

National Imaging Associates, Inc.*

2021

Magellan Clinical Guidelines For Medical Necessity Review

EXPANDED CARDIAC GUIDELINES

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of Magellan Healthcare, Inc.

Guidelines for Clinical Review Determination

Preamble

Magellan 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 Magellan Healthcare 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. Magellan'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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33225 – Cardiac Resynchronization Therapy (CRT)

CPT Codes: 33221, 33224, 33225, 33231

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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

INDICATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY (CRT):

(Brignole, 2013; Cleland, 2005; Epstein, 2012; Ponikowski, 2016; Russo, 2013; Yancy, 2013)

- Left ventricular ejection fraction (LVEF) \leq 35%, sinus rhythm, left bundle branch block (LBBB) with a QRS \geq 150 ms, and New York Heart Association (NYHA) class II, III, or ambulatory class IV symptoms on guideline-directed medical therapy (GDMT) (Adelstein, 2018; Ponikowski, 2016).
- LVEF \leq 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory class IV symptoms on GDMT.
- LVEF \leq 35%, sinus rhythm, a non-LBBB pattern with a QRS duration \geq 150 ms, and NYHA class III or ambulatory class IV symptoms on GDMT (Epstein, 2012; Ponikowski, 2016; Yancy, 2013).
- Atrial fibrillation and LVEF \leq 35% on GDMT if:
 - Patient requires ventricular pacing or otherwise meets CRT criteria; **AND**
 - AV nodal ablation or pharmacologic rate control will allow nearly 100% ventricular pacing with CRT (Yancy, 2013).
- LVEF \leq 35% and undergoing new or replacement device with anticipated requirement for significant ($>$ 40%) ventricular pacing (Adelstein, 2018; Brignole, 2013; Curtis, 2013; Ponikowski, 2016; Yancy, 2013).

NOT Indicated for Cardiac Resynchronization Therapy (CRT)

- NYHA class I or II symptoms and non-LBBB pattern with QRS duration $<$ 150 ms (Epstein, 2012).
- Comorbidities and/or frailty expected to limit survival with good functional capacity to $<$ 1 year.

INDICATIONS FOR CRT IN ADULT CONGENITAL HEART DISEASE:

(Hernandez-Madrid, 2018; Khairy, 2014; Stout, 2018)

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- Systemic LVEF \leq 35%, sinus rhythm, complete LBBB with a QRS complex \geq 150 ms (spontaneous or paced) and NYHA class II, III, or ambulatory IV.
- Systemic LVEF \leq 35%, sinus rhythm, complete LBBB with a QRS complex 120-149 ms (spontaneous or paced), and NYHA class II, III, or ambulatory IV.
- Systemic ventricular EF \leq 35%, intrinsic narrow QRS complex, NYHA class I to ambulatory class IV and undergoing new or replacement device implantation with anticipated requirement for significant ($>$ 40%) ventricular pacing.
- Systemic right ventricle (RV) with an EF \leq 35%, NYHA class II, III, or ambulatory class IV, complete right bundle branch block (RBBB) with a QRS complex \geq 150 ms (spontaneous or paced).
- Single ventricle with an ejection fraction (EF) \leq 35%, NYHA class II, III, or ambulatory class IV and a QRS complex \geq 150 ms due to intraventricular conduction delay causing either a complete right or left bundle branch block morphology (spontaneous or paced).

NOT Indicated for CRT in Adult Congenital Heart Disease

- Patients with a narrow QRS complex ($<$ 120 ms).
- Patients whose co-morbidities and/or frailty limit survival with good functional capacity to less than 1 year.

INDICATIONS FOR CRT AS THE APPROPRIATE PACING MODALITY IN SPECIAL SITUATIONS WITH $<$ 3 MONTHS OF GDMT

(Katsumoto, 2014; Marine, 2018; Russo, 2013)

- 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.

BACKGROUND:

(Brignole, 2013; Epstein, 2012; Ponikowski, 2016; Russo, 2013; Yancy, 2013)

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.

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CRT improves cardiac function and quality of life, and it decreases cardiac events and mortality among appropriately chosen patients. The improved survival in patients with CRT is 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 (Russo, 2013).

GDMT should have been in place continuously for at least 3 months (Epstein, 2012; Ponikowski, 2016; Yancy, 2013) 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.

- The patient should have expected survival with reasonably good functional status for more than 1 year (Epstein, 2012; Khairy, 2014; Ponikowski, 2016).

OVERVIEW:

NYHA Class Definitions

(Goldman, 1981; Russo, 2013)

- Class I: No limitation of functional activity or only at levels of exertion that would limit normal individuals (patient can carry 24 pounds up 8 stairs, play basketball, and shovel soil).
- Class II: Slight limitation of activity. Fatigue, palpitation, or dyspnea with moderate exercise (patient able to dance, garden, and walk 4 mph on level ground).
- Class III: Marked limitation of activity. Fatigue, palpitation, or dyspnea with minimal activity (patient able to shower, make bed, bowl or golf, dress, and walk 2.5 mph on level).
- Class IV: Severe limitation of activity. Symptoms even at rest, worse with activity (patient unable to comfortably perform any significant activity).
- Ambulatory Class IV: Class IV heart failure that is not refractory due to fluid retention, frequent hospitalization for heart failure, or dependent on continuous intravenous inotropic therapy.

Heart Block Definitions

(Epstein, 2012)

- 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.

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- 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

(Yancy, 2013, 2017)

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

Abbreviations

ACE-I	Angiotensin converting enzyme inhibitor
ARNI	Combined angiotensin receptor inhibitor and neprilysin inhibitor
AV	Atrioventricular
CAD	Coronary artery disease, same as ischemic heart disease
CHF	Congestive heart failure
CRT	Cardiac resynchronization therapy (also known as biventricular pacing)
CHD	Congenital heart disease
ECG	Electrocardiogram
eGFR	Estimated glomerular filtration rate
EPS	Electrophysiologic Study
GDMT	Guideline-Directed Medical Therapy
HF	Heart Failure
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
STEMI	ST-Elevation Myocardial Infarction
SND	Sinus node dysfunction
VT	Ventricular tachycardia

POLICY HISTORY:

Review Date: August 13, 2019

Review Summary:

- Changed ms from 130 to 150 in indication: ‘left ventricular ejection fraction (LVEF) \leq 35%, sinus rhythm, left bundle branch block (LBBB) with a QRS \geq 150 ms, and NYHA class II, III or ambulatory class IV symptoms on GDMT’
- Added indication for LVEF \leq 35%, sinus rhythm, LBBB with a QRS duration 120 to 149 ms, and NYHA class II, III, or ambulatory class IV symptoms on GDMT
- Changed ms from 130 to 150 in indication: ‘LVEF \leq 35%, sinus rhythm, a non-LBBB pattern with a QRS duration \geq 150 ms, and NYHA III or ambulatory class IV symptoms on GDMT’
- Revised indication to state that LVEF \leq 35% and are undergoing new or replacement device placement with anticipated requirement for significant ($>$ 40%) ventricular pacing
- Removed indication for LVEF \leq 30%, ischemic etiology of HF, sinus rhythm, LBBB with a QRS duration \geq 150 ms, and NYHA class I on GDMT
- Removed indication for LVEF \leq 35%, sinus rhythm, a non LBBB pattern with a QRS duration \geq 150 ms, and NYHA class II on GDMT
- Adult congenital heart disease, added indication for systemic LVEF \leq 35%, sinus rhythm, complete LBBB with a QRS complex 120 - 149 ms (spontaneous or paced), and NYHA class II to ambulatory IV
- Adult congenital heart disease, removed the following indications:
 - Cardiac surgery with a QRS duration $>$ 150 ms
 - Systemic RV with significant tricuspid valve regurgitation
 - Severe subpulmonic RV dysfunction
 - Severe ventricular dysfunction and NYHA class IV in attempt to delay transplant or mechanical support
- The following statement has been revised to add ‘or 3 months post-revascularization.’ Criteria are met for a non-elective implantable cardioverter defibrillator (ICD) or a non-elective pacemaker, either initial or replacement, 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. The following statement has been added: ‘This avoids a second implantation procedure within less than 3 months.’

Review Date: March 2020

Review Summary:

- Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review
- Removed comment that single site pacing from the systemic ventricular apex or mid-lateral wall may be considered as an alternative from the indication systemic ventricular EF \leq 35%, intrinsic

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narrow QRS complex, NYHA class I to ambulatory class IV and undergoing new or replacement device implantation with anticipated requirement for significant (>40%) ventricular pacing.

- Removed the following from the Guideline Directed Medical Therapy section: Ivabradine listed as a class IIa recommendation, while others are class I recommendations. CRT trials antedated routine use of ivabradine.

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33249 – Implantable Cardioverter Defibrillator (ICD)

CPT Codes: 33230, 33240, 33249

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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

INDICATIONS FOR ICD INSERTION

(Al-Khatib, 2017; Epstein, 2012; Ponikowski, 2016; Priori, 2015; Russo, 2013; Shen, 2017; Yancy, 2013)

Ischemic Heart Disease (CAD)

(Al-Khatib, 2017; Priori, 2015; Russo, 2013)

- Patients with documented ventricular fibrillation (VF), hemodynamically unstable ventricular tachycardia (VT), or sustained VT, after exclusion of reversible causes
- Syncope of undetermined origin, with one of the following:
 - Inducible VF or sustained VT at electrophysiological study (EPS), or
 - Left ventricular ejection fraction (LVEF) \leq 35%
- LVEF \leq 35% due to ischemic heart disease and NYHA class II or III, despite guideline-directed medical therapy (GDMT), and at least 40 days post myocardial infarction (MI) and 90 days post-revascularization
- LVEF \leq 30% due to ischemic heart disease, NYHA class I, II, or III despite GDMT, and at least 40 days post-MI and 90 days post-revascularization (Al-Khatib, 2017; Russo, 2013)

Nonischemic cardiomyopathy (NICM)

(Al-Khatib, 2017)

- Patients with documented VF, hemodynamically unstable VT, or sustained VT, after exclusion of reversible causes
- Syncope that is presumed to be due to ventricular arrhythmia
- NICM with LVEF \leq 35% and NYHA functional Class II or III, despite at least 3 months of GDMT
- NICM due to a *Lamin A/C* gene mutation, with \geq 2 risk factors from the following (NSVT, LVEF $<$ 45%, male sex, nonmissense mutation)

Advanced Heart Failure & Transplantation

(Al-Khatib, 2017; Priori, 2015)

- In non-hospitalized patients with NYHA class IV who are candidates for cardiac transplantation or

left ventricular assist device (LVAD) (Al-Khatib, 2017; Priori, 2015; Russo, 2013)

- In a patient with an LVAD, sustained ventricular arrhythmias (Al-Khatib, 2017)
- In NYHA ambulatory class IV, with appropriate indications for CRT (see Background Information section for definition of ambulatory NYHA class IV)

Myocardial Diseases

- **Hypertrophic cardiomyopathy (HCM)** with ≥ 1 major risk factors for sudden cardiac death (SCD) (Al-Khatib, 2017; Epstein, 2012; Gersh, 2011; Shen, 2017):
 - Prior sudden cardiac arrest due to VT or VF
 - Documentation of sustained VT with syncope or hemodynamic compromise
 - Maximum LV wall thickness ≥ 30 mm
 - SCD in 1 or more first degree relatives
 - ≥ 1 episode of unexplained syncope within the preceding 6 months
 - Documented NSVT with an additional SCD risk modifier (age < 30 yr, delayed hyperenhancement on cardiac MRI, LVOT obstruction, or syncope > 5 yr ago) or high-risk feature (LV aneurysm or LVEF $< 50\%$)
 - Abnormal BP response to exercise with an additional SCD risk modifier or high-risk feature (see above)
 - BP rise < 20 mmHg or fall of > 20 mmHg during exercise
- **Cardiac Sarcoidosis** with one of the following (Al-Khatib, 2017; Priori, 2015; Shen, 2017):
 - Cardiac arrest or documented sustained VT
 - LVEF $\leq 35\%$
 - LVEF $> 35\%$ with inducible sustained ventricular arrhythmia at EPS
 - Syncope and/or scar on CMR or positron emission tomography (PET)
 - Requires a permanent pacemaker
- **Neuromuscular Disorders** with one of the following (Al-Khatib, 2017):
 - Primary and secondary prevention, with same indications as for NICM (Priori, 2016)
 - Emery-Dreifuss or limb-girdle type I-B muscular dystrophy with progressive cardiac involvement
- **Arrhythmogenic right ventricular cardiomyopathy** and ≥ 1 of the following risk factors for SCD: (Al-Khatib, 2017; Calkins, 2017; Corado, 2015; Epstein, 2012; Shen, 2017)
 - Resuscitated sudden cardiac arrest
 - Sustained VT
 - Right or left ventricular systolic dysfunction with an ejection fraction $\leq 35\%$
 - Syncope with documented or presumed ventricular arrhythmia

Channelopathies

- **Congenital long QT syndrome** with **one** of the following (Al-Khatib, 2017; Epstein, 2012; Goldenberg, 2008; Priori, 2015; Schwartz, 2012)
 - Sudden cardiac arrest
 - Sustained VT or recurrent syncope when beta blocker is ineffective or not tolerated

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- QTc > 500 ms on a beta blocker (Al-Khatib, 2017)
- Strong family history of SCD
- High risk genotype (type 2 and type 3)

- **Brugada syndrome and spontaneous type 1 Brugada electrocardiographic pattern with one of the following:**
(Al-Khatib, 2017; Epstein, 2012; Katsumoto, 2018; Priori, 2015)
 - Cardiac arrest
 - Documented sustained ventricular arrhythmia
 - Syncope due to ventricular arrhythmia

- **Catecholaminergic polymorphic VT with one of the following** (Al-Khatib, 2017; Priori, 2013, Epstein, 2012; Russo, 2013):
 - Sudden cardiac arrest
 - Syncope or sustained VT
 - Inducible VT or VF

- **Early Repolarization or Short QT Syndrome with one of the following** (Al-Khatib, 2017; Priori, 2015):
 - Cardiac arrest
 - Sustained ventricular arrhythmia

- **Idiopathic Polymorphic VT/VF with one of the following** (Al-Khatib, 2017):
 - Cardiac arrest due to polymorphic VT or VF

Miscellaneous

Adult & Pediatric Congenital Heart Disease (CHD)

(Al-Khatib, 2017; Brugada, 2013; Hernandez-Madrid, 2018; Khairy, 2014; Priori, 2015; Shen, 2017)

- Cardiac arrest due to VF or VT after exclusion of a reversible etiology

- Systemic LVEF ≤ 35%, biventricular physiology, and NYHA class II or III on GDMT.

- Tetralogy of Fallot with one of the following (Al-Khatib, 2017; Shen, 2017):
 - Spontaneous sustained VT
 - Inducible VF or sustained VT
 - ≥ 1 risk from the following list:
 - Prior palliative systemic to pulmonary shunts
 - Unexplained syncope
 - Frequent PVCs
 - Atrial tachycardia
 - Left ventricular dysfunction or diastolic dysfunction
 - NSVT

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- QRS duration \geq 180 ms
 - Dilated right ventricle
 - Severe pulmonary regurgitation or stenosis
- Single or systemic right ventricular ejection fraction (RVEF) $<$ 35%, in the presence of an additional risk factor such as:
 - NSVT
 - Unexplained syncope
 - NYHA class II or III, despite GDMT (Al-Khatib, 2017; Priori, 2015)
 - QRS duration \geq 140 ms
 - Severe systemic AV valve regurgitation
 - Syncope of unknown origin in the presence of either advanced ventricular dysfunction (EF $<$ 35%) or marked hypertrophy or inducible sustained VT or VF (Al-Khatib, 2017; Shen, 2017)
 - Syncope and moderate or complex CHD, with high clinical suspicion of ventricular arrhythmias
 - Non-hospitalized patients with CHD awaiting heart transplantation
 - Left ventricular non-compaction that meets same indications as NICM, including a familial history of SCD (Biagini, 2006; Russo, 2018)

EXEMPTIONS:

Indications for ICD with an Appropriate Pacing Modality in Special Situations

(Katsumoto, 2014; Russo, 2013)*

- ICD criteria met, and elevated troponin is deemed not due to a myocardial infarction (Al-Khatib, 2017)
- 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 (Russo, 2013)**
- 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 (Katsumoto, 2014)

*** 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**

**** These indications avoid a second implantation procedure within less than 3 months.**

BACKGROUND:

(Al-Khatib, 2017; Epstein, 2012; Ponikowski, 2016; Priori, 2015; Russo, 2013; Shen, 2017; Yancy, 2013)

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).

Patient eligibility for an ICD presumes all of the following:

- Anticipated reasonable quality of life for ≥ 1 year post implantation (Katsumoto, 2018)
- 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 (see Background Information section on reversible causes)
- Completion of ≥ 3 months of guideline directed medical therapy (GDMT) for heart failure (HF), unless an intervening indication for pacemaker implantation arises (see Background Information section for definition of GDMT)
- ICD indications are present in the vast majority of scenarios in which cardiac resynchronization therapy (CRT) is appropriate
- Sustained VT is defined as having duration > 30 seconds or requiring termination due to hemodynamic compromise in < 30 seconds

Guidelines for the pediatric population are extrapolated from the adult population, due to a lack of relevant trials (Brugada, 2013; Priori, 2015)

OVERVIEW:

General

(Al-Khatib, 2017; Epstein, 2012; Ponikowski, 2016; Priori, 2015; Russo, 2013; Shen, 2017; Yancy, 2013)

Implantable cardioverter defibrillators (ICDs) are indicated for the treatment of life-threatening ventricular tachycardia and ventricular fibrillation. 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)

- An ICD continually monitors heart rhythm. If a rapid rhythm is detected, the device delivers electrical therapy directly to the heart muscle in order to terminate the rapid rhythm and restore a normal heart rhythm. There are two types of therapy that can be delivered:
 - Rapid pacing OR
 - High-voltage shocks are necessary for ventricular fibrillation and also when rapid pacing has failed to correct the abnormal rhythm
- In addition, all ICDs have pacing capability, and deliver pacing therapy for slow heart rhythms (bradycardia)
- The parameters defining limits for pacing therapy and for tachycardia therapy are programmable using noninvasive radio signals on all available ICDs

NYHA Class Definitions

(Campeau, 1976; Goldman, 1981; Russo, 2013)

- **Class I:** No limitation of functional activity or only at levels of exertion that would limit normal individuals (patient can carry 24 pounds up 8 stairs, play basketball, and shovel soil).
- **Class II:** Slight limitation of activity. Fatigue, palpitation, or dyspnea with moderate exercise (patient able to dance, garden, and walk 4 MPH on level ground).
- **Class III:** Marked limitation of activity. Fatigue, palpitation, or dyspnea with minimal activity (patient able to shower, make bed, bowl or golf, dress, and walk 2.5 MPH on level ground).
- **Class IV:** Severe limitation of activity. Symptoms even at rest, worse with activity (patient unable to comfortably perform any significant activity).
- **Ambulatory Class IV:** Class IV heart failure with: 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT.

Guideline Directed (or Optimal) Medical Therapy for Heart Failure

(Yancy, 2013, 2017)

- Angiotensin converting enzyme (ACE-I), angiotensin receptor blockers (ARB), or combined angiotensin receptor inhibitor and neprilysin inhibitor (ARNI)
- Beta blocker (might be less critical in permanent atrial fibrillation, still recommended) (Kotech, 2017)
- Addition of loop diuretic for all NYHA class II – IV patients
- Addition of hydralazine and nitrate for persistently symptomatic African Americans
- Addition of an aldosterone antagonist, provided eGFR is > 30 ml/mi
- 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.

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
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
MI	Myocardial infarction
ms	Milliseconds
NICM	Nonischemic cardiomyopathy
NYHA	New York Heart Association
RV	Right ventricular/right ventricle
STEMI	ST-elevation myocardial infarction
SND	Sinus node dysfunction
VT	Ventricular tachycardia
VF	Ventricular fibrillation

POLICY HISTORY:

Review Date: August 14, 2019

Review Summary:

- Removed indications under ischemic heart disease for NSVT due to prior MI, LVEF \leq 40%, and inducible VT or VF at EPS
- Removed indications under ischemic heart disease for VT or VF < 48 hours post MI or elective coronary revascularization
- Under NICM, removed indication for peripartum cardiomyopathy with LVEF \leq 35% that persists > 3 months
- Under advanced heart failure and transplantation, removed indication for severe allograft vasculopathy
- Revision to cardiac sarcoidosis indication to add cardiac arrest
- Under hypertrophic cardiomyopathy revised indications for documented NSVT to include an additional SCD risk modifier (age < 30 yr, delayed hyperenhancement on cardiac MRI, LVOT obstruction, or syncope > 5 yr ago) or high risk feature (LV aneurysm or LVEF < 50%)
- Removed indications for giant cell myocarditis and chronic Chagas cardiomyopathy
- Removed indication for hypertensive heart disease with LVH and LVEF \leq 35%
- Under Tetralogy of Fallot added the following indications :
 - Prior palliative systemic to pulmonary shunts
 - Unexplained syncope
 - Frequent PVCs
 - Atrial tachycardia
 - Left ventricular diastolic dysfunction
 - Dilated right ventricle

Review Date: March 2020

Review Summary:

- Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review
- Removed the statement regarding waiting period from the Overview section
- Updated and added new references

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33208 – Pacemaker

CPT Codes:

33206, 33207, 33208, 33212, 33213, 33214, 33227, 33228

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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

INDICATIONS FOR PACEMAKERS – ADULT (Excludes conditions that are expected to resolve) (Epstein, 2013; Hayes, 2018; Kusumoto, 2019)

Sinus Node Dysfunction (SND)

- Documented symptomatic sinus bradycardia, including frequent sinus pauses
- Symptomatic chronotropic incompetence (broadly defined as an inability to increase heart rate commensurate with activity or demand), documented by stress test or electrocardiography (ECG) recording data
- Symptomatic sinus bradycardia that results from required guideline-directed medical therapy (GDMT) for which there is no alternative treatment
- Heart rate less than 40 while awake, even without definite association with significant symptoms consistent with bradycardia
- Tachycardia-bradycardia syndrome and symptoms attributable to bradycardia (Kusumoto, 2019)
- Syncope of unexplained origin with clinically significant SND, either documented or provoked in electrophysiologic study (EPS)

Acquired Atrioventricular (AV) Block

- Persistent third-degree (complete) AV block, regardless of symptoms
- Second-degree Mobitz Type II AV block and high-grade AV block, regardless of symptoms
- Atrial fibrillation while awake, with pauses ≥ 5 seconds, or symptomatic bradycardia
- 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
- Following catheter ablation of the AV junction
- Second-degree AV block, third degree AV block, or an H-V interval ≥ 70 ms, associated with neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy, Kearns-Sayre syndrome, and peroneal muscular atrophy, regardless of symptoms
- Symptomatic AV block that results from required medical therapy for which there is no alternative treatment

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- Exercise-induced second or third-degree AV block without myocardial ischemia
- Symptomatic bradycardia associated with second-degree AV block, either Mobitz I or II
- Second-degree AV block associated with a wide QRS, or EPS-documented intra- or infra-His conduction
- First- or second-degree AV block with “pacemaker syndrome” symptoms (chronic fatigue, dyspnea on exertion, symptomatic hypotension) or hemodynamic compromise
- Marked first-degree or second-degree Mobitz Type 1 AV block with symptoms clearly attributable to the AV block

Chronic Bifascicular Block

- Type II second-degree AV block, advanced second-degree AV block (see definitions section) or intermittent third-degree AV block
- Alternating bundle-branch block
- Syncope of unexplained origin when other likely causes have been excluded, specifically ventricular tachycardia (Shen, 2017)
- Syncope and bundle branch block with an HV interval ≥ 70 ms, or evidence of infranodal block at EPS (Kusomoto, 2018)
- Incidental findings at EPS study of an H-V interval ≥ 100 milliseconds, or non-physiological, pacing-induced infra-His block in asymptomatic patients

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, or AV block, or ≥ 50 mmHg drop in systolic BP (Epstein 2008, Shen 2017)
- Syncope without clear, provocative events and with a hypersensitive cardioinhibitory response (asystole) ≥ 3 seconds
- Recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by ECG recording data (Brignole, 2012; Varosy, 2017)

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
- Sustained pause-dependent ventricular tachycardia (VT)

INDICATIONS FOR PEDIATRIC AND CONGENITAL HEART DISEASE PACING

(Brignole, 2013; Brugada, 2013; Epstein, 2013)

Children, Adolescents (< 19 years), and Patients with Congenital Heart Disease (CHD)

Sinus Node Dysfunction (SND)

- SND with symptomatic age- and activity-inappropriate bradycardia
- Sinus bradycardia with complex CHD AND a resting heart rate < 40 bpm **OR** pauses in ventricular rate > 3 seconds

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- 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 (Brignole, 2013; Brugada, 2013; Khairy, 2014).

AV Block

- Second- or third-degree AV block with symptomatic bradycardia, ventricular dysfunction, or low cardiac output
- Congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction
- 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
- 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 (Kusomoto, 2018)
- Adults with congenital complete AV block, regardless of symptoms (Kusomoto, 2018)
- 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

- 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 (left anterior or posterior fascicular block)
- Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms
- Asymptomatic bifascicular block +/- first-degree AV block after surgery for CHD without prior transient complete AV block

BACKGROUND

(Epstein, 2013; Hayes, 2018)

Pacemaker implantation generally serves to address bradycardia, with the intention of ameliorating related symptoms, preventing complications of syncope, and/or reducing mortality risk.

This guideline is not intended to cover the type of bradycardia pacing device. CRT (cardiac resynchronization therapy or biventricular pacing) and ICD (implantable cardioverter defibrillator) implantation are covered in separate guidelines.

OVERVIEW

General

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. Additionally, the Micra transcatheter pacing system is a leadless pacemaker system for indicated patients.

Heart Block Definitions

(Epstein, 2013)

- 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

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
LBBB	Left bundle-branch block
LV	Left ventricular/left ventricle
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
ms	Milliseconds
s	Seconds
STEMI	ST-elevation Myocardial Infarction
SND	Sinus node dysfunction
VT	Ventricular tachycardia

POLICY HISTORY:

Review Date: July 2019

Review Summary:

- Added broad definition of chronotropic incompetence
- For sinus node dysfunction added indication for tachycardia-bradycardia syndrome “and symptoms attributable to bradycardia”
- Indications after the acute phase of myocardial infarction were removed
- For hypersensitive carotid sinus syndrome and neurocardiogenic syncope:
 - Added indication for recurrent syncope and asystole ≥ 3 seconds with syncope or ≥ 6 seconds without symptoms or with presyncope, documented by implantable loop recorder
 - Removed indication for neurocardiogenic syncope associated with bradycardia occurring spontaneously or at the time of tilt table testing
- For hypertrophic cardiomyopathy, removed symptomatic hypertrophic cardiomyopathy and hemodynamically significant resting (peak > 30 mmHg) or provoked (peak > 50 mmHg) LV outflow tract gradient, refractory to medical therapy, and suboptimal candidates for septal reduction therapy (including high risk for developing heart block post procedure)
- For pediatric and congenital heart disease pacing, AV block, the following indications were added:

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- 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
- Adults with congenital complete AV block, regardless of symptoms
- For pediatric and congenital heart disease pacing, AV block, removed postoperative advanced second- or third-degree AV block that is expected to be permanent or that persists ≥ 7 days after cardiac surgery; and transient postoperative third degree AV block that reverts to sinus rhythm with residual bifascicular block
- For pediatric and congenital heart disease pacing, scenarios in which pacemakers are not indicated, the following were added:
 - Asymptomatic first-degree AV block or Mobitz I second-degree AV block with a narrow QRS
 - Asymptomatic fascicular block (left anterior or posterior fascicular block)
 - Hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms

Review Date: March 2020

Review Summary:

- Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review
- Added information regarding a leadless pacemaker system for indicated patients to the Overview section

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93307 – Transthoracic Echocardiology (TTE)

CPT codes: 93303, 93304, 93306, 93307, 93308, +93320, +93321, +93325, +93356

National Imaging Associates, Inc.*	
Clinical guideline TRANSTHORACIC (TTE) ECHO	Original Date: October 2009
CPT codes: 93303, 93304, 93306, 93307, 93308, +93320, +93321, +93325, +93356	Last Revised Date: March 2020
Guideline Number: NIA_CG_067	Implementation Date: January 2021

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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

ADULT PATIENTS – INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE)

(Indications for pediatric patients follows this section)

(Douglas, 2011)

Evaluation of Cardiac Structure and Function

- When initial evaluation including history, physical examination, electrocardiogram (ECG) or other testing suggests a cardiac etiology for symptoms including but not limited to:
 - Chest pain
 - Shortness of breath
 - Palpitations
- Hypotension suggestive of cardiac etiology not due to other causes such as:
 - medications, dehydration, or infection
- ECG evidence of prior MI (pathologic Q waves) defined below:
 - > 40 ms (1 mm) wide
 - > 2 mm deep
 - > 25% of depth of QRS complex

Murmur or Click

- Initial evaluation when there is a reasonable suspicion for valvular or structural heart disease such as:
 - High grade $\geq 3/6$

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

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- Holosystolic
- Continuous
- Diastolic

Arrhythmias

- Frequent premature ventricular contractions (PVCs, greater than 30 per hour on remote monitoring)
- Sustained or nonsustained ventricular tachycardia (VT) or ventricular fibrillation (VF), or ventricular bigeminy
- New onset atrial fibrillation (as documented in MD notes) which was not evaluated by a prior transthoracic echocardiogram (TTE)
- New left bundle branch block (as documented in MD notes)

Syncope (Doherty, 2017; Shen, 2017)

- History, physical examination, or electrocardiogram (ECG) consistent with a cardiac diagnosis known to cause presyncope or syncope, including but not limited to known or suspected:
 - Hypertrophic cardiomyopathy
 - Heart failure
- Exercise-induced syncope

Perioperative Evaluation (Fleischer, 2014; Lentine, 2012)

- Preoperative left ventricular function assessment in patients who are candidates for solid organ transplantation (can be done yearly prior to transplant)

Pulmonary Hypertension

- Evaluation of suspected pulmonary hypertension including evaluation of right ventricular function and estimated pulmonary artery pressure
- Re-evaluation of known pulmonary hypertension if there is a change in clinical status or cardiac exam or a need to change medications (can be done every 6-12 months) (Nazzareno, 2016) such as:
 - New chest pain
 - Worsening shortness of breath
 - Syncope
 - Increased murmur
 - Worsening rales on lung examination
- Evaluation of patients with pulmonary embolism to risk stratify and initiate appropriate therapy (Saric, 2016)
- Screening test for pulmonary hypertension in patients with scleroderma

Evaluation of Valvular Function

(Doherty, 2017, 2018; Nishimura, 2014)

Native Valvular Stenosis

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- Routine surveillance (≥ 3 yrs) of bicuspid aortic valve, aortic sclerosis, or mild valvular stenosis
- Re-evaluation (≥ 1 yr) of moderate stenosis
- Re-evaluation of severe aortic stenosis (AS) every 6 - 12 month
- Re-evaluation after starting medication in patients with low flow/low gradient severe aortic stenosis

Native Valvular Regurgitation with TTE (Bonow, 2020; Doherty, 2017; Lancellotti, 2013)

- Re-evaluation (≥ 3 yrs.) of mild valvular regurgitation
- Re-evaluation (≥ 1 yr.) of moderate valvular regurgitation
- Re-evaluation of asymptomatic patient every 6 - 12 months with severe aortic regurgitation
- Re-evaluation of asymptomatic patient every 6 - 12 months with severe mitral regurgitation

Prosthetic Valves with TTE

- Initial evaluation of prosthetic valve or native valve repair, for establishment of baseline, typically 6 weeks to 3 months postoperative
- Routine surveillance (≥ 3 yrs. after valve implantation) of prosthetic valve or native valve repair
- Evaluation of prosthetic valve or native valve repair with suspected dysfunction, with symptoms including but not limited to:
 - Chest pain
 - Shortness of breath
 - New or Increased murmur on heart examination
 - New rales on lung examination
 - Elevated jugular venous pressure on heart exam
- Annual evaluation of bioprosthetic heart valves older than 10 years

Transcatheter Heart Interventions

Transcatheter Aortic Valve Replacement (TAVR) (Doherty, 2017; Otto, 2017)

- Pre TAVR evaluation
- Post TAVR at 30 days (6 weeks to 3 months also acceptable) and annually
- Assessment post TAVR when there is suspicion of valvular dysfunction included but not limited to:
 - Chest pain
 - Shortness of breath
 - New or increased murmur on heart examination
- Assessment of stroke post TAVR

Percutaneous Mitral Valve Repair (Bonow, 2020; Doherty, 2017)

- Pre-procedure evaluation
- Reassessment for degree of MR and left ventricular function (1, 6, and 12 months post procedure, and then annually to 5 yrs.)

Closure of PFO or ASD (Doherty, 2019)

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- Pre-procedure evaluation
- Routine follow-up at 6 months post procedure for device position and integrity
- Evaluation for clinical concern for infection, malposition, embolization, or persistent shunt
- Routine surveillance of an asymptomatic patient with a PFO is **not** indicated (Sachdeva, 2020)

Left Atrial Appendage (LAA) Occlusion (Doherty, 2019)

- Pre-procedure evaluation

Pericardial Disease (Chiabrando, 2020; Doherty, 2017; Klein, 2013; Saric, 2016)

- Suspected pericardial effusion
- Re-evaluation of known pericardial effusion when findings would lead to change in management
- Suspected pericardial constriction or reevaluation of status when management would be changed

Evaluation of Cardiac Source of Emboli or Cardiac Mass (Doherty, 2017)

- Embolic source in patients with recent transient ischemic attack (TIA), stroke, or peripheral vascular emboli
- Evaluation of intracardiac mass or re-evaluation of known mass

Infective Endocarditis (Native or Prosthetic Valves) (Doherty, 2017; Habib, 2010; Nishimura, 2014)

- Initial evaluation of suspected infective endocarditis with positive blood cultures or a new murmur
- Re-evaluation of infective endocarditis with, but not limited to:
 - 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 EKG
- Re-evaluation of patient with infective endocarditis at high risk of progression or complication (extensive infective tissue/large vegetation, or staphylococcal, enterococcal, or fungal infections)
- At completion of antimicrobial therapy and serial examinations at 1,3, 6, and 12 months during the subsequent year (Habib, 2010)

Thoracic Aortic Disease (Bhave, 2018; Erbel, 2014; Hiratzka, 2010; Hiratzka, 2016; Svensson, 2013; Terdjman, 1984)

In the absence of recent computed tomography (CT) or cardiovascular magnetic resonance (CMR), which are preferred for imaging beyond the proximal ascending aorta

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- Screening of first-degree relatives of individuals with a thoracic aortic aneurysm (defined as \geq 50% above normal) or dissection, or if an associated high-risk mutation is present
- 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 \geq 4.5 cm or showing growth rate \geq 0.5 cm/year
 - 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 \geq 4.5 or expanding \geq 0.5 cm/yr
 - Patients with Turner's syndrome should undergo imaging to assess for bicuspid aortic valve, coarctation of the aorta or dilation of the ascending or thoracic aorta. If the initial imaging is normal and there are no additional risk factors for dissection, imaging can be done every 5 - 10 years. If an abnormality exists, annual imaging is recommended
 - Screening of first-degree relatives of patients with a 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
 - Re-evaluation ($<$ 1 y, generally twice a year) of the size and morphology of the aortic sinuses and ascending aorta in patients with a bicuspid aortic valve with 1 of the following:
 - Aortic diameter \geq 4.5 cm
 - Rapid rate of change in aortic diameter when an annual growth rate of \geq 0.5 cm is suspected.
 - Family history (first-degree relative) of aortic dissection
 - 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 post either: Root repair or AVR plus ascending aortic root/arch repair: baseline post-op, then annually (Svensson, 2013)
 - Evaluation of sinus of valsalva aneurysms and associated shunting secondary to rupture (Terdjman, 1984). Echo imaging every 4-12 weeks is recommended during pregnancy and 6 months post-partum in patients with ascending aortic dilation (Regitz-Zagrosek 2018)

Hypertension (Doherty 2018)

- Initial evaluation of suspected hypertensive heart disease including but not limited to the following:
 - Left ventricular hypertrophy on EKG
 - Cardiomegaly
 - Evidence of clinical heart failure

Heart Failure (Doherty, 2018; Nagueh, 2016; Patel, 2013; Yancy, 2013)

- Initial evaluation of suspected heart failure (HF) (systolic or diastolic) based on symptoms, signs, or abnormal test result, including but not limited to:
 - Dyspnea
 - Orthopnea
 - Paroxysmal nocturnal dyspnea
 - Worsening edema
 - Elevated BNP
- Re-evaluation of known HF (systolic or diastolic) with a change in clinical status or cardiac exam (as listed above),

Cardiomyopathy (Doherty, 2018; Gersh, 2011; Patel, 2013; Regitz-Zagrosek, 2018; Yancy, 2013)

- Initial evaluation of suspected inherited or acquired cardiomyopathy including but not limited to:
 - Restrictive
 - Infiltrative
 - 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
- Screening evaluation in first-degree relatives of a patient with an inherited cardiomyopathy
- Suspected cardiac sarcoidosis
- 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) (Dorbala, 2019)
- Hypertrophic Cardiomyopathy (HCM) (Gersh, 2011)
 - Initial evaluation of suspected HCM
 - Re-evaluation of patients with HCM with new symptoms including but not limited to the following:
 - Chest pain

- Shortness of breath
- Palpitations
- Syncope
- Evaluation of the result of surgical myomectomy or alcohol septal ablation
- Re-evaluation every 1 - 2 years for symptomatically stable patients to assess degree of myocardial hypertrophy, dynamic obstruction, and myocardial function
- Re-evaluation of clinically unaffected patients with a first-degree relative with HCM every 5 years

Imaging Surveillance for Cardiotoxic Chemotherapy

(Maleszewski, 2018; Plana, 2014; Zamorano, 2016)

TTE is the method of choice for the evaluation of patients prior to cardiotoxic chemotherapy, and subsequently for monitoring and follow up. The frequency of testing should be left to the discretion of the ordering physician, but generally no more often than at baseline and every 6 weeks thereafter.

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 (Al-Khatib, 2017)
- Initial evaluation for CRT device optimization after implantation
- Re-evaluation for CRT device optimization in a patient with worsening heart failure
- Known implanted pacing device with symptoms possibly due to device complication or suboptimal pacing device settings

Ventricular Assist Devices (VADs) and Cardiac Transplantation

(Doherty, 2018; Stainback, 2015)

- To determine candidacy for VAD
- Optimization of VAD settings and assessment of response post device
- Re-evaluation for signs/symptoms suggestive of VAD-related complications including but not limited to:
 - TIA or stroke
 - Infection
 - Murmur suggestive of aortic insufficiency
 - Worsening heart failure
- Monitoring for rejection in a cardiac transplant recipient

Cardiovascular Disease in Pregnancy

(Davis, 2020; Regitz-Zagrosek, 2018)

- Valvular stenosis:
 - Mild- can evaluate each trimester and prior to delivery
 - Moderate-severe can be evaluated monthly
- Valvular regurgitation:

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- Mild-moderate regurgitation can be evaluated each trimester and prior to delivery
- Severe regurgitation can evaluate monthly
- Pre-pregnancy evaluation with mechanical or bioprosthetic heart valves if not done within the previous year

Prior Postpartum Cardiomyopathy: can be repeated at the end of the 1st and 2nd trimesters, 1 month prior to delivery, after delivery prior to hospital discharge, 1 month postpartum, and serially including up to 6 months after normalization of ejection fraction.

- Syndromes potentially involving the aorta (i.e, Marfan’s, Ehlers-Danlos, Loeys-Dietz, or Turner syndrome): for mildly dilated aorta can repeat TTE every 12 weeks; for severely dilated aorta can repeat TTE monthly. Continued evaluation allowable for 6 months postpartum

Adult Congenital Heart Disease

(Sachdeva, 2020; Stout, 2019; Warnes, 2008)

- Initial evaluation of suspected adult congenital heart disease
- 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 Overview

Coronary Anomalies (Sachdeva, 2020)

- Routine surveillance (2–5 years) in an asymptomatic patient with anomalous right coronary artery from the left aortic sinus
- Routine surveillance (2–5 years) in an asymptomatic patient with small coronary fistula and 1-2 years for moderate or large coronary fistula

PEDIATRIC PATIENTS - INDICATIONS FOR TRANSTHORACIC ECHOCARDIOGRAPHY (TTE) (PATIENTS UNDER THE AGE OF 18)

(Campbell, 2014)

- Hypertension
- Renal failure
- Palpitations, if one:
 - Family history at age < 50 of either:
 - Sudden cardiac death/arrest **OR**
 - Pacemaker or ICD
 - History or family history of cardiomyopathy
- Chest pain, if one or more of the following:
 - Exertional chest pain
 - Abnormal ECG
 - Family history with unexplained sudden death or cardiomyopathy
- Syncope, if any one of:

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- Abnormal ECG
- Exertional syncope
- Family history at age < 50 of either one:
 - Sudden cardiac death/arrest **OR**
 - Pacemaker or ICD
- Family history of cardiomyopathy
- Signs and/or symptoms of heart failure, including, but not limited to:
 - 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
- Arrhythmia, if one of the following:
 - Supraventricular tachycardia
 - Ventricular tachycardia
- 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 are become louder with changes in position
 - Presumptively innocent murmur, but in the presence of signs, symptoms, or findings of cardiovascular disease
- Abnormal basic data, including any one of the following:
 - Abnormal electrocardiogram (ECG)
 - Abnormal cardiac biomarkers
 - Desaturation on pulse oximetry
 - Abnormal chest x-ray
- Suspected pulmonary hypertension
 - Signs and symptoms of endocarditis
 - Thromboembolic events:
 - Patients on anticoagulants, when required to evaluate for thrombus
 - Thromboembolic events or stroke (Saric, 2016)
 - Systemic hematologic diseases that are associated with cardiac findings:
 - Sickle cell disease and other hemoglobinopathies
 - HIV infection
- Chemotherapy or radiation therapy, anyone of the following:
 - Cardiotoxic chemotherapy, before and following exposure
 - Radiation therapy to chest, before and long term follow up (Lancellotti, 2013)

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- Inflammatory & Autoimmune, including any one of the following:
 - Suspected Rheumatic Fever
 - Systemic lupus erythematosus
 - Takayasu Arteritis
 - Kawasaki Disease (Newburger, 2004)
- 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
- Genetic & Syndrome Related, including any one of the following:
 - 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, Allagille 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)
 - Known or suspected muscular dystrophies associated with congenital heart disease.
 - Mitochondrial or metabolic storage disease (e.g. Fabry's disease)
 - 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
 - Maternal phenylketonuria
 - Suspected cardiovascular abnormality on fetal echocardiogram

INDICATIONS FOR FOLLOW-UP ECHOCARDIOGRAPHY IN PEDIATRIC PATIENTS

Specific Indications for Follow-Up Echocardiograms in Pediatric Patients:

(Infancy is defined as between birth and 1 year of age; childhood from 1-11 years of age; and adolescence from 11 to 21 years of age (Hagin, 2017) The guidelines for adult congenital heart disease (Stout, 2018) are not intended to be used for patients under 18 years of age.

- Congenital Heart Disease (CHD) with a change in clinical status or to guide therapy
- For follow up of specific lesions with CHD, see Overview

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- 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 arrhythmias
- Kawasaki Disease, upon diagnosis, two weeks later and 4 to 6 weeks after diagnosis. If any coronary abnormalities are present, echocardiograms may need to be more frequent as clinically indicated (Newburger, 2004)
- Periodic screening of children of patients with hypertrophic cardiomyopathy every 12-18 months starting by age 12 or earlier if a growth spurt or signs of puberty are evident and/or when there are plans for engaging in intensive competitive sports or there is a family history of sudden cardiac death (Gersh, 2011)

BACKGROUND:

Transthoracic echocardiography (TTE) uses ultrasound to image the structures of the heart in a real time format, 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.

TTE's safety and versatility in examining cardiac structure, function, and hemodynamics lends to its utility for numerous indications in children and adults.

TEE (transesophageal echocardiography) widens the scope of utility for echocardiographic imaging, and its indications are covered in a separate guideline.

OVERVIEW:

Adult and Pediatric Congenital Heart Disease Follow-Up (Sachdeva, 2020)

- All surgical or catheter-based repairs allow evaluation prior to the procedure and postprocedural evaluation (within 30 days)
- After any surgical or catheter-based repair, evaluation (3-12 months) for a patient with heart failure symptoms

Unrepaired Lesion	1-3 months	3- 6 months	6-12 months	1-2 years	3-5 years
Aortic stenosis (AS) and/or aortic regurgitation (AR) in a child	-		Moderate or more AS/AR and increasing aortic size	Stable aortic size (2-3 years)	

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Bicuspid aortic valve with ≤ mild AS/AR and no aortic dilation in a child	-				X
Atrial septal defect				Moderate size (6-12 mm)	Small size (3-6 mm)
Mitral regurgitation (MR): asymptomatic	Infant with ≥ moderate MR		Infant with mild MR, Child with ≥ moderate MR	Child with mild MR (2-5 years)	
Unrepaired Lesion	1-3 months	3- 6 months	6-12 months	1-2 years	3-5 years
Mitral Stenosis (MS)	Infant with any MS	Child with ≥ moderate MS		Child with mild MS	
Tricuspid regurgitation (TR): asymptomatic		Infant with ≥ moderate TR	Child & Adult with ≥ moderate TR	Infant or child with mild TR	Adult with mild TR
Patent Ductus Arteriosus		Infant			Adult
Pulmonary stenosis (PS): asymptomatic		Infant		Child & Adult	
Coarctation		Infant		Child & Adult	
Ventricular septal defect (VSD)	Infant with ≥ moderate VSD			Child with VSD in other location	Child with small muscular VSD; Adult with any VSD
<u>Postprocedure: Surgical or Catheter-Based</u>	1-3 months	3- 6 months	6-12 months	1-2 years	3-5 years

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Postprocedural 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: asymptomatic	X	X	1 year		2-5 years
ASD surgical repair: asymptomatic			X		2-5 years
ASD: device closure or surgical repair with residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		3-12 months			
Unrepaired Lesion	1-3 months	3- 6 months	6-12 months	1-2 years	3-5 years
MS or MR	Infant with ≥moderate MS or MR	Infant with mild MS or MR	Child with ≥moderate MS or MR	Child with mild MS or MR	
Tricuspid valve surgery or catheter-based procedure: asymptomatic				X	
Tricuspid valve surgery or catheter-based procedure: valvular or ventricular dysfunction or arrhythmias			Child	Adult	
Pulmonary stenosis: asymptomatic child			Moderate or severe sequelae	No or mild sequelae	
Coarctation: asymptomatic		Within the 1st year		After the 1st year	
PDA: asymptomatic				Annually within 2 years	5 years after first 2

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PDA: postprocedural left PA stenosis or aortic obstruction				X	
Tetralogy of Fallot (ToF): asymptomatic after transcatheter pulmonary valve replacement	1 month	6 months		Annually	
ToF: patient with conduit dysfunction, valvular or ventricular dysfunction, pulmonary artery stenosis, or arrhythmias			X		
VSD: small residual shunt			X		2-3 years
VSD: significant residual shunt, valvular or ventricular dysfunction, arrhythmias, or pulmonary hypertension		3-12 months			

Double Outlet Right Ventricle, Transposition of the Great Arteries, and Truncus Arteriosus Unrepaired:

- Routine surveillance (1-3 months) in an asymptomatic infant
- Routine surveillance (3-6 months) in an asymptomatic child

Post procedure: Surgical or Catheter-based

- Routine surveillance if asymptomatic with mild sequelae at 6 months, 1-2 years, and 3-5 years
- Routine surveillance if valvular or ventricular dysfunction, outflow tract obstruction, branch pulmonary artery stenosis, or arrhythmias at 3-12 months and 1-2 years

Abbreviations:

AS	Aortic stenosis
AR	Aortic regurgitation
ASD	Atrial septal defect
CABG	Coronary artery bypass grafting surgery
CAD	Coronary artery disease
CMR	Cardiovascular magnetic resonance
CRT	Cardiac resynchronization therapy
CT	Computed tomography
ECG	Electrocardiogram
HCM	Hypertrophic cardiomyopathy

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HF	Heart failure
ICD	Implantable cardioverter-defibrillator
LV	Left ventricular
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
MR	Mitral regurgitation
MS	Mitral stenosis
PDA	Patent ductus arteriosus
PFO	Patent foramen ovale
PS	Pulmonary stenosis
TAVR	Transcatheter aortic valve replacement
TEE	Transesophageal echocardiogram
TIA	Transient ischemic attack
ToF	Tetralogy of Fallot
TR	Tricuspid regurgitation
TTE	Transthoracic echocardiogram
PVC	Premature ventricular contraction
VSD	Ventricular septal defect
VT	Ventricular tachycardia

POLICY HISTORY:

Review date: July 2019

Review Summary:

- Added indication for hypotension of suspected cardiac etiology
- Removed indication for respiratory failure or hypoxemia of uncertain etiology
- Clarification of murmur indication with “when there is a reasonable suspicion of valvular heart disease such as high grade, holosystolic, continuous, or diastolic murmur”
- Clarified frequent PVCs as greater than 30 per hour
- Added indication for unevaluated left bundle branch block
- Added indication for exercise induced syncope
- For perioperative evaluation for solid organ transplantation, added annual study prior to transplantation
- Removed indication for re-evaluation (<1 yr) in patients with moderate or severe aortic stenosis, who will be subjected to increased hemodynamic demands (e.g. noncardiac surgery, pregnancy)
- Removed tertiary syphilis or Takayasu’s Arteritis indication
- Pulmonary hypertension:
 - Clarified re-evaluation for a change in clinical status or cardiac exam, or to guide therapy (every 6 - 12 months, or more frequently to guide therapy). Annual indication removed.
 - Screening for scleroderma added

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- Removed indications for history of rheumatic heart disease and exposure to medications that could result in valvular heart disease
- Added mild valvular regurgitation as an indication for testing every 3 years
- Added indication for annual evaluation of prosthetic heart valves older than 10 years
- In depth indications for HOCM
- LVAD and transplant indications added
- Removed chart on specific chemotherapeutic agents
- Added detailed indications for adult congenital heart disease and serial follow up
- Removed indications for presyncope for pediatric patients
- Revised murmur indication in pediatric patients with more criteria for pathologic murmur
- Added definitions of age groups for pediatric patients (infancy, childhood, and adolescence)

November 2019

- Added CPT code +93356

Review Date: March 1, 2020

Review Summary:

- Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review.
- Added clarification of abnormal EKG to include evidence of prior myocardial infarction, including pathologic Q waves
- Added clarification of indication for frequent PVCs to include greater than 30 per hour on remote monitoring
- Added clarification that annual evaluation of bioprosthetic heart valves older than 10 years, to replace prosthetic heart valves
- Added statement about routine surveillance of PFO not indicated
- Separated sections on pericardial disease and cardiac source of emboli/ cardiac mass
- Added clarification cardiac source of emboli to include the following: Embolic source in patients with recent transient ischemic attack (TIA), stroke, or peripheral vascular emboli
- Added clarification of cardiac mass to include the following: evaluation of mass and re-evaluation when findings would alter therapy
- Added clarification of hypertensive heart disease to include asymptomatic left ventricular hypertrophy, cardiomegaly, or evidence of clinical heart failure
- Added indication for suspected cardiac amyloid to monitor disease progression and/or response to therapy, and to guide initiation and management of anticoagulation (TEE may be preferred)
- Added clarification of imaging for surveillance for cardiotoxic chemotherapy to include the following: TTE is the method of choice for the evaluation of patients prior to cardiotoxic chemotherapy, and subsequently for monitoring and follow up. The frequency of testing should be left to the discretion of the ordering physician, but generally no more often than at baseline and every 6 weeks thereafter.
- Added separate section on indications for TTE during pregnancy to include the following:

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- Valvular stenosis: mild-can evaluate each trimester and prior to deliver; moderate to severe can evaluate monthly
- Valvular regurgitation: mild-moderate can evaluate each trimester and prior to delivery; severe regurgitation can evaluate monthly
- Pre-pregnancy evaluation with mechanical or bioprosthetic heart valves if not done within the previous year
- Prior postpartum cardiomyopathy: can repeat at the end of the 1st and 2nd trimesters, 1 month prior to delivery, after delivery prior to hospital discharge, 1 month postpartum, and serially including up to 6 months after normalization of ejection fraction
- Syndromes potentially involving the aorta (I,e, Marfan’s, Ehlers-Danlos, Loeys-Dietz, or Turner syndrome): for mildly dilated aorta can repeat TTE every 12 weeks; for severely dilated aorta can repeat TTE monthly. Continued evaluation allowable for 6 months postpartum
- Extensive update to adult and pediatric congenital heart disease sections to include the following:
 - Evaluation prior to surgical or catheter-based procedure and postprocedural evaluation (within 30 days)
 - Evaluation after any surgical or catheter-based repair (3-12 months) for a patient with heart failure symptoms
 - Complete chart added to include timing of TTE follow-up in infants, children, and adults based on the lesion present and whether the lesion was unrepaired or surgical or catheter-based repair had been performed
 - Added separate section on follow-up of patients with double outlet right ventricle, transposition of the great arteries, and truncus arteriosus
- Removed chart and background information regarding physiologic stages of adult CHD
- Added separate section for coronary anomalies to include the following:
 - Routine surveillance (2-5 years) in an asymptomatic patient with anomalous right coronary artery from the left aortic sinus
 - Routine surveillance (2-5 years) in an asymptomatic patient with small coronary fistula and 1-2 years for moderate or larger coronary fistula
- Updates to TTE in pediatric patients include the following:
 - Clarification of congenital heart disease with a change in clinical status with the addition of “or to guide therapy”
 - Added annual surveillance in a child with normal prosthetic mitral valve function and no LV dysfunction
 - Added surveillance (3-12 months) in a child with prosthetic mitral valve and ventricular dysfunction and/or arrhythmias
- Updated and added new references

Review Date: August 2020

Review Summary:

- For prosthetic valve with TTE specified routine surveillance as ≥ 3 yrs. (after valve implantation) of prosthetic valve or native valve repair
- Valvular dysfunction defined as including but not limited to:

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- Chest pain
- Shortness of breath
- New or increased murmur on heart examination
- Clarified syncope can be either known or suspected
- Further definition of ECG evidence of prior MI (pathologic Q waves) defined as below:
 - > 40 ms (1 mm) wide
 - > 2 mm deep]
 - > 25% of depth of QRS complex
- Added 12 months to the following statement: 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
- For heart failure removed the requirement for a clear precipitating change in medication or diet.
- Further defined signs/symptoms suggestive of VAD-related complications as including but not limited to:
 - TIA or stroke
 - Infection
 - Murmur suggestive of aortic insufficiency
 - Worsening heart failure
- 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

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93312 – Transesophageal Echocardiology (TEE)

CPT codes: 93312, 93313, 93314, 93315, 93316, 93317, 93318, +93320, +93321, +93325

INDICATIONS FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)

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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted

General Criteria (Doherty, 2019; Flachskampf, 2014; Hahn, 2013; Lancelotti, 2013; Ogbara, 2011)

- 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

Aortic Pathology

- Suspected acute aortic pathology such as aortic dissection (Bhave, 2018; Doherty, 2019)
- Dilated aortic sinuses or ascending aorta on TTE
- 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 have not been done

Valvular Disease (Doherty, 2017; Nishimura, 2014)

- Discordance between clinical assessment and TTE assessment of the severity of mitral regurgitation (MR)
- 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)
- Evaluation of native or prosthetic valves with clinical signs or symptoms suggesting valve dysfunction, when TTE is inadequate
- Re-evaluation of known prosthetic valve dysfunction when it would change management or guide therapy, (and TTE is inadequate)

Infective Endocarditis (Doherty, 2017; Douglas, 2011; Saric, 2016)

- Suspected infective endocarditis (IE) of native valve, prosthetic valve, or endocardial lead with positive blood culture or new murmur

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- Moderate to high pretest probability of IE (i.e. staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device) when TTE is negative
- 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)
- Re-evaluation of IE if the patient is at high risk for progression/complications or when the findings would 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 (Doherty, 2018)
- Evaluation of cardiac mass, suspected tumor or thrombus (Doherty, 2017; Saric, 2016)
- Re-evaluation of prior TEE finding for interval change (e.g. resolution of thrombus after anticoagulation), when the findings would change therapy

Atrial Fibrillation/Flutter (Doherty, 2019)

- Evaluation for clinical decision-making regarding anticoagulation, cardioversion, and/or radiofrequency ablation

TAVR (Transcatheter Aortic Valve Replacement/Repair) (Doherty, 2017; Otto, 2017)

- Pre-procedural assessment of annular size and shape, number of cusps, and degree of calcification, when computed tomography (CT) or CMR 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 (Doherty, 2019; Sachdeva, 2020)

- 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 (Doherty, 2019)

- Evaluation for anatomy, potential cardiac source of emboli, and suitability for percutaneous occlusion device placement
- Surveillance at 45 days or FDA guidance/guidelines for follow-up to assess device stability and device leak, and exclude migration, displacement, or erosion

Percutaneous Mitral Valve Repair (Doherty, 2017)

- Determination of patient eligibility for percutaneous mitral valve procedures
- Pre-procedural evaluation for percutaneous mitral valve procedures may be performed in addition to CT imaging (Wunderlich, 2018)
- To exclude the presence of intracardiac mass, thrombus, or vegetation prior to (within 3 days of) the procedure

Adult Congenital Heart Disease (Sachdeva, 2020; Stout, 2018)

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- Imaging with provocative maneuvers (Valsalva, cough) to assess for the presence of right-to-left cardiac shunt
- Evaluation prior to planned repair of the following lesions when TTE, CMR, or CT are not adequate:
 - Isolated secundum atrial septal defect
 - Sinus venosus defect and/or partial anomalous pulmonary venous connection
 - Congenital mitral stenosis or mitral regurgitation
 - Subvalvular aortic stenosis
 - Transposition of the Great Arteries
- 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

Ventricular Assist Devices (Doherty, 2019; Stainback, 2015)

- Preoperative evaluation of suitability for ventricular assist device (VAD)
- Re-evaluation for VAD-related complication or suspected infection

BACKGROUND:

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).

Abbreviations

AR	aortic regurgitation
CMR	cardiac magnetic resonance
CT(A)	computed tomography (angiography)
IE	infective endocarditis
MR	mitral regurgitation
MRI	magnetic resonance imaging
TEE	transesophageal echocardiography
TTE	transthoracic echocardiography
VAD	ventricular assist device

POLICY HISTORY:

Review Date: July 26, 2019

Review Summary:

- For ventricular assist devices added indication for re-evaluation for VAD-related complication or suspected infection
- Aortic Pathology section rewritten as follows:
 - Suspected acute aortic pathology such as aortic dissection (Bhave 2018, Doherty 2019)
 - Dilated aortic sinuses or ascending aorta on transthoracic echocardiogram (TTE)

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- 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 have not been done
- Added infective endocarditis indication for moderate to high pretest probability of IE (i.e. staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device) when TTE is negative
- For cardiac mass or source of emboli added indication for re-evaluation of prior TEE finding for interval change (e.g., resolution of thrombus after anticoagulation) when the findings would change therapy
- Added indications for Patent Foramen Ovale or Atrial Septal Defect as follows:
 - 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
- Added indications for Left Atrial Appendage Occlusion as follows:
 - Evaluation for anatomy, potential cardiac source of emboli, and suitability for percutaneous occlusion device placement
 - Surveillance at 45 days or FDA guidance/guidelines for follow-up to assess device stability and device leak, and exclude migration, displacement, or erosion
- Added indications for Adult Congenital Heart Disease as follows:
 - Imaging with provocative maneuvers (Valsalva, cough) to assess for the presence of right-to-left cardiac shunt
 - Evaluation when TTE, CMR, or CTA are not adequate in the setting of:
 - Pulmonary venous connections with ASD
 - Aortic imaging in Williams syndrome or patient suspected of having supralvalvular stenosis
 - Surgical planning for Ebstein’s anomaly
 - Evaluation of baffle leak after atrial switch repair for d-Transposition of the Great Arteries
 - Removed section on “Frequency of Echo Studies”

Review Date: March 2020

Review Summary:

- Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review.
- Added specific indication for initial evaluation of patient to exclude cardiac origin of TIA or ischemic stroke
- Updated indications for Congenital Heart Disease to include the following:
 - Evaluation prior to planned repair of the following lesions when TTE, CMR, or CT are not adequate:
 - Isolated secundum atrial septal defect
 - Sinus venosus defect and/or partial anomalous pulmonary venous connection
 - Congenital mitral stenosis or mitral regurgitation

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- Subvalvular aortic stenosis
- Transposition of the Great Arteries
- 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
- Updated and added new references

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93350 – Stress Echocardiography

CPT Codes: 93350, 93351, +93320, +93321, +93325, +93352, +93356

INDICATIONS for STRESS ECHO

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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

SUSPECTED CORONARY ARTERY DISEASE (CAD)

Symptomatic patients without known CAD (use Diamond Forrester table)

- Low or intermediate pretest probability, and electrocardiogram (ECG) is uninterpretable
- High pretest probability
- 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

- Evidence of possible myocardial ischemia which was not seen on prior EKG including but not limited to:
 - Ischemic ST segment or T wave abnormalities (See Overview Section)
 - Q waves
 - Complete left bundle branch block

INCONCLUSIVE CAD EVALUATION WITHIN THE PAST 2 YEARS AND OBSTRUCTIVE CAD REMAINS A CONCERN

- Exercise stress ECG with low risk Duke treadmill score ≥ 5 , but patient's current symptoms indicate an intermediate or high pretest probability
- Exercise stress ECG with an intermediate Duke treadmill score
- Intermediate coronary computed tomography angiography (CCTA) defined as:
 - 30 -70% lesion

FOLLOW-UP OF PATENTS POST CORONARY REVASCULARIZATION (PCI or CABG)

(Doherty, 2019)

- Asymptomatic follow-up stress imaging (MPI or SE), 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 a history of silent ischemia or a history of a prior left main stent (Wolk, 2014)

OR

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- For patients with high occupational risk including any of the following:
 - 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 is an indication for stress imaging

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 stenosis greater than or equal to 70% of a major vessel), over two years ago without intervening coronary revascularization, is an appropriate indication for stress imaging (MPI or SE)

SPECIAL DIAGNOSTIC CONDITIONS REQUIRING CORONARY EVALUATION

- Prior acute coronary syndrome (with documentation in MD notes), within last three months, without a prior stress test or coronary angiography performed since that time
- Newly diagnosed systolic heart failure (EF < 50%), when invasive coronary angiography has not been performed, especially when symptoms or signs of ischemia are present or suspected such as:
 - Chest pain
 - EKG changes such as new ST segment depression or T wave inversions
 - New wall motion abnormalities
- Ventricular arrhythmias:
 - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise induced VT, when invasive coronary arteriography has not been performed (Al-Khatib, 2018)
 - Nonsustained VT, multiple episodes, each \geq 3 beats at \geq 100 bpm, frequent VPC's (defined as greater than or equal to 30/hour on remote monitoring), when an exercise ECG cannot be performed (Zimetbaum, 2018)
- Prior to Class IC antiarrhythmic drug initiation (Propafenone or Flecainide), in intermediate and high global risk patients (Reiffel, 2015)
- Hemodynamic Assessment of ischemia in one of the following documented conditions:
 - Anomalous coronary arteries in an asymptomatic individual without prior stress echocardiography (Grani, 2017);
 - Myocardial bridging of a coronary artery (perform with exercise stress) (Tang, 2011);
- Coronary aneurysms in Kawasaki's disease (McCrinkle, 2017)
- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter (Lancellotti, 2013)

CHRONIC VALVULAR DISEASE

Evaluation with Inclusion of Doppler

(Baumgartner, 2017; Bonow, 2020; Nishimura, 2014; Steiner, 2017)

- Dobutamine SE 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%
- Exercise echo Doppler evaluation for 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
- Exercise echo Doppler 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; **OR**
 - The echocardiogram is not able to distinguish whether the MR is moderate or severe in a patient that is asymptomatic

PRIOR TO ELECTIVE NON-CARDIAC SURGERY

(Fleischer, 2014; Patel, 2015)

- Patients who would otherwise not be planned for a non-invasive coronary evaluation, but are referred for preoperative cardiac evaluation, are eligible for SE if **ALL 4** criteria are met:
 - Surgery is supra-inguinal vascular, intrathoracic, or intra-abdominal; **AND**
 - The patient has **at least one** of these additional cardiac complication risk factors:
 - Ischemic Heart Disease
 - History of stroke or transient ischemic attack (TIA)
 - History of congestive heart failure (CHF) or ejection fraction $\leq 35\%$
 - Insulin-requiring diabetes mellitus
 - Creatinine ≥ 2.0 mg/dl
- AND**
 - The patient has limited functional capacity (< 4 metabolic equivalents) such as one of the following (would likely be requested as MPI):
 - Cannot take care of their ADLs which include but not limited to:
 - Independently eating, bathing or ambulating
 - Cannot walk 2 blocks on level ground
 - Cannot climb 1 flight of stairs
- AND**
 - There has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, and the results would be likely to preclude proceeding with the intended surgery
- Planning for solid organ transplantation (liver or kidney), is an indication for preoperative dobutamine SE, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year and **with ≥ 3** of the following risk factors (Lentine, 2012):
 - Age > 60

- Smoking
- Hypertension
- Dyslipidemia
- Left ventricular hypertrophy
- > 1 year on dialysis (for renal transplant patients)
- Diabetes mellitus
- Prior ischemic heart disease

POST CARDIAC TRANSPLANTATION

- Annually, for the first five years post cardiac transplantation, in a patient not undergoing invasive coronary arteriography
- After the first five years post cardiac transplantation, patients with transplant coronary vasculopathy can be screened annually with **ONE** of the following:
 - MPI
 - SE
 - Left heart catheterization

BACKGROUND:

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).

Stable patients without known CAD fall into 2 categories:
(Fihn, 2012; Montalescot, 2013; Wolk, 2013)

- **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 3 Types of Chest Pain or Discomfort:

- **Typical Angina (Definite)** is defined as including all **3** of these characteristics:

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- Substernal chest pain or discomfort with characteristic quality and duration such as
 - Pressure-like
 - Radiating
 - Dull or aching
- 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

Once the type of chest pain has been established from the medical record, 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 (Fihn, 2012; Wolk, 2013):

Diamond Forrester Table

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 (Fihn, 2012)
- **Low:** 5 - 10% pretest probability of CAD
- **Intermediate:** 10% - 90% pretest probability of CAD
- **High:** > 90% pretest probability of CAD

OVERVIEW

MPI may be performed without diversion to SE in any of the following (Henzlova, 2016; Wolk, 2013):

- 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)
 - Obesity with body mass index (BMI) over 40 kg/m² or 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)
 - Arrhythmia risk with exercise

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 (Wolk, 2013):

- The (symptomatic) low or intermediate pretest probability patient who is able to exercise and has an interpretable ECG
- The (asymptomatic) high global risk patient who can exercise and has an interpretable ECG
- The patient who is under evaluation for exercise induced arrhythmia (Al-Khatib, 2017)
- The patient who requires an entrance stress test ECG for a cardiac rehab program or for an exercise prescription.

Duke Exercise ECG Treadmill Score (Mark, 1987)

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 (Fihn, 2012):

- ST segment depression 1 mm or more; (not for non-specific ST- T wave changes)
- Ischemic looking T wave -- at least 2.5 mm inversions (excluding V1 and V2)
- LVH, 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, or patients with a CAC score > 400 Agatston units, when global risk is moderate or high.

- **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*

*Patients who have known CAD are already at high global risk and are not applicable to the calculators (Arnet, 2019; D’Agostino, 2008; Goff, 2014; McClelland, 2015; Ridker, 2007).

Risk Calculator	Link to Online Calculator
Framingham Cardiovascular Risk	https://reference.medscape.com/calculator/framingham-cardiovascular-disease-risk
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

Definitions of Coronary Artery Disease

(Fihn, 2012; Mintz, 2016; Montalescot, 2013; Patel, 2017; Tobis, 2007)

- Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and refers to cross sectional narrowing when IVUS (intravascular ultrasound) is the method of determination
- 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, for which revascularization might be appropriate), generally implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; borderline lesions are 40 - 70% (Fihn, 2012; Tobis, 2007)
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ or minimum lumen cross sectional area on IVUS ≤ 6 square mm (Fihn, 2012; Lofti, 2018; Mintz, 2016)
 - FFR (fractional flow reserve) ≤ 0.80 for a major vessel (Lofti, 2018; Mintz, 2016)
 - iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel (Davies, 2017; Gotberg, 2017; Lofti, 2018)
- 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.
- iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel (Davies, 2017; Gotberg, 2017)

Anginal Equivalent

(Fihn, 2012; Moya, 2009; Shen, 2017)

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.

Abbreviations

AAD	Antiarrhythmic drug
ADLs	Activities of daily living
BSA	Body surface area in square meters
CAD	Coronary artery disease
ECG	Electrocardiogram
FFR	Fractional flow reserve

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LBBB	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
PFT	Pulmonary function test
PVCs	Premature ventricular contractions
SE	Stress echocardiography
VT	Ventricular tachycardia
VF	Ventricular fibrillation
WPW	Wolf Parkinson White

POLICY HISTORY:

Review Date: July 23, 2019

Review Summary:

- Stress echo for suspected CAD deleted the following indication: Repeat testing in patient with recurrent symptomatic presentation and negative result over 2 years ago
- Added indications: ‘For assessment of hemodynamic significance due to atherosclerosis or following radiation therapy to the anterior or left chest, at 5 years post initiation inception of radiation and every 5 years thereafter’; and ‘Following radiation therapy to the anterior or left chest, at 5 years post initiation inception of radiation and every 5 years thereafter’
- Removed secondary mitral regurgitation indication under doppler evaluation section
- Clarified indication as follows: 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 less than or equal to 0.80 or stenosis greater than or equal to 70% of a major vessel) over two years ago without intervening coronary revascularization is an appropriate indication for stress imaging (MPI or SE) in patients if it will alter management

November 2019

- Added CPT code +93356

Review Date: March 2020

Review Summary:

- Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review
- Added clarification of repeat testing in a patient with new or worsening symptoms and negative result at least one year prior to include the statement “AND meets one of the criteria above”
- Added clarification of frequent PVCs under ventricular arrhythmias which states defined as greater than or equal to 30/hour to include “on remote monitoring”

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- Edited indication of planning for solid organ transplantation to remove the requirement of limited functional capacity but maintaining requirement of ≥ 3 listed risk factors
- Added edits to the Coronary Artery Disease definition section
- Updated and added new references

Review Date: August, 2020

Review Summary:

- For asymptomatic patients without a history of CAD, the wording for previously unevaluated was changed for Q waves and complete BBB
- For newly diagnosed systolic heart failure (EF < 50%), when invasive coronary angiography has not been performed, especially when symptoms or signs of ischemia are present or suspected were further defined to state such as:
 - Chest pain
 - EKG changes such as new ST segment depression or T wave inversions
 - New wall motion abnormalities
- Stress echo with Doppler indication further defined as exertional shortness of breath which suggests the amount of MS is worse than is seen on the resting echocardiogram
- After the first five years post cardiac transplantation, patients with transplant coronary vasculopathy can be screened annually with ONE of the following:
 - MPI
 - SE
 - Left heart catheterization

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93452 – Heart Catheterization

CPT Codes: 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, +93462, +93463, +93464, +93565, +93566, +93567, +93568

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. All prior relevant imaging results, and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

INDICATIONS FOR INVASIVE CORONARY ARTERIOGRAPHY

(Fihn, 2012, 2014; Patel, 2012, 2017; Wolk, 2013)

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 several minutes of ST segment depression post exercise (Patel, 2012).
- Stress imaging with high risk findings (see Overview section)
- Stress imaging with intermediate risk findings (see Overview section) in a patient with one of the following:
 - Symptoms consistent with ischemia (Patel, 2012)
 - Unsatisfactory quality of life due to angina (Fihn, 2012)
 - Ejection fraction (EF) $< 50\%$ (Fihn, 2012)
- Non-invasive test with low risk findings with new, worsening, or limiting symptoms with reasonable suspicion of cardiac origin despite optimal medical therapy (OMT) or inability to tolerate OMT (Fihn, 2012, 2014; Patel, 2012)
- New, worsening, or limiting symptoms, with known unrevascularized obstructive coronary artery disease (CAD), in a patient eligible for revascularization (Fihn, 2012, 2014)
- Discordant, equivocal, or inconclusive non-invasive evaluation in patients with suspected symptomatic stable ischemic heart disease, including the following (Montalescot, 2013; Patel, 2012; Wolk, 2013):
 - Low risk stress imaging with high risk stress ECG response or stress induced typical angina (Patel, 2012)
 - Equivocal, uninterpretable, or inconclusive stress imaging due to issues of attenuation or other problems with interpretability (Fihn, 2012; Patel, 2012)

CCTA Abnormalities

- Symptomatic patient with one of the following (Fihn, 2012; Patel, 2012, 2017):

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- One vessel CAD with $\geq 70\%$ stenosis
- Two or three vessel CAD with moderate stenosis (50% to 69% stenosis)
- A stenosis $\geq 30\%$ with FFR-CT ≤ 0.8 (Douglas, 2016)
- Any patient with evidence of $\geq 50\%$ left main stenosis

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 (Fihn, 2012; Patel, 2012, 2013; Wolk, 2013; Yancy, 2013):
 - Newly recognized reduction in EF to $\leq 50\%$, with intermediate risk findings on noninvasive testing and symptoms or signs of ischemia
 - Newly recognized reduction in EF to $\leq 40\%$ with evidence of viability on stress imaging
 - Symptomatic heart failure or ischemia with new, unexplained wall motion abnormality (Fihn, 2012; Patel, 2012)
 - 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 (Sarda, 2010)

Ventricular Arrhythmias

- Ventricular Arrhythmias, without identified non-cardiac cause:
 - Following recovery from unexplained sudden cardiac arrest (Al-Khatib, 2017)
 - Sustained VT or VF (Patel, 2012)
 - Exercise-induced non-sustained VT in a patient with signs or symptoms of ischemia (Patel, 2012)

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 (Doherty, 2017; Nishimura, 2014, 2017; Rame, 2016; Svensson, 2013):
 - 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
 - Chronic severe secondary mitral regurgitation
 - Requirement for detailed assessment of coronary artery anatomy prior to aortic valve homograft surgery, pulmonary autograft (Ross procedure), or aortic root procedure

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- Patients undergoing transcatheter aortic valve replacement (TAVR) or other transcatheter valve procedures

Post Cardiac Transplantation

(Costanzo, 2010)

- Assessment for allograft vasculopathy annually for the first 5 years, followed by annual assessment in those with documented allograft vasculopathy, if stress imaging has not been performed
- Assessment of change in clinical status, including any of the following, if stress imaging has not been performed:
 - New left ventricular dysfunction
 - Symptoms of ischemia
 - Non-invasive findings of ischemia

Hemodynamic Assessment*

- Indications for angiographic and/or hemodynamic assessment of valvular function or shunt physiology (Doherty, 2017; Patel, 2012; Stout, 2018)
 - Assessment of bioprosthetic valve when transthoracic echocardiography (TTE) and transesophageal electrocardiography (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 CCT 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 (Patel, 2012; Stout, 2018)
 - 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

**** These guidelines only cover procedures that include left heart catheterization. NIA does not manage right heart catheterization as a stand-alone procedure.**

BACKGROUND:

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 (Fihn, 2012; Lotfi, 2018; Montalescot, 2013; Wolk, 2013).

This guideline applies to patients with a stable clinical presentation, not to those with acute coronary 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.

Stable Patients without Known CAD fall into 2 categories (Fihn, 2012; Montalescot, 2013; Wolk, 2013):

- **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

Once the type of chest pain has been established from the medical record, 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 (Fihn, 2012; Wolk, 2013).

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

(Fihn, 2012; Patel, 2017)

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 ≥ 10%)
- Stress-induced perfusion abnormalities involving ≥ 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 (Weiss, 1987)
- Inducible wall motion abnormality (involving > 2 segments or 2 vascular territories)

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- Wall motion abnormality developing at low dose of dobutamine (≤ 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
- ≥ 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
- Small wall motion abnormality involving 1 to 2 segments and only 1 vascular territory
- CAC score 100 to 399 Agatston units (only for use in primary prevention, not for heart catheterization decision making) (Fihn, 2012; Goff, 2014; Montalescot, 2013; Patel, 2012)
- One vessel CAD with $\geq 70\%$ stenosis or moderate CAD stenosis (50% to 69% stenosis) in ≥ 2 arteries on CCTA

Low risk (< 1% annual death or MI)

- Low-risk treadmill score (score ≥ 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) (Fihn, 2012; Goff, 2014; Montalescot, 2013; Patel, 2012)
- 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. **High global risk by itself generally lacks scientific support as an indication for stress imaging** (Douglas, 2018). 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.

- **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*

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

(Arnet, 2019, D’Agostino, 2008; Goff, 2014; McClelland, 2015; Ridker, 2007)

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

Definitions of Coronary Artery Disease

(Fihn, 2012; Mintz, 2016; Montalescot, 2013; Patel, 2017)

- 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, for which revascularization might be appropriate) generally implies at least one of the following:
 - Suggested by percentage diameter stenosis $\geq 70\%$ by angiography; borderline lesions are 40 - 70% (Fihn, 2012)
 - For a left main artery, suggested by a percentage stenosis $\geq 50\%$ or minimum luminal cross-sectional area on IVUS ≤ 6 square mm (Fihn, 2012, Lotfi, 2018, Mintz, 2016)

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- FFR (fractional flow reserve) ≤ 0.80 for a major vessel (Lotfi, 2018; Mintz, 2016)
- iFR (instantaneous wave-free ratio) ≤ 0.89 for a major vessel (Davies, 2017; Gotberg, 2017; Lotfi, 2018)
- 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 (Gotberg, 2017; Davies, 2017)

Anginal Equivalent

(Fihn, 2012; Moya, 2009; Shen, 2017)

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.

Abbreviations

CAC	Coronary artery calcium
CAD	Coronary artery disease
CCT	Cardiac computed tomography
CCTA	Coronary computed tomographic angiography
CMR	Cardiac magnetic resonance
LV	Left ventricular
LVEF	Left ventricular ejection fraction
MI	Myocardial infarction
MR	Mitral regurgitation
TAVR	Transcatheter aortic valve replacement
TTE	Transthoracic echocardiography
TEE	Transesophageal echocardiography
VT	Ventricular tachycardia
VF	Ventricular fibrillation

POLICY HISTORY:

Review Date: August 14, 2019

Review Summary:

- Added indications for new heart failure/ cardiomyopathy/wall motion abnormality, in patients who are candidates and would be eligible for coronary revascularization including one of the following:
 - Newly recognized reduction in ejection fraction to $\leq 50\%$, with intermediate risk findings on noninvasive testing and symptoms or signs of ischemia
 - Newly recognized reduction in ejection fraction to $\leq 40\%$ with evidence of viability on stress imaging
- Removed indication for diastolic heart failure, when symptoms, signs or stress imaging provides evidence of contributory ischemia
- Clarified indication for evaluation of coronary anatomy prior to TAVR
- Clarified indication for assessment of allograft vasculopathy if stress imaging has not been performed
- Clarified indications for assessment of hemodynamics in heart failure, cardiomyopathy or adult congenital heart disease.

Review Date: March 2020

Review Summary:

- Added general information section as Introduction which outlines requirements for documentation of pertinent office notes by a licensed clinician, and inclusion of laboratory testing and relevant imaging results for case review
- Added indication for coronary angiography prior to transcatheter valve procedures in addition to transcatheter aortic valve replacement (TAVR)
- Added edits to the Coronary Artery Disease definition section
- Updated and added new references

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