one hypertensive agent with severe unilateral RAS
- Solitary or bilateral severe RAS with controlled BP and normal renal function
- CKD class II with unilateral severe RAS
- Bilateral or unilateral severe RAS with controlled BC and normal renal function
- Bilateral severe RAS with chronic end stage renal disease on hemodialysis > 3 months

CODING AND STANDARDS

Coding

CPT Codes

37236, 37237, 37246, 37247

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Renal Artery Angioplasty is an endovascular procedure to widen narrowed or obstructed renal arteries typically to treat arterial atherosclerosis. An empty, collapsed balloon, known as a balloon catheter, is passed over a wire into the narrowed locations and then inflated to a fixed size. The balloon forces expansion of the stenosis (narrowing) within the vessel and the surrounding muscular wall, opening up the blood vessel for improved flow, and the balloon is then deflated and withdrawn. A stent may or may not be inserted at the time of ballooning to ensure the vessel remains open.

Renovascular hypertension is one of many clinical syndromes of renovascular disease, derived most often from atherosclerosis, followed by fibromuscular dysplasia (FMD). Other less common causes include renal artery aneurysm, dissection, extravascular compression, infarction, mid aortic coarctation, partial or complete renal artery coverage by stent grafts, allograft inflow obstruction, and anatomic variants. ⁽⁸⁾

Definitions ⁽⁷⁾

- Hemodynamically significant RAS is defined as either:
 - Angiographic stenosis severity between 50-70% stenosis with resting or hyperemic mean pressure gradient ≥ 10 mm Hg
 - Angiographic stenosis severity between 50-70% stenosis with resting or hyperemic systolic pressure gradient ≥ 20 mm Hg
 - Angiographic stenosis severity between 50-70% stenosis with Renal Pd/Pa ≤ 0.8
 - Angiographic stenosis severity with $\geq 70\%$ stenosis.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ACE: Angiotensin-converting enzyme

ARB: Angiotensin II receptor blockers

BP: Blood pressure

CKD: Chronic kidney disease

FMD: Fibromuscular dysplasia

GDMT: Guideline-directed medical therapy

RAS: Renal artery stenosis

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1294 Renal Artery Intervention (Angioplasty or Stent) ● Updated clinical indication, limitation, and background sections ● Removed special note section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND. 2001; Accessed: 08/12/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Anderson J, Halperin J, Albert N, Bozkurt B, Brindis R et al. Management of Patients With Peripheral Artery Disease (Compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations) A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013; 127: 1425 - 1443. 10.1161/CIR.0b013e31828b82aa.
7. Klein A, Jaff M, Gray B, Aronow H, Bersin R et al. SCAI appropriate use criteria for peripheral arterial interventions: An update. *Catheterization and cardiovascular interventions*. 2017; 90: E90-E110.
8. Bhalla V, Textor S, Beckman J, Casanegra A, Cooper C et al. Revascularization for Renovascular Disease: A Scientific Statement From the American Heart Association. *Hypertension (Dallas, Tex.: 1979)*. 2022; 79: e128-e143.
9. Mazzolai L, Teixeira-Tura G, Lanzi S, Boc V, Bossone E et al. 2024 ESC Guidelines for the management of peripheral arterial and aortic diseases. *European heart journal*. 2024.
10. Aboyans V, Ricco J, Bartelink M E L, Björck M, Brodmann M et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases in collaboration with the European Society for Vascular Surgery (ESVS). *European heart journal*. 2018; 39: 763-816.

Evolut Clinical Guideline 7326 for Renal/Retroperitoneal Vascular Duplex Ultrasound

Guideline Number: Evolut_CG_7326	<u>Applicable Codes</u>	
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Original Date: July 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Renal/Retroperitoneal Vascular Duplex Ultrasound.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS BY ORGAN

Kidney

- Initial imaging of renal transplant dysfunction ⁽⁶⁾
- Symptomatic renovascular hypertension ⁽⁷⁾
 - with worsening renal function tests
 - resistant hypertension
- Suspected renovascular hypertension ^(7,8)
 - abdominal bruit
 - malignant or accelerated hypertension
 - significant hypertension in patients under 35 years of age
 - sudden onset or worsening of hypertension

- Suspected ischemic neuropathy ⁽⁸⁾
- Suspected thromboembolism ⁽⁸⁾
- Suspected fibromuscular dysplasia ⁽⁸⁾
- Follow-up after renal artery intervention ⁽⁹⁾
 - within 1 month after procedure
 - 6 months, 12 months and then annually after procedure
- Evaluation of renal artery stenosis ^(7,8):
 - To determine hemodynamic significance
 - With worsening renal function
 - With resistant hypertension
 - In symptomatic patients less than 35 years
 - In symptomatic patients with evidence of kidney size discrepancy
- As part of initial work-up for organ transplant

Mesentery

- Initial screening for suspected chronic mesenteric ischemia ^(8,10)
 - best performed in a fasting state to avoid bowel gas
- Follow-up after surgical bypass procedure or stent insertion ^(8,9)
 - Clinical follow-up and baseline within 1 month of procedure ⁽⁹⁾
 - Follow-up 6 months, 12 months, and then annually after procedure ⁽⁹⁾
- Suspected stenosis or restenosis of the superior mesenteric artery ⁽¹¹⁾

Liver

- Suspected portal hypertension or portal vein thrombosis in the presence of:
 - known hepatic disease ^(12,13)
 - abnormal liver function tests with hepatocellular dominance and moderate to severe aminotransferase increase ⁽¹²⁾
- Chronic liver disease with suspected hepatocellular carcinoma ⁽¹³⁾
 - to identify tumor in vein
- Evaluation for liver transplant ⁽¹⁴⁾

Scrotum/Testicles

- Pain or swelling of scrotal contents
 - Newly diagnosed palpable scrotal abnormality, with or without history of trauma or infection ⁽¹⁵⁾

CODING AND STANDARDS

Coding

CPT Codes

93975, 93976

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM 1125 Renal/Retroperitoneal Vascular Duplex Ultrasound • Clarified surveillance timelines for post-surgical imaging • Added indications for suspected renal conditions: ischemia, thromboembolism, fibromuscular dysplasia • Updated citations

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACCF Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Taffel M T, Nikolaidis P, Beland M D, Blaufox M D, Dogra V S et al. ACR Appropriateness Criteria Renal Transplant Dysfunction. *Journal of the American College of Radiology*. 2017; 14: S272 - S281. 10.1016/j.jacr.2017.02.034.
7. Harvin H J, Verma N, Nikolaidis P, Hanley M, Dogra V S et al. ACR Appropriateness Criteria Renovascular Hypertension. *Journal of the American College of Radiology*. 2017; 14: S540 - S549. 10.1016/j.jacr.2017.08.040.
8. Kupinski A. Mesenteric and renal arterial duplex ultrasound: A review. *Vascular Medicine*. 2023; 28: 463 - 475. 10.1177/1358863X231172247.
9. Zierler R, Jordan W, Lal B, Mussa F, Leers S et al. The Society for Vascular Surgery practice guidelines on follow-up after vascular surgery arterial procedures. *Journal of Vascular Surgery*. 2018; 68: 256 - 284. 10.1016/j.jvs.2018.04.018.
10. Ginsburg M, Obara P, Lambert D L, Hanley M, Steigner M L et al. ACR Appropriateness Criteria Imaging of Mesenteric Ischemia. *Journal of the American College of Radiology*. 2018; 15: S332 - S340. 10.1016/j.jacr.2018.09.018.
11. Pamulapati V, Guitart J, Helenowski I, Resnick S, Ho K. Use of computed tomographic and digital subtraction angiography to determine optimal duplex ultrasound criteria for predicting superior mesenteric artery in-stent restenosis. *Vascular Medicine*. 2021; 26: 566 - 568. 10.1177/1358863X211025615.
12. Arif-Tiwari H, Porter K K, Kamel I R, Bashir M R, Fung A et al. ACR Appropriateness Criteria Abnormal Liver Function Tests. *Journal of the American College of Radiology*. 2023; 20: S302 - S314. 10.1016/j.jacr.2023.08.023.
13. Bashir M R, Horowitz J M, Kamel I R, Arif-Tiwari H, Asrani S K et al. ACR Appropriateness Criteria Chronic Liver Disease. *Journal of the American College of Radiology*. 2020; 17: S70 - S80. 10.1016/j.jacr.2020.01.023.
14. Martin P, DiMartini A, Feng S, Brown Jr. R, Fallon M. Evaluation for liver transplantation in adults: 2013 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. *Hepatology*. 2014; 59: 1144 - 1165. <https://doi.org/10.1002/hep.26972>.

15. Gerena M, Allen B C, Turkbey B, Barker S J, Costa D N et al. ACR Appropriateness Criteria Acute Onset of Scrotal Pain-Without Trauma, Without Antecedent Mass: 2024 Update. Journal of the American College of Radiology. 2024; 21: S364 - S371. 10.1016/j.jacr.2024.08.011.



Evolut Clinical Guideline 7327 for Right Heart Catheterization Only

Guideline or Policy Number: Evolut_CG_7327	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Right heart catheterization is an invasive hemodynamic procedure used to evaluate right-sided cardiac pressures, calculate cardiac output, and pulmonary pressures. ⁽¹⁾

This guideline applies to patients with a stable clinical presentation, not to those with acute syndromes or acute valvular abnormalities.

In stable patients, preliminary evaluation with non-invasive cardiac testing is usually indicated prior to a recommendation for cardiac catheterization.

These guidelines **ONLY** covers procedures that include standalone right heart catheterization.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(2,3,4,5,6)

INDICATIONS FOR RIGHT CARDIAC CATHETERIZATION

Determining Medical Necessity

No prior heart Cath performed within the last 6 months

- Patients with known history of congestive heart failure **(AUC Score 7)**
- Patients with cardiomyopathy (EF less than 40%) with or without heart failure and or for re- evaluation due to change in clinical status or to guide therapy. **(AUC Score 7)**

- Patients with known or suspected valvular heart disease **(AUC Score 8)**
- Patients with known or suspected intracardiac shunt **(AUC Score 8)**
- Patients with recent myocardial infarction in presence of LVEF less than 45% **(AUC Score 7)**
- Patients with worsening symptoms of pulmonary hypertension or is suspected to have Pulmonary Hypertension (Pulmonary Artery Systolic Pressure greater than 40 mm Hg) on echocardiogram. **(AUC Score 8)**
- Patients at least 6 months post-LVAD placement as a bridge to transplant in whom pulmonary hypertension existed (PVR greater than 2.5 Wood units) or mean PA pressure greater than 20 mmHg on RHC performed prior to LVAD implant **(AUC Score 8)**

Suspected or with Known Constrictive or Effusive/Constrictive Pericarditis

After undergoing the following imaging tests: (no RIGHT heart cardiac catheterization within the last 6 months) **(AUC Score 7)**

- Transthoracic Echocardiogram
- Cardiac MRI or MRA
- Cardiac CT or CTA

CODING AND STANDARDS

Coding

CPT Codes

93451, 93463, 93503, 93530, 93593, 93594, 93598

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Heart catheterization is the passage of a thin flexible tube (catheter) into the right heart systems via veins (femoral vein, internal jugular vein, or antecubital vein), respectively, for the purposes of hemodynamic measurements, acquisition of blood samples from specific locations, and/or the injection of radiopaque medium for the purposes of visualizing vascular anatomy. Angiography is the passage of a catheter into the right side of the heart to diagnose chronic pulmonary disease or congenital heart diseases. ⁽¹⁾

Definitions

Right Heart Failure ^(7,8,9)

Right heart failure is often a result of LV failure due to volume or pressure overload. Symptoms can include chest pain, shortness of breath, palpitations, and increase in water retention causing peripheral/body edema.

Other causes of right heart failure include:

- Acute RVF
 - Volume overload from LHF or LVAD implant
 - Pressure overload from PE or hematological disorders (e.g., sickle cell disease, acute chest syndrome)
- Chronic RHF
 - Pulmonary Hypertension (e.g., result from LHF)
 - Congenital Heart Disease (e.g., atrial or ventricular septal defects, Ebstein's anomaly)
 - Valvular insufficiency (e.g., pulmonary valve stenosis, tricuspid valve regurgitation)
 - Right ventricular myocardial disease (e.g., Right sided MI, amyloidosis, sarcoidosis, ARVD, cardiomyopathy)

Congenital Heart Disease ^(10,11)

Congenital heart disease is one cause of Right Ventricular Heart Failure. Congenital heart defects are malformations of the heart's valves, chambers, arteries, or veins that are present at birth. Common congenital heart defects that can lead to right ventricular heart failure include:

- Atrial Septal Defect
- Ebstein's Anomaly
- I-Transposition of the great arteries
- Pulmonary Valve Stenosis
- Single Ventricle Defects (Hypoplastic Left Heart Syndrome, Pulmonary
- Tetralogy of Fallot

Hemodynamic parameters and pressure measurements ^(1,8)

- Mean Right Atrial pressure
 - Normal: 1-5 mmHg
- Mean pulmonary artery systolic and diastolic pressure
 - Normal systolic pressure: 15 to 30 mmHg
 - Normal diastolic pressure: 4 to 12 mmHg
- Mean pulmonary artery pressure
 - mPAP Normal: 15mmHg
 - mPAP Abnormal: > 20 mmHg ⁽¹²⁾
- Pulmonary capillary wedge pressure (PCWP)
 - PCWP Normal: 4 to 12 mmHg

NOTE: The above measured pressures can calculate cardiac output, cardiac index, pulmonary vascular resistance, systemic vascular resistance, stroke work index, right ventricular stroke work, PAPI.

- Pulmonary Vascular Resistance ⁽¹²⁾
 - Normal upper limit: ≈2 Wood units (WU)
- Pulmonary Artery Pulsatility Index (PAPi) ⁽¹³⁾
 - PAPi is the ratio between pulmonary artery pressure and right atrial pressure and is calculated using [(Systolic pulmonary artery pressure – diastolic pulmonary artery pressure) / right atrial pressure]
 - PAPi < 0.9: high sensitivity and specificity for right ventricular failure
 - PAPi < 1.85: high sensitivity a patient will experience right ventricular failure and require ventricular hemodynamic device support such as LVAD

Constrictive Pericarditis ^(14,15)

Constrictive Pericarditis is a condition in which granulation tissue develops in the pericardium over time resulting in the loss of the pericardial elasticity restricting ventricular filling. When ventricular filling is impeded throughout diastole the result is decreased end diastolic volume, decreased stroke volume, and decreased cardiac output.

Cardiac catheterization may be considered to assess the hemodynamic pressures when other noninvasive imaging is inconclusive.

Pulmonary Hypertension ^(12,13)

Pulmonary hypertension is a progressive chronic disease caused by pulmonary vascular remodeling which overtime can lead to RHF and is associated with high rates of morbidity and mortality.

Classification of PH is defined by having a mean pulmonary arterial pressure (mPAP) > 25 mmHg at rest ⁽⁹⁾

- mPAP ≥ 25 mmHg (pre and post capillary)
- PCWP Precapillary ≤ 15 mmHg

- PRV > 3 Wood Units

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ARVD: Arrhythmogenic right ventricular dysplasia

CCT: Cardiac computed tomography

CCTA: Coronary computed tomographic angiography

EF: Ejection fraction

LHF: Left heart failure

LVAD: Left ventricular assist device

MI: Myocardial Infarction

mPAP: Mean pulmonary arterial pressure

MRA: Magnetic resonance angiography

MRI: Magnetic resonance imaging

PA: Pulmonary artery

PAPi: Pulmonary Artery Pulsatility Index

PCWP: Pulmonary capillary wedge pressure

PE: Pulmonary Embolism

PH: Pulmonary hypertension

PVR: Pulmonary vascular resistance

RHC: Right heart catheterization

RHF: Right heart failure

RVSP: Right ventricular systolic pressure

RVF: Right ventricular failure

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> Added CPT code 93463
November 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1460 Right Heart Catheterization Only

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Chokkalingam Mani B, Chaudhari S. Right Heart Cardiac Catheterization. StatPearls [Internet]. Treasure Island (FL). 2023; <https://www.ncbi.nlm.nih.gov/books/NBK557404/>.
2. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
3. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
4. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
5. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
6. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
7. Mandras S, Desai S. Right Heart Failure. StatPearls [Internet]. Treasure Island (FL). 2023; <https://www.ncbi.nlm.nih.gov/books/NBK459381/>.
8. Monteagudo-Vela M, Tindale A, Monguió-Santín E, Reyes-Copa G, Panoulas V. Right ventricular failure: Current strategies and future development. *Frontiers in Cardiovascular Medicine*. 2023; 10: 10.3389/fcvm.2023.998382.
9. Konstam M A, Kiernan M S, Bernstein D, Bozkurt B, Jacob M et al. Evaluation and Management of Right-Sided Heart Failure: A Scientific Statement From the American Heart Association. *Circulation*. 2018; 137: 10.1161/CIR.0000000000000560.
10. American Heart Association. Common Types of Heart Defects. American Heart Association. 2022; <https://www.heart.org/en/health-topics/congenital-heart-defects/about-congenital-heart-defects/common-types-of-heart-defects>.
11. Foschi M, Di Mauro M, Tancredi F, Capparuccia C, Petroni R et al. The Dark Side of the Moon: The Right Ventricle. *Journal of Cardiovascular Development and Disease*. 2017; 4: 18. 10.3390/jcdd4040018.
12. Humbert M, Kovacs G, Hoeper M, Badagliacca R, Berger R et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *European Heart Journal*. 2022; 43: 3618-3731. 10.1093/eurheartj/ehac237.
13. Ostad S, Sugarman J, Alkhodair A, Liang J, Mielniczuk L et al. Association Between the Pulmonary Artery Pulsatility Index and Prognosis in Pulmonary Arterial Hypertension: A Multicentre Study. *CJC Open*. 2023; 5: 545-553. 10.1016/j.cjco.2023.04.005.
14. Dababneh E, Siddique M. Pericarditis. StatPearls [Internet]. Treasure Island (FL). 2023; <https://www.ncbi.nlm.nih.gov/books/NBK431080/>.
15. Doshi S, Ramakrishnan S, Gupta S. Invasive hemodynamics of constrictive pericarditis. *Indian Heart Journal*. 2015; 67: 175-182. 10.1016/j.ihj.2015.04.011.

Evolut Clinical Guideline 7328-01 for Stress Echocardiography

Guideline Number: Evolut_CG_7328-01	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

This guideline is for stress imaging, specifically Stress Echocardiography (SE) with appropriate preference for suitable alternatives, such as an exercise treadmill exam without imaging, when more suitable, unless otherwise stated (refer to **Background section**).

Special Note

See Legislative Language for specific mandates in **Washington**.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR STRESS ECHOCARDIOGRAPHY (6,7,8)

Suspected Coronary Artery Disease (CAD)

- **Symptomatic patients without known CAD. No imaging stress test within the last 12 months.** The terms "typical," "atypical," and "non-anginal symptoms" can still be observed in medical records (consult the **Diamond Forrester table** in the **Definitions** section). However, the ACC has simplified its terminology to "Less likely anginal symptoms" and "Likely anginal symptoms" (refer to **Definitions**) and utilized below.
 - Less-likely anginal symptoms (**AUC Score 4-6**)

- When baseline EKG makes standard exercise test inaccurate (see **Definitions** section).
- When a noncardiac explanation is provided for symptoms, no testing is required (**AUC Score 8**)
- Likely Anginal Symptoms (typical angina)
 - < 50 years old with ≤ one risk factor if an ECG treadmill test cannot be done. **AUC scores for this bullet point are identical for MPI, stress echo, and ETT (**AUC Score 7**). Although the ACC guideline does not specify youth and gender, decisions should be guided by best medical judgment, considering factors such as safety and radiation exposure.
 - ≥ 50 years old (**AUC Score 8**)
- Repeat testing in patient with new or worsening symptoms and negative result at least one year ago AND meets one of the criteria above
- **Asymptomatic patients without known CAD**
 - Previously unevaluated ECG evidence of possible myocardial ischemia including ischemic ST segment or T wave abnormalities (see **Background** section)
 - Previously unevaluated pathologic Q waves (see **Background** section)
 - Previously unevaluated complete left bundle branch block

Abnormal Calcium Scores (8,9,10,11,12)

- STABLE SYMPTOMS with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months ⁽¹⁰⁾
- ASYMPTOMATIC high global CAD risk patient with a prior Coronary Calcium Agatston Score of >100. No prior stress imaging done within the last 12 months ⁽¹⁰⁾
- Asymptomatic patient with Coronary Calcium Agatston Score > 400. No prior stress imaging done within the last 12 months

Inconclusive CAD Evaluation and Obstructive CAD Remains a Concern

- Exercise stress ECG with low-risk Duke treadmill score ≥5, but patient's current symptoms indicate an increasing likelihood of disease
- Exercise stress ECG with an intermediate Duke treadmill score
- A previously unevaluated ventricular wall motion abnormality demonstrated by another imaging modality and stress echo is being performed to determine if the patient has myocardial ischemia. ^(8,13) (**AUC Score 8**) ⁽⁸⁾
- Intermediate coronary computed tomography angiography (CCTA) defined as 40%-70% lesion
- Coronary stenosis of unclear significance on previous coronary angiography not previously evaluated ⁽⁸⁾

Follow-Up of Patient's Post Coronary Revascularization (PCI or CABG) ⁽¹⁴⁾

- **Asymptomatic follow-up stress imaging** at a minimum of 2 years post coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI) (whichever is later) is appropriate for patients with: **(AUC Score 6)**
 - **High risk:** diabetes with accelerated progression of CAD, CKD, PAD, prior brachytherapy, ISR, or SVG intervention.
 - A history of silent ischemia or
 - A history of a prior left main stent

OR

- For patients with high occupational risk, associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers and firefighters
- **New, recurrent, or worsening symptoms, treated medically or by revascularization** is an indication for stress imaging, if it will alter management for typical anginal symptoms or symptoms documented to be similar to those prior to revascularization if no imaging stress test within the last 12 months. **(AUC Score 8)** ⁽¹⁰⁾

Follow-Up of Known CAD

- **Routine follow-up of asymptomatic or stable symptoms** when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test or $FFR \leq 0.80$ or significant stenosis in a major vessel ($\geq 50\%$ left main coronary artery or $\geq 70\%$ LAD, LCX, RCA)), over two years ago without intervening coronary revascularization, is an appropriate indication for stress imaging

Special Diagnostic Conditions Requiring Coronary Evaluation

- Prior acute coronary syndrome (with documentation in MD notes), within last 12 months, without a prior stress test or coronary angiography performed since that time
- Newly diagnosed systolic heart failure or diastolic heart failure, **with reasonable suspicion of cardiac ischemia (prior events, risk factors)**, unless invasive coronary angiography is immediately planned ^(10,14) **(AUC Score 8)** ⁽⁸⁾
- Ventricular arrhythmias **(AUC Score 7)** ⁽⁸⁾
 - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise-induced VT, when invasive coronary arteriography has not been performed ⁽¹⁵⁾
 - Non-sustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVCs (defined as greater than or equal to 30/hour on remote monitoring), when an exercise ECG cannot be performed ⁽¹⁵⁾
- For intermediate and high-risk global patients who require initiation of Class IC antiarrhythmic drugs. It can be performed annually thereafter until discontinuation of

drug use ⁽¹⁶⁾ **(AUC Score 7)** ⁽⁸⁾

- Hemodynamic assessment of ischemia in one of the following documented conditions:
 - Anomalous coronary arteries in an asymptomatic individual without prior stress echocardiography;⁽¹⁷⁾
 - Myocardial bridging of a coronary artery ⁽¹⁸⁾
- Coronary aneurysms in Kawasaki's disease ⁽¹⁹⁾
- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter ⁽²⁰⁾

Chronic Vascular Disease

Evaluation with Inclusion of Doppler ^(21,22,23,24)

- For the evaluation of aortic stenosis and flow (contractile) reserve in symptomatic patients with severe aortic stenosis by calculated valve area, low flow / low gradient, and ejection fraction < 50% **(AUC Score 8)** ⁽¹⁴⁾
- For evaluation of asymptomatic moderate or severe aortic stenosis (AS) for measurement of changes in valve hemodynamics **(AUC Score 8)** ⁽¹⁴⁾
- Non-severe aortic regurgitation (AR) with symptoms: Assessment of functional capacity and to assess for other causes of symptoms ^(8,14) **(AUC Score 7)** ⁽¹⁴⁾
- For evaluation of mitral stenosis (MS) if there is:
 - Exertional shortness of breath which suggests the amount of MS is worse than is seen on the resting echocardiogram **(AUC Score 8)** ⁽¹⁴⁾
- For evaluation for mitral regurgitation (MR) if there is:
 - Exertional shortness of breath which suggests the amount of MR is worse than is seen on the resting echocardiogram, **(AUC Score 8)** ⁽¹⁴⁾ **OR**
 - The echocardiogram is not able to distinguish whether the MR is moderate or severe in a patient that is asymptomatic **(AUC Score 7)** ⁽¹⁴⁾
- For symptomatic patients with HCM, who do not have resting or provokable outflow tract gradient \geq 50 mmHg on TTE, for detection and quantification of dynamic LVOT obstruction ⁽²⁵⁾
- For asymptomatic patients with HCM who do not have a resting or provokable outflow tract gradient \geq 50 mmHg on TTE (Class 2A)

Diastolic Function

- For unexplained dyspnea and suspected heart failure with preserved LVEF ⁽⁸⁾ (HFpEF) with normal or equivocal diastolic function on resting images

Prior To Elective Non-Cardiac Surgery ^(7,26,27,28)

- An intermediate or high-risk surgery with of one or more risk factors (see below), **AND** documentation of an inability to walk (or < 4 METs) **AND** there has not been an imaging stress test within 1 year ^(26,27,29) **(AUC Score 8)**

- **Risk factors:** history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, and preoperative serum creatinine >2.0 mg/dL.
- **Surgical Risks:**
 - **High risk surgery:** Aortic and other major vascular surgery, peripheral vascular surgery, anticipated prolonged surgical procedures associated with large fluid shifts and/or blood loss
 - **Intermediate risk surgery:** Carotid endarterectomy, head and neck surgery, intraperitoneal and intrathoracic surgery, orthopedic surgery, prostate surgery
 - **Low risk surgery:** Endoscopic procedures, superficial procedure, cataract surgery, breast surgery

Pre Organ-Transplant

- Planning for any organ or stem cell transplantation is an indication for preoperative stress imaging, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, at the discretion of the transplant service ^(7,30) (AUC Score 8).

Post Cardiac Transplantation

- Annually, post cardiac transplantation, in a patient not undergoing invasive coronary arteriography

LEGISLATIVE LANGUAGE

Washington

20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease ⁽³¹⁾

Number and coverage topic:

20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease

HTCC coverage determination:

Noninvasive cardiac imaging is a **covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage: The following noninvasive cardiac imaging technologies are **covered with conditions**:

- Stress echocardiography for:
 - Symptomatic adult patients (≥ 18 years of age) at intermediate or high risk of Coronary Artery Disease (CAD), or
 - Adult patients with known CAD who have new or worsening symptoms.
- Single Positron Emission Tomography (SPECT) for:
 - Patients under the same conditions as stress echocardiography when stress

echocardiography is not technically feasible or clinically appropriate.

- Positron Emission Tomography (PET) for:
 - Patients under the same conditions as SPECT, when SPECT is not technically feasible or clinically appropriate.
- Coronary Computed Tomographic Angiography (CCTA) for:
 - Symptomatic adult patients (≥18 years of age) at intermediate or high risk of CAD, or
 - Adult patients with known CAD who have new or worsening symptoms.
- CCTA with Fractional Flow Reserve (FFR) for:
 - Patients under the same conditions as CCTA, when further investigation of functional significance of stenoses is clinically indicated.

Non-covered indicators:

N/A

Notes:

- Out of scope/data not reviewed for this decision:
 - Asymptomatic individuals, follow up of prior abnormal cardiac imaging studies, myocardial viability, preoperative evaluation
 - Patients presenting for evaluation of cardiac pathologies other than CAD
- This determination supersedes the following previous determinations:
 - Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease (20081114A)
 - Cardiac Nuclear Imaging (20130920A)

CODING AND STANDARDS

Coding

CPT Codes

+93320, +93321, +93325, 93350, 93351, +93352, +93356

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Stress echocardiography is an exercise stress test which utilizes echocardiography to provide information on exercise tolerance, ischemic burden, and structural heart disease including valvular disease and provides analysis of left ventricular function.

Stress echocardiography (SE) refers to ultrasound imaging of the heart during exercise electrocardiography (ECG) testing, during which visualized wall motion abnormalities can provide evidence of potential significant coronary artery disease (CAD).

While drug-induced stress with dobutamine can be an alternative to exercise stress testing in patients who are unable to exercise, this guideline does not require use of this modality. Hence, reference in this document to SE predominantly refers to exercise stress echocardiography.

Although SE provides comparable accuracy without radiation risk, relative to myocardial perfusion imaging (MPI), scenarios which do not permit effective use of SE might be better suited for stress imaging with MPI, cardiovascular magnetic resonance imaging (CMR) or positron emission tomography (PET), or coronary computed tomography angiography (CCTA).

Cardiac Doppler ultrasound is a form of ultrasound that can detect and measure blood flow. Doppler ultrasound depends on the Doppler Effect, a change in the frequency of a wave resulting from the motion of a reflector, the red blood cell. There are three types of Doppler ultrasound performed during a cardiac Doppler examination:

- Pulsed Doppler
- Continuous wave Doppler
- Color flow Doppler

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner ⁽³⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Definitions

- Stable patients without known CAD fall into 2 categories: ^(6,7,8)
 - **Asymptomatic patients**, for whom Global Risk of CAD events can be determined from coronary risk factors using calculators available online (see **Websites for Global Cardiovascular Risk Calculators** section)
 - **Symptomatic patients**, for whom we estimate the Pretest Probability that their chest-related symptoms are due to clinically significant CAD (see below):
- The medical record should provide enough detail to establish the type of chest pain:
 - **Likely Anginal symptoms** encompass chest/epigastric/shoulder/arm/jaw pain, chest pressure/discomfort occurring with exertion or emotional stress and

relieved by rest, nitroglycerine or both.

- **Less-Likely Anginal symptoms** include dyspnea, or fatigue not relieved by rest/nitroglycerin, as well as generalized fatigue or chest discomfort with a time course not indicative of angina (e.g., resolving spontaneously within seconds or lasting for an extended period unrelated to exertion).
- **Risk Factors for Coronary disease include (but not limited to):** diabetes mellitus, smoking, family history of premature CAD (men age less than 55, females less than 65), hypertension, dyslipidemia.
- Beginning 2023, the classification terms for angina were updated within the ACC’s Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease to **Less Likely Anginal Symptoms** and **Likely Anginal Symptoms** as in #2. Previously, the document referred to “Typical Angina”, “Atypical Angina” and “Non-Anginal” symptoms, defined by the **Diamond Forrester Table**. We still provide this information for your reference ^(6,7,8):

Diamond Forrester Table ^(32,33)

Age (Years)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain
≤ 39	Men	Intermediate	Intermediate	Low
	Women	Intermediate	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate
	Women	Intermediate	Low	Very low
50 – 59	Men	High	Intermediate	Intermediate
	Women	Intermediate	Intermediate	Low
≥ 60	Men	High	Intermediate	Intermediate
	Women	High	Intermediate	Intermediate

Very low: < 5% pretest probability of CAD, usually not requiring stress evaluation

Low: 5 - 10% pretest probability of CAD

Intermediate: 10% - 90% pretest probability of CAD

High: > 90% pretest probability of CAD

- MPI may be performed without diversion to SE in any of the following ^(8,34):
 - Inability to exercise
 - Physical limitations precluding ability to exercise for at least 3 full minutes of Bruce protocol
 - Limited functional capacity (< 4 metabolic equivalents) **such as one** of the following:

- Cannot take care of their activities of daily living (ADLs) or ambulate
 - Cannot walk 2 blocks on level ground
 - Cannot climb 1 flight of stairs
 - Cannot vacuum, dust, do dishes, sweep, or carry a small grocery bag
- Other Comorbidities
 - Severe chronic obstructive pulmonary disease with pulmonary function test (PFT) documentation, severe shortness of breath on minimal exertion, or requirement of home oxygen during the day
 - Poorly controlled hypertension, with systolic BP > 180 or Diastolic BP > 120 (and clinical urgency not to delay MPI)
- ECG and Echo-Related Baseline Findings
 - Prior cardiac surgery (coronary artery bypass graft or valvular)
 - Documented poor acoustic imaging window
 - Left ventricular ejection fraction ≤ 40%
 - Pacemaker or ICD
 - Persistent atrial fibrillation
 - Resting wall motion abnormalities that would make SE interpretation difficult
 - Complete LBBB
- Risk-related scenarios
 - High pretest probability in suspected CAD
 - Intermediate or high global risk in patients requiring type IC antiarrhythmic drugs (prior to initiation of therapy and annually)
 - Arrhythmia risk with exercise
- Previously unevaluated pathologic Q waves (in two contiguous leads) defined as the following:
 - 40 ms (1 mm) wide
 - 2 mm deep
 - 25% of depth of QRS complex
- ECG Stress Test Alone versus Stress Testing with Imaging

Prominent scenarios suitable for an ECG stress test **WITHOUT** imaging (i.e., exercise treadmill ECG test) are inferred from the guidelines presented above, often requiring that the patient can exercise for at least 3 minutes of Bruce protocol with achievement of near maximal heart rate **AND** has an interpretable ECG for ischemia during exercise ⁽⁸⁾:

 - The (symptomatic) low or intermediate pretest probability patient who can exercise and has an interpretable ECG
 - The patient who is under evaluation for exercise-induced arrhythmia
 - For the evaluation of syncope or presyncope during exertion
 - The patient who requires an entrance stress test ECG for a cardiac rehab

program or for an exercise prescription

- When exercise cannot be performed, pharmacologic stress can be considered.
- Duke Exercise ECG Treadmill Score ⁽³⁵⁾

Calculates risk from ECG treadmill alone:

 - The equation for calculating the Duke treadmill score (DTS) is: $DTS = \text{exercise time in minutes} - (5 \times \text{ST deviation in mm or } 0.1 \text{ mV increments}) - (4 \times \text{exercise angina score})$, with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
 - The score typically ranges from - 25 to + 15. These values correspond to low-risk (with a score of $\geq + 5$), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of ≤ -11) categories.
- An uninterpretable baseline ECG includes ⁽⁶⁾:
 - ST segment depression is considered significant when there is 1 mm or more, not for non-specific ST- T wave changes
 - Ischemic looking T waves are considered significant when there are at least 2.5 mm inversions (excluding V1 and V2)
 - LVH with associated STT abnormalities, pre-excitation pattern such as WPW, a ventricular paced rhythm, or left bundle branch block
 - Digitalis use
 - Resting HR under 50 bpm on a medication, such as beta-blockers or calcium channel blockers, that is required for patient's treatment and cannot be stopped, with an anticipated suboptimal workload
- Global Risk of Cardiovascular Disease
 - **Global risk** of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to **asymptomatic** patients without known cardiovascular disease. It should be determined using one of the risk calculators below. A high risk is considered greater than a 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging. There are rare exemptions, such as patients requiring IC antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug.
 - **CAD Risk—Low**
10-year absolute coronary or cardiovascular risk less than 10%.
 - **CAD Risk—Moderate**
10-year absolute coronary or cardiovascular risk between 10% and 20%.
 - **CAD Risk—High**
10-year absolute coronary or cardiovascular risk of greater than 20%.

Websites for Global Cardiovascular Risk Calculators* (36,37,38,39,40)

Risk Calculator	Link to Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
Reynolds Risk Score Can use if no diabetes Unique for use of family history	http://www.reynoldsriskscore.org/
Pooled Cohort Equation	http://clinicalcalc.com/Cardiology/ASCVD/PooledCohort.aspx?example
ACC/AHA Risk Calculator	http://tools.acc.org/ASCVD-Risk-Estimator/
MESA Risk Calculator With addition of Coronary Artery Calcium Score, for CAD-only risk	https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

*Patients who have known CAD are already at high global risk and are not applicable to the calculators.

- **Definitions of Coronary Artery Disease** (6,7,11,41,42)

Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography or more accurately measured with intravascular ultrasound (IVUS).

- Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. Its incorporation into Global Risk can be achieved by using the MESA risk calculator.
- Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate), generally implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; intermediate lesions are 50 – 69% (8)
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ or minimum lumen cross-sectional area on IVUS ≤ 6 square mm (6,42,43)
 - FFR (fractional flow reserve) ≤ 0.80 for a major vessel (42,43)
- FFR (fractional flow reserve) is the distal to proximal pressure ratio across a

coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a significant reduction in coronary flow

- Anginal Equivalent ^(6,44,45)
 - Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia). This may include respiratory rate, oximetry, lung exam, etc. (as well as d-dimer, chest CT(A), and/or PFTs, when appropriate), and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

Acronyms/Abbreviations

AAD: Antiarrhythmic drug

ADLs: Activities of daily living

BSA: Body surface area in square meters

CABG: Coronary artery bypass grafting surgery

CAC: Coronary artery calcium

CAD: Coronary artery disease

CCTA: Coronary computed tomography angiography

CMR: Cardiovascular magnetic resonance imaging

CT(A): Computed tomography (angiography)

DTS: Duke Treadmill Score

ECG: Electrocardiogram

FFR: Fractional flow reserve

HCM: Hypertrophic cardiomyopathy

IVUS: Intravascular ultrasound

LBBB: Left bundle-branch block

LVEF: Left ventricular ejection fraction

LVH: Left ventricular hypertrophy

LVOT: Left ventricular outflow tract

MESA: Multi-Ethnic Study of Atherosclerosis

MET: Estimated metabolic equivalent of exercise

MI: Myocardial infarction

MPI: Myocardial perfusion imaging

MR: Mitral regurgitation

MS: Mitral stenosis

PCI: Percutaneous coronary intervention

PET: Positron emission tomography
 PFT: Pulmonary function test
 PVCs: Premature ventricular contractions
 SE: Stress echocardiography
 TTE: Transthoracic echocardiography
 VT: Ventricular tachycardia
 VF: Ventricular fibrillation
 WPW: Wolff-Parkinson-White

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> This guideline replaces UM CARDIO_1123 Stress Echocardiography

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483 - 1502. [10.1161/CIR.0b013e31822935fc](https://doi.org/10.1161/CIR.0b013e31822935fc).
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. 2001; https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. <https://doi.org/10.1016/j.jacc.2018.01.007>.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF Appropriate Use Criteria Methodology Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2013; 61: 1305 - 1317. <https://doi.org/10.1016/j.jacc.2013.01.025>.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Fihn S D, Gardin J M, Abrams J, Berra K, Blankenship J C et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease. *Circulation*. 2012; 126: e354-471. [10.1161/CIR.0b013e318277d6a0](https://doi.org/10.1161/CIR.0b013e318277d6a0).
7. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J*. Oct 2013; 34: 2949-3003. [10.1093/eurheartj/ehs296](https://doi.org/10.1093/eurheartj/ehs296).
8. Winchester D, Maron D, Blankstein R, Chang I, Kirtane A et al. ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *Journal of Cardiovascular Magnetic Resonance*. 2023; 25: true. <https://doi.org/10.1186/s12968-023-00958-5>.
9. Budoff M, Raggi P, Beller G, Berman D, Druz R et al. Noninvasive Cardiovascular Risk Assessment of the Asymptomatic Diabetic Patient: The Imaging Council of the American College of Cardiology. *JACC Cardiovasc Imaging*. Feb 2016; 9: 176-92. [10.1016/j.jcmg.2015.11.011](https://doi.org/10.1016/j.jcmg.2015.11.011).
10. Gulati M, Levy P, Mukherjee D, Amsterdam E, Bhatt D et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Cardiovasc Comput Tomogr*. Dec 01, 2021; [10.1016/j.jcct.2021.11.009](https://doi.org/10.1016/j.jcct.2021.11.009).
11. Patel M, Calhoun J, Dehmer G, Grantham J, Maddox T et al. ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. May 2, 2017; 69: 2212-2241. [10.1016/j.jacc.2017.02.001](https://doi.org/10.1016/j.jacc.2017.02.001).
12. Guzmán A, Navarro E, Obando L, Pacheco J, Quirós K et al. Effectiveness of interventions for the reversal of a metabolic syndrome. *Biomedica: revista del Instituto Nacional de Salud*. 2019; 39: 647-662. [doi: 10.7705/biomedica.4684](https://doi.org/10.7705/biomedica.4684).

13. Douglas P S, Khandheria B, Stainback R F, Weissman N J, Peterson E D et al. ACCF/AHA/ACEP/AHA/ASNC/SCAI/SCCT/SCMR 2008 Appropriateness Criteria for Stress Echocardiography*. *Circulation*. 2008; 117: 1478 - 1497. 10.1161/CIRCULATIONAHA.107.189097.
14. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease. *J Nucl Cardiol*. 2019; 26: 1392-1413. 10.1007/s12350-019-01751-7.
15. Lasica R, Djukanovic L, Savic L, Krljanac G, Zdravkovic M et al. Update on Myocarditis: From Etiology and Clinical Picture to Modern Diagnostics and Methods of Treatment. 2023; 13: 10.3390/diagnostics13193073.
16. Reiffel J, Camm A, Belardinelli L, Zeng D, Karwatowska-Prokopczuk E et al. The HARMONY Trial: Combined Ranolazine and Dronedarone in the Management of Paroxysmal Atrial Fibrillation: Mechanistic and Therapeutic Synergism. *Circ Arrhythm Electrophysiol*. Oct 2015; 8: 1048-56. 10.1161/circep.115.002856.
17. Gräni C, Bigler M, Kwong R. Noninvasive Multimodality Imaging for the Assessment of Anomalous Coronary Artery. *Current Cardiology Reports*. 2023; 25: 1233 - 1246. 10.1007/s11886-023-01948-w.
18. Evbayekha E O, Nwogwugwu E, Olawoye A, Bolaji K, Adeosun A A et al. A Comprehensive Review of Myocardial Bridging: Exploring Diagnostic and Treatment. *Cureus*. 2023; 15: e43132. doi: 10.7759/cureus.43132.
19. McCrindle B, Rowley A, Newburger J, Burns J, Bolger A et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the American Heart Association. *Circulation*. Apr 25, 2017; 135: e927-e999. 10.1161/cir.0000000000000484.
20. Lancellotti P, Nkomo V, Badano L, Bergler-Klein J, Bogaert J et al. Expert consensus for multimodality imaging evaluation of cardiovascular complications of radiotherapy in adults: a report from the European Association of Cardiovascular Imaging and the American Society of Echocardiography. *Eur Heart J Cardiovasc Imaging*. Aug 2013; 14: 721-40. 10.1093/ehjci/jet123.
21. Bonow R, O'Gara P, Adams D, Badhwar V, Bavaria J et al. 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. May 5, 2020; 75: 2236-2270. 10.1016/j.jacc.2020.02.005.
22. Otto C, Nishimura R, Bonow R, Carabello B, Erwin J et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021; 143: e35 - e71. 10.1161/CIR.0000000000000932.
23. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease: Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2022; 43: 561 - 632. 10.1093/eurheartj/ehab395.
24. Steiner J, Rodés-Cabau J, Holmes D J, LeWinter M, Dauerman H. Mechanical Intervention for Aortic Valve Stenosis in Patients With Heart Failure and Reduced Ejection Fraction. *J Am Coll Cardiol*. Dec 19, 2017; 70: 3026-3041. 10.1016/j.jacc.2017.10.040.
25. Ommen S, Mital S, Burke M, Day S, Deswal A et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. Dec 22, 2020; 76: 3022-3055. 10.1016/j.jacc.2020.08.044.
26. Fleisher L, Fleischmann K, Auerbach A, Barnason S, Beckman J et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *J Am Coll Cardiol*. Dec 9, 2014; 64: e77-137. 10.1016/j.jacc.2014.07.944.

27. Kristensen S, Knuuti J, Saraste A, Anker S, Bøtker H et al. 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management: The Joint Task Force on non-cardiac surgery: cardiovascular assessment and management of the European Society of Cardiology (ESC) and the European Society of Anaesthesiology (ESA). *Eur Heart J*. Sep 14, 2014; 35: 2383-431. 10.1093/eurheartj/ehu282.
28. Patel A, Eagle K, Vaishnava P. Cardiac risk of noncardiac surgery. *J Am Coll Cardiol*. Nov 10, 2015; 66: 2140-2148. 10.1016/j.jacc.2015.09.026.
29. Velasco A, Reyes E, Hage F. Guidelines in review: Comparison of the 2014 ACC/AHA guidelines on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery and the 2014 ESC/ESA guidelines on noncardiac surgery: Cardiovascular assessment and management. *J Nucl Cardiol*. 02 2017; 24: 165-170. 10.1007/s12350-016-0643-8.
30. Lentine K, Costa S, Weir M, Robb J, Fleisher L et al. Cardiac disease evaluation and management among kidney and liver transplantation candidates: a scientific statement from the American Heart Association and the American College of Cardiology Foundation. *J Am Coll Cardiol*. Jul 31, 2012; 60: 434-80. 10.1016/j.jacc.2012.05.008.
31. Washington State Health Care Authority. WSHCA Health Technology Clinical Committee: 20211105A – Noninvasive Cardiac Imaging for Coronary Artery Disease. [Final Adoption: March 18, 2022]. 2022; <https://www.hca.wa.gov/assets/program/noninvasive-cardiac-imaging-final-findings-and-decision-2022-03-18.pdf>.
32. Diamond G A, Forrester J S. Analysis of Probability as an Aid in the Clinical Diagnosis of Coronary Artery Disease. *New England Journal of Medicine*. 1979; 300: 1350 - 1358. 10.1056/NEJM197906143002402.
33. Wolk M, Bailey S, Doherty J, Douglas P, Hendel R et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. Feb 4, 2014; 63: 380-406. 10.1016/j.jacc.2013.11.009.
34. Henzlova M, Duvall W, Einstein A, Travin M, Verberne H. ASNC imaging guidelines for SPECT nuclear cardiology procedures: Stress, protocols, and tracers. *J Nucl Cardiol*. Jun 2016; 23: 606-39. 10.1007/s12350-015-0387-x.
35. Shaw L J, Peterson E D, Shaw L K, Kesler K L, DeLong E R et al. Use of a Prognostic Treadmill Score in Identifying Diagnostic Coronary Disease Subgroups. *Circulation*. 1998; 98: 1622 - 1630. 10.1161/01.CIR.98.16.1622.
36. Arnett D, Blumenthal R, Albert M, Buroker A, Goldberger Z et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. Sep 10, 2019; 74: e177-e232. 10.1016/j.jacc.2019.03.010.
37. D'Agostino R S, Vasan R, Pencina M, Wolf P, Cobain M et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation*. Feb 12, 2008; 117: 743-53. 10.1161/circulationaha.107.699579.
38. Goff D J, Lloyd-Jones D, Bennett G, Coady S, D'Agostino R S et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. Jul 1, 2014; 63: 2935-2959. 10.1016/j.jacc.2013.11.005.
39. McClelland R, Jorgensen N, Budoff M, Blaha M, Post W et al. 10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and

the DHS (Dallas Heart Study). *J Am Coll Cardiol*. Oct 13, 2015; 66: 1643-53.
10.1016/j.jacc.2015.08.035.

40. Ridker P, Buring J, Rifai N, Cook N. Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *Jama*. Feb 14, 2007; 297: 611-9. 10.1001/jama.297.6.611.

41. Tobis J, Azarbal B, Slavin L. Assessment of intermediate severity coronary lesions in the catheterization laboratory. *J Am Coll Cardiol*. Feb 27, 2007; 49: 839-48. 10.1016/j.jacc.2006.10.055.

42. Shlofmitz E, Ali Z A, Maehara A, Mintz G S, Shlofmitz R. Intravascular Imaging-Guided Percutaneous Coronary Intervention. *Circulation: Cardiovascular Interventions*. 2020; 13: true. 10.1161/CIRCINTERVENTIONS.120.008686.

43. Lotfi A, Davies J, Fearon W, Grines C, Kern M. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society of cardiac angiography and interventions. *Catheter Cardiovasc Interv*. Aug 1, 2018; 92: 336-347. 10.1002/ccd.27672.

44. Shen W, Sheldon R, Benditt D, Cohen M, Forman D et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. Aug 1, 2017; 70: 620-663. 10.1016/j.jacc.2017.03.002.

45. Brignole M, Moya A, de Lange F J, Deharo J, Elliott P M et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J*. 2018; 39: 1883 - 1948. 10.1093/eurheartj/ehy037.



Evolut Clinical Guideline 7329 for Subcutaneous ICD Device Implantation and Removal

Guideline Number: Evolut_CG_7329	<u>Applicable Codes</u>	
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Original Date: February 2020	Last Revised Date: November 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Subcutaneous ICD (S-ICD) device.

Special Note

To review a request for medical necessity, the following items must be submitted for review:

- Progress note that prompted request
- Echo or MUGA or Cardiac CATH for LV function
- Previous Holter/Event/Loop recorder report

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR SUBCUTANEOUS ICD DEVICE IMPLANTATION AND REMOVAL

Patients should be on maximally tolerated GDMT.

For patients being considered for a S-ICD, a preimplant electrocardiogram (ECG) to establish QRS-T wave morphology is needed to reduce the risk of under sensing of VT/VF and the risk of inappropriate shocks. ⁽⁶⁾

S-ICD is appropriate in patients with:

- Congenital heart diseases ⁽⁶⁾
- No venous access and are unsuitable for transvenous ICD ⁽⁶⁾
- Pacing for bradycardia or ventricular tachycardia (VT) termination or as part of cardiac resynchronization therapy (CRT) is neither needed nor anticipated ⁽⁶⁾
- High-risk cases for infection ^(6,7):
 - Prior device infection
 - Hemodialysis
 - ESRD
 - Diabetes mellitus
 - Chronic immunosuppression therapy immunodeficiencies
 - Artificial heart valves.
- Candidates for cardiac transplant ^(6,7)
- Hypertrophic cardiomyopathy where there is no indication for Anti-Tachycardia Pacing (ATP) ^(6,8)
- Primary prevention of sudden cardiac death in patients with ischemic/non ischemic dilated cardiomyopathy where pacing indication for bradycardia or likelihood of first-time monomorphic VT is rare ^(7,9)
- Procedures for lead repositioning or replacement are appropriate in cases of ^(6,7):
 - Lead complications
 - Inappropriate shocks
 - Oversensing
 - Other specified lead failure

LIMITATIONS FOR SUBCUTANEOUS ICD DEVICE IMPLANTATION AND REMOVAL

S-ICD is **NOT** indicated in patients with ^(6,7):

- Symptomatic bradycardia requiring permanent pacing.
- Systolic heart failure and left bundle branch block and has indication for cardiac resynchronization therapy (CRT)
- Recurrent sustained monomorphic VT treatable with ATP
- Recurrent idiopathic ventricular fibrillation (VF) treated with catheter ablation due to high risk of T-wave oversensing
- Thin patients with poor subcutaneous tissue and abnormalities of chest wall like pectus excavatum
- Before Subcutaneous ICD Device can be implanted in a patient with heart failure and/or ventricular arrhythmias the following must be considered:
 - Predicted or observed lack of adequate response to maximally tolerated GDMT

CODING AND STANDARDS

Coding

CPT Codes

- 33270 - Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
- 33271 - Insertion of subcutaneous implantable defibrillator electrode
- 33272 - Removal of subcutaneous implantable defibrillator electrode
- 33273 - Repositioning of previously implanted subcutaneous implantable defibrillator electrode
- 93644 – EP eval of Subcutaneous ICD leads including DFT and programming and reprogramming of sensing and therapeutic parameters

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

The S-ICD System is a Subcutaneous (under the skin) Implantable Cardioverter Defibrillator for people who are at risk of Sudden Cardiac Arrest. Unlike a transvenous ICD, where the leads are fed into the heart through a vein and attached to the heart wall, the leads for S-ICD are placed just under the skin and not in the heart, leaving the heart and veins untouched and intact. The pulse generator is implanted on the left side of the chest next to the rib cage, just under the arm. The lead is vertically positioned in the subcutaneous tissue of the chest, parallel to and 1-2 cm to the left sternal midline followed by a horizontal segment, at the level of the 6th rib, until it reaches the left anterior axillary line. The lead has an 8-cm shock coil, flanked by two sensing electrodes - the distal one positioned adjacent to the manubriosternal junction and the proximal one adjacent to the xiphoid process.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

ATP: Anti-Tachycardia Pacing

CRT: Cardiac resynchronization therapy

ECG: Electrocardiogram

ESRD: End-stage renal disease

GDMT: Guideline Directed Medical Therapy

S-ICD: Subcutaneous Implantable Cardioverter Defibrillator

T-ICD: Transvenous Implantable Cardioverter Defibrillator

VF: Ventricular fibrillation

VT: Ventricular tachycardia

Guideline Directed Medical Therapy (GDMT)

GDMT are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1389 for Subcutaneous ICD Device Implantation and Removal

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Al-Khatib S, Stevenson W, Ackerman M, Bryant W, Callans D et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary. *Journal of the American College of Cardiology*. 2018; 72: 1677-1749. 10.1016/j.jacc.2017.10.053.
7. Cappelli S, Olaru A, De Maria E. The subcutaneous defibrillator: who stands to benefit. *E-Journal of Cardiology Practice*. 2014; 12:
8. Maron M, Steiger N, Burrows A, Madias C, Weinstock J et al. Evidence That Subcutaneous Implantable Cardioverter-Defibrillators Are Effective and Reliable in Hypertrophic Cardiomyopathy. *JACC: Clinical Electrophysiology*. 2020; 6: 1019-1021. 10.1016/j.jacep.2020.03.015.
9. Arbelo E, Protonotarios A, Gimeno J, Arbustini E, Barriales-Villa R et al. 2023 ESC Guidelines for the management of cardiomyopathies. *European Heart Journal*. 2023; 44: 3503-3626. 10.1093/eurheartj/ehad194.



Evolut Clinical Guideline 7330 for Cardioversion of Atrial Fibrillation

Guideline Number: Evolut_CG_7330	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

To provide guidance pertaining to cardioversion from atrial fibrillation to sinus rhythm.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

ANTICOAGULATION AND LEFT ATRIAL APPENDAGE IMAGING PRIOR TO ELECTIVE CARIOVERSION OF ATRIAL FIBRILLATION ⁽⁶⁾

- In patients with Atrial Fibrillation (AF) duration of ≥ 48 hours, a 3-week duration of uninterrupted therapeutic anticoagulation or imaging evaluation to exclude intracardiac thrombus is indicated before elective cardioversion, unless the patient is hemodynamically unstable
- In patients with AF in whom cardioversion is deferred due to LAA thrombus detected on pre-cardioversion imaging, therapeutic anticoagulation should be instituted for at least 3 to 6 weeks, after which imaging should be repeated before cardioversion

DIRECT CURRENT SYNCHRONIZED CARDIOVERSION OF ATRIAL FIBRILLATION (6)

- In patients with hemodynamic instability attributable to AF, immediate electrical cardioversion should be performed to restore sinus rhythm
- In patients with AF who are hemodynamically stable, electrical cardioversion may be performed as initial rhythm-control strategy or after unsuccessful pharmacological cardioversion
 - In patients with AF undergoing electrical cardioversion, energy delivery should be synchronized to the QRS to reduce the risk of inducing VF

INTRAVENOUS PHARMACOLOGICAL CARDIOVERSION OF ATRIAL FIBRILLATION (6)

- For patients with AF, pharmacological cardioversion is an appropriate alternative to electrical cardioversion for those who are hemodynamically stable or when electrical cardioversion cannot be performed
 - For patients with AF and an LVEF >40%, ibutilide may be used pharmacological cardioversion
 - For patients with AF, intravenous amiodarone may be used for pharmacological cardioversion, although time to conversion is generally longer than with other agents (typically 8 hours)
 - For patients with AF, intravenous procainamide may be used for pharmacological cardioversion when other intravenous agents are contraindicated

CODING AND STANDARDS

Coding

CPT Codes

92960, 92961

Applicable Lines of Business

☒	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Atrial fibrillation (AF) is the most common heart rhythm disturbance, with a prevalence of 5.2 million persons in the US in 2010, expected to reach 12.1 million by 2030. It is associated with a 1.5 to 2.0-fold increase in mortality and a 2.4-fold increase in stroke. ⁽⁶⁾ It is associated with increased risks for myocardial infarction, heart failure, and chronic kidney disease, among others. It is widely recognized that “atrial fibrillation begets atrial fibrillation;” prolonged AF results in electrical remodeling of the atria that reduces the potential to sustain sinus rhythm. Thus, expedient conversion to sinus rhythm, utilizing pharmacologic therapy, cardioversion, or ablation can restore sinus rhythm and ameliorate the risks associated with AF.

Because of the propensity for thrombus formation, especially in the left atrial appendage, during AF, anticoagulation therapy is indicated in patients with prolonged (>48 hour) duration and with CHA₂DS₂-VASc scores of 2 or greater. ⁽⁶⁾

Imaging of the left atrium, typically with transesophageal echocardiography (TEE) or with cardiac CTA, to exclude left-sided thrombus formation, is typically performed in higher risk patients before elective cardioversion (either electrical or pharmacological), particularly when continuity of effective anticoagulation is not certain. ⁽⁶⁾

Definitions

CHA₂DS₂-VASc score: A system used to evaluate the risk of stroke in patients with atrial fibrillation, in which points are assigned for age >65 (1 point) or >75 (2 points); female gender (1 point); heart failure history (1 point); hypertension (1 point); prior stroke or thromboembolism (2 points); history of vascular disease (1 point); and diabetes (1 point). A score of 2 or greater is considered an indication for systemic anticoagulation therapy. ⁽⁶⁾

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AF: atrial fibrillation

AUC: appropriate use criteria

CTA: Computerized Tomographic Angiogram

LVEF: left ventricular ejection fraction

TTE: Transesophageal Echocardiogram

VF: ventricular fibrillation

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> <li data-bbox="531 421 1294 488">This guideline replaces UM Cardio 1148 Cardio Policy: Synchronized Electrical Cardioversion

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

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2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Joglar J A, Chung M K, Armbruster A L, Benjamin E J, Chyou J Y et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024; 149: e1-e156. 10.1161/CIR.0000000000001193.



Evolut Clinical Guideline 7331 for Temporal Artery Biopsy

Guideline Number: Evolut_CG_7331	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for a temporal artery biopsy, which is primarily used to diagnose Giant Cell Arteritis and Temporal Arteritis.

Special Note

In order to review a request for medical necessity, the following items must be submitted for review:

- Progress note that prompted request from Vascular Surgeon

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

*Particularly when occurring in conjunction with patient age > 50 years and/or elevated CRP ($\geq 10\text{mg/liter}$) ^(6,7)

- Vision problems including ^(6,7,8):
 - Anterior ischemic optic neuropathy
 - Cotton wool spots
 - Cilio-retinal or central retinal artery occlusion
 - Cranial nerve palsy

- Double vision
- Sudden vision loss
- Jaw claudication ^(6,7)
- Pulseless temporal artery ⁽⁷⁾
- Temporal tenderness ^(6,7)
- New onset, localized headache, particularly if presenting with ^(6,8)
 - Night sweats
 - Weight loss
 - Malaise
 - Depression
- Elevated ESR (maximum ≥ 50 mm/hr) ^(7,8)

CODING AND STANDARDS

Coding

CPT Codes

37609

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

Temporal arteritis (TA) is an inflammatory vasculopathy affecting medium- and large-sized arteries, also referred to as giant cell arteritis leading to granulomatous pan arteritis with mononuclear cell infiltrates and giant cell formation within the vessel wall. It predominantly affects the cranial branches of arteries arising from the arch of the aorta, mainly the superficial temporal branch of the carotid artery. Mean onset for TA is at age 70 years.

Temporal Artery biopsy is a surgical procedure performed under local anesthesia where at least 1 cm of temporal artery on the symptomatic side is biopsied and looked under

microscope for evidence of multinucleated giant cells. Biopsy of bilateral temporal arteries are usually not required. Temporal artery biopsy has a very low complication rate. Most commonly encountered complications are scarring, hematoma, wound infection, and skin necrosis.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1321 for Temporal Artery Biopsy

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Bilton E, Mollan S. Giant cell arteritis: reviewing the advancing diagnostics and management. *Eye*. 2023; 37: 2365-2373. 10.1038/s41433-023-02433-y.
7. Aghdam K A, Sanjari M S, Manafi N, Khorramdel S, Alemzadeh S A. Temporal Artery Biopsy for Diagnosing Giant Cell Arteritis: A Ten-year Review. *Journal of Ophthalmic and Vision Research*. 2020; 10.18502/jovr.v15i2.6738.
8. Ponich B, Hartley R, Lafreniere A, Temple-Oberle C. Necessity of Temporal Artery Biopsy for Giant Cell Arteritis: A Systematic Review. *Plastic and Reconstructive Surgery - Global Open*. 2022; 10: e4185. 10.1097/GOX.0000000000004185.



Evolut Clinical Guideline 7332 for Thoracentesis and Pleurodesis

Guideline Number: Evolut_CG_7332	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Thoracentesis.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Indications for Thoracentesis

- Evaluation of undiagnosed pleural effusion ⁽⁶⁾
- Therapeutic drainage of symptomatic pleural effusion ^(6,7,8)
- Therapeutic drainage of infected fluid ⁽⁶⁾

Indications for Pleurodesis

- Pleural Effusion
 - symptomatic malignant pleural effusion and known (or suspected) expandible lung, as an alternative to repeat thoracentesis ⁽⁸⁾
- Pneumothorax
 - primary (see **Definitions** section) spontaneous pneumothorax with one or more of the following characteristics: ^(6,8,9,10)

- recurrent effusion
- persistent air leak (>3-5 days)
- bilateral pneumothorax
- hemopneumothorax
- tension pneumothorax
- professions/hobbies at risk for recurrence (e.g., flying, diving)
- secondary (see **Definitions** section) spontaneous pneumothorax ^(8,9)

CODING AND STANDARDS

Coding

CPT Codes

32550, 32552, 32554, 32555, 32556, 32557, 32560

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Limitations

There are currently no established guidelines and limited data on the best treatment for refractory non-malignant pleural effusions. Invasive treatments such as pleurodesis and indwelling pleural catheters are options once standard medical therapy for the underlying condition(s) has been maximized. ⁽⁸⁾

Definitions

Thoracentesis is a procedure that is done to remove a sample of fluid from around the lung.

Pleurodesis is a procedure that induces pleural inflammation resulting in adhesions between the parietal and visceral pleura, and prevention of fluid re-accumulation. Pleurodesis can be accomplished by medical (instillation of a chemical or material in the pleural space) or surgical (mechanical abrasion of the pleura) techniques.

Primary pneumothorax: pneumothorax occurring in the absence of underlying lung disease.

Secondary pneumothorax: pneumothorax occurring as a consequence of underlying lung disease.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM 1370 Thoracentesis and Pleurodesis • Indications for pleurodesis were broken down by method • Indications for thoracentesis were broken down by diagnosis

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACCF Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Roberts M, Rahman N, Maskell N, Bibby A, Blyth K et al. British Thoracic Society Guideline for pleural disease. *Thorax*. 2023; 78: true. 10.1136/thorax-2022-219784.
7. Muruganandan S, Azzopardi M, Thomas R, Fitzgerald D, Kuok Y et al. The Pleural Effusion And Symptom Evaluation (PLEASE) study of breathlessness in. *The European respiratory journal*. 2020; 55.
8. Castaldo N, Fantin A, Palou-schwartzbaum M, Viterale G, Crisafulli E et al. Exploring the efficacy and advancements of medical pleurodesis: a comprehensive review of current research. *Breathe*. 2024; 20: true. 10.1183/20734735.0002-2024.
9. Baumann M, Strange C, Heffner J, Light R, Kirby T et al. Management of spontaneous pneumothorax: an American College of Chest Physicians. *Chest*. 2001; 119: 590-602.
10. Tschopp J, Bintcliffe O, Astoul P, Canalis E, Driesen P et al. ERS task force statement: diagnosis and treatment of primary spontaneous. *The European respiratory journal*. 2015; 46: 321-35.



Evolent Clinical Guideline 7333 for Tilt Table Testing

Guideline Number: Evolent_CG_7333	<u>Applicable Codes</u>	
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Original Date: August 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Tilt Table Testing.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

If initial testing results were unclear or not diagnostic, tilt-table testing may be appropriate for:

- suspected vasovagal syncope (especially if syncope is recurrent) ⁽⁶⁾
- syncope and suspected orthostatic hypotension ^(6,7,8)
- suspected POTS (postural orthostatic tachycardia syndrome) ^(7,8)
- distinguishing convulsive/myoclonic syncope from epilepsy ^(6,8)
- distinguishing psychogenic pseudosyncope from vasovagal syncope ^(6,8)

CODING AND STANDARDS

Coding

CPT Codes

93660

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Tilt table testing is used to evaluate the autonomic nervous system control of cardiovascular function in patients with syncope, generally after other, potentially more harmful, likely, or readily managed causes have been ruled out by history, physical examination or other appropriate tests. The test utilizes a specialized table which passively takes the patient from a supine position to a head-up position (60 or 90 degrees). Heart rate, blood pressure and ECG are continuously monitored.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM 1159 Tilt Table Testing ● Added guidance for distinguishing between convulsive syncope and epilepsy ● Added guidance for distinguishing between pseudosyncope and vasovagal syncope

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Shen W, Sheldon R, Benditt D, Cohen M, Forman D et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*. 2017; 70: e39 - e110. <https://doi.org/10.1016/j.jacc.2017.03.003>.
7. Brignole M, Moya A, de Lange F, Deharo J, Elliott P et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J*. 2018; 39: 1883 - 1948. 10.1093/eurheartj/ehy037.
8. Thijs R, Brignole M, Falup-Pecurariu C, Fanciulli A, Freeman R et al. Recommendations for tilt table testing and other provocative cardiovascular. *Clinical autonomic research: official journal of the Clinical Autonomic Research*. 2021; 31: 369-384.



Evolut Clinical Guideline 7334 for Transcatheter Aortic Valve Replacement (TAVR)

Guideline Number: Evolut_CG_7334	<u>Applicable Codes</u>	
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Original Date: May 2016	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Transcatheter Aortic Valve Replacement (TAVR).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Symptomatic

- Symptoms or signs with activities of daily living or with physiologic testing (i.e., exercise treadmill test) include exertional dyspnea, decreased exercise tolerance, exertional angina, heart failure, exertional syncope, pre-syncope, or abnormal blood pressure response on exercise treadmill test (see **Definitions**) ^(6,7)
- Severe (see **Definitions**) aortic stenosis (AS) in patients of any age ⁽⁶⁾:
 - High or prohibitive surgical risk as determined by the Society of Thoracic Surgeons predicted risk of mortality score (STS-PROM, see **Definitions**) for conventional surgical AVR (SAVR) **AND**
 - Predicted post-TAVR survival > 12 months **AND**
 - Acceptable quality of life (> 1 year)

- Severe AS, > 80 years of age or for younger patients with life expectancy < 10 years ⁽⁶⁾
- Severe AS, 65 to 80 years of age, as an alternative to SAVR after shared decision-making related to valve durability and expected longevity ⁽⁶⁾

Note: Surgical aortic valve replacement (SAVR) recommended if patient is < 65 years of age or has life expectancy > 20 years ⁽⁶⁾

- Severe AS with multiple comorbidities (high or extreme risk patients) ⁽⁷⁾:
 - Frail (see **Definitions**) with fatigue but no chest pain or shortness of breath
 - Severe AS, high surgical risk
 - B-type Natriuretic Peptide (BNP) elevated **(AUC Score 7)**
 - Normal BNP **(AUC Score 5)**
 - Very severe AS (see **Definitions**), high surgical risk
 - Normal BNP **(AUC Score 7)**
 - BNP elevated **(AUC Score 8)**
 - Oxygen dependent pulmonary disease with dyspnea
 - High surgical risk
 - BNP normal **(AUC Score 7)**
 - BNP elevated **(AUC Score 8)**
 - End-stage renal disease on dialysis with symptomatic AS
 - Extreme surgical risk, multiple comorbidities, not a renal transplant candidate, longstanding dialysis **(AUC Score 6)**
 - High surgical risk, nondiabetic/nonhypertensive etiology, renal transplant candidate, short time on dialysis **(AUC Score 7)**
 - Cirrhosis (high surgical risk) **(AUC Score 7)**
 - Malignancy with high surgical risk
 - Life expectancy > 1 year **(AUC Score 7)**
- Severe AS with additional anatomical risks not captured in the STS-PROM such as hostile chest or porcelain aorta (see **Definitions**); and otherwise, low, intermediate or high surgical risk by STS-PROM score **(AUC Score 8)** ⁽⁷⁾
- Prior to non-cardiac surgery with nonobstructive coronary artery disease (CAD), as an alternative to SAVR ⁽⁷⁾:
 - Severe/very severe AS, elective major surgery planned **(AUC Score 8)**
 - Severe/very severe AS, urgent major surgery planned **(AUC Score 7)**
- Severe AS with associated CAD (i.e., TAVR plus percutaneous coronary intervention (PCI) as an alternative to SAVR plus CABG) ⁽⁷⁾
 - 1 or 2 vessel CAD, with or without proximal left anterior descending artery (LAD) involvement:
 - High or intermediate surgical risk **(AUC Score 7)**
 - 3-vessel CAD:

- Low (< 22) SYNTAX score (see **Definition**):
 - High or intermediate surgical risk (**AUC Score 7**)
 - Intermediate or high (≥ 22) SYNTAX score:
 - High or intermediate surgical risk (**AUC Score 6**)
 - Left main coronary artery:
 - Intermediate or low (< 33) SYNTAX score:
 - High or intermediate surgical risk (**AUC Score 7**)
 - High (≥ 33) SYNTAX score:
 - High or intermediate surgical risk (**AUC Score 6**)
- Severe AS with other valve or anatomical pathology:
 - Severe rheumatic mitral stenosis (MS) and no contraindication to balloon mitral valvuloplasty (i.e., TAVR plus balloon mitral valvuloplasty):
 - High surgical risk (**AUC Score 7**)
 - Severe primary (see **Definitions**) mitral regurgitation (i.e., TAVR plus mitral transcatheter edge-to-edge repair (TEER))
 - High surgical risk (**AUC Score 6**)
 - Severe secondary (see **Definitions**) tricuspid regurgitation with dilated right ventricle and/or tricuspid valve annulus ≥ 40 mm, moderate to severe right ventricular dysfunction and:
 - Moderate to severe pulmonary hypertension, high surgical risk (**AUC Score 7**)
 - Minimal pulmonary hypertension, intermediate surgical risk (**AUC Score 5**)
 - Prominent basal left ventricular hypertrophy with left ventricular outflow tract (LVOT) obstruction (narrowing with flow acceleration) and intermediate or high surgical risk (**AUC Score 6**)
- Failing aortic valve bioprosthesis (i.e., valve-in-valve procedure for severe AS or aortic regurgitation (AR) and degenerative surgical bioprosthesis) ⁽⁷⁾
 - Bioprosthesis size ≥ 23 mm:
 - High surgical risk (**AUC Score 8**)
 - Intermediate surgical risk (**AUC Score 7**)
 - Bioprosthesis size 21 mm:
 - High surgical risk (**AUC Score 6**)
 - Intermediate surgical risk (**AUC Score 5**)
 - Bioprosthesis size ≤ 19 mm:
 - High surgical risk (**AUC Score 5**)
- AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, low flow/low gradient (see **Definitions**), with severely calcified valve, and clinical, hemodynamic and anatomic data support valve obstruction as the most likely cause of symptoms, as an alternative to SAVR ⁽⁷⁾:

- High or intermediate surgical risk (**AUC Score 8**)
- Low surgical risk (**AUC Score 9**)

Asymptomatic

- Severe AS and LVEF < 50%, and ≤ 80 years of age as an alternative to SAVR after shared decision-making related to valve durability and expected longevity, including the following situations ^(6,7):
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, **LVEF < 20%**, high or intermediate risk for surgery:
 - Aortic valve peak velocity ≥ 4 m/s or mean gradient ≥ 40 mmHg on resting echo (**AUC Score 7**)
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, **LVEF < 20%**, low flow/low gradient with flow reserve on dobutamine echocardiogram (i.e., truly severe AS):
 - High or intermediate surgical risk (**AUC Score 7**)
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6cm²/m²) on resting echo, **LVEF 20%-49%**, low flow/low gradient with flow reserve on dobutamine echocardiogram (i.e., truly severe AS):
 - High or intermediate surgical risk (**AUC Score 8**)
 - Low surgical risk (**AUC Score 9**)
 - AVA (aortic valve area) ≤ 1.0 cm² (or AVA index ≤ 0.6 cm²/m²) on resting echo, **LVEF 20%-49%**, low flow/low gradient with no flow reserve on dobutamine echocardiogram but with very calcified valve on imaging (TTE or CT) or projected valve area calculation suggesting truly severe AS:
 - High or intermediate surgical risk (**AUC Score 7**)
- Severe AS and LVEF ≥ 50% with low surgical risk (see **Definitions**), with a high-risk profession (e.g., airline pilot), lifestyle (competitive athlete), or anticipated prolonged period away from medical supervision ⁽⁷⁾ (**AUC Score 7**)
- Very severe AS, LVEF ≥ 50% ⁽⁷⁾:
 - High or intermediate surgical risk (**AUC Score 7**)
 - Low surgical risk (**AUC Score 8**)
- Severe AS prior to non-cardiac surgery with nonobstructive CAD, as an alternative to SAVR ⁽⁷⁾:
 - Severe/very severe AS, elective major surgery planned (**AUC Score 7**)
 - Severe/very severe AS, urgent major surgery planned (**AUC Score 5**)
- Severe AS, LVEF ≥ 50%, with ≥ 1 predictor(s) of symptom onset or of rapid progression such as: rapid progression (peak velocity increasing > 0.3 m/s per year, severe valve calcification, elevated BNP, significant LVH in the absence of hypertension), and a negative ETT, as an alternative to SAVR ⁽⁷⁾:
 - High or intermediate surgical risk (**AUC Score 7**)
 - Low surgical risk (**AUC Score 8**)

CODING AND STANDARDS

Coding

CPT Codes

- 33361: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
- 33362: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
- 33363: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
- 33364: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
- 33365: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
- 33366: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical approach (eg, left thoracotomy)

Places of Service

Inpatient hospital (21)

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

- Aortic Stenosis Severity ⁽⁶⁾:
 - Severe AS: Aortic peak velocity (Vmax) ≥ 4 m/s or mean gradient ≥ 40 mm Hg
 - Aortic valve area (AVA) typically is ≤ 1.0 cm² (or valve index (AVAi) 0.6 cm²/m²) but is not required to define severe AS (6)
 - Very severe AS: aortic Vmax ≥ 5 m/s or mean gradient ≥ 60 mm Hg
 - Low flow/low gradient severe AS: defined by a mismatch between reduced aortic

valve area (AVA, < 1 cm²) and a non-severe increase mean valve pressure gradient (i.e., < 40 mmHg) with an impaired left ventricular stroke volume (volume of blood pumped with each beat, similar to LVEF) at rest. This creates a diagnostic and therapeutic dilemma: choosing between aortic valve replacement (AVR) and medical therapy vs optimal medical therapy alone. Low dose dobutamine stress echo (DSE) is recommended as a means of increasing stroke volume with a simultaneous reassessment of aortic valve indices. **Flow reserve** is defined as a 20% increase in stroke volume demonstrated by DSE. DSE can yield three possible results in this situation:

- Truly severe AS: significant increase in stroke volume (i.e. flow reserve is demonstrated) and mean valve gradient (>40 mmHg). Aortic valve is severely stenotic, and the low gradient measured at rest is a consequence of the LV contractile dysfunction.
 - Pseudo-severe AS: significant increase in stroke volume and persistent low mean valve gradient (< 40 mmHg) and AS does not meet the hemodynamic criteria to be defined as severe.
 - Undetermined AS severity: Absence of significant increase in stroke volume and mean valve gradient (< 40 mmHg): In this case, DSE fails to demonstrate an increase in stroke volume (lack of flow reserve) and the AS severity grade remains undetermined. In this situation clinicians have to rely on the morphologic features of the valve on imaging (such as cardiac CT).⁽⁸⁾
- Risk Assessment for Valve Procedures:
 - **STS-PROM** (Society of Thoracic Surgeons predicted risk of surgical mortality)^(6,7)
 - Low risk: STS score < 3%
 - Intermediate: 3 to 8%
 - High: STS score > 8% to <15%
 - Extreme: ≥ 15%
 - Society of Thoracic Surgeons (STS) Risk Calculations
 - The Society of Thoracic Surgeons Risk Calculator is an interactive algorithm that produces risk percentages for a range of likelihoods based on specific patient characteristics. It draws from a database that incorporates data on all adult cardiac surgical procedures. The calculator can be located at the Society of Thoracic Surgeons website, www.sts.org.
- Anatomical Factors Favoring TAVR over Surgical Valve Replacement

Note: these anatomical factors increase surgical risk and are not captured in the STS-PROM risk calculator⁽⁷⁾

 - Porcelain aorta: severe calcification of the ascending aorta extending to the aortic arch preventing safe cannulation or cross-clamping during cardiac surgery⁽⁹⁾
 - Hostile chest: condition(s) that make chest surgery prohibitively risky such as radiation damage, abnormal chest wall anatomy (i.e. severe kyphoscoliosis), complications from prior surgery⁽¹⁰⁾
- **SYNTAX** Score - SYNTAX (Synergy between PCI with Taxus and Cardiac Surgery) Score⁽¹¹⁾

Note: The SYNTAX score is designed to predict outcomes of coronary

revascularization by grading the complexity of coronary artery lesions. A higher score indicates more complex coronary artery disease and would favor surgical revascularization (CABG) over PCI.

- Low (0-22)
- Intermediate (23-32)
- High >33
- Frailty ⁽⁷⁾
 - Determining whether a patient is symptomatic from AS can be difficult, particularly in elderly, sedentary population that often has multiple comorbidities. Frailty falls along a spectrum and is characterized as impaired resilience to stressors. This information is considered when assessing patient reported symptoms, procedural risk, and anticipated benefit after the various treatment options. ⁽⁷⁾ There is no universal definition of frailty, and many criteria have been proposed. The Fried criteria ⁽¹²⁾ are commonly used:
 - Slow gait speed
 - Weak handgrip
 - Exhaustion
 - Physical inactivity
 - Weight loss
- Abnormal ETT Definition ⁽⁷⁾
 - In relation to the functional assessment of seemingly asymptomatic AS, an abnormal exercise stress test is characterized by:
 - Exercise-induced angina
 - Excessive dyspnea early in exercise
 - Dizziness, or syncope
 - Limited exercise capacity (below age and sex-specific predicted metabolic equivalent of task, or MET)
 - Abnormal blood pressure response (e.g., hypotension during exercise or failure to increase blood pressure with exercise)
 - Increase in the mean gradient with exercise ≥ 18 mmHg (i.e., on stress echocardiogram)

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

- AR: Aortic regurgitation
- AS: Aortic stenosis
- AVA: Aortic valve area
- BNP: B-type natriuretic peptide
- CABG: Coronary artery bypass grafting
- CAD: Coronary artery disease
- CT: Computed tomography
- ETT: Exercise treadmill test
- LAD: Left anterior descending artery
- LVEF: Left ventricular ejection fraction
- LVH: Left ventricular hypertrophy
- LVOT: Left ventricular outflow tract
- MS: Mitral stenosis
- PCI: Percutaneous coronary intervention
- SAVR: Surgical aortic valve replacement
- STS-PROM: Society of Thoracic Surgeons predicted risk of mortality score
- SYNTAX: Synergy between PCI with Taxus and Cardiac Surgery
- TAVR: Transcatheter aortic valve replacement
- TEER: Transcatheter edge-to-edge repair
- TTE: Transthoracic echocardiogram

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1295 Transcatheter Aortic Valve Replacement (TAVR) ● Updated clinical indications for Transcatheter Aortic Valve Replacement ● Updated Background section ● Removed Special Note and Limitation sections ● Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Otto C M, Nishimura R A, Bonow R O, Carabello B A, Erwin J P 3 et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. *Journal of the American College of Cardiology*. 2021; 77: e25-e197.
7. Bonow R O, Brown A S, Gillam L D, Kapadia S R, Kavinsky C J et al. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients With Severe Aortic Stenosis: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *Journal of the American College of Cardiology*. 2017; 70: 2566-2598.
8. Contorni F, Fineschi M, Iadanza A, Santoro A, Mandoli G E. How to deal with low-flow low-gradient aortic stenosis and reduced left ventricle ejection fraction: from literature review to tips for clinical practice. *Heart failure reviews*. 2022; 27: 697-709.
9. Abramowitz Y, Jilaihawi H, Chakravarty T, Mack M, Makkar R. Porcelain aorta: a comprehensive review. *Circulation*. 2015; 131: 827-36.
10. Kappetein A P, Head S J, Généreux P, Piazza N, van Mieghem N M et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document (VARC-2). *The Journal of thoracic and cardiovascular surgery*. 2013; 145: 6-23.
11. Serruys P W, Morice M, Kappetein A P, Colombo A, Holmes D R et al. Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. *The New England journal of medicine*. 2009; 360: 961-72.
12. Fried L P, Tangen C M, Walston J, Newman A B, Hirsch C et al. Frailty in older adults: evidence for a phenotype. *The journals of gerontology. Series A, Biological sciences and medical sciences*. 2001; 56: M146-56.

Evolut Clinical Guideline 7335 for Transcatheter Edge to Edge Repair (TEER) of Mitral Valve

Guideline Number: Evolut_CG_7335	<u>Applicable Codes</u>	
<p><i>"Evolut" refers to Evolut Health LLC and Evolut Specialty Services, Inc.</i> © 2016- 2025 Evolut. All rights Reserved.</p>		
Original Date: May 2016	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Transcatheter Edge to Edge Repair (TEER or MITRACLIP) of Mitral Valve.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Primary MR

- Severe chronic MR with severe symptoms (NYHA class III or IV) when ^(6,7):
 - surgical risk is high or prohibitive AND
 - patient life expectancy is at least 1 year AND
 - mitral valve anatomy favorable for repair

Secondary MR

Chronic secondary mitral regurgitation typically develops because of LV systolic dysfunction. Therefore, GDMT for heart failure, including standard medication (and, as indicated, coronary revascularization and biventricular pacing) should be the foundation of treatment. Surgical or transcatheter therapies should only be contemplated in those patients who are genuinely refractory to full GDMT.

- Severe chronic MR related to LV systolic dysfunction (LVEF < 50%) with persistent symptoms (NYHA class II, III or IV) despite optimal GDMT for HF when ^(6,7,8):
 - patient anatomy is appropriate (as defined on TEE) AND
 - LVEF between 20% and 50% AND
 - LVESD less than or equal to 70 mm AND
 - pulmonary artery systolic pressure is less than or equal to 70 mm Hg

Mixed Valvular Heart Disease ⁽⁶⁾

A statement of estimated surgical risk or a surgical risk score (**STS risk calculation**) must be provided.

- Combined severe AS and severe primary MR:
 - TAVI candidate with **prohibitive surgical risk** and MV is repairable:
 - TAVI and mitral TEER (possibly as a staged procedure if severe symptomatic MR persists after TAVI)
- Combined severe AS and severe secondary MR:
 - TAVI candidate with **acceptable surgical risk** and MV is repairable:
 - SAVR and surgical mitral valve repair/replacement
 - TAVI and mitral TEER (possibly as a staged procedure if severe symptomatic MR persists after TAVI)
 - TAVI candidate with **prohibitive surgical risk** and MV is repairable:
 - TAVI and mitral TEER (possibly as a staged procedure if severe symptomatic MR persists after TAVI)

CODING AND STANDARDS

Coding

CPT Codes

33418, 33419

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Surgical repair or replacement of the mitral valve is considered the gold standard of treatment and has the highest documented success rates. Transcatheter Edge-to-Edge Repair (TEER) is percutaneous procedure during which the anterior and posterior mitral valve leaflets are clipped together ⁽⁶⁾. This results in a reduction in the degree of mitral regurgitation. In most cases TEER should only be considered for patients with severe MR who are symptomatic, not eligible for surgical repair or replacement, have favorable anatomy for the TEER procedure, and for whom the procedure is not considered futile. ^(7,9)

The following lists some of the less or unfavorable features that recommend AGAINST feasibility of TEER ⁽⁹⁾:

- Leaflet pathology involving commissural segments, or leaflet clefts or perforations
- Severe leaflet or annular calcification (or calcification in area of grasping zone)
- Mitral stenosis (rheumatic or calcific)
 - mean mitral gradient > 5mm Hg
 - MVA < 4.0 cm²
- Grasping zone length < 7mm
- Primary MR
 - flail width > 15 mm and flail gap > 10 mm
 - multisegment pathology, highly mobile flail leaflet with multiple ruptured chords
 - severely and diffusely thickened and redundant leaflets
 - LVESD > 55 mm
- Secondary MR
 - LVESD > 70 mm

Definitions

NYHA Class Definitions

- Class I: No limitation of functional activity. Ordinary physical activity does not cause

symptoms of HF

- Class II: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF
- Class III: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF
- Class IV: Unable to continue any physical activity without symptoms of HF, or symptoms of HF at rest

Society of Thoracic Surgeons (STS) Risk Calculations

The Society of Thoracic Surgeons Risk Calculator is an interactive algorithm that produces risk percentages for a range of likelihoods based on specific patient characteristics. It draws from a database that incorporates data on all adult cardiac surgical procedures. The calculator can be located at the Society of Thoracic Surgeons website, www.sts.org.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AF: Atrial fibrillation

AS: Aortic stenosis

CABG: Coronary artery bypass graft

EF: Ejection fraction

GDMT: Guideline-directed medical therapy

HF: Heart failure

LV: Left ventricle

LVEF: Left ventricular ejection fraction

LVESD: Left ventricular end-systolic dimension

MR: Mitral regurgitation

MS: Mitral stenosis

NYHA: New York Heart Association

PMBC: Percutaneous mitral balloon commissurotomy

SAVR: Surgical aortic valve replacement

SPAP: Systolic pulmonary artery pressure

TAVI: Transcatheter aortic valve implantation

TEE: Transesophageal echocardiogram
 TTE: Transthoracic echocardiogram
 TEER: Transcatheter edge-to-edge repair

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> ● This guideline replaces UM 1296 Transcatheter Edge to Edge Repair (TEER) of Mitral Valve ● Added indications for mixed valve disease

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Otto C, Nishimura R, Bonow R, Carabello B, Erwin J et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. *Journal of the American College of Cardiology*. 2021; 77: e25 - e197. 10.1016/j.jacc.2020.11.018.
7. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease: Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2022; 43: 561 - 632. 10.1093/eurheartj/ehab395.
8. Coats A, Anker S, Baumbach A, Alfieri O, von Bardeleben R et al. The management of secondary mitral regurgitation in patients with heart failure: a joint position statement from the Heart Failure Association (HFA), European Association of Cardiovascular Imaging (EACVI), European Heart Rhythm Association (EHRA), and European Association of Percutaneous Cardiovascular Interventions (EAPCI) of the ESC. *Eur Heart J*. 2021; 42: 1254 - 1269. 10.1093/eurheartj/ehab086.
9. Bonow R, O'Gara P, Adams D, Badhwar V, Bavaria J et al. 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. *Journal of the American College of Cardiology*. 2020; 75: 2236 - 2270. <https://doi.org/10.1016/j.jacc.2020.02.005>.

Evolut Clinical Guideline 7336-01 for Transesophageal Echocardiography

Guideline Number: Evolut_CG_7336-01	<u>Applicable Codes</u>	
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Original Date: July 2011	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Transesophageal echocardiography (TEE) enables cardiac ultrasound imaging from within the esophagus, which provides a window for enhanced quality images as well as additional views, beyond that acquired by standard transthoracic echocardiography (TTE).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)

General Criteria ^(6,7,8,9,10)

- TEE may be performed after a nondiagnostic transthoracic echocardiogram (TTE) due to inadequate visualization of relevant structures, or if there is a high likelihood of a nondiagnostic TTE **(AUC Score 7)** ⁽¹¹⁾

Aortic Pathology

- Suspected acute aortic pathology, such as aortic dissection ^(6,12)
- Dilated aortic sinuses or ascending aorta on TTE **(AUC Score 7)** ⁽¹¹⁾
- Evaluation of aortic sinuses, sinotubular junction, or ascending aorta in patients with bicuspid aortic valve when morphology cannot be assessed by TTE, and other

imaging including CT or MRI (Magnetic Resonance Imaging) have not been done **(AUC Score 7)** ⁽¹¹⁾

Valvular Disease ^(6,13)

- Discordance between clinical assessment and TTE assessment of the severity of mitral regurgitation (MR) **(AUC Score 9)** ⁽⁶⁾
- Evaluation of mitral stenosis, when there is a discrepancy between clinical signs or symptoms, and TTE is inadequate
- Discordance between clinical assessment and TTE assessment of the severity of aortic regurgitation (AR) **(AUC Score 8)** ⁽⁶⁾
- Evaluation of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE is inadequate **(AUC Score 8)** ⁽⁶⁾
- Re-evaluation of known prosthetic valve dysfunction when it would change management or guide therapy, (and TTE is inadequate) **(AUC Score 7)** ⁽⁶⁾

Infective Endocarditis ^(6,14,15)

- Suspected infective endocarditis (IE) of native valve, prosthetic valve, or endocardial lead with positive blood culture or new murmur **(AUC Score 8)** ⁽⁶⁾
- Moderate to high pretest probability of IE (i.e., staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device) when TTE is negative **(AUC Score 9)** ⁽⁶⁾
- Re-evaluation of IE in a patient with a change in clinical status or cardiac examination (e.g., new murmur, embolism, persistent fever, heart failure (HF), abscess, or atrioventricular block) **(AUC Score 8)** ⁽⁶⁾
- Re-evaluation of IE if the patient is at elevated risk for progression/complications or when the findings alter therapy, when TTE is inadequate

Cardiac Mass or Source of Emboli

- Initial evaluation of patient to exclude cardiac origin of TIA or ischemic stroke **(AUC Score 7)** ⁽⁶⁾
- Evaluation of cardiac mass, suspected tumor, or thrombus, when other cardiac imaging is inconclusive ^(6,15)
- Re-evaluation of prior TEE finding for interval change (e.g., resolution of thrombus after anticoagulation), when the findings would change therapy **(AUC Score 7)** ⁽⁶⁾

Atrial Fibrillation/Flutter ⁽⁶⁾

- Evaluation for clinical decision-making regarding anticoagulation, cardioversion, and/or radiofrequency ablation

TAVR (Transcatheter Aortic Valve Replacement/Repair) ^(6,16)

(AUC Score 7) ⁽⁶⁾

- Pre-procedural assessment of annular size and shape, number of cusps, and degree of calcification, when computed tomography (CT) or CMR (Cardiovascular Magnetic

Resonance) cannot be performed

- Post-procedural assessment of degree of aortic regurgitation (including valvular and paravalvular) with suspicion of valve dysfunction, if TTE is inadequate

Patent Foramen Ovale or Atrial Septal Defect ^(6,17)

(AUC Score 8) ⁽¹¹⁾

- Evaluation for anatomy, potential cardiac source of emboli, and suitability for percutaneous device closure
- Evaluation post device closure with clinical concern for infection, malposition, embolization, or persistent shunt

Left Atrial Appendage Occlusion ⁽¹¹⁾

- Evaluation of anatomy, potential cardiac source of emboli, and suitability for percutaneous occlusion device placement **(AUC Score 9)** ⁽¹¹⁾
- Surveillance at 45 days and 1 year or FDA (U.S. Food and Drug Administration) guidance/guidelines for follow-up to assess device stability and device leak, and exclude migration, displacement, or erosion ^(18,19) **(AUC Score 8)** ⁽¹¹⁾
 - Reassessment at 6 months if 45-day TEE shows incomplete closure of left atrial appendage ^(18,19)

Percutaneous Mitral Valve Repair ⁽⁶⁾

- Determination of patient eligibility for percutaneous mitral valve procedures **(AUC Score 9)** ⁽⁶⁾
- Procedural evaluation for percutaneous mitral valve procedures may be performed in addition to CT imaging ⁽²⁰⁾
- To exclude the presence of intracardiac mass, thrombus, or vegetation prior to (within 3 days of) the procedure **(AUC Score 9)** ⁽⁶⁾

Hypertrophic Cardiomyopathy ⁽²¹⁾

- When TTE is inconclusive in planning for myectomy, to exclude subaortic membrane or mitral regurgitation, or to assess need for septal ablation

Adult Congenital Heart Disease ^(17,22)

- Imaging with provocative maneuvers (Valsalva, cough) to assess the presence of right-to-left cardiac shunt **(AUC Score 7)** ⁽¹⁷⁾
- Evaluation prior to planned repair of the following lesions when TTE, CMR, or CT are not adequate:
 - Isolated secundum atrial septal defect **(AUC Score 7)** ⁽¹⁷⁾
 - Sinus venosus defect and/or partial anomalous pulmonary venous connection **(AUC Score 7)** ⁽¹⁷⁾
 - Congenital mitral stenosis or mitral regurgitation **(AUC Score 7)** ⁽¹⁷⁾

- Subvalvular aortic stenosis **(AUC Score 7)** ⁽¹⁷⁾
- Transposition of the Great Arteries **(AUC Score 8)** ⁽¹⁷⁾
- Evaluation postoperative or post catheter-based repair due to change in clinical status and/or new concerning signs or symptoms when TTE, CMR, or CT are not adequate **(AUC Score 7)** ⁽¹⁷⁾

Ventricular Assist Devices ^(6,23)

- Preoperative evaluation of suitability for ventricular assist device (VAD)
- Re-evaluation of VAD-related complication or suspected infection **(AUC Score 7)** ⁽¹¹⁾

CODING AND STANDARDS

Coding

CPT Codes

93312, 93313, 93314, 93315, 93316, 93317, 93318, 93319, +93320, +93321, +93325, 96374

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽⁴⁾

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Acronyms/Abbreviations

- AR: Aortic regurgitation
- CMR: Cardiac magnetic resonance
- CT(A): Computed tomography (angiography)
- HF: Heart failure
- IE: Infective endocarditis
- MR: Mitral regurgitation
- MRI: Magnetic resonance imaging
- TAVR: Transcatheter aortic valve replacement/repair
- TEE: Transesophageal echocardiography
- TIA: Transient ischemia attack
- TTE: Transthoracic echocardiography
- VAD: Ventricular assist device

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● Corrected CPT code typo
November 2024	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1122 Transesophageal Echocardiography (TEE)

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483 - 1502. [10.1161/CIR.0b013e31822935fc](https://doi.org/10.1161/CIR.0b013e31822935fc).
2. Fitch K, Bernstein S, Aguilar M, Burnand B, LaCalle J et al. The RAND/UCLA Appropriateness Method User's Manual. 2001.
3. Hendel R, Patel M, Allen J, Min J, Shaw L et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF Appropriate Use Criteria Methodology Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2013; 61: 1305 - 1317. <https://doi.org/10.1016/j.jacc.2013.01.025>.
4. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. <https://doi.org/10.1016/j.jacc.2018.01.007>.
5. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease. *J Am Coll Cardiol*. 2017; 70: 1647-1672. [10.1016/j.jacc.2017.07.732](https://doi.org/10.1016/j.jacc.2017.07.732).
7. Flachskampf F, Wouters P, Edvardsen T, Evangelista A, Habib G et al. Recommendations for transoesophageal echocardiography: EACVI update 2014. *Eur Heart J Cardiovasc Imaging*. Apr 2014; 15: 353-65. [10.1093/ehjci/jeu015](https://doi.org/10.1093/ehjci/jeu015).
8. Hahn R, Abraham T, Adams M, Bruce C, Glas K et al. Guidelines for performing a comprehensive transesophageal echocardiographic examination: recommendations from the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists. *J Am Soc Echocardiogr*. Sep 2013; 26: 921-64. [10.1016/j.echo.2013.07.009](https://doi.org/10.1016/j.echo.2013.07.009).
9. Lancellotti P, Tribouilloy C, Hagendorff A, Popescu B, Edvardsen T et al. Recommendations for the echocardiographic assessment of native valvular regurgitation: an executive summary from the European Association of Cardiovascular Imaging. *Eur Heart J Cardiovasc Imaging*. Jul 2013; 14: 611-44. [10.1093/ehjci/jet105](https://doi.org/10.1093/ehjci/jet105).
10. Win T T, Alomari I B, Awad K, Ratliff M D, Qualls C R. Transesophageal Versus Transthoracic Echocardiography for Assessment of Left. *Journal of integrative cardiology open access*. 2020; 3: [10.31487/j.jicoa.2020.01.05](https://doi.org/10.31487/j.jicoa.2020.01.05).
11. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease. *J Am Coll Cardiol*. 2019; 73: 488-516. [10.1016/j.jacc.2018.10.038](https://doi.org/10.1016/j.jacc.2018.10.038).
12. Bhave N, Nienaber C, Clough R, Eagle K. Multimodality Imaging of Thoracic Aortic Diseases in Adults. *JACC Cardiovasc Imaging*. Jun 2018; 11: 902-919. [10.1016/j.jcmg.2018.03.009](https://doi.org/10.1016/j.jcmg.2018.03.009).
13. Otto C M, Nishimura R A, Bonow R O, Carabello B A, Erwin J P et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021; 143: e35 - e71. [10.1161/CIR.0000000000000932](https://doi.org/10.1161/CIR.0000000000000932).
14. Douglas P S, Garcia M J, Haines D E, Lai W W, Manning W J et al. ACCF/ASE/AHA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 Appropriate Use Criteria for Echocardiography. *J Am Coll Cardiol*. 2011; 57: 1126-66. [10.1016/j.jacc.2010.11.002](https://doi.org/10.1016/j.jacc.2010.11.002).

15. Saric M, Armour A, Arnaout M, Chaudhry F, Grimm R et al. Guidelines for the Use of Echocardiography in the Evaluation of a Cardiac Source of Embolism. *J Am Soc Echocardiogr.* Jan 2016; 29: 1-42. 10.1016/j.echo.2015.09.011.
16. Otto C, Kumbhani D, Alexander K, Calhoun J, Desai M et al. 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol.* Mar 14, 2017; 69: 1313-1346. 10.1016/j.jacc.2016.12.006.
17. Sachdeva R, Valente A M, Armstrong A K, Cook S C, Han B K et al. ACC/AHA/ASE/HRS/ISACHD/SCAI/SCCT/SCMR/SOPE 2020 Appropriate Use Criteria for Multimodality Imaging During the Follow-Up Care of Patients With Congenital Heart Disease. *J Am Coll Cardiol.* 2020; 75: 657-703. 10.1016/j.jacc.2019.10.002.
18. Watchman(tm) Left Atrial Appendage Closure Device Patient Information Guide. 2023:
19. P130013 Watchman Left Atrial Appendage (LAA) Closure Technology. 2023:
20. Wunderlich N, Beigel R, Ho S, Nietlispach F, Cheng R et al. Imaging for Mitral Interventions: Methods and Efficacy. *JACC Cardiovasc Imaging.* Jun 2018; 11: 872-901. 10.1016/j.jcmg.2018.02.024.
21. Ommen Steve R, Mital S, Burke Michael A, Day Sharlene M, Deswal A et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy. *Journal of the American College of Cardiology.* 2020/12/22; 76: e159-e240. 10.1016/j.jacc.2020.08.045.
22. Stout K, Daniels C, Aboulhosn J, Bozkurt B, Broberg C et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* Apr 2, 2019; 73: 1494-1563. 10.1016/j.jacc.2018.08.1028.
23. Stainback R, Estep J, Agler D, Birks E, Bremer M et al. Echocardiography in the Management of Patients with Left Ventricular Assist Devices: Recommendations from the American Society of Echocardiography. *J Am Soc Echocardiogr.* Aug 2015; 28: 853-909. 10.1016/j.echo.2015.05.008.

Evolent Clinical Guideline 7337-01 for Transthoracic Echocardiogram

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Transthoracic echocardiography (TTE) uses ultrasound to image the structures of the heart providing 2-dimensional, cross-sectional images. The addition of Doppler ultrasound derives hemodynamic data from flow velocity versus time measurements, as well as from color-coded two-dimensional representations of flow velocities.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE) ADULT PATIENTS ⁽⁶⁾

(Indications for pediatric patients follow this section)

Evaluation of Cardiac Structure and Function

- When initial evaluation including history, physical examination, electrocardiogram (ECG), remote monitor or other testing suggests a cardiac etiology for symptoms, including but not limited to: **(AUC 9)** ⁽⁷⁾
 - Chest pain when another study is not planned to evaluate.
 - Shortness of breath
 - Palpitations

- Hypotension suggestive of cardiac etiology not due to other causes, such as: **(AUC 8)**⁽⁷⁾
 - Medications, dehydration, or infection
- ECG Abnormalities
 - Previously unevaluated pathological Q waves (in two contiguous leads) defined as the following:
 - 40 ms (1 mm) wide
 - > 2 mm deep
 - > 25% of depth of QRS complex
 - New left bundle branch block **(AUC 7)**⁽⁷⁾
 - New isolated RBBB is **not** an indication for TTE.
 - Symptomatic or asymptomatic patients with previously unevaluated left ventricular hypertrophy (i.e., concern for hypertrophic cardiomyopathy). **(AUC 9)**⁽⁷⁾

Murmur or Click

- Initial evaluation when there is a reasonable suspicion for valvular or structural heart disease such as: **(AUC 9)**⁽⁸⁾
 - High grade $\geq 3/6$: Note that TTE can be approved for documented concern that murmur suggests a **specific valve pathology** (such as “aortic valve sclerosis/stenosis” or “mitral regurgitation”) **regardless of grade of murmur.**
 - Holosystolic
 - Continuous
 - Diastolic

Arrhythmias

- Frequent premature ventricular contractions (PVCs, greater than 30 per hour on remote monitoring or ≥ 1 PVC on 12 lead ECG) **(AUC 7)**⁽⁷⁾
 - Isolated premature atrial complexes (PACs) are not an indication for TTE.
- Sustained or nonsustained ventricular tachycardia (VT) or ventricular fibrillation (VF), or ventricular bigeminy **(AUC 9)**⁽⁷⁾
- New onset atrial fibrillation (as documented in MD notes and on ECG) which was not evaluated by a prior transthoracic echocardiogram (TTE) **(AUC 8)**⁽⁷⁾
- Initial evaluation of SVT seen on ECG or remote monitoring without other evidence of heart disease **(AUC 6)**⁽⁹⁾

Syncope^(8,10)

- History, physical examination, or electrocardiogram (ECG) consistent with a cardiac diagnosis known to cause presyncope or syncope, including but not limited to: **(AUC 9)**⁽⁷⁾

- Structural heart disease (including but limited to):
 - Hypertrophic cardiomyopathy
 - Systolic heart failure
- Exercise-induced syncope.
- And not due to other causes such as:
 - Vaso-vagal syncope, neurogenic orthostatic syncope
 - Orthostasis related to medication or dehydration.

Perioperative Evaluation (11,12)

- Preoperative left ventricular function assessment in patients who are candidates for solid organ transplantation (can be done yearly prior to transplant) **(AUC 8)** ⁽⁷⁾

Pulmonary Hypertension

- Evaluation of suspected pulmonary hypertension including evaluation of right ventricular function and estimated pulmonary artery pressure **(AUC 9)** ⁽⁷⁾
- Re-evaluation of known pulmonary hypertension if there is a change in clinical status or cardiac exam or a need to change medications, ⁽¹³⁾ such as: **(AUC 8)** ⁽⁷⁾
 - New chest pain
 - Worsening shortness of breath
 - Syncope
 - Increased murmur
 - Worsening rales on lung examination
- Initial evaluation of patients with pulmonary embolism to risk stratify and initiate appropriate therapy ⁽¹⁴⁾
 - Repeat TTE can be approved for persistent dyspnea 3-6 months after PE ⁽¹⁵⁾ to evaluate for possible chronic thromboembolic pulmonary hypertension (CTEPH)
- Annual screening can be performed for pulmonary hypertension in patients with: ^(13,16)
 - Scleroderma
 - Portal hypertension (including evaluation prior to TIPS procedure)
 - Carriers of Bone Morphogenic Protein Receptor 2 (BMP2) mutation
 - Sickle cell disease

Known Valvular Heart Disease

Symptomatic

- **New clinical signs and symptoms** (SOB/fatigue) with known **mild** valvular heart disease or known **moderate to severe** valvular heart disease. **(AUC 9)** ⁽⁸⁾

Native Valvular Stenosis⁽⁸⁾

Asymptomatic (Routine re-evaluation)

- Routine surveillance every three years of bicuspid aortic valve, or mild valvular stenosis
- Re-evaluation annually of moderate stenosis
- Re-evaluation of severe aortic stenosis (AS) every 6 months
- Re-evaluation after control of hypertension in patients with low flow/low gradient severe aortic stenosis

Native Valvular Regurgitation^(8,17,18)

Asymptomatic (Routine re-evaluation)

- every 3 yrs. of mild valvular regurgitation **(AUC 8)**⁽⁸⁾
- annually of moderate valvular regurgitation
- Asymptomatic patient every 6 months with severe valvular regurgitation

Prosthetic Valves/Native Valve Repair⁽¹⁹⁾

- Initial evaluation of prosthetic valve or native valve repair, for establishment of baseline, typically 6 weeks to 3 months postoperative and: **(AUC 9)**⁽⁸⁾
 - **Routine surveillance (Asymptomatic)**
 - Surgical bioprosthetic valve
 - Every 3 years after surgery **(AUC 7)**⁽⁸⁾
 - Surgical mechanical valve
 - 10 years postoperatively and annually thereafter **(AUC 9)**⁽⁸⁾
 - Surgical mitral valve repair
 - 1-year post-op and then every 2 years **(AUC 8)**⁽⁸⁾
 - Evaluation of prosthetic valve or native valve repair with suspected dysfunction, with symptoms including but not limited to: **(AUC 9)**⁽⁸⁾
 - Chest pain
 - Shortness of breath
 - New or Increased murmur on heart examination
 - New rales on lung examination
 - Elevated jugular venous pressure on exam

Transcatheter Heart Interventions

Transcatheter Aortic Valve Replacement (TAVR)^(8,20,21)

- Pre TAVR evaluation
- Post TAVR at 30 days (6 weeks to 3 months also acceptable) and annually **(AUC 8)**

(8)

- Assessment post TAVR when there is suspicion of valvular dysfunction, including but not limited to: **(AUC 8)** ⁽⁸⁾
 - Chest pain
 - Shortness of breath
 - New or increased murmur on heart examination
 - CVA post TAVR **(AUC 7)**
- Assessment of stroke post TAVR **(AUC 7)** ⁽⁸⁾

Percutaneous Mitral Valve Repair (PMVR) ^(8,17,20)

- Pre-procedure evaluation **(AUC 8)** ⁽⁸⁾
- Reassessment for degree of MR and left ventricular function (1, 6 months, and annually) **(AUC 9)** ⁽⁷⁾
- Assessment post TMVR when there is suspicion of valvular dysfunction, including but not limited to: **(AUC 8)** ⁽⁸⁾
 - Chest pain
 - Shortness of breath
 - New or increased murmur on heart examination
 - CVA post TMVR

Closure of PFO or ASD ⁽⁷⁾

- Pre-procedure evaluation **(AUC 9)** ⁽²²⁾
- Routine follow-up post procedure for device position and integrity (see **Table 2: Adult and Pediatric Congenital Heart Disease Follow-Up**) **(AUC 9)** ⁽²²⁾
- Evaluation for clinical concern for infection, malposition, embolization, or persistent shunt **(AUC 9)** ⁽²²⁾
- Routine surveillance of an asymptomatic patient with a PFO is **not** indicated ⁽²²⁾
- **Left Atrial Appendage (LAA) Occlusion** ⁽⁷⁾
- Pre-procedure evaluation **(AUC 8)** ⁽⁷⁾

Pericardial Disease ^(7,14,23,24)

- Suspected pericarditis or pericardial effusion **(AUC 9)** ⁽⁷⁾
- Re-evaluation of a significant known pericardial effusion when findings would lead to change in management **(AUC 7)** ⁽⁷⁾
- Suspected pericardial constriction or reevaluation of status when management would be changed.

Evaluation of Cardiac Source of Emboli or Cardiac Mass ⁽⁸⁾

- Embolic source in patients with recent transient ischemic attack (TIA), stroke, or

peripheral vascular emboli **(AUC 9)**⁽⁷⁾

- Evaluation of intracardiac mass or re-evaluation of known mass. No echo performed within the last three months⁽²⁵⁾ **(AUC 8)**⁽⁷⁾

Infective Endocarditis (Native or Prosthetic Valves) (8,20,26)

- Initial evaluation of suspected infective endocarditis with positive blood cultures or a new murmur **(AUC 9)**⁽⁸⁾
- Re-evaluation
 - Infective endocarditis with, but not limited to: **(AUC 9)**⁽⁸⁾
 - Changing cardiac murmur
 - Evidence of embolic phenomena such as TIA or CVA
 - New chest pain, shortness of breath, or syncope
 - A need to change medications due to ongoing fever, positive blood cultures, or evidence of new AV block on ECG.
 - Infective endocarditis at high risk of progression or complication (extensive infective tissue/large vegetation, or staphylococcal, enterococcal, or fungal infections) **(AUC 7)**⁽⁸⁾
- At completion of antimicrobial therapy and serial examinations at 1, 3, 6, and 12 months during the subsequent year⁽²⁶⁾

Thoracic Aortic Disease (27,28,29,30,31,32)

In the absence of recent computed tomography (CT) or cardiovascular magnetic resonance (CMR), which are preferred for imaging beyond the proximal ascending aorta.

- Screening of first-degree relatives of individuals with:
 - Thoracic aortic aneurysm (defined as $\geq 50\%$ above normal) or dissection.
 - Bicuspid aortic valve
 - Presence of an aortopathic syndrome (i.e., Marfan's, Ehlers-Danlos, Loeys-Dietz, or Turner's)
- If one or more first-degree relatives of a patient with a known thoracic aortic aneurysm or dissection, have thoracic aortic dilatation, aneurysm, or dissection; then imaging of 2nd degree relatives is reasonable.
- Six-month follow-up after initial finding of a dilated thoracic aorta
- Annual follow-up of enlarged thoracic aorta that is above top normal for age, gender, and body surface area.
- Biannual (twice/year) follow-up of enlarged aortic root ≥ 4.5 cm or showing growth rate ≥ 0.5 cm in one year or ≥ 0.3 cm per year in 2 consecutive years for sporadic aneurysms and ≥ 0.3 cm in 1 year for heritable thoracic aortic disease or bicuspid aortic valve⁽²⁸⁾
- Evaluation of the ascending aorta in known or suspected connective tissue disease or genetic conditions that predispose to aortic aneurysm or dissection (e.g., Marfan syndrome, Ehlers-Danlos or Loeys-Dietz syndromes) at time of diagnosis and 6

months thereafter for growth rate assessment, followed by annual imaging, or biannual (twice yearly) if diameter ≥ 4.5 or expanding ≥ 0.3 cm/yr. **(AUC 8)**⁽⁷⁾

- Turner's Syndrome:
 - Baseline evaluation at the time of diagnosis to assess for bicuspid aortic valve, coarctation of the aorta, aortic root and ascending aortic dilatation and other congenital defects.
 - Surveillance imaging (initial imaging normal and no additional risk factors for dissection such as HTN or bicuspid aortic valve):
 - Children: every 5 years
 - Adults: every 10 years
 - Prior to planned pregnancy
 - Annual imaging can be approved if an abnormality is found (such as bicuspid aortic valve)
- Re-evaluation of known ascending aortic dilation or history of aortic dissection with one of the following:
 - New chest pain
 - Shortness of breath
 - Syncope
 - TIA or CVA
 - New or increased aortic valve murmur on clinical examination.
 - New rales on lung examination or increased jugular venous pressure.
 - **OR** when findings would lead to referral to a procedure or surgery
- Follow-up of aortic disease when there has been no surgical intervention:
 - Acute dissection: 1 month, 6 months, 12 months, then annually
 - Chronic dissection: annually
- Follow-up thoracic aortic aneurysm repair: chest CTA or chest MRA are the recommended surveillance imaging modalities.
- Follow-up post either: Root repair or AVR plus ascending aortic root/arch repair: baseline post-op, then annually
- Evaluation of sinus of Valsalva aneurysms and associated shunting secondary to rupture.⁽³²⁾

Hypertension (HTN) (Adult) (7,28)

- Initial evaluation of suspected hypertensive heart disease including but not limited to the following:
 - Left ventricular hypertrophy on ECG.
 - Cardiomegaly
 - Evidence of clinical heart failure
- Initial evaluation of uncontrolled, resistant HTN without symptoms on three or more

anti-hypertensive drugs.

Hypertension (HTN) (Pediatric) ⁽³³⁾

(AUC 9) ⁽³⁴⁾

- Initial evaluation at time of consideration of pharmacologic treatment of HTN
- Re-evaluation at 6–12-month intervals for:
 - Persistent HTN despite treatment
 - Concentric LVH on prior study
 - Reduced LVEF on prior study
- Re-evaluation of patients without LVH on initial evaluation can have TTE annually for:
 - Stage 2 HTN (BP \geq 140/90 mmHg)
 - Secondary HTN
 - Chronic stage 1 HTN (BP between 130/80 mmHg and 139/89 mmHg) incompletely treated, including drug resistance and noncompliance.

Heart Failure ^(7,35,36,37)

- Initial evaluation of suspected HF (systolic or diastolic) based on symptoms, signs, or abnormal test result, including but not limited to: (AUC 9) ⁽⁷⁾
 - Dyspnea
 - Orthopnea
 - Paroxysmal nocturnal dyspnea
 - Worsening edema
 - Elevated BNP
- Re-evaluation
 - Known HF (systolic or diastolic)
 - With a change in clinical status or cardiac exam (as listed above)
 - Asymptomatic patient with change in GDMT

Cardiomyopathy

- Initial evaluation of suspected inherited or acquired cardiomyopathy, including but not limited to: (AUC 9) ⁽⁷⁾
 - Restrictive
 - Infiltrative/Depositional (i.e., hemochromatosis/iron overload, mucopolysaccharidoses, mitochondrial or metabolic storage disease (e.g., Danone disease, Fabry disease))
 - Fabry disease: annual surveillance TTE may be approved for patients receiving enzyme replacement ⁽²⁵⁾
 - Dilated

- Hypertrophic
- Re-evaluation of known cardiomyopathy if there is a need to monitor a change in medications or new symptoms, including but not limited to:
 - Chest pain
 - Shortness of breath
 - Palpitations
 - Syncope
- Heart failure (including Takotsubo cardiomyopathy)⁽²⁵⁾ with recovered left ventricular ejection fraction defined as (must meet all 3 criteria):
 - Documentation of a decreased LVEF <40% at baseline
 - ≥10% absolute improvement in LVEF
 - A second measurement of LVEF >40%:⁽³⁸⁾
 - Repeat echocardiogram every 6 months until 12-18 months after recovery of EF, then annually for 2 years, then every 3-5 years
 - Higher risk patient (persistent left bundle branch block, genetic cardiomyopathy, higher biomarker profiles) may have annual follow-up.
- Screening evaluation in first-degree relatives of a patient with an inherited cardiomyopathy **(AUC 9)**⁽⁷⁾
- Suspected cardiac sarcoidosis, including as a screening study in patients with biopsy proven extracardiac sarcoidosis⁽³⁹⁾
- Suspected cardiac amyloid and to monitor disease progression and/or response to therapy, and to guide initiation and management of anticoagulation (TEE may be preferred)⁽⁴⁰⁾
 - Light chain amyloidosis (AL): TTE may be repeated every 3-6 months.
 - Transthyretin amyloidosis (ATTR): TTE may be repeated every 6-12 months⁽²⁵⁾

Hypertrophic Cardiomyopathy (HCM)⁽⁴¹⁾

- Initial evaluation of suspected HCM
- Re-evaluation of patients with HCM with a change in clinical status or a new clinical event
- Evaluation of the result of surgical myomectomy or alcohol septal ablation
- Re-evaluation in patients with no change in clinical status or events or annually to assess degree of myocardial hypertrophy, dynamic obstruction, MR, and myocardial function.
- Evaluation of patients with HCM who have undergone septal reduction therapy within 3-6 months after the procedure.
- Screening for patients who are clinically unaffected or (genotype-positive and phenotype-negative):
 - Children and adolescents annually

- Adults every 3 years
- Screening of first-degree relatives is recommended at the time HCM is diagnosed in the family member and serial follow-up as below:
 - Children and adolescents from genotype-positive families and families with early onset disease annually
 - All other children and adolescents every 2 years
 - Adults every 3 years
- To guide therapy
 - Camzyos (mevacamten): baseline TTE prior to initiation. Repeat TTE during therapy at the discretion of the ordering specialist. ⁽⁴²⁾

Imaging Surveillance for Cardiotoxic Exposures ^(43,44)

- TTE is the method of choice for the evaluation of patients who will receive or have received cardiotoxic medication. TTE may be approved for:
 - Baseline assessment prior to initiation of therapy **(AUC 9)** ⁽⁷⁾
 - Monitoring during therapy. The frequency of testing should be left to the discretion of the ordering physician, but in the absence of new abnormal findings, generally no more often than every 6 weeks while on active therapy. **(AUC 7)** ⁽⁷⁾
 - Long term surveillance after completion of therapy may be required, especially for those who have been exposed to anthracycline medication. The frequency of testing is generally every 6-12 months, or at the discretion of the provider. **(AUC 7)** ⁽⁷⁾

Imaging Surveillance for Previous Radiation Therapy with Cardiac Exposure ⁽⁴⁵⁾

- TTE is indicated for long term surveillance, generally at 5 years and at 10 years following radiation exposure. More frequent surveillance may be indicated at the discretion of the provider.

Device Candidacy or Optimization (Pacemaker, ICD, or CRT)

- Initial evaluation or re-evaluation after revascularization (≥ 90 days) and/or myocardial infarction (≥ 40 days) and/or 3 months of guideline-directed medical therapy when ICD is planned ⁽⁴⁶⁾ **(AUC 9)** ⁽⁷⁾
- Initial evaluation for CRT device optimization after implantation **(AUC 7)** ⁽⁷⁾
- Re-evaluation for CRT device optimization in a patient with worsening heart failure **(AUC 8)** ⁽⁷⁾
- Known implanted pacing device with symptoms possibly due to device complication or suboptimal pacing device settings **(AUC 8)** ⁽⁷⁾

Ventricular Assist Devices (VADs) and Cardiac Transplantation (7,47)

- To determine candidacy for VAD **(AUC 9)** ⁽⁷⁾
- Optimization of VAD settings and assessment of response post device **(AUC 8)** ⁽⁷⁾
- Re-evaluation for signs/symptoms suggestive of VAD-related complications, including but not limited to: **(AUC 8)** ⁽⁷⁾
 - TIA or stroke
 - Infection
 - Murmur suggestive of aortic insufficiency.
 - Worsening heart failure

Post Heart Failure Transplant Surveillance Imaging

- Monitoring at the discretion of the transplant center for rejection in a cardiac transplant recipient. ⁽⁴⁸⁾ **(AUC 8)** ⁽⁷⁾

Cardiovascular Disease in Pregnancy (9,49)

- Valvular stenosis
 - Mild can be evaluated each trimester and prior to delivery.
 - Moderate-severe can be evaluated monthly.
- Valvular regurgitation
 - Mild-moderate regurgitation can be evaluated each trimester and prior to delivery.
 - Severe regurgitation can be evaluated monthly.
- Pre-pregnancy evaluation with mechanical or bioprosthetic heart valves (if not done within the previous year) **(AUC 9)** ⁽⁸⁾
- Peripartum Cardiomyopathy: can be repeated at the end of the 1st and 2nd trimesters, 1 month prior to delivery, 1 month postpartum, and serially including up to 6 months after normalization of ejection fraction.
- Aortopathic syndromes (i.e., Marfan's, Ehlers-Danlos, Loeys-Dietz Syndrome, or Turner's Syndrome) or known dilated aortic root or ascending aorta: may be approved for pre-pregnancy planning and for monitoring each trimester during pregnancy and again several weeks post-partum. More frequent imaging may be approved depending on aortic diameter, aortic growth rate and comorbidities predisposing to dissection (i.e., presence of an aortopathic syndrome, HTN). ⁽²⁸⁾

Adult Congenital Heart Disease (22,50)

- Initial evaluation including history, physical examination, electrocardiogram (ECG), or other imaging modality suggest adult congenital heart disease.
- Screening of first-degree relatives of patients with a bicuspid aortic valve **(AUC 8)** ⁽⁸⁾
- Known adult congenital heart disease with a change in clinical status or cardiac

exam, including but not limited to:

- Chest Pain
- Shortness of breath
- New or increased murmur on physical exam
- Evaluation prior to surgical or transcatheter procedure
- For follow-up of specific lesions, see **Table 1** and **Table 2: Adult and Pediatric Congenital Heart Disease Follow-up**

Inflammatory and Autoimmune

- Including any one of the following:
 - Suspected rheumatic fever ⁽⁵¹⁾
 - Systemic lupus erythematosus ⁽⁵²⁾
 - Takayasu arteritis ⁽⁵³⁾
 - Multisystem Inflammatory Syndrome in children (MIS-C): at baseline and for surveillance when there is documented concern for coronary involvement or other late sequelae ⁽⁵⁴⁾
 - Kawasaki disease ⁽⁵⁵⁾
 - Upon diagnosis, 1-2 weeks later, and 4 to 6 weeks after diagnosis
 - For patients with important and evolving coronary artery abnormalities during the acute illness, echocardiograms may need to be more frequent. In the setting of increasing size of coronary aneurysms, echocardiogram can be performed up to twice per week until dimensions have stopped progressing, then at least once per week in the first 45 days of illness, and then monthly until the third month after onset.
 - For persistent coronary aneurysm after the acute illness, echocardiogram surveillance intervals are based on the size of the aneurysm:
 - Small: at 6 months. and then yearly
 - Medium: at 3, 6 and 12 months and then every 6-12 months
 - Large/Giant: at 3, 6, 9 and 12 months and then every 3-6 months

COVID-19 ⁽⁵⁶⁾

- Acute infection
 - Cardiopulmonary signs or symptoms (ECG abnormalities, elevated biomarkers, chest pain, dyspnea, syncope, palpitations)
- Post-Acute Sequelae (PASC) defined as new or returning cardiopulmonary symptoms 4 or more weeks and persisting more than 2 months following confirmed COVID infection, not explained by an alternative diagnosis (World Health Organization definition).
- Post Vaccination
 - Symptoms or signs of myocarditis (ECG abnormalities, chest pain, elevated

biomarkers)

Surveillance for Neuromuscular Disorders ⁽⁵⁷⁾

Asymptomatic surveillance intervals (genetically affected individuals with no signs or symptoms of cardiac involvement). Development of signs or symptoms of cardiac involvement necessitates more frequent assessment.

- Duchenne muscular dystrophy (DMD) and Becker muscular dystrophy (BMD)
 - age <10 years, TTE every 2 years
 - age 10 years or older, TTE annually
- Emery-Dreifuss muscular dystrophy (EDMD)
 - X-linked form: at least annual TTE
 - Autosomal form: TTE at initial diagnosis, surveillance TTE only if initial TTE abnormal
- Myofibrillar myopathy (MFM)
 - Annual TTE
- Barth (BTHS)-X linked recessive (only males develop disease)
 - Infant males TTE every 6 months
 - Age 1 year or older, annual TTE
- Limb-Girdle muscular dystrophy (LGMD)
 - TTE may be performed annually.
- Friedrich's ataxia (FA)
 - TTE can be performed at least annually.
- Myotonic dystrophy (DM)
 - TTE every 2-4 years

Indications for Transthoracic Echocardiography (TTE) Pediatric Patients (Patients Under the Age of 18) ⁽³⁴⁾

- Hypertension (see section: **Hypertension (Pediatric)**) (AUC 9) ⁽³⁴⁾
 - Initial evaluation (one time only)
 - Persistent hypertension despite two or more medications can be performed annually ⁽³³⁾
- Initial evaluation of Renal failure (AUC 7) ⁽³⁴⁾
- Palpitations, if one:
 - Family history at age < 50 of either: (AUC 7) ⁽³⁴⁾
 - Sudden cardiac death/arrest **OR**
 - Pacemaker or ICD
 - History or family history of cardiomyopathy (AUC 9) ⁽³⁴⁾

- Chest pain, if one or more of the following:
 - Exertional chest pain **(AUC 8)** ⁽³⁴⁾
 - Abnormal ECG **(AUC 7)** ⁽³⁴⁾
 - Family history with unexplained sudden death or cardiomyopathy **(AUC 8)** ⁽³⁴⁾
- Syncope, if any of the following:
 - Abnormal ECG **(AUC 7)** ⁽³⁴⁾
 - Exertional syncope **(AUC 9)** ⁽³⁴⁾
 - Family history at age < 50 of either one: **(AUC 9)** ⁽³⁴⁾
 - Sudden cardiac death/arrest **OR**
 - Pacemaker or ICD
 - Family history of cardiomyopathy
- Signs and/or symptoms of heart failure, including, but not limited to: **(AUC 9)** ⁽³⁴⁾
 - Respiratory distress
 - Poor peripheral pulses
 - Feeding difficulty
 - Decreased urine output.
 - Edema
 - Hepatomegaly
- Abnormal physical findings, including any one of the following:
 - Clicks, snaps, or gallops
 - Fixed and/or abnormally split S2.
 - Decreased pulses.
 - Central cyanosis **(AUC 8)** ⁽³⁴⁾
- Arrhythmia, if one of the following:
 - Supraventricular tachycardia **(AUC 7)** ⁽³⁴⁾
 - Ventricular tachycardia **(AUC 9)** ⁽³⁴⁾
- Murmur
 - Pathologic sounding or harsh murmur, diastolic murmur, holosystolic or continuous murmur, late systolic murmur, grade 3/6 systolic murmur or louder, or murmurs that are provoked and become louder with changes in position **(AUC 9)** ⁽³⁴⁾
 - Presumptively innocent murmur, but in the presence of signs, symptoms, or findings of cardiovascular disease **(AUC 7)** ⁽³⁴⁾
- Abnormal basic data, including any one of the following:
 - Abnormal ECG **(AUC 7)** ⁽³⁴⁾
 - Abnormal cardiac biomarkers **(AUC 9)** ⁽³⁴⁾

- Desaturation on pulse oximetry **(AUC 9)** ⁽³⁴⁾
- Abnormal chest x-ray **(AUC 9)** ⁽³⁴⁾
- Sickle cell **(AUC 8)** ⁽³⁴⁾
 - One time screening for risk stratification for pulmonary hypertension in children ≥ 8 years of age ⁽⁵⁸⁾
- Suspicion of Structural Disease, including any one of the following:
 - Premature birth where there is suspicion of a Patent Ductus Arteriosus
 - Vascular Ring, based upon either one:
 - Difficulty breathing with stridor and eating solid foods that might suggest a vascular ring.
 - Abnormal barium swallow or bronchoscopy suggesting a vascular ring **(AUC 7)** ⁽³⁴⁾
- Genetic & Syndrome Related, including any one of the following: **(AUC 7)** ⁽³⁴⁾
 - Genotype positive for cardiomyopathy, family history of hypertrophic cardiomyopathy or heritable pulmonary arterial hypertension
 - Patient with a known syndrome associated with congenital or acquired heart disease (Down's syndrome, Noonan's syndrome, DiGeorge syndrome, William's syndrome, Trisomy Thirteen, Trisomy Eighteen, Alagille syndrome, chromosomal abnormality associated with cardiovascular disease)
 - Abnormalities of visceral or cardiac situs
 - Known or suspected connective tissue diseases that are associated with congenital or acquired heart disease. (e.g., Marfan's, Loeys-Dietz)
 - Patients with a first-degree relative with a genetic abnormality, such as cardiomyopathies (hypertrophic, dilated, arrhythmogenic right ventricular dysplasia, restrictive, left ventricular noncompaction).
- Maternal-Fetal related, including any one of the following:
 - Maternal infection during pregnancy or delivery with potential fetal/neonatal cardiac sequelae **(AUC 7)** ⁽³⁴⁾
 - Maternal phenylketonuria **(AUC 7)** ⁽³⁴⁾
 - Suspected cardiovascular abnormality on fetal echocardiogram **(AUC 9)** ⁽³⁴⁾

Congenital Heart Disease Follow-Up†* (22)

Adult and Pediatric

[†All surgical or catheter-based repairs allow evaluation PRIOR to the procedure and POSTPROCEDURAL evaluation (within 30 days)]

- For all lesions, TTE is indicated for change in clinical status and/or development of new signs or symptoms.
- Infant with any degree of unrepaired valvular AS/AR may have surveillance TTE every 1 – 4 weeks as needed.
- Surveillance interval for patients with subvalvular stenosis **plus** aortic regurgitation

will be dictated by the magnitude of the more significant abnormality (e.g., mild stenosis with moderate regurgitation would have surveillance interval as though stenosis were also moderate).

- Infant with any degree of unrepaired MS may have surveillance TTE every 1 – 4 weeks as needed.
- After any surgical or catheter-based repair, evaluation (3-12 months) for a patient with heart failure symptoms
- Annual surveillance in a child with normal prosthetic mitral valve function and no LV dysfunction
- Surveillance (3-12 months) in a child with prosthetic mitral valve and ventricular dysfunction and/or arrhythmia
- Annual surveillance for incomplete or palliative repair (including but not limited to Glenn shunt, Fontan procedure and RV-PA conduit)
- TTE may be unnecessary in a year when cardiac MRI is performed unless clinical indication warrants otherwise.

[*Note: See tables below for specific surveillance intervals.]

Infancy is defined as between birth and 2 years of age; childhood from 2-12 years of age; and adolescence from 12 to 21 years of age⁽⁵⁹⁾

Table 1: Unrepaired Lesion Follow-Up‡ (22)

‡Blue shading indicates lifetime surveillance interval

Unrepaired Lesion	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
Aortic Stenosis (AS) and/or aortic regurgitation (AR) (See <u>section above</u> for surveillance intervals for infants)			Child Asymptomatic ≥ moderate AS/AR	Child Asymptomatic mild AS/AR	
Bicuspid aortic valve with ≤ mild AS/AR and no aortic dilation in a child				For adolescent	3 Years

Unrepaired Lesion	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
Atrial septal defect				Moderate size (6-12mm)	Small size (3-6mm)
Double outlet right ventricular (DORV): with balanced systemic and pulmonary circulation	Infant	Child			
Mitral regurgitation (MR)	Infant with \geq moderate MR		Infant with mild MR. Child with \geq moderate MR.		Child with mild MR (2-5 years)
Mitral Stenosis (MS) (See section above for surveillance intervals for infants)		Child with \geq moderate MS		Child with mild MS	
Congenitally corrected transposition of the Great Arteries (ccTGA)		Infant	Moderate or greater A-V valve regurgitation	< Moderate A-V valve regurgitation	
Tricuspid regurgitation (TR)		Infant with \geq moderate TR	Child with \geq moderate TR	Child with mild TR	
Patent Ductus Arteriosus		Infant		Child	Adult
Pulmonary stenosis (PS)		Infant		Child	
				Adult	
Coarctation		Infant		Child	

Unrepaired Lesion	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
				Adult	
Ventricular septal defect (VSD)	Infant with \geq moderate VSD			Child with non-muscular VSD	Child with small muscular VSD
					Adult with any VSD
Anomalous coronary arteries				Moderate to large coronary fistula	Small coronary fistula or RCA arising from left coronary sinus (2-5 years)
Subvalvular AS See section above for information on surveillance intervals for stenosis plus regurgitation	Infant with any degree of stenosis		Child with \geq moderate stenosis	Child with mild stenosis	
			Adult with \geq moderate stenosis	Adult with mild stenosis	
Supravalvular AS		Infant with any degree of stenosis	Child with \geq moderate stenosis	Child with mild stenosis	2-5 years Adult with \geq moderate stenosis
			Adult with \geq moderate stenosis	Adult with mild stenosis	
Total anomalous pulmonary venous connection (TAPVC)	Prior to planned repair or for change in clinical status and/or development of new signs and symptoms				

Note: Despite surgical or catheter-based procedures, most patients with congenital heart disease are left with disorders or **sequelae** that are known consequences of the reparative intervention. These disorders can include arrhythmias, valvular and myocardial dysfunction, and vascular and non-cardiovascular abnormalities. These sequelae can be categorized as mild, moderate, or severe. Use clinical judgement to assess the nature of the sequelae when adjudicating cases based on the follow-up criteria below.

Table 2: Postprocedural Follow-Up‡ (22)

‡Blue shading indicates lifetime surveillance interval

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
Post-procedural treatment of AS or AR with repair or replacement	Infant with ≥ moderate AS or AR or LV dysfunction	Infant with ≤ mild AS or AR and no LV dysfunction	Child with ≥ moderate AS or AR	Child with ≤ mild AS or AR	
ASD device closure: no or mild sequelae	Within 1 st year	Within 1 st year	At 1 year		2-5 years
ASD surgical repair: no or mild sequelae			Within 1 st year		2-5 years
ASD: device closure or surgical repair with residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		3-12 months			
DORV: no or mild sequelae			Within 1 st year	1-2 Years	
DORV: valvular or ventricular dysfunction, outflow obstruction, arrhythmias, branch pulmonary artery stenosis, presence of RV-PA conduit		3-12 months			

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
Tricuspid valve surgery or catheter-based procedure: no or mild sequelae				1-2 years	
Tricuspid valve surgery or catheter-based procedure: valvular or ventricular dysfunction or arrhythmias			Child	Adult	
Pulmonary Stenosis: no or mild sequelae			Child with moderate or severe sequelae	Child with no or mild sequelae	Adult
Coarctation: no or mild sequelae		Within 1 st year		After 1 st year	
PDA: no or mild sequelae				Annually within 1 st two years	Five years after 1 st two years*
PDA: post-procedural left PA stenosis or aortic obstruction				1-2 years	
Tetralogy of Fallot (ToF): after transcatheter pulmonary valve replacement, with no or mild sequelae	1 month	6 months		Annually	
ToF: patient with conduit dysfunction valvular or ventricular dysfunction, pulmonary artery			6-12 months		

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
stenosis, or arrhythmias					
Congenitally corrected transposition on the Great Arteries (ccTGA): no or mild sequelae		Within 1 st year		1-2 years	
ccTGA: valvular or ventricular dysfunction, outflow obstruction, ventricular - PA conduit		3-12 months			
d-TGA: no or mild sequelae	Infant with moderate sequelae	Within 1 st year		1-2 years	
d-TGA: moderate or greater valvular or ventricular dysfunction, outflow obstruction, branch pulmonary artery stenosis or arrhythmias, presence of RV-PA conduit		3-12 months			
d-TGA: dilated neo-aortic root and increasing Z-Score or neo-aortic regurgitation				1-2 years	
Truncus Arteriosus (TA): no or mild sequelae	Within 1 st year		After 1 st year		
TA:		3-6 months			

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
moderate or greater truncal stenosis / regurgitation					
TA: residual VSD, RV-PA conduit, branch pulmonary artery obstruction		3-12 months			
VSD: no or mild sequelae or small residual shunt			Within 1 st year		2-3 years
VSD: significant residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		3-12 months			
Anomalous coronary arteries	Within 1 st year	Infant with or without ventricular or valvular dysfunction Child or adult with ventricular or valvular dysfunction		Annually	
Subvalvular AS See section above for information on surveillance intervals plus regurgitation	Infant with \geq moderate stenosis	Infant with \leq mild stenosis		Child with \leq mild stenosis and/or AR Adult with \leq mild stenosis and/or AR	

Post-procedure: Surgical or Catheter- Based	Surveillance Intervals				
	1-3 months	3-6 months	6-12 months	1-2 years	3-5 years
Subvalvular AS <i>continued</i>		3-12 months Child \geq moderate stenosis			
		3-12 months Adult \geq moderate stenosis			
Supravalvular AS			Patient with \geq moderate stenosis		2-5 years Patient with \leq mild stenosis
Total anomalous pulmonary venous connection		Infant with mild or no sequelae		Child with mild or no sequelae	Adult with mild or no sequelae

*PDA lifetime surveillance applies only to device closure; PDA lifetime surveillance is not indicated for surgical closure.

CODING AND STANDARDS

Coding

CPT Codes

93303, 93304, 93306, 93307, 93308, 93320, 93321, 93325, 93356, 96374

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner ⁽³⁾.

- Appropriate Care - Median Score 7-9
- May be Appropriate Care - Median Score 4-6
- Rarely Appropriate Care - Median Score 1-3

Acronyms / Abbreviations

AS: Aortic stenosis

AR: Aortic regurgitation

ASD: Atrial septal defect

BNP: B-type natriuretic peptide or brain natriuretic peptide

CABG: Coronary artery bypass grafting surgery

CAD: Coronary artery disease

ccTGA: Congenitally corrected transposition of the Great Arteries

CMR: Cardiovascular magnetic resonance

CRT: Cardiac resynchronization therapy

CT: Computed tomography

CVA: Cerebrovascular accident

DORV: Double outlet right ventricle

d-TGA: D-Transposition of the Great Arteries

ECG: Electrocardiogram

EF: Ejection fraction

HCM: Hypertrophic cardiomyopathy

HTN: Hypertension

HF: Heart failure

ICD: Implantable cardioverter-defibrillator

LAA: Left atrial appendage

LV: Left ventricular/ventricle

LVEF: Left ventricular ejection fraction

LVH: Left ventricular hypertrophy

MI: Myocardial infarction

MR: Mitral regurgitation

MS: Mitral stenosis

PA: Pulmonary artery
 PAC: Premature atrial complex
 PDA: Patent ductus arteriosus
 PFO: Patent foramen ovale
 PMVR: Percutaneous Mitral Valve Repair
 PS: Pulmonary stenosis
 PVC: Premature ventricular contraction
 RV: Right ventricular/ventricle
 TA: Truncus arteriosus
 TAVR: Transcatheter aortic valve replacement
 TEE: Transesophageal echocardiogram
 TIA: Transient ischemic attack
 ToF: Tetralogy of Fallot
 TR: Tricuspid regurgitation
 TTE: Transthoracic echocardiogram
 VAD: Ventricular assist device
 VF: Ventricular fibrillation
 VSD: Ventricular septal defect
 VT: Ventricular tachycardia

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> Corrected CPT code typo
November 2024	<ul style="list-style-type: none"> This guideline replaces UM 1121 Transthoracic Echocardiography Simplified surveillance schedule ranges

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R, Douglas P, Buxton A, Cohen D, Curtis J et al. ACCF/AHA Methodology for the Development of Quality Measures for Cardiovascular Technology. *Circulation*. 2011; 124: 1483 - 1502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S, Aguilar M, Burnand B, LaCalle J et al. The RAND/UCLA Appropriateness Method User's Manual. 2001.
3. Hendel R, Lindsay B, Allen J, Brindis R, Patel M et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935 - 948. <https://doi.org/10.1016/j.jacc.2018.01.007>.
4. Hendel R, Patel M, Allen J, Min J, Shaw L et al. Appropriate Use of Cardiovascular Technology: 2013 ACCF Appropriate Use Criteria Methodology Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2013; 61: 1305 - 1317. <https://doi.org/10.1016/j.jacc.2013.01.025>.
5. Patel M, Spertus J, Brindis R, Hendel R, Douglas P et al. ACCF proposed method for evaluating the appropriateness of cardiovascular. *Journal of the American College of Cardiology*. 2005; 46: 1606-13.
6. Douglas P S, Garcia M J, Haines D E, Lai W W, Manning W J et al. ACCF/AHA/ASA/ASNC/HFSA/HRS/SCAI/SCCM/SCCT/SCMR 2011 Appropriate Use Criteria for Echocardiography. *J Am Coll Cardiol*. 2011; 57: 1126-66. 10.1016/j.jacc.2010.11.002.
7. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease. *J Am Coll Cardiol*. 2019; 73: 488-516. 10.1016/j.jacc.2018.10.038.
8. Doherty J U, Kort S, Mehran R, Schoenhagen P, Soman P. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease. *J Am Coll Cardiol*. 2017; 70: 1647-1672. 10.1016/j.jacc.2017.07.732.
9. Regitz-Zagrosek V, Roos-Hesselink J W, Bauersachs J, Blomström-Lundqvist C, Cifková R et al. 2018 ESC Guidelines for the management of cardiovascular diseases during pregnancy: The Task Force for the Management of Cardiovascular Diseases during Pregnancy of the European Society of Cardiology (ESC). *Eur Heart J*. 2018; 39: 3165 - 3241. 10.1093/eurheartj/ehy340.
10. Shen W, Sheldon R S, Benditt D G, Cohen M I, Forman D E et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope. *Circulation*. 2017; 136: e60 - e122. 10.1161/CIR.0000000000000499.
11. Fleisher L A, Fleischmann K E, Auerbach A D, Barnason S A, Beckman J A et al. 2014 ACC/AHA Guideline on Perioperative Cardiovascular Evaluation and Management of Patients Undergoing Noncardiac Surgery. *Circulation*. 2014; 130: 2215 - 2245. 10.1161/CIR.0000000000000105.
12. Lentine K L, Costa S P, Weir M R, Robb J F, Fleisher L A et al. Cardiac Disease Evaluation and Management Among Kidney and Liver Transplantation Candidates. *Circulation*. 2012; 126: 617 - 663. 10.1161/CIR.0b013e31823eb07a.
13. Galiè N, Humbert M, Vachiery J, Gibbs S, Lang I et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2016; 37: 67 - 119. 10.1093/eurheartj/ehv317.
14. Saric M, Armour A, Arnaout M, Chaudhry F, Grimm R et al. Guidelines for the Use of Echocardiography in the Evaluation of a Cardiac Source of Embolism. *J Am Soc Echocardiogr*. Jan 2016; 29: 1-42. 10.1016/j.echo.2015.09.011.

15. Humbert M, Kovacs G, Hoeper M M, Badagliacca R, Berger R M F et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022; 43: 3618 - 3731. 10.1093/eurheartj/ehac237.
16. Klings E S, Machado R F, Barst R J, Morris C R, Mubarak K K et al. An official American Thoracic Society clinical practice guideline: diagnosis, risk stratification, and management of pulmonary hypertension of sickle cell disease. *American journal of respiratory and critical care medicine*. 2014; 189: 727-40.
17. Bonow R O, O’Gara P T, Adams D H, Badhwar V, Bavaria J E et al. 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. *Journal of the American College of Cardiology*. 2020; 75: 2236 - 2270. <https://doi.org/10.1016/j.jacc.2020.02.005>.
18. Lancellotti P, Tribouilloy C, Hagendorff A, Popescu B, Edvardsen T et al. Recommendations for the echocardiographic assessment of native valvular regurgitation: an executive summary from the European Association of Cardiovascular Imaging. *Eur Heart J Cardiovasc Imaging*. Jul 2013; 14: 611-44. 10.1093/ehjci/jet105.
19. Zoghbi W A, Chambers J B, Dumesnil J G, Foster E, Gottdiener J S et al. Recommendations for Evaluation of Prosthetic Valves With Echocardiography and Doppler Ultrasound. *Journal of the American Society of Echocardiography*. 2009; 22: 975 - 1014. 10.1016/j.echo.2009.07.013.
20. Otto C M, Nishimura R A, Bonow R O, Carabello B A, Erwin J P et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2021; 143: e35 - e71. 10.1161/CIR.0000000000000932.
21. Otto C, Kumbhani D, Alexander K, Calhoun J, Desai M et al. 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol*. Mar 14 2017; 69: 1313-1346. 10.1016/j.jacc.2016.12.006.
22. Sachdeva R, Valente A M, Armstrong A K, Cook S C, Han B K et al. ACC/AHA/ASE/HRS/ISACHD/SCAI/SCCT/SCMR/SOPE 2020 Appropriate Use Criteria for Multimodality Imaging During the Follow-Up Care of Patients With Congenital Heart Disease. *J Am Coll Cardiol*. 2020; 75: 657-703. 10.1016/j.jacc.2019.10.002.
23. Chiabrando J G, Bonaventura A, Vecchié A, Wohlford G F, Mauro A G et al. Management of Acute and Recurrent Pericarditis: JACC State-of-the-Art Review. *Journal of the American College of Cardiology*. 2020; 75: 76 - 92. <https://doi.org/10.1016/j.jacc.2019.11.021>.
24. Klein A L, Abbara S, Agler D A, Appleton C P, Asher C R et al. American Society of Echocardiography Clinical Recommendations for Multimodality Cardiovascular Imaging of Patients with Pericardial Disease. *Journal of the American Society of Echocardiography*. 2013; 26: 965 - 1012.e15. 10.1016/j.echo.2013.06.023.
25. Ohte N, Ishizu T, Izumi C, Itoh H, Iwanaga S et al. JCS 2021 Guideline on the Clinical Application of Echocardiography. *Circulation Journal*. 2022; 86: 2045 - 2119. 10.1253/circj.CJ-22-0026.
26. Habib G, Lancellotti P, Antunes M J, Bongioni M G, Casalta J et al. 2015 ESC Guidelines for the management of infective endocarditis. *Eur Heart J*. 2015; 36: 3075 - 3128. 10.1093/eurheartj/ehv319.
27. Bhave N, Nienaber C, Clough R, Eagle K. Multimodality Imaging of Thoracic Aortic Diseases in Adults. *JACC Cardiovasc Imaging*. Jun 2018; 11: 902-919. 10.1016/j.jcmg.2018.03.009.
28. Isselbacher E M, Preventza O, Hamilton Black J, Augoustides J G, Beck A W et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease. *Circulation*. 2022; 146: e334 - e482. 10.1161/CIR.0000000000001106.
29. Hiratzka L F, Creager M A, Isselbacher E M, Svensson L G, Nishimura R A et al. Surgery for Aortic Dilatation in Patients With Bicuspid Aortic Valves. *Journal of the American College of Cardiology*. 2016; 67: 724 - 731. 10.1016/j.jacc.2015.11.006.

30. Hiratzka L F, Bakris G L, Beckman J A, Bersin R M, Carr V F et al. 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease. *Journal of the American College of Cardiology*. 2010; 55: 1509 - 1544. 10.1016/j.jacc.2010.02.010.
31. Svensson L G, Adams D H, Bonow R O, Kouchoukos N T, Miller D C et al. Aortic Valve and Ascending Aorta Guidelines for Management and Quality Measures. *The Annals of Thoracic Surgery*. 2013; 95: S1 - S66. 10.1016/j.athoracsur.2013.01.083.
32. Terdjman M, Bourdarias J, Farcot J, Gueret P, Dubourg O et al. Aneurysms of sinus of Valsalva: Two-dimensional echocardiographic diagnosis and recognition of rupture into the right heart cavities. *Journal of the American College of Cardiology*. 1984; 3: 1227 - 1235. [https://doi.org/10.1016/S0735-1097\(84\)80181-3](https://doi.org/10.1016/S0735-1097(84)80181-3).
33. Flynn J T, Kaelber D C, Baker-Smith C M, Blowey D, Carroll A E et al. Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents. *Pediatrics*. 2017; 140: true. 10.1542/peds.2017-1904.
34. Campbell R M, Douglas P S, Eidem B W, Lai W W, Leo L. 2014 Appropriate Use Criteria for Initial Transthoracic Echocardiography in Outpatient Pediatric Cardiology. *Journal of the American College of Cardiology*. 2014; 64: 2039 - 2060. 10.1016/j.jacc.2014.08.003.
35. Nagueh S F, Smiseth O A, Appleton C P, Byrd B F, Dokainish H et al. Recommendations for the Evaluation of Left Ventricular Diastolic Function by Echocardiography. *Journal of the American Society of Echocardiography*. 2016; 29: 277 - 314. <https://doi.org/10.1016/j.echo.2016.01.011>.
36. Patel M R, White R D, Suhny A, Bluemke D A, Herfkens R J et al. 2013 ACCF/ACR/ASE/ASNC/SCCT/SCMR Appropriate Utilization of Cardiovascular Imaging in Heart Failure. *Journal of the American College of Cardiology*. 2013; 61: 2207 - 2231. 10.1016/j.jacc.2013.02.005.
37. Yancy C W, Jessup M, Bozkurt B, Butler J, Casey D E et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation*. 2013; 128: e240 - e327. 10.1161/CIR.0b013e31829e8776.
38. Wilcox J E, Fang J C, Margulies K B, Mann D L. Heart Failure With Recovered Left Ventricular Ejection Fraction. *Journal of the American College of Cardiology*. 2020; 76: 719 - 734. 10.1016/j.jacc.2020.05.075.
39. Birnie D H, Nery P B, Ha A C, Beanlands R S. Cardiac Sarcoidosis. *Journal of the American College of Cardiology*. 2016; 68: 411 - 421. <https://doi.org/10.1016/j.jacc.2016.03.605>.
40. Maddox T M, Januzzi J L, Allen L A, Khadijah B, Javed B et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction. *Journal of the American College of Cardiology*. 2021; 77: 772 - 810. 10.1016/j.jacc.2020.11.022.
41. Ommen S R, Mital S, Burke M A, Day S M, Deswal A et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy. *Circulation*. 2020; 142: e558 - e631. 10.1161/CIR.0000000000000937.
42. U.S. Food & Drug Administration. FDA approves new drug to improve heart function in adults with rare heart condition. 29 April 2022. [Online]. Available: <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-new-drug-improve-heart-function-adults-rare-heart-condition>. [Accessed 29 December 2023].
43. Plana J C, Galderisi M, Barac A, Ewer M S, Ky B et al. Expert consensus for multimodality imaging evaluation of adult patients during and after cancer therapy. *Eur Heart J Cardiovasc Imaging*. 2014; 15: 1063 - 1093. 10.1093/ehjci/jeu192.
44. Zamorano J L, Lancellotti P, Rodriguez Muñoz D, Aboyans V, Asteggiano R et al. 2016 ESC Position Paper on cancer treatments and cardiovascular toxicity. *Eur Heart J*. 2016; 37: 2768 - 2801. 10.1093/eurheartj/ehw211.

45. Baldassarre L A, Sarju G, Juan L, Yang E H, Zaha V G et al. Advances in Multimodality Imaging in Cardio-Oncology. *Journal of the American College of Cardiology*. 2022; 80: 1560 - 1578. 10.1016/j.jacc.2022.08.743.
46. Al-Khatib S M, Stevenson W G, Ackerman M J, Bryant W J, Callans D J et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Journal of the American College of Cardiology*. 2018; 72: 1677 - 1749. 10.1016/j.jacc.2017.10.053.
47. Stainback R, Estep J, Agler D, Birks E, Bremer M et al. Echocardiography in the Management of Patients with Left Ventricular Assist Devices: Recommendations from the American Society of Echocardiography. *J Am Soc Echocardiogr*. Aug 2015; 28: 853-909. 10.1016/j.echo.2015.05.008.
48. Velleca A, Shullo M A, Dhital K, Azeka E, Colvin M et al. The International Society for Heart and Lung Transplantation (ISHLT) guidelines for the care of heart transplant recipients. *The Journal of Heart and Lung Transplantation*. 2023; 42: e1 - e141. 10.1016/j.healun.2022.10.015.
49. Davis M B, Zolt A, McNamara M D M, Sorel G, Uri E. Peripartum Cardiomyopathy. *Journal of the American College of Cardiology*. 2020; 75: 207 - 221. 10.1016/j.jacc.2019.11.014.
50. Stout K K, Daniels C J, Aboulhossn J A, Bozkurt B, Broberg C S et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease. *J Am Coll Cardiol*. 2019; 73: 1494-1563. 10.1016/j.jacc.2018.08.1028.
51. Gewitz M H, Baltimore R S, Tani L Y, Sable C A, Shulman S T et al. Revision of the Jones Criteria for the Diagnosis of Acute Rheumatic Fever in the Era of Doppler Echocardiography. *Circulation*. 2015; 131: 1806 - 1818. 10.1161/CIR.0000000000000205.
52. Miner J J, Kim A H. Cardiac Manifestations of Systemic Lupus Erythematosus. *Rheumatic Disease Clinics*. 2014; 40: 51 - 60. 10.1016/j.rdc.2013.10.003.
53. Cicco S, Desantis V, Vacca A, Cazzato G, Solimando A G et al. Cardiovascular Risk in Patients With Takayasu Arteritis Directly Correlates With Diastolic Dysfunction and Inflammatory Cell Infiltration in the Vessel Wall: A Clinical, ex vivo and in vitro Analysis. *Frontiers in Medicine*. 2022; 9:
54. Alsaied T, Tremoulet A H, Burns J C, Saidi A, Dionne A et al. Review of Cardiac Involvement in Multisystem Inflammatory Syndrome in Children. *Circulation*. 2021; 143: 78 - 88. 10.1161/CIRCULATIONAHA.120.049836.
55. McCrindle B W, Rowley A H, Newburger J W, Burns J C, Bolger A F et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the American Heart Association. *Circulation*. 2017; 135: e927 - e999. 10.1161/CIR.0000000000000484.
56. Gluckman T J, Bhave N M, Allen L A, Chung E H, Spatz E S et al. 2022 ACC Expert Consensus Decision Pathway on Cardiovascular Sequelae of COVID-19 in Adults: Myocarditis and Other Myocardial Involvement, Post-Acute Sequelae of SARS-CoV-2 Infection, and Return to Play: A Report of the American College of Cardiology Solution Set Oversight Committee. *Journal of the American College of Cardiology*. 2022; 79: 1717 - 1756. <https://doi.org/10.1016/j.jacc.2022.02.003>.
57. Feingold B, Mahle W T, Auerbach S, Clemens P, Domenighetti A A et al. Management of Cardiac Involvement Associated With Neuromuscular Diseases: A Scientific Statement From the American Heart Association. *Circulation*. 2017; 136: e200 - e231. 10.1161/CIR.0000000000000526.
58. Benza R L. Pulmonary Hypertension Associated with Sickle Cell Disease: Pathophysiology and Rationale for Treatment. *Lung*. 2008; 186: 247 - 254. 10.1007/s00408-008-9092-8.
59. Hardin A P, Hackell J M, Simon G R, Boudreau A D A, Baker C N et al. Age Limit of Pediatrics. *Pediatrics*. 2017; 140: 10.1542/peds.2017-2151.



Evolut Clinical Guideline 7338 for Tricuspid Valve Surgery

Guideline Number: Evolut_CG_7338	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Tricuspid Valve Surgery.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Tricuspid Regurgitation (TR)

Primary TR results from a structural abnormality of the valve. This may be the result of congenital abnormalities, rheumatic heart disease, endocarditis, carcinoid, radiation, device leads or trauma.

Secondary TR is significantly more common and can be due annular dilatation, leaflet tethering secondary to right ventricular dilatation (due to cardiomyopathy, volume overload, shunts, etc.), or pulmonary hypertension from various causes including left-sided heart disease. ⁽⁶⁾

Tricuspid valve surgery is recommended for patients having:

- Severe TR and one or more of the following ⁽⁶⁾:
 - undergoing left-sided valve surgery
 - isolated tricuspid valve surgery for primary TR with signs and symptoms of right-sided HF

- isolated tricuspid valve surgery for TR secondary to annular dilatation (without left-sided disease or pulmonary hypertension) in patients who are poorly responsive to medical therapy
- isolated tricuspid valve surgery for signs and symptoms of right-sided HF and history of previous left-sided valve surgery
- isolated tricuspid valve surgery for asymptomatic patients with primary TR and progressive right ventricular dilation or systolic dysfunction
- Progressive TR (i.e. mild or moderate) undergoing left-sided valve surgery if there is ^(6,7):
 - tricuspid annular dilation (annulus end diastolic diameter >4.0 cm) OR
 - signs and symptoms of right sided heart failure
- Ebstein anomaly and significant tricuspid regurgitation with any of the following ⁽⁸⁾:
 - HF signs and symptoms
 - objective evidence of worsening exercise capacity
 - progressive RV systolic dysfunction
 - progressive RV enlargement
 - atrial tachyarrhythmias
 - paradoxical embolism
 - systemic desaturation from a right-to-left atrial shunt

Tricuspid Stenosis (TS) ⁽⁷⁾

Tricuspid valve surgery is recommended for:

- Severe TS and one or more of the following:
 - patients undergoing left-sided valve intervention OR
 - symptomatic patients

CODING AND STANDARDS

Coding

CPT Codes

33463, 33464, 33465, 33530

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

HF: heart failure

RV: right ventricle

TR: tricuspid regurgitation

TS: tricuspid stenosis

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM 1100 Tricuspid Valve Surgery • Added indications for repeat surgery • Added indications for Ebstein anomaly • Added indications for patients undergoing left-sided interventions

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACCF Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Otto C M, Rick N A, Robert B O, Carabello B A, Erwin J P et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. *Journal of the American College of Cardiology*. 2021; 77: e25 - e197. 10.1016/j.jacc.2020.11.018.
7. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *European heart journal*. 2022; 43: 561-632.
8. Stout K K, Daniels C J, Aboulhosn J A, Bozkurt B, Broberg C S et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2019; 73: e81 - e192. <https://doi.org/10.1016/j.jacc.2018.08.1029>.

Evolut Clinical Guideline 7339 for Ultrasound-Guided Vascular Access

Guideline Number: Evolut_CG_7339	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for ultrasound-guided vascular access.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR ULTRASOUND-GUIDED VASCULAR ACCESS

The use of ultrasound-guided vascular access is recommended for procedures necessitating cannulation of any central or peripheral artery or vein as part of a diagnostic or interventional procedure where anatomical location may be obscured, or where direct visualization or palpation may not be sufficient. ^(6,7)

CODING AND STANDARDS

Coding

CPT Codes

76937

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Attaining precise access to the intravascular space connotes the commencement of all invasive procedures involving the circulation, and failure to do so adeptly may have adverse consequences for the entire procedure. Assistance may be achieved by using an ultrasound-tipped needle that can locate the target blood vessel and allow it to be precisely cannulated to mitigate risks for the remainder of the procedure. At present, the use of ultrasound guidance is recommended for all intravascular procedures to increase safety, improve first-time success, reduce total procedure time, and reduce the overall risk of complications.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1453 for Ultrasound-Guided Vascular Access • Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Lamperti M, Biasucci D G, Disma N, Pittiruti M, Breschan C et al. European Society of Anaesthesiology guidelines on peri-operative use of ultrasound-guided for vascular access (PERSEUS vascular access). *European Journal of Anaesthesiology*. 2020; 37: 344-376. 10.1097/EJA.0000000000001180.
7. Schmidli J, Widmer M K, Basile C, de Donato G, Gallieni M et al. Editor's Choice – Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). *European Journal of Vascular and Endovascular Surgery*. 2018; 55: 757-818. 10.1016/j.ejvs.2018.02.001.

Evolut Clinical Guideline 7340 for Vascular Embolization or Occlusion

Guideline Number: Evolut_CG_7340	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for vascular embolization or occlusion.

Special Note

To review a request for medical necessity, the following items must be submitted for review:

- Provider notes that indicate the medical necessity for the service.
- Non-Invasive vascular duplex/CTA/MRA and recent angiogram report(s)

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS ⁽⁶⁾

- Occlusion of congenital or acquired aneurysms, pseudoaneurysms, vascular malformations, and other vascular abnormalities that could potentially cause adverse health effects
- Devascularization of benign or nonneoplastic tissues that affect patient health, including, but not limited to:
 - Hypersplenism
 - Chemotherapy-induced thrombocytopenia
 - Uterine fibroids

- Refractory renovascular hypertension
- Proteinuria in end-stage kidney disease
- Varicocele
- Pelvic congestion syndrome
- Prostatic artery embolization
- Priapism
- Ectopic pregnancy
- Flow redistribution to protect normal tissue or facilitate other medical treatment(s)
- Management of endoleaks, including but not limited to:
 - Direct sac puncture or collateral vessel embolization for type-II endoleaks
 - Intraoperative aneurysm sac embolization during stent graft placement to minimize the need for future reintervention.
- Treatment of acute or recurrent hemorrhage, including, but not limited to:
 - Hemoptysis
 - Gastrointestinal bleeding
 - Traumatic events
 - Surgical, or treatment-induced bleeding
 - Hemorrhagic neoplasms
- All of these indications may also be applicable in the pediatric population

CODING AND STANDARDS

Coding

CPT Codes

37241, 37242, 37243, 37244

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Therapeutic embolization involves the placement of a device or substance to produce an intentional vessel occlusion; thereby inducing ischemia within a given tissue, redirecting bulk blood flow away from an area in which perfusion is undesirable, or preventing additional blood loss during a hemorrhagic event.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AUC: Appropriate use criteria

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none">• This guideline replaces UM CARDIO_1456 for Vascular Embolization or Occlusion

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this



Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Dariushnia S R, Redstone E A, Heran M K, Cramer H R, Ganguli S et al. Society of Interventional Radiology Quality Improvement Standards for Percutaneous Transcatheter Embolization. *Journal of Vascular and Interventional Radiology*. 2021; 32: 476.e1-476.e33. 10.1016/j.jvir.2020.10.022.

Evolut Clinical Guideline 7341 for Venogram Invasive Vein Mapping

Guideline Number: Evolut_CG_7341	<u>Applicable Codes</u>	
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Original Date: October 2018	Last Revised Date: January 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Venogram/Invasive Vein mapping.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS ⁽⁶⁾

- Diagnosis of deep vein thrombosis, under the following conditions:
 - Duplex ultrasound is limited or negative, but there is a high clinical suspicion for deep vein thrombophlebitis or calf-vein thrombosis
 - The patient is not a candidate for CT or MR venogram, or the CT or MR venogram is limited
- Venous mapping before, during, or following a surgical or interventional procedure such as dialysis access
- Evaluation of venous conditions, including:
 - Perforator incompetency before sclerotherapy, thermal ablation, or subfascial endoscopic ligation
 - Venous stenosis, hypertension, or malformations
 - Valvular insufficiency before treatment (thermal ablation, stripping, ligation, etc.)
 - Anatomic entrapment

- Deep pelvic, thoracic, or caval thrombosis in patients who are not candidates for CT or MR venogram, or when CT or MR venogram is limited
- Preoperative evaluation for tumor involvement or encasement in patients that are not a candidate for, or with limited, CT or MR venogram
- Evaluation for central venous catheter (CVC) placement, when anatomic landmarks, duplex ultrasound, CT venography, or MR venography are not feasible
 - May also be reasonable to assess the patency of a CVC when malfunctioning is suspected
- Acute iliofemoral thrombophlebitis
- In the workup for possible iliac vein stenosis or obstruction prior to stent placement (6,7,8,9,10,11,12):
 - Post-thrombotic syndrome (PTS) with venous claudication
 - Symptomatic unilateral C3 swelling especially if left sided
 - Bilateral C3 swelling above the knee or severe calf swelling with no other explanation
 - Varicosities of the lower abdominal wall and groin
 - Ipsilateral recurrent leg deep vein thrombophlebitis
 - CEAP C5-6
 - CEAP C3 or C4 and **ANY** of the following:
 - Duplex imaging, CT or MR venography suggestive of iliofemoral stenosis
 - Prior history of vena cava filter, central vein catheterization or venography
 - Persistent symptoms or findings with absence of, or successfully treated leg truncal reflux
 - PTS

Limitations (6)

- Severe allergy to iodinated or other contrast media

CODING AND STANDARDS

Coding

CPT Codes

36005, 36010, 36011, 36012, 75820, 75822, 75825, 75827

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Definitions

Conventional venography is an invasive procedure that uses X-rays and a contrast dye to create images of vein(s) for anatomic localization and hemodynamic quantification when non-invasive study like venous duplex is limited.

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AV: Arteriovenous

AICD: Automated implantable cardioverter defibrillator

AUC: Appropriate use criteria

CRT-D: Cardiac resynchronization therapy defibrillator

CVC: Central venous catheter

PTS: Post-thrombotic syndrome

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> • This guideline replaces UM CARDIO_1319 for Venogram Invasive Vein Mapping • Clinical indications were updated per societal guidance

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. ACR-SIR. PRACTICE PARAMETER FOR THE PERFORMANCE OF DIAGNOSTIC INFUSION VENOGRAPHY. 2023; 1-13. www.acr.org/-/media/ACR/Files/Practice-Parameters/Venography.pdf.
7. Birn J, Vedantham S. May–Thurner syndrome and other obstructive iliac vein lesions: Meaning, myth, and mystery. *Vascular Medicine*. 2015; 20: 74-83. 10.1177/1358863X14560429.
8. De Maeseneer M, Kakkos S, Aherne T, Baekgaard N, Black S et al. European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. *European Journal of Vascular and Endovascular Surgery*. 2022; 63: 184-267. 10.1016/j.ejvs.2021.12.024.
9. Desai K, Sabri S, Elias S, Gagne P, Garcia M et al. Consensus Statement on the Management of Nonthrombotic Iliac Vein Lesions From the VIVA Foundation, the American Venous Forum, and the American Vein and Lymphatic Society. *Circulation: Cardiovascular Interventions*. 2024; 17: e014160. 10.1161/CIRCINTERVENTIONS.124.014160.
10. Farsad K, Kapoor B, Fidelman N, Cain T, Caplin D et al. ACR Appropriateness Criteria® Radiologic Management of Iliofemoral Venous Thrombosis. *Journal of the American College of Radiology*. 2020; 17: S255-S264. 10.1016/j.jacr.2020.01.035.
11. Mahnken A, Thomson K, de Haan M, O'Sullivan G. CIRSE Standards of Practice Guidelines on Iliocaval Stenting. *Cardiovascular and Interventional Radiology*. 2014; 37: 889-897. 10.1007/s00270-014-0875-4.
12. Vedantham S, Weinberg I, Desai K, Winokur R, Kolli K et al. Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents. *Journal of Vascular and Interventional Radiology*. 2023; 34: 1643-1657. 10.1016/j.jvir.2023.06.013.

Evolent Clinical Guideline 7342 for Venous Duplex

Guideline Number: Evolent_CG_7342	<u>Applicable Codes</u>	
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Original Date: April 2011	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for Venous Duplex.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

Upper Extremity

Venous Duplex Ultrasound of the upper extremity is appropriate for the following:

- Swelling ⁽⁶⁾
 - acute:
 - unilateral (**AUC 9**)
 - bilateral (i.e., suspected central venous obstruction) (**AUC 8**)
 - chronic, persistent
 - unilateral (**AUC 7**)
 - bilateral (i.e., suspected central venous obstruction and no alternative diagnosis identified such as HF or hypoalbuminemia) (**AUC 7**)
- Pain ⁽⁶⁾

- nonarticular, and an indwelling UE venous catheter is present **(AUC 7)**
- evidence of superficial thrombophlebitis (tender, palpable cord in UE) **(AUC 8)**
- Venous Malformation ⁽⁷⁾ **(AUC 7-9)**
 - known or suspected as evidenced by:
 - swelling, pain
 - discoloration or ulceration
 - thrill or vascular bruit
- Pulmonary embolism ⁽⁶⁾ **(AUC 6)**
- diagnosed or suspected PE *in the presence of indwelling UE venous catheter or device (i.e., pacemaker, ICD)*
- Venous Thrombosis ^(6,8)
 - suspected DVT **(AUC 7-9)**
 - known DVT with new UE pain or swelling while on anticoagulation, or not on anticoagulation due to contraindication **(AUC 7)**
 - surveillance of UE superficial thrombophlebitis **(AUC 6)**
 - not on anticoagulation with phlebitis ≤5 cm from deep vein junction **(AUC 6)**
- Thoracic Outlet Syndrome ⁽⁹⁾
 - vascular (venous or arterial) **(AUC 7-9)**
 - for initial evaluation and post-intervention follow-up
 - neurogenic **(AUC 4-6)**
 - for initial evaluation and post-intervention follow-up
- Vein Mapping ⁽⁶⁾
 - for coronary or peripheral vessel bypass surgery, when there are no adequate leg veins for harvesting **(AUC 8)**
 - for hemodialysis access:
 - preoperative mapping study, <3 months prior to access placement **(AUC 8)**
 - "failure to mature" on basis of physical exam:
 - 0-6 weeks after placement **(AUC 6)**
 - > 6 weeks after placement **(AUC 8)**

Lower Extremity

Venous Duplex Ultrasound of the lower extremity is appropriate for the following:

- Swelling ⁽⁶⁾
 - acute
 - unilateral **(AUC 9)**
 - bilateral **(AUC 8)**

- chronic, persistent
 - unilateral **(AUC 7)**
 - bilateral (and no alternative diagnosis identified such as HF or hypoalbuminemia) **(AUC 6)**
- Pain ⁽⁶⁾
 - non-articular, thigh or calf **(AUC 7)**
 - evidence of superficial thrombophlebitis (tender, palpable cord in LE) **(AUC 8)**
- Venous Malformation ⁽⁷⁾ **(AUC 7-9)**
 - known or suspected
 - swelling, pain
 - discoloration or ulceration
 - thrill or vascular bruit
- Pulmonary embolism ^(6,10)
 - suspected PE-*initial* imaging (**Wells criteria** for assessing Pre-Test Probability (PTP))
 - high PTP **(AUC 4-6)**
 - pregnant patient **(AUC 7-9)**
 - diagnosed PE **(AUC 7)**
- Venous Thrombosis ^(6,11)
 - suspected DVT **(AUC 7-9)**
 - surveillance of calf vein thrombosis for propagation within 2 weeks of diagnosis in patient with contraindication to anticoagulation **(AUC 7)**
 - known DVT with new LE pain or swelling:
 - while on anticoagulation **(AUC 7)**
 - not on anticoagulation (i.e. due to contraindication) **(AUC 8)**
 - surveillance of LE superficial thrombophlebitis
 - not on anticoagulation with phlebitis ≤5 cm from deep vein junction **(AUC 7)**
- Vein Mapping ⁽⁶⁾
 - for coronary or peripheral vessel bypass surgery vein harvest, with or without prior lower extremity vein harvest or ablation procedure **(AUC 8)**
- Post-endovascular (Great or Small) Saphenous Vein Ablation
 - LE swelling or pain **(AUC 8)**
 - routine follow-up within 10 days of procedure, no LE pain or swelling **(AUC 7)**
- Chronic Venous Disease ⁽¹²⁾ **(AUC 7-9)**
 - initial diagnosis
 - varicose veins

- suspected ilio caval or LE disease with severe post-thrombotic changes
 - venous leg ulcer
- Other Symptoms or Signs of Vascular Disease ⁽⁶⁾
 - venous obstruction noted on physiologic testing (i.e. plethysmography) **(AUC 7)**
 - suspected paradoxical embolism in patient with patent foramen ovale **(AUC 7)**

CODING AND STANDARDS

Coding

CPT Codes

93970, 93971, 93985, 93986

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Wells Criteria ⁽¹³⁾

Pretest probability (PTP) assessment is an important step in the diagnosis of pulmonary embolism because correct interpretation of subsequent testing depends upon it. The Wells criteria, a points-based scoring system, have been extensively validated and are widely used to determine the PTP of pulmonary embolism.

Criterion	Points
Clinical signs of DVT	3.0
Recent surgery/immobilization	1.5
Heart rate > 100 bpm	1.5

Criterion	Points
Previous history of PE/DVT	1.5
Hemoptysis	1.0
Malignancy	1.0
Alternative Diagnosis less likely than PE	3.0

Table 1: Pretest probability - Low < 2pts, Intermediate 2-6 pts, High > 6pts

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

BPM: beats per minute

DVT: deep vein thrombosis

HF: heart failure

ICD: implantable cardioverter defibrillator

LE: lower extremity

PE: pulmonary embolism

PTP: pretest probability

UE: upper extremity

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This policy replaces UM 1093 Venous Duplex and UM 1083 Vessels Mapping for Hemodialysis or CABG • Indications added for Thoracic Outlet Syndrome, vein mapping

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Gornik H, Gerhard-Herman M, Misra S, Mohler E, Zierler R et al. ACCF/ACR/AIUM/ASE/IAC/SCAI/SCVS/SIR/SVM/SVS/SVU 2013 appropriate use criteria for. *Journal of the American College of Cardiology*. 2013; 62: 649-65.
7. Obara P, McCool J, Kalva S P, Majdalany B S, Collins J D et al. ACR Appropriateness Criteria Clinically Suspected Vascular Malformation of the Extremities. *Journal of the American College of Radiology*. 2019; 16: S340 - S347. 10.1016/j.jacr.2019.05.013.
8. Desjardins B, Hanley M, Steigner M L, Aghayev A, Azene E M et al. ACR Appropriateness Criteria Suspected Upper Extremity Deep Vein Thrombosis. *Journal of the American College of Radiology*. 2020; 17: S315 - S322. 10.1016/j.jacr.2020.01.020.
9. Zurkiya O, Ganguli S, Kalva S P, Chung J H, Shah L M et al. ACR Appropriateness Criteria Thoracic Outlet Syndrome. *Journal of the American College of Radiology*. 2020; 17: S323 - S334. 10.1016/j.jacr.2020.01.029.
10. Kirsch J, Wu C C, Bolen M A, Henry T S, Rajiah P S et al. ACR Appropriateness Criteria Suspected Pulmonary Embolism: 2022 Update. *Journal of the American College of Radiology*. 2022; 19: S488 - S501. 10.1016/j.jacr.2022.09.014.
11. Hanley M, Steigner M L, Ahmed O, Azene E M, Bennett S J et al. ACR Appropriateness Criteria Suspected Lower Extremity Deep Vein Thrombosis. *Journal of the American College of Radiology*. 2018; 15: S413 - S417. 10.1016/j.jacr.2018.09.028.
12. Rochon P J, Reghunathan A, Kapoor B S, Kalva S P, Fidelman N et al. ACR Appropriateness Criteria Lower Extremity Chronic Venous Disease. *Journal of the American College of Radiology*. 2023; 20: S481 - S500. 10.1016/j.jacr.2023.08.011.
13. Ceriani E, Combescure C, Le Gal G, Nendaz M, Perneger T et al. Clinical prediction rules for pulmonary embolism: a systematic review and. *Journal of thrombosis and haemostasis : JTH*. 2010; 8: 957-70.

Evolut Clinical Guideline 7343 for Mechanical Circulatory Support (Ventricular Assist Device) - Percutaneous and Permanent

Guideline Number: Evolut_CG_7343	<u>Applicable Codes</u>	
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Original Date: February 2020	Last Revised Date: January 2025	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for the utilization of Mechanical Circulatory Support/Ventricular Assist Devices (VAD).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS FOR MECHANICAL CIRCULATORY SUPPORT (LVAD)

Overview

Mechanical Circulatory Support (MCS or Ventricular Assist) Devices are indicated for management of patients presenting with advanced heart failure (see Definitions) refractory to the administration of maximally tolerated Guideline Directed Medical Therapy (GDMT) when heart transplantation is not immediately available. The approach to MCS is dependent on the clinical scenario. MCS may be used as a bridge to recovery, when return of satisfactory ventricular function is anticipated; as bridge to transplantation in critically ill patients listed for heart transplantation (OHT); and as destination therapy when the patient is not a candidate for transplantation. These designations are not rigid and may change as the patient's clinical course evolves.

Bridge to recovery (AUC Score 5) ⁽⁸⁾

Potentially fatal low cardiac output in situations where recovery is possible or probable. Clinical scenarios for MCS for Bridge to Recovery include:

- Acute myocardial infarction complicated by cardiogenic shock
- Acute myocarditis with shock ⁽⁷⁾
- Acute cardiac failure following cardiac surgery
- MCS using a nondurable (temporary) support device is recommended in patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurological assessment before consideration of a long-term device. ⁽⁷⁾
- Dilated nonischemic cardiomyopathy of recent onset refractory to maximally tolerated GDMT ⁽⁷⁾
- Post-cardiotomy shock with failure to wean from cardiopulmonary bypass ⁽⁹⁾
- For patients with severe renal dysfunction, initial support with a nondurable MCS (temporary device) to assess for potential of renal recovery before implanting durable MCS may be undertaken. ⁽⁷⁾

Bridge to Transplantation (AUC Score 8) ⁽⁸⁾

- Device must be FDA-approved for bridge-to-transplant use and used according to labeling instructions. These are durable devices, and include extracorporeal MCS, implantable MCS, and total artificial heart (TAH) *and*
- The patient must be approved and listed as a candidate for heart transplantation or be undergoing evaluation of candidacy by an interdisciplinary patient selection committee *and*
- NYHA class IV symptoms despite optimal GDMT or patients deemed to be dependent on IV inotropes. ⁽⁶⁾

Clinical Scenarios for MCS for Bridge to Transplantation MCS include ⁽⁸⁾:

- Severe reductions in cardiac output or noncardiac-co-morbidities such that survival and successful cardiac transplantation are unlikely without mechanical circulatory support.
- Impending cardiogenic shock despite inotropic support and intra-aortic balloon pump (\pm IABP) in presence of acute renal dysfunction (creatinine > 2.0) that is deemed secondary to insufficient renal blood flow and is unresponsive to inotropic support
- Pulmonary hypertension (PA systolic pressure > 60) that persists despite optimal medical and inotropic therapy
- In patients with treatment-refractory recurrent sustained ventricular tachycardia or ventricular fibrillation in the presence of an untreatable arrhythmogenic substrate (e.g., giant cell myocarditis, scar, sarcoidosis), biventricular support or a TAH is preferred over isolated LV support ⁽⁷⁾

Destination Therapy (DT) or Long-term therapy (AUC Score 8) (8)

- Device must be FDA-approved for destination therapy use and used according to labeling instructions, *and*
- Patients with a major contraindication to cardiac transplantation, *and*
- Dependence on intravenous inotropic support, *or*
- Class IV heart failure with expected mortality exceeding 50% in one year despite maximum GDMT

INDICATIONS FOR RIGHT VENTRICULAR ASSIST DEVICE IMPLANTATION/UTILIZATION (7)

- Support with an RVAD should be performed in patients with medically refractory RV failure after durable LVAD implantation
- Patients with high-risk preoperative features for right ventricular failure may undergo planned RVAD implantation before worsening of cardiogenic shock

CONTRAINDICATIONS FOR VENTRICULAR ASSIST DEVICE (6, 7, 10)

- Irreversible hepatic disease
- Irreversible renal disease
- Irreversible neurological disease
- Patient refusal of medical adherence that is necessary for post-operative recovery
- Severe psychosocial limitation
- Severely restricted pulmonary function
- Neuromuscular or musculoskeletal disease that impairs rehabilitation
- Active systemic infection
- Prolonged intubation
- Untreated/active malignancy with < 2 years life expectancy
- Severe peripheral vascular disease (PVD); (note: durable MCS may be used in selected patients with manageable peripheral vascular disease).
- Active substance use
- Impaired cognitive function
- Unstable psychiatric conditions
- Lack of social support

- DMCS is relatively contraindicated in the setting of diabetes-related proliferative retinopathy, very poor glycemic control, severe nephropathy, vasculopathy, or peripheral neuropathy
- Active pregnancy ⁽⁷⁾

CODING AND STANDARDS

Coding

CPT Codes

- 33975 – Insertion of ventricular assist device; extracorporeal, single ventricle
- 33976 – Insertion of ventricular assist device; extracorporeal, biventricular
- 33979 – Insertion of ventricular assist device, implantable intracorporeal, single ventricle
- 33980 – Removal of ventricular assist device, implantable intracorporeal, single ventricle
- 33981 – Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
- 33982 – Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
- 33983 – Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
- 33991 – Insertion of ventricular assist devices, percutaneous including radiological supervision and interpretation; arterial and venous access, with transseptal puncture
- 33995 – Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
- 33997 – Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Bridge to Recovery

This category of MCS includes the use of nondurable percutaneous support devices (VADs), which are used for cardiogenic shock when the risk of implantation of a durable device is prohibitive or recovery of function after short-term support is anticipated. These devices are removed once clinical recovery has occurred, or at the time of implantation of durable MCS. Under certain conditions, durable LVADs may be implanted as a bridge to recovery when the recovery period is anticipated to be prolonged.

Nondurable MCS devices include:

- Intra-Aortic Balloon Counter-Pulsation (IABP)
- Extracorporeal Membrane Oxygenation (ECMO)
- Extracorporeal MCS pump (implanted via sternotomy)
- Percutaneous MCS pump

Bridge to Transplantation

Implantation of a durable left ventricular assist device (LVAD) in patients who are eligible for cardiac transplantation but in whom a donor heart is not available in the setting of refractory Class IV heart failure requiring inotropic support despite maximally tolerated GDMT

Destination Therapy

Implantation of a durable left ventricular assist device (LVAD) in patients who have refractory Class IV heart failure requiring inotropic support despite maximally tolerated GDMT but are not candidates for heart transplantation.

Right Ventricular Assist Devices (RVADs)

Right heart failure after DLVAD implantation may be managed medically in many cases. RVAD is indicated when hemodynamic indices fail to improve with medical therapy, and before end-organ damage is encountered. Both ECMO and RVAD have been used to support RV recovery after DLVAD implantation. Newer percutaneous RVAD devices provide hemodynamic unloading comparable to surgical devices with less morbidity and may be appropriate for selected patients. ⁽⁷⁾

Definitions

Advanced Heart Failure: Consensus for this definition is difficult to achieve but is widely accepted to include: (1) Clinically significant circulatory compromise with class IV symptoms and requiring inotropic support; (2) Frequent hospitalizations for heart failure, resulting in consideration of heart transplantation or resulting in anticipated life expectancy < 2 years; and (3) Interference with activities of daily living. ⁽⁶⁾ Objective measurements may include $VO_2 \leq 14$ ml/kg/min, or 6-min walk distance < 300 m. Patients may manifest intolerance to recommended heart failure therapy due to hemodynamic instability.

Clinical manifestations of advanced heart failure include, but are not limited to, the following ⁽⁶⁾:

- Left ventricular ejection fraction (LVEF) \leq 30%
- Inotrope dependence
- Frequent hospitalizations for HF in the past 12 months
- Refractory clinical congestion
- Progressive deterioration in renal or hepatic function
- Worsening right-sided HF or secondary pulmonary hypertension
- Low systolic blood pressure (SBP) \leq 90 mm Hg
- Cardiac cachexia
- Persistent hyponatremia (serum sodium, $<$ 134 mEq/L)
- Refractory or recurrent ventricular arrhythmias; frequent ICD shocks
- Increased predicted 1-year mortality (eg, $>$ 20%) according to HF survival models (e.g., MAGGIC, SHFM) (<https://www.mdcalc.com/calc/3803/maggic-risk-calculator-heart-failure>)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

BTT: Bridge to Transplantation

DT: Destination Therapy

GDMT: Guideline-Directed Medical Therapy

LVEF: Left Ventricular Ejection Fraction

MAGGIC: Meta-analysis Global Group in Chronic Heart Failure

PVD: Peripheral Vascular Disease

SHFM: Seattle Heart Failure Model

VAD: Ventricular Assist Device

TAH: Total Artificial Heart

MCS: mechanical circulatory support

DMCS: Durable Mechanical Circulatory Support

POLICY HISTORY

Date	Summary
January 2025	<ul style="list-style-type: none"> ● This guideline replaces UM CARDIO_1390 Ventricular Assist Device (VAD) - Percutaneous and Permanent ● Indications updated per societal guidance ● Removed bullet-point for “Age greater than 80 for destination therapy” from the Contraindications section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 145: e895-e1032. 10.1161/CIR.0000000000001063.
7. Saeed D, Feldman D, Banayosy A, Birks E, Blume E et al. The 2023 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: A 10- Year Update. *The Journal of Heart and Lung Transplantation*. 2023; 42: e1-e222. 10.1016/j.healun.2022.12.004.
8. Kirklin J, Naftel D. Mechanical Circulatory Support. *Circulation: Heart Failure*. 2008; 1: 200-205. 10.1161/CIRCHEARTFAILURE.108.782599.
9. Peura J, Colvin-Adams M, Francis G, Grady K, Hoffman T et al. Recommendations for the Use of Mechanical Circulatory Support: Device Strategies and Patient Selection. *Circulation*. 2012; 126: 2648-2667. 10.1161/CIR.0b013e3182769a54.
10. Guglin M, Zucker MJ, Borlaug BA, Breen E, Cleveland J, Johnson MR, Panjath GS, Patel JK, Starling RC, Bozkurt B; ACC Heart Failure and Transplant Member Section and Leadership Council. Evaluation for Heart Transplantation and LVAD Implantation: JACC Council Perspectives. *J Am Coll Cardiol*. 2020 Mar 31;75(12):1471-1487. doi: 10.1016/j.jacc.2020.01.034. PMID: 32216916.

Evolut Clinical Guideline 7345 for Wireless Pulmonary Artery Pressure Device Placement and Monitoring

Guideline or Policy Number: Evolut_CG_7345	<u>Applicable Codes</u>	
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Original Date: June 2020	Last Revised Date: December 2024	Implementation Date: February 2025

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STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

Purpose

Indications for determining medical necessity for the implantation of a Wireless Invasive Pulmonary Artery Pressure Monitoring device and ongoing data collection. Wireless pulmonary artery pressure monitors are implantable devices that monitor the pressure in the pulmonary artery and output data to an external analyzer.

Special Note

Guideline Directed Medical Therapy

Documentation is required confirming that patient is receiving optimal GDMT for heart failure, including standard medication (and, as indicated, coronary revascularization and biventricular pacing).

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. ^(1,2,3,4,5)

INDICATIONS

- Patients with **NYHA Class** II or III Heart Failure (systolic or diastolic) with any of the following ^(6,7,8,9)
 - Hospitalization for heart failure in the past year
 - Persistent or worsening symptoms when hemodynamics are uncertain

- Elevated natriuretic peptides

Limitations

Implantable hemodynamic monitoring is not recommended for patients with ⁽⁹⁾:

- an inability to take dual antiplatelet or anticoagulants for one-month post implant
- a history of recurrent pulmonary embolism or deep vein thrombosis
- a right-sided mechanical valve

CODING AND STANDARDS

Coding

CPT Codes

33289, 93264

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

NYHA Class Definitions ⁽¹⁰⁾

- Class I: No limitation of functional activity. Ordinary physical activity does not cause symptoms of HF
- Class II: Slight limitation of activity. Comfortable at rest but ordinary physical activity results in symptoms of HF
- Class III: Marked limitation of activity. Comfortable at rest but less than ordinary activity causes symptoms of HF
- Class IV: Unable to continue any physical activity without symptoms of HF, or symptoms of HF at rest

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽³⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

POLICY HISTORY

Date	Summary
December 2024	<ul style="list-style-type: none"> • This guideline replaces UM 1402 Wireless Pulmonary Artery Pressure Device • Added requirement for maximally tolerated GDMT • Removed GFR, CHD and heart tx from limitations

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. *Circulation*. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.
2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. *Journal of the American College of Cardiology*. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. *Journal of the American College of Cardiology*. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*. 2022; 79: e263 - e421. <https://doi.org/10.1016/j.jacc.2021.12.012>.
7. Members: A F, McDonagh T, Metra M, Adamo M, Gardner R et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur J Heart Fail*. 2022; 24: 4 - 131. <https://doi.org/10.1002/ejhf.2333>.
8. United States Food and Drug Administration. Premarket Approval (PMA) for CardioMEMs HF System. 2022; Accessed: August 28, 2024. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045S056>.
9. Lundgren S, Garvin R, Abraham W. Hemodynamic Monitoring Devices in the Management of Outpatient Heart Failure. *Journal of the Society for Cardiovascular Angiography & Interventions*. 2023; 2: 10.1016/j.jscai.2023.101186.
10. Goldman L, Hashimoto B, Cook E, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. *Circulation*. 1981; 64: 1227-34. 10.1161/01.cir.64.6.1227.