2018-2019 Magellan Clinical Guidelines for Medical Necessity Review

MUSCULOSKELETAL AND SURGERY GUIDELINES

HAWAI’I MEDICAL SERVICE ASSOCIATION (HMSA)

Effective: July 1, 2018
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. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new 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 for the purpose of making clinical review determinations for requests for diagnostic tests. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, and cardiology. They were developed following a literature search pertaining to established clinical guidelines and accepted diagnostic imaging practices.

All inquiries should be directed to:
Magellan Healthcare
6950 Columbia Gateway Drive
Columbia, MD 21046
Attn: Magellan Associate Chief Medical Officer
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MUSCULOSKELETAL & SURGERY GUIDELINES

22612/63030 – Lumbar Spinal Surgery

CPT Codes:
- Lumbar Fusion (Single level) = 22533, 22558, 22612, 22630, 22633 Plus Decompression
- Lumbar Fusion (Multiple levels) = 22533, +22534, 22558, +22585, 22612, +22614, 22630, +22632, 22633, +22634 (+indicates multiple levels) Plus Decompression
- Lumbar Decompression = 63030, +63035, 63005, 63012, 63017, 63042, +63044, 63047, +63048, 63056, +63057
- Lumbar Discectomy/Microdiscectomy = 63030, +63035, 62380
- Lumbar Artificial Disc Replacement = 22857, 22862, 22865

OVERVIEW:
This guideline outlines the key surgical treatments and indications for common lumbar spinal disorders and is a consensus document based upon the best available evidence. Spine surgery is a complex area of medicine and this document breaks out the treatment modalities for lumbar spine disorders into surgical categories: lumbar discectomy/microdiscectomy, lumbar decompression, and lumbar fusion surgery. See the additional information section for procedures considered not medically necessary.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

INTRODUCTION
I. **Lumbar Discectomy/Microdiscectomy** is a surgical procedure to remove part of the damaged spinal disc. The damaged spinal disc herniates into the spinal canal and compresses the nerve roots. Nerve root compression leads to symptoms like low back pain, radicular pain, numbness and tingling, muscular weakness, and paresthesia. Typical disc herniation pain is exacerbated with any movement that causes the disc to increase pressure on the nerve roots.

II. **Lumbar Decompression (Laminectomy, Laminotomy, Facetectomy, and Foraminotomy):** Laminectomy is a common decompression surgery. The American Association of Neurological Surgeons defines laminectomy as a surgery to remove the back part of vertebra, lamina, to create more space for the spinal cord and nerves. The most common indication for laminectomy is spinal stenosis. Spondylolisthesis and herniated disk are also frequent indications for laminectomy. Decompression surgery is usually performed as part of lumbar fusion surgery.

III. **Lumbar Fusion Surgery:** Lumbar spinal fusion (arthrodesis) is a surgical procedure used to treat spinal conditions of the lumbar, e.g., degenerative disc disease, spinal stenosis,
injuries/fractures of the spine, spinal instability, and spondylolisthesis. Spinal fusion is a “welding” process that permanently fuses or joins together two or more adjacent bones in the spine, immobilizing the vertebrae and restricting motion at a painful joint. It is usually performed after other surgical procedures of the spine, such as discectomy or laminectomy. The goal of fusion is to increase spinal stability, reduce irritation of the affected nerve roots, compression on the spinal cord, disability, and pain and/or numbness. Clinical criteria for single level fusion versus multiple level fusions are outlined under the indications section.

INDICATIONS FOR LUMBAR SURGERY: (This section of the clinical guidelines provides the clinical criteria for each of the lumbar and pre-sacral spine surgery categories.)

I. Indications for Lumbar Discectomy/Microdiscectomy: Surgical indications for inter-vertebral disc herniation*:

a) When ALL of the following are present:
   i) Primary radicular symptoms noted upon clinical exam that significantly hinders daily activities (Chou 2009; Kreiner 2014; Peul 2007; Tosteson 2011): AND
   ii) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative treatment to include at least 2 of the following (Kreiner 2013; Kreiner 2014; Peul 2007):
       1) Analgesics, steroids, and/or NSAIDs
       2) Structured program of physical therapy
       3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
       4) Epidural steroid injections and or selective nerve root block: AND
   iii) Imaging studies showing evidence of inter-vertebral disc herniation that correlate exactly with the patient’s symptoms / signs (Fardon 2001; Kreiner 2014).

OR

*Other indications: Microdiscectomy may be used as the first line of treatment (no conservative treatment required) in the following clinical scenarios (Kreiner 2014):

b) Progressive nerve compression resulting in an acute motor neurologic deficit sensory or motor due to herniated disc. The neurological deficits should be significant: 0-2/5 on the motor function scale for L5 or S1 roots; 0-3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with conservative treatment and are not considered an indication for early surgery;

OR

c) Cauda equina syndrome (loss of bowel or bladder control).

NOTE: Percutaneous lumbar discectomy, radiofrequency disc decompression, and related procedures are deemed investigational procedures and are not approved. Discectomy and microdiscectomy are the gold standards.
II. Indications for Lumbar Decompression: Laminectomy, Laminotomy, Facetectomy, and Foraminotomy. These procedures allow decompression by partial or total removal of various parts of vertebral bone and ligaments. Surgical Indications for spinal canal decompression due to lumbar spinal stenosis*:

a) When **ALL of the following** are present:
   ii) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative therapy to include **at least two (2) of the following** (Kreiner 2013; Peul 2007):
      1) Analgesics, steroids, and/or NSAIDs
      2) Structured program of physical therapy
      3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
      4) Epidural steroid injections and or selective nerve root block; **AND**
   iii) Imaging findings demonstrating moderate to severe stenosis consistent with clinical signs/symptoms (Genevay 2010; Kreiner 2013; Weinstein 2007).

OR

**Other Indications**: Lumbar decompression may be used as the first line of treatment (**no conservative treatment required**) in any of the following clinical scenarios (Kreiner 2013; Kreiner 2014):

b) Progressive nerve compression resulting in an acute neurologic (sensory or motor) deficit. The neurological deficits should be significant—0-2/5 on the motor function scale for L5 or S1 roots; 0-3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with conservative treatment and are not considered an indication for early surgery;

OR

c) Cauda equina syndrome (loss of bowel or bladder control);

OR

d) Spinal stenosis due to tumor, infection, or trauma

**NOTE**: Percutaneous decompressions, endoscopic decompression, and related procedures (laser, etc.) are deemed investigational procedures and are not approved. Open or microdecompressions via laminectomy or laminotomy are the gold standards (Kreiner 2014).

III. Indications for Lumbar Spine Fusion:

A. Single Level Fusion with or without decompression

Because of variable outcomes with fusion surgery, patients should be actively involved in the decision-making process and provided appropriate decision-support materials when considering this intervention.

a) When **All of the following** are present*:
a) Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for at least 6 months (Bogduk 2009; Brox 2003; Carreon 2008; Chou 2009; Fritzell 2001; Kreiner 2013; Mannion 2016; Matz 2014; NASS 2009; Resnick 2005; Tosteson 2011; Tosteson 2008; Weinstein 2007): **AND**

b) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative therapy (six months for isolated LBP) to include at least two (2) of the following (Brox 2003; Chou 2009; Kreiner 2013; Matz 2014; NASS 2009; Resnick 2005):  
1) Analgesics, steroids, and/or NSAIDs  
2) Structured program of physical therapy  
3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician  
4) Epidural steroid injections and or facet injections /selective nerve root block: **AND**

c) Imaging studies corresponding to the clinical findings (Genevay 2010; Kreiner 2013; Matz 2014; NASS 2009; Resnick 2005; Weinstein 2007): **AND**

d) At least one of the following clinical conditions:
2) Evidence of segmental instability -Excessive motion, as in degenerative spondylolisthesis, segmental instability, and surgically induced segmental instability (Carreon 2008; Kwon 2005; Matz 2014: NASS 2009; Weinstein 2007): OR
3) Revision surgery for failed previous operation(s) for pseudoarthrosis at the same level at least 6-12 months from prior surgery** if significant functional gains are anticipated(Trumeees 2017): OR
4) Revision surgery for failed previous operation(s) repeat disk herniations if significant functional gains are anticipated (Note: Many recurrent disc herniations can be treated with discectomy alone, so specific indications for the addition of fusion will be required) (Kreiner 2014): OR
5) Fusion for the treatment of spinal tumor, cancer, or infection (Trumeees 2017): OR
6) Chronic low back pain or degenerative disc disease (disc degeneration without significant neurological compression presenting with low back pain) must have failed at least 6 months of appropriate active non-operative treatment (completion of a comprehensive cognitive -behavioral rehabilitation program is mandatory) and must be evaluated on a case-by-case basis (Bogduk 2009; Brox 2003; Chou 2009; Fardon 2001; Fritzell 2001; Mannion 2016).

**NOTE:** The results of several randomized trials suggests that in many degenerative cases uninstrumented posterolateral intertransverse fusion has similar results to larger instrumented (PLIF, TLIF, etc.) fusion techniques with fewer morbidities and less likelihood of revision surgery. Accordingly, specific findings suggesting more significant instability should be present when larger techniques are used (gaping of facets, gross motion on flexion / extension radiographs, wide disc spaces) (Carreon 2008; Deyo 2010).

**OR**
**Other Indications**: Lumbar spinal fusion may be used as the first line of treatment (*no conservative treatment required*) in the following clinical scenarios (Kreiner 2014):

b) Progressive nerve compression resulting in an acute neurologic deficit (motor): **AND**
   - One of the aforementioned clinical conditions, *except* chronic low back pain or degenerative disc disease. The neurologic deficits must be significant: 0–2/5 on the motor function scale for L5 or S1 roots; or 0–3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with conservative treatment and are not considered an indication for early surgery.

c) Cauda equina syndrome (loss of bowel or bladder control): **AND**
   - One of the aforementioned clinical conditions, *except* chronic low back pain or degenerative disc disease.

**REPEAT LUMBAR SPINE FUSION OPERATIONS**: Repeat lumbar fusion operations will be reviewed on a case-by-case basis upon submission of medical records and imaging studies that demonstrate remediable pathology. The below must also be documented and available for review of repeat fusion requests (Bogduk 2009; Chou 2009; Mannion 2016):

1) Rationale as to why surgery is preferred over other non-invasive or less invasive treatment procedures.
2) Signed documentation that the patient has participated in the decision-making process and understands the high rate of failure/complications.

Instrumentation, bone formation or grafting materials, including biologics, should be used at the surgeon’s discretion; however, use should be limited to FDA approved indications regarding the specific devices or biologics.

**NOTE**: Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is not an approved surgical approach due to insufficient evidence. Artificial lumbar disc replacement or other lumbar implants are not an approved procedure due to insufficient evidence.

B. Multi-level Fusion with or without decompression (all multi-level fusion surgeries will be reviewed on a case-by-case basis).

Because of variable outcomes with fusion surgery, patients should be actively involved in the decision-making process and provided appropriate decision-support materials when considering this intervention.

a) When **ALL of the following** are present*:

i) Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for at least 6 months (Bogduk 2009; Brox 2003; Chou 2009; Fritzell 2001; Mannion 2016; Tosteson 2011; Tosteson 2008; Weinstein 2007): **AND**

ii) Failure to improve with at least six (6) consecutive weeks of documented, physician directed appropriate conservative therapy to include at least two (2) of the following (Brox 2003; Matz 2014; NASS 2009):
   1) Analgesics, steroids, and/or NSAIDs
2) Structured program of physical therapy
3) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
4) Epidural steroid injections and or facet injections /selective nerve root block: AND

iii) Imaging studies corresponding to the clinical findings (Genevay 2010; Kreiner 2013; Matz 2014; NASS 2009; Resnick 2005; Weinstein 2007): AND

iv) At least one of the following clinical conditions (Carreon 2008; Kwon 2005; Matz 2014; NASS 2009):
   1) Multiple level spondylolisthesis (Note: Fusions in cases with single level spondylolisthesis should be limited to the unstable level); OR
   2) Fusion for the treatment of spinal tumor, trauma, cancer, or infection affecting multiple levels; OR
   3) Intra-operative segmental instability

OR

*Other Indications:* Lumbar spinal fusion may be used as the first line of treatment (no conservative treatment required) in the following clinical scenarios (Kreiner 2014):

b) Progressive nerve compression resulting in an acute neurologic deficit (motor): AND
   - One of the aforementioned clinical conditions except chronic low back pain or degenerative disc disease. The neurological deficits must be significant: 0-2/5 on the motor function scale for L5 or S1 roots; or 0-3/5 for L3 or L4 roots. Lesser degrees of motor dysfunction may resolve with appropriate conservative treatment and are not considered an indication for early surgery.

OR

c) Cauda equina syndrome (loss of bowel or bladder control): AND
   - One of the aforementioned clinical conditions, except chronic low back pain or degenerative disc disease.

NOTE: Instrumentation, bone formation or grafting materials, including biologics, should be used at the surgeon’s discretion; however, use should be limited to FDA approved indications regarding the specific devices or biologics.

NOTE: This lumbar surgery guideline does not address spinal deformity surgeries or the clinical indications for spinal deformity surgery.

NOTE: Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is not an approved surgical approach due to insufficient evidence. Artificial lumbar disc replacement or other lumbar implants are not an approved procedure due to insufficient evidence.

IV. CONTRAINDICATIONS FOR SPINE SURGERY (Note: Cases will not be approved if the below contraindications exist):

1) Medical contraindications to surgery, e.g., severe osteoporosis; infection of soft tissue adjacent to the spine and may be at risk for spreading to the spine; severe
cardiopulmonary disease; anemia; malnutrition and systemic infection (Puvanesarajah 2016).

2) **Psychosocial risk factors.** It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sympathetically mediated pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention (Kreiner 2014). Patients with clinically significant depression or other psychiatric disorders being considered for elective spine surgery will be reviewed on a case-by-case basis and the surgery may be denied for risk of failure.

3) **Active Tobacco or Nicotine** use prior to fusion surgery. Patients must be free from smoking and/or nicotine use for at least six weeks prior to surgery and during the entire period of fusion healing (Andersen 2001; Glassman 2000; Patel 2013).

4) **Morbid Obesity.** Contraindication to surgery in cases where there is significant risk and concern for improper post-operative healing, post-operative complications related to morbid obesity, and/or an inability to participate in post-operative rehabilitation (Epstein 2017). These cases will be reviewed on a case-by-case basis and may be denied given the risk of failure.

V. ADDITIONAL INFORMATION

1) **Spinal surgeries should be performed only by those with extensive surgical training (neurosurgery, orthopaedic surgery)**

2) **Services Not Covered:** The following procedures are considered either still under investigation or are not recommended based upon the current evidence: Percutaneous lumbar discectomy; Laser discectomy; Percutaneous Radiofrequency Disc Decompression; intradiscal electrothermal annuloplasty (IDEA) or more commonly called IDET (Intradiscal Electrothermal therapy); Nucleus Pulpous Replacement; Pre-Sacral Fusion, or Lumbar Artificial Disc Replacement.

   a) **PERCUTANEOUS DISCECTOMY** is an invasive operative procedure to accomplish partial removal of the disc through a needle which allows aspiration of a portion of the disc under imaging control. It’s only indication is in order to obtain diagnostic tissue, due to lack of evidence to support long-term improvement compared to gold standard discectomy. This includes radiofrequency disc decompression.

   b) **LASER DISCECTOMY** is a procedure which involves the delivery of laser energy into the center of the nucleus pulposus using a fluoroscopically guided laser fiber under local anesthesia. The energy denatures protein in the nucleus, causing a structural change which is intended to reduce intradiscal pressure. Its effectiveness has not been fully established.

   c) **INTRADISCAL ELECTROTHERMAL ANNULOPLASTY (IDEA) (more commonly called IDET, or Intradiscal Electrothermal therapy)** is an outpatient non-operative procedure in which a wire is guided into the identified painful disc using fluoroscopy. The wire is then heated at the nuclear-annular junction within the disc. It has not been shown to be effective.

   d) **NUCLEUS PULPOSUS REPLACEMENT** Involves the introduction of a prosthetic implant into the intervertebral disc, replacing the nucleus pulposus while preserving
the annulus fibrosus. It has not been shown to be effective relative to other gold standard interventions.

e) **LUMBAR ARTIFICIAL DISC REPLACEMENT:** Involves the insertion of a prosthetic device into an intervertebral space from which a degenerated disc has been removed, sparing only the peripheral annulus. The prosthetic device is designed to distribute the mechanical load of the vertebrae in a physiologic manner and maintain range of motion. Studies do not demonstrate a long-term advantage of measured function or pain over comparison groups undergoing fusion. The longevity of this prosthetic device has not yet been determined.

3) **Conservative Therapy:** (Musculoskeletal) includes primarily physical therapy and/or injections; and a combination of modalities, such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, diathermy, chiropractic treatments, or physician supervised home exercise program. Part of this combination may include the physician instructing patient to rest the area or stay off the injured part.

4) **Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan AND
   b) Follow up with member with information provided regarding completion of HEP (after suitable 4-6 week period), or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

5) **Isolated Low Back Pain** - Pain isolated to the lumbar region of the spine and the surrounding paraspinal musculature. Also referred to ‘mechanical low back pain’ or ‘discogenic pain’. No associated neurogenic claudication or radiculopathy.

6) **Claims Billing & Coding:**
   a) Magellan uses a combination of internally developed edits in addition to an enhanced set of industry standard editing. Magellan’s Claims Edit Module is a group of system edits that run multiple times per day. Edits that are part of this module include industry standard edits that apply to spine surgery services and Magellan custom edits developed specifically for spine surgery. The following describes each of the edits Magellan applies:

7) **Outpatient Code Editor (OCE):** This edit performs all functions that require specific reference to HCPCS codes, HCPCS modifiers, and ICD-9-CM diagnosis codes. The OCE only functions on a single claim and does not have any cross claim capabilities. Magellan is consistent with CMS.

8) **National Correct Coding Initiative (NCCI) editing:** The edit prevents improper payment when incorrect code combinations are reported. The NCCI contains two tables of edits. The Column One/Column Two Correct Coding Edits table and the Mutually Exclusive Edits table include code pairs that should not be reported together for a number of reasons explained in the Coding Policy Manual. Magellan is consistent with CMS.

   a) Incidental edits: This edit applies if a procedure being billed is a component of another procedure that occurred on the same date of service for the same provider and tax ID and claimant.
b) Mutually exclusive editing: This edit applies if a procedure being billed is mutually exclusive with a procedure that occurred on the same date of service for the same provider tax ID and claimant.

9) **Multiple Procedure Discounts (MPD):** This edit applies a reduction to the second and any other subsequent services by the same provider, in the same setting, for the same member. We typically apply a 50% reduction. Magellan follows the CMS methodology that began in January 2011 which allows for application of MPD to codes within CMS’s two specific advanced imaging code families. However, Magellan differs from CMS in that we apply MPD to all provider types unless health plan contracts prohibit this.

10) **Lumbar Fusion** - Fusions can be performed either anteriorly, laterally, or posteriorly, or via a combined approach; although simple posterolateral fusions are indicated in the great majority of cases requiring fusion. Aggressive surgical approaches to fusion may be an indication for denial of cases (when such techniques have not been demonstrated to be superior to less morbid techniques) or recommendation for alternative procedure. These are the surgical approaches:
   a) Intertransverse Fusion or Posterolateral Fusion
   b) Anterior Interbody Fusion (ALIF)
   c) Lateral or Transpsoas Interbody Fusion (XLIF)
   d) Posterior or Trans-foraminal Interbody Fusion (PLIF or TLIF)
   e) Anterior/posterior Fusion (360-degree)
   f) Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is still being investigated and is not recommended.

11) Use of bone grafts including autologous or allograft which might be combined with metal or biocompatible devices to produce a rigid, bony connection between two or more adjacent vertebrae are common. Bone formation or grafting materials including biologics should be used at the surgeon’s discretion; however, use of biologics should be limited to FDA approved indications in order to limit complications (especially BMP).

12) All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests and must be performed by surgeons with appropriate training (neurosurgery, orthopaedic surgery). A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). A failure of accurate correlation may be an indication for denial of cases. It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sympathetically mediated pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention.

13) Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.
   a) All patients being considered for surgical intervention should first undergo a comprehensive neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention.
   b) While sufficient time allowances for non-operative treatment are required to determine the natural cause and response to non-operative treatment of low back
pain disorders, timely decision making for operative intervention is critical to avoid de-conditioning and increased disability (exclusive of "emergent" or urgent pathology such as cauda equina syndrome or associated rapidly progressive neurologic loss).

14) In general, if the program of non-operative treatment fails, operative treatment is indicated when:
   a) Improvement of the symptoms has plateaued or failed to occur and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 weeks of active treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems; and/or
   b) Frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides satisfactory relief of symptoms, and restoration of function on each recurrence.

15) **Lumbar spinal stenosis and associated lumbar spondylolisthesis** - Spinal stenosis is narrowing of the spinal column or of the neural foramina where spinal nerves leave the spinal column, causing pressure on the spinal cord. The most common cause is degenerative changes in the lumbar spine. Neurogenic claudication is the most common symptom, referring to “leg symptoms encompassing the buttock, groin and anterior thigh, as well as radiation down the posterior part of the leg to the feet.” In addition to pain, leg symptoms can include fatigue, heaviness, weakness and/or paresthesia. Some patients may also suffer from accompanying back pain. Symptoms are worse when standing or walking and are relieved by sitting. Lumbar spinal stenosis is often a disabling condition, and it is the most common reason for lumbar spinal surgery in adults over 65 years.

16) **Degenerative lumbar spondylolisthesis** - is the displacement of a vertebra in the lower part of the spine; one lumbar vertebra slips forward on another with an intact neural arch and begins to press on nerves. The slippage occurs at the L4-L5 level most commonly. The most common cause, in adults, is degenerative disease although it may also result from bone diseases and fractures. Spondylolisthesis seldom occurs before the age of 50 years and it disproportionately affects women, especially black women. Degenerative spondylolisthesis is not always symptomatic. *The indications for fusion in this group are evolving and as more evidence emerges, changes to the accepted indications and acceptable techniques used may be made.*

17) **Lumbar degenerative disease without stenosis or spondylolisthesis** - Spondylosis is an umbrella term describing age-related degeneration of the spine. Lumbar degenerative disease without stenosis or spondylolisthesis is characterized by disabling low back pain and spondylosis at L4-5, L5-S1, or both levels.

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**REFERENCES**

Atlas SJ, Keller RB, Wu YA, et al. Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the Maine lumbar spine


CPT Codes:
Cervical Thoracic Region: 62320, 62321, 64479 (+64480)
Lumbar Sacral Region: 62322, 62323, 64483 (+64484)

INTRODUCTION
Therapeutic Spinal Epidural Injections or Select Nerve Root Blocks (Transforaminal) are types of interventional pain management procedures. The therapeutic use of epidural injections is for short-term pain relief associated with acute back pain or exacerbation of chronic back pain. With therapeutic injections a corticosteroid is injected close to the target area with the goal of pain reduction. Epidural injections should be used in combination with other active conservative treatment modalities and not as stand alone treatment for long-term back pain relief. There are different approaches used when administering spinal epidural injections:

1. **Interlaminar** epidural injections, with steroids, access the epidural space between two vertebrae (Interlaminar) to treat cervical, lumbar or thoracic pain with radicular pain. These procedures should be performed using fluoroscopic guidance (AHRQ 2013). Interlaminar epidural injections are the most common type of epidural injection.

2. **Transforaminal** epidural injections (also called selective nerve root blocks) access the epidural space via the intervertebral foramen where the spinal nerves exit (cervical, lumbar or thoracic region). It is used both diagnostically and therapeutically. Some studies report lack of evidence and risks of transforaminal epidural injections. These procedures are always aided with fluoroscopic guidance (AHRQ 2013).

3. **Caudal** epidural injections, with steroids, are used to treat back and lower extremity pain, accessing the epidural space through the sacral hiatus, providing access to the lower nerve roots of the spine. These procedures should be performed using fluoroscopic guidance (AHRQ 2013). Failed back surgery syndrome is the most common reason for the caudal approach.

The rationale for the use of spinal epidural injections is that the sources of spinal pain, e.g., discs and joints, are accessible and amendable to neural blockade.

Medical necessity management for epidural injections includes an initial evaluation including history and physical examination and a psychosocial and functional assessment. The following must be determined: nature of the suspected organic problem; non-responsiveness to active conservative treatment*; level of pain and functional disability; conditions which may be contraindications to epidural injections; and responsiveness to prior interventions.
Interventional pain management specialists do not agree on how to diagnose and manage spinal pain; there is a lack of consensus with regards to the type and frequency of spinal interventional techniques for treatment of spinal pain. The American Society of Interventional Pain Physicians (ASIPP) guidelines and International Spine Intervention Society (SIS) guidelines provide an algorithmic approach which provides a step-by-step procedure for managing chronic spinal pain based upon evidence-based guidelines. It is based on the structural basis of spinal pain and incorporates acceptable evidence of diagnostic and therapeutic interventional techniques available in managing chronic spinal pain.

The guidelines and algorithmic approach referred to above include the evaluation of evidence for diagnostic and therapeutic procedures in managing chronic spinal pain and recommendations for managing spinal pain. The Indications and Contraindications presented within this document are based on the guidelines and algorithmic approach. Prior to performing this procedure, shared decision-making between patient and physician must occur, and patient must understand the procedure and its potential risks and results (moderate short-term benefits, and lack of long-term benefits).

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

I. INDICATIONS FOR EPIDURAL INJECTIONS OR SELECTIVE NERVE BLOCKS (caudal, interlaminar, and transforminal) (Injection of local anesthetics with corticosteroids)

1) Acute pain or exacerbation of chronic radicular pain with the following clinical timeframes:
   - Neck or back pain with acute radicular pain (AHRQ 2013; Summers 2013):
     i) after 2 weeks or more of acute radicular pain that has failed to respond or poorly responded to conservative (including medication) management unless the medical reason this conservative treatment cannot be done is clearly documented (AHRQ 2013; Manchikanti 2013; Summers 2013; ODG 2017); OR
   - Failed back surgery syndrome or epidural fibrosis causing radicular pain (AHRQ 2013; ODG 2017):
     i) typically not done immediately post-surgery. Documentation requires a medical reason that clearly indicates why an injection is needed.
     ii) patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months or details of engagement in other forms of active conservative non-operative treatment if the patient had any prior spinal injections prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented (AHRQ 2017; Manchikanti 2013; Summers 2013; ODG 2017); OR
   - Spinal stenosis (foraminal, central or disc disease) causing radicular pain (AHRQ 2017; ODG 2017):
     - patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months or details of engagement in other forms of active conservative non-operative treatment if the patient had any
prior spinal injections prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented; (AHRQ 2017; Manchikanti 2013; Summers 2013; ODG 2017); OR
d) Diagnostic transforaminal injection to identify the pain generator for surgical planning (Manchikanti 2013; AND
e) Pain causing functional disability or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ 2013; Manchikanti 2011; NASS 2013; NASS 2012; Manchikanti 2013; Summers 2013).

II. FREQUENCY OF REPEAT THERAPEUTIC INJECTIONS:
1) Epidural injections may be repeated only as medically necessary. Each epidural injection requires an authorization and the following criteria must be met for repeat injections:
   a) Documented proof that the prior injection had a positive response by significantly decreasing the patient’s pain (at least 30% reduction in pain after initial injections or significant documented functional improvement) (NASS 2013; ODG 2017). Or a second injection may be performed at a different spinal level or with a different epidural technique if there is documentation of a question about the pain generator or there is evidence of multilevel pathology (ODG 2017); AND
   b) No more than 3 procedures in a 12-week period of time per region with at least 14 days between injections in the initial diagnostic phase. At least 50% or more cumulative pain relief obtained for a minimum of 6 weeks after initial injections (Manchikanti 2013); AND
   c) The patient continues to have ongoing pain or documented functional disability (pain causing functional disability or pain level ≥ 6 on a scale of 0 to 10 (AHRQ 2013; Manchikanti 2011; NASS 2013; Manchikanti 2013; Summers 2013); AND
   d) The patient is actively engaged in other forms of active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy*) (AHRQ 2013; Qassem 2017; Summers 2013); AND
   e) In the first year of treatment, which may include an initial series of 3 injections in the initial diagnostic phase and additional injections in the treatment phase, a total of 6 epidural injections may be performed (Manchikanti 2013).
   f) Repeat injections after the initial diagnostic phase should be done at intervals of at least 2 months provided that previous injections resulted in at least 50% relief or functional improvement for at least 2 months and are limited to a maximum total of 4 therapeutic procedures per region per 12 months (Manchikanti 2013; NASS 2013). If special circumstances are documented (e.g. elderly patient with severe spinal stenosis and not an operative candidate) then repeat injections are limited to a maximum of 6 procedures in 12 months (NASS 2013).
   NOTE: Each epidural injection requires an authorization.
   g) If the neural blockade is applied for different regions), injections may be administered at intervals of no sooner than 7 days for most types of procedures (Manchikanti 2013).
h) **Injecting multiple regions or performing multiple procedures during the same visit may be deemed medically unnecessary unless documentation is provided outlining an unusual situation (ODG 2017).**

i) No more than 2 levels of transforaminal blocks should be done in one day (ODG 2017).

**NOTE:** An injection of opioid or other substance for the purpose of completing a trial for an implantable infusion pump is approvable.

### III. CONTRAINDICATIONS FOR EPIDURAL INJECTIONS

1) Bleeding diathesis and full anticoagulation (risk of epidural hematoma);
2) Severe spinal stenosis resulting in intraspinal obstruction;
3) Local infection at injection site;
4) Predominantly psychogenic pain;
5) Sepsis;
6) Hypovolemia;
7) Uncontrolled diabetes;
8) Uncontrolled glaucoma;
9) High concentrations of local anesthetics in patients with multiple sclerosis;
10) For diagnosis or treatment of facet mediated pain;
11) Known or suspected allergic reaction to steroid medications;
12) Spinal infection; OR
13) Acute fracture.

### IV. ADDITIONAL INFORMATION:

1) **Conservative Therapy:** (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care (AHRQ 2013; Qassem 2017; Summers 2013).

2) **Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan and may include yoga, Tai chi, or supervised aerobic exercise (Qassem 2017; Sculpo 2001), AND
   b) Follow up with member with documentation provided regarding completion of HEP, (after suitable 4-6 week period) or inability to complete HEP due to physical reason - i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP) (AHRQ 2013; Qassem 2017; Summers 2013).

3) **Terminology:** Interlaminar Epidural; Selective Nerve Root Injection (transforaminal only); Transforaminal Injection; Injections of Spinal Canal

4) **Hip-spine syndrome** - Hip-spine syndrome is a condition that includes both debilitating hip osteoarthritis and low back pain. Abnormal spinal sagittal alignment and difficulty in maintaining proper balance, as well as a wobbling gait, may be caused by severe
osteoarthritis of the hip joint. Epidural injections are used to determine a primary pain generator in this condition.

5) **Spondylolisthesis and nerve root irritation** - Degenerative lumbar spondylolisthesis is the displacement of a vertebra in the lower part of the spine; one lumbar vertebra slips forward on another with an intact neural arch and begins to press on nerves. The most common cause, in adults, is degenerative disease although it may also result from bone diseases and fractures. Degenerative spondylolisthesis is not always symptomatic. Epidural injections may be used to determine a previously undocumented nerve root irritation as a result of spondylolisthesis.

6) **Lumbar spinal stenosis with radiculitis** - Spinal stenosis is narrowing of the spinal column or of the neural foramina where spinal nerves leave the spinal column, causing pressure on the spinal cord. The most common cause is degenerative changes in the lumbar spine. Neurogenic claudication is the most common symptom, referring to “leg symptoms encompassing the buttock, groin and anterior thigh, as well as radiation down the posterior part of the leg to the feet.” In addition to pain, leg symptoms can include fatigue, heaviness, weakness and/or paresthesia. Some patients may also suffer from accompanying back pain. Symptoms are worse when standing or walking and are relieved by sitting. Lumbar spinal stenosis is often a disabling condition, and it is the most common reason for lumbar spinal surgery in adults over 65 years. The most common levels of stenosis are L3 through L5, but it may occur at multilevels in some patients. Radiculitis is the inflammation of a spinal nerve root that causes pain to radiate along the nerve paths. Epidural injections help to ascertain the level of the pain generator in this condition.

7) **Postoperative epidural fibrosis** - Epidural fibrosis is a common cause of failed back surgery syndrome. With the removal of a disc, the mechanical reason for pain may be removed, but an inflammatory condition may continue after the surgery and may cause pain. Epidural corticosteroids, with their anti-inflammatory properties, are used to treat postoperative fibrosis and may be used along with oral Gabapentin to reduce pain.

8) **Lumbar herniated disc** - Epidural steroid injections have been proven to be effective at reducing symptoms of lumbar herniated discs. Evidence shows that they can be successful in 42% to 56% of patients who do not improve after 6 weeks of conservative treatment. Observation and epidural steroid injection are effective nonsurgical treatments for this condition.

9) **Failed back surgery syndrome** - Failed back surgery syndrome (FBSS) is characterized by persistent or recurring low back pain, with or without sciatica, following lumbar surgery. The most common cause of FBSS is epidural fibrosis which be triggered by a surgical procedure such as disectomy. The inflammation resulting from the surgical procedure may start the process of fibrosis and cause pain. Epidural steroid injections are administered to reduce pain.
REFERENCES


ODG- Official Disability Evidence-Based Guideline, 22nd annual edition, 2017


INTRODUCTION

Facet joints (also called zygapophysial joints or z-joints), posterior to the vertebral bodies in the spinal column and connecting the vertebral bodies to each other, are located at the junction of the inferior articular process of a more cephalad vertebra and the superior articular process of a more caudal vertebra. These joints provide stability and enable movement, allowing the spine to bend, twist, and extend in different directions. They also restrict hyperextension and hyperflexion.

Facet joints are clinically important spinal pain generators in patients with chronic spinal pain. In patients with chronic low back pain, facet joints have been implicated as a cause of the pain in 15% to 45% of patients. Facet joints are considered as the cause of chronic spinal pain in 48% of patients with thoracic pain and 54% to 67% of patients with chronic neck pain. Facet joints may refer pain to adjacent structures, making the underlying diagnosis difficult as referred pain may assume a pseudoradicular pattern. Lumbar facet joints may refer pain to the back, buttocks, and lower extremities while cervical facet joints may refer pain to the head, neck and shoulders.

Imaging findings are of little value in determining the source and location of ‘facet joint syndrome’, a term originally used by Ghormley and referring to back pain caused by pathology at the facet joints. Imaging studies may detect changes in facet joint architecture, but correlation between radiologic findings and symptoms is unreliable. Although clinical signs are also unsuitable for diagnosing facet joint-mediated pain, they may be of value in selecting patients for controlled local anesthetic blocks of either the medial branches or the facet joint itself.

Medical necessity management for paravertebral facet injections includes an initial evaluation including history and physical examination and a psychosocial and functional assessment. The following must be determined: nature of the suspected organic problem; non-responsiveness to conservative treatment; level of pain and functional disability; conditions which may be contraindications to paravertebral facet injections; and responsiveness to prior interventions.

The most common source of chronic pain is the spine and about two-thirds of the U.S. population suffers from spinal pain sometime during their life span. Facet joint interventions are used in the treatment of pain in certain patients with a confirmed diagnosis of facet joint pain. Interventions include intraarticular injections and medial branch nerve blocks in the lumbar, cervical and thoracic spine. Prior to performing this procedure, shared decision-making between patient and physician must occur, and patient must understand the procedure and its potential risks and results. Facet joint injections or medial branch nerve blocks require guidance imaging.
Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**Indications for Facet Joint Injections or Medial Branch Nerve Blocks:**

1) To confirm disabling non-radicular low back (lumbosacral), mid back (thoracic) or neck (cervical) pain*, suggestive of facet joint origin as documented in the medical record based upon ALL of the following:
   a) history, consisting of mainly axial or non-radicular pain unless stenosis is caused by synovial cyst (Khan, 2006; Manchikanti, 2009; Manchikanti, 2013): **AND**
   b) Lack of evidence, either for discogenic or sacroiliac joint pain as the main pain generators (Manchikanti, 2009; Manchikanti, 2013): **AND**
   c) Lack of disc herniation or evidence of radiculitis as the main pain generators unless stenosis is caused by synovial cyst (Khan, 2006; Manchikanti, 2009; Manchikanti, 2013): **AND**
   d) Facet blocks should not be performed at same levels as previous surgical fusion 15: **AND**
   e) Pain causing functional disability or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013; Summers, 2013): **AND**
   f) Duration of pain of at least **3months** (Manchikanti, 2009; Manchikanti, 2013): **AND**
   g) Failure to respond to conservative non-operative therapy management* for a minimum of 6 weeks in the last 6 months prior to facet injections or details of active engagement in other forms of active conservative non-operative treatment if the patient had prior spinal injections unless the medical reason this treatment cannot be done is clearly documented (AHRQ, 2013; Manchikanti, 2013; ODG, 2017; Summers, 2014): **AND**
   h) All procedures must be performed using fluoroscopic or CT guidance (AHRQ, 2013).

**NOTE:** Ultrasound guidance is not a covered benefit and procedure performed using ultrasound guidance are not reimbursable.

II. **FREQUENCY OF FACET BLOCK:**

1) There must be a minimum of **14 days** between therapeutic injections or any injection (therapeutic or diagnostic) where steroids are injected (Manchikanti, 2013).

2) There must be a positive response of ≥ 50% pain relief or improved ability to function or a change in technique, for example from an initial intraarticular facet block to a facet joint nerve block can be considered. Repeat therapeutic injections should be performed at a frequency of 2 months or longer provided that at least 50% relief is obtained for a minimum of 2 months after the previous injection (Manchikanti, 2013). The patient is actively engaged in other forms of active conservative non-operative treatment if the patient is receiving therapeutic facet joint injections unless pain prevents the patient from participating in conservative therapy*) (AHRQ, 2013; Qassem, 2017; Summers, 2013).

3) In the diagnostic phase a **maximum of 2 procedures may be performed.** In the therapeutic phase a maximum of **4 procedures per region every 12 months except under unusual circumstances such as a recurrent injury.** *(NOTE: Unilateral facet blocks*
performed at the same level on the right vs. left within 2 weeks of each other would be considered as one procedure) (Manchikanti, 2013).

4) If the procedures are applied for different regions, they may be performed at intervals 1-2 weeks for most types of procedures (Manchikanti, 2013).

5) **Maximum of 2 levels injected on same date of service** (AHRQ, 2013; ODG, 2017).

6) **Radiofrequency** neurolysis procedures should be considered in patients with positive facet blocks (with at least 70% pain relief and/or improved ability to function, but with insufficient sustained relief (less than 2-3 months improvement) (AHRQ, 2013; Manchikanti, 2013; Summers, 2013; ODG, 2017).

7) The patient continues to have ongoing pain or documented functional disability (pain causing functional disability or pain level ≥ 6 on a scale of 0 to 10) (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013; Summers, 2013).

III. CONTRAINDICATIONS FOR FACET JOINT INJECTIONS:
1) History of allergy to contrast administration, local anesthetics, steroids, or other drugs potentially utilized;
2) Hypovolemia;
3) Infection over puncture site;
4) Bleeding disorders or coagulopathy;
5) History of allergy to medications to be administered;
6) Inability to obtain percutaneous access to the target facet joint;
7) Progressive neurological disorder which may be masked by the procedure;
8) Pregnancy;
9) Spinal infection; OR
10) Acute fracture

IV. ADDITIONAL INFORMATION:
1) *Conservative Therapy:* (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care (AHRQ, 2013; Qassem, 2017; Summers, 2013).

2) **Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan and may include yoga, Tai chi, or supervised aerobic exercise (Qassem, 2017; Sculpo, 2001), AND
   b) Follow up with member with documentation provided regarding completion of HEP, (after suitable 4-6 week period) or inability to complete HEP due to physical reason- i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).
3) **Terminology:** Facet Injections; Facet Joint Blocks; Paravertebral Facet Injections; Paravertebral Facet Joint Injections; Paravertebral Facet Joint Nerve Injections; Zygapophyseal injections; Lumbar Facet Blockade; Medial Branch blocks
REFERENCES


CPT Codes:
Cervical Thoracic Region: 64633, +64634
Lumbar Sacral Region: 64635, +64636

INTRODUCTION
Facet joints (also called zygapophysial joints or z-joints), posterior to the vertebral bodies in the spinal column and connecting the vertebral bodies to each other, are located at the junction of the inferior articular process of a more cephalad vertebra and the superior articular process of a more caudal vertebra. These joints provide stability and enable movement, allowing the spine to bend, twist, and extend in different directions. They also restrict hyperextension and hyperflexion.

Facet joints are clinically important spinal pain generators in patients with chronic spinal pain. Pain mediated by the facet joints may be caused by repetitive stress and/or cumulative low-level trauma resulting in osteoarthritis and inflammation. In patients with chronic low back pain, facet joints have been implicated as a cause of the pain in 15% to 45% of patients. They are considered as the cause of chronic spinal pain in 48% of patients with thoracic pain and 54% to 67% of patients with chronic neck pain. Facet joints may refer pain to adjacent structures, making the underlying diagnosis difficult as referred pain may assume a pseudoradicular pattern. Lumbar facet joints may refer pain to the back, buttocks, and proximal lower extremities while cervical facet joints may refer pain to the head, neck and shoulders.

Imaging findings are of little value in determining the source and location of ‘facet joint syndrome’, a term originally used by Ghormley and referring to back pain caused by pathology at the facet joints. Imaging studies may detect changes in facet joint architecture, but correlation between radiologic findings and symptoms is unreliable. Although clinical signs are also unsuitable for diagnosing facet joint-mediated pain, they may be of value in selecting patients for controlled local anesthetic blocks of either the medial branches or the facet joint itself. This is an established tool in diagnosing facet joint syndrome.

Facet joints are known to be a source of pain with definitive innervations. Interventions used in the treatment of patients with a confirmed diagnosis of facet joint pain include: medial branch nerve blocks in the lumbar, cervical and thoracic spine; and radiofrequency neurolysis (see additional terminology). The medial branch of the primary dorsal rami of the spinal nerves has been shown to be the primary innervations of facet joints. Substance P, a physiologically potent neuropeptide considered to play a role in the nociceptive transmission of nerve impulses, is found in the nerves within the facet joint.

Radiofrequency neurolysis is a minimally invasive treatment for cervical, thoracic and lumbar facet joint pain. It involves using energy in the radiofrequency range to cause necrosis of specific nerves.
(medial branches of the dorsal rami), preventing the neural transmission of pain. The objective of radiofrequency neurolysis is to both provide relief of pain and reduce the likelihood of recurrence.

Members of the American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Medicine (ASRA) have agreed that conventional or thermal radiofrequency ablation of the medial branch nerves to the facet joint should be performed for neck or low back pain. Radiofrequency neurolysis has been employed for over 30 years to treat facet joint pain. Prior to performing this procedure, shared decision-making between patient and physician must occur, and patient must understand the procedure and its potential risks and results.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

**I. INDICATIONS FOR THERAPEUTIC PARAVERTEBRAL FACET JOINT DENERVATION (RADIOFREQUENCY NEUROLYSIS)** (local anesthetic block followed by the passage of radiofrequency current to generate heat and coagulate the target medial branch nerve)

1) **Positive response to one or two controlled local anesthetic blocks of the facet joint nerves (medial branch blocks), with at least 70% pain relief and/or improved ability to function for a minimal duration at least equal to that of the local anesthetic, but with insufficient sustained relief (less than 2-3 months relief); AND a failure to respond to more active conservative non-operative management for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented** (AHRQ 2013; Manchikanti, 2009; Manchikanti, 2013; ODG, 2017; Summers, 2013); **OR**

2) **Positive response to prior radiofrequency neurolysis procedures with at least 50% pain relief and/or improved ability to function for at least 4 months, and the patient is actively engaged in other forms of appropriate active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy*) (AHRQ, 2013; Manchikanti, 2013; Qassem, 2017; Sculpo, 2001; Summers, 2013); AND**

3) **The presence of ALL of the following:**
   a) **Lack of evidence that the primary source of pain being treated is from discogenic pain, sacroiliac joint pain, disc herniation or radiculitis (Manchikanti, 2009; Manchikanti, 2013);**
   b) **Pain causing functional disability or an average pain levels of ≥ 6 on a scale of 0 to 10 prior to each radiofrequency procedure including radiofrequency procedures done unilaterally on different days (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013; Summers, 2013);**
   c) **Duration of pain of at least 3 months (AHRQ, 2013; Manchikanti, 2013; Summers, 2013); AND**
   d) **Maximum of 2 facet joint levels performed on same date of service (AHRQ, 2013; ODG, 2017).**

**II. FREQUENCY:**

1) Limit to 2 facet neurolysis procedures every 12 months, per region (cervical, thoracic and lumbar are each considered one region) (Manchikanti, 2013).

**NOTE:** Unilateral radiofrequency denervations performed at the same level on the right vs left within 2 weeks of each other would be considered as one procedure toward the total number of radiofrequency procedures allowed per 12 months. Every radiofrequency procedure requires pre-authorization.
III. CONTRAINDICATIONS FOR PARAVETERBRAL FACET JOINT DENERVATION (RADIOFREQUENCY NEUROLYSIS):
1) History of allergy to local anesthetics or other drugs potentially utilized;
2) Lumbosacral radicular pain (dorsal root ganglion);
3) Conditions/diagnosis for which procedure is used are other than those listed in Indications;
4) Absence of positive diagnostic blocks; OR
5) For any nerve other than the medial branch nerve.

IV. ADDITIONAL INFORMATION:
1) *Conservative Therapy:* (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture and/or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities may consist of physical therapy, a physician supervised home exercise program**, and/or chiropractic care (AHRQ, 2013; Summers, 2013; Qassem, 2017).

2) **Home Exercise Program** – (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan and may include yoga, Tai Chi, or supervised aerobic exercise (Qassem, 2017; Sculpo, 2001): **AND**
   b) Follow up with member with documentation provided regarding completion of HEP, (after suitable 4-6 week period) or inability to complete HEP due to physical reason – i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).


REFERENCES


INTRODUCTION

This guideline addresses the use of sacroiliac joint injections for the treatment of low back pain that originates in the region of the sacroiliac joint. An injection of anesthetic and/or steroid may be used for the diagnosis and treatment of sacroiliac joint (SIJ) pain syndrome disorders (such as degenerative joint disease, postsurgical injuries, or traumatic injuries), or for treatment of spondyloarthropathy (inflammatory disorders of the joints and ligaments of the spine).

Sacroiliac joint injections are typically used for the following conditions:

Sacroiliac joint pain syndrome may be caused by various events, including pain secondary to postsurgical or traumatic injury, degeneration (wear and tear), or pregnancy. Physical examination (history and physical, provocative maneuvers) and diagnostic injection help to identify the source of pain as the SIJ.

Diagnostic SIJ injections are used to determine if the SIJ pain originates with the SIJ. Diagnostic blocks can reveal (or fail to reveal) that the source of pain is originating from the SIJ, and then an appropriate treatment plan can be developed (Curatolo et al, 2010; Manchikanti et al, 2013a).

Therapeutic SIJ injections may be used to treat SIJ pain once it has been determined that the SIJ is the origin of the pain. A therapeutic injection typically includes a corticosteroid and a local anesthetic that can be injected directly into the joint (intra-articular) or into the tissues surrounding the joint (periarticular).

Spondyloarthropathy (also known as spondyloarthritis) is the name for a family of rheumatic diseases that cause arthritis. Sacroilitis is a key indicator of spondyloarthritis and is diagnosed with imaging. Patients with spondyloarthropathy are generally managed by rheumatologists and account for only a small percentage of the cases that present in interventional pain management settings.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

I. INDICATIONS FOR SACROILIAC JOINT INJECTIONS (SJI)

1) For the treatment of SIJ pain:

   All of the following must be met:
   a) Low back pain maximal below level of L5 which may radiate to the groin or lower extremity persisting at least 3 months (Manchikanti, 2013a; ODG, 2016); AND
   b) Positive exam findings to suggest the diagnosis which may include the pelvic distraction test, pelvic compression test, thigh thrust test, FABER (Patrick’s test) or Gaenslen’s test (Laslett, 2008; MacVicar, 2017; ODG, 2016); AND
c) Active conservative treatment for a minimum of 6 weeks in the last 6 months (including physical therapy, home exercise, patient education, psychosocial support, and/or medication) has failed unless the medical reason this conservative treatment cannot be done is clearly documented (AHRQ, 2013; Manchikanti, 2013a; ODG, 2016; Summers, 2013); **AND**

d) Pain causing functional limitations or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013a; Summers, 2013); **AND**

e) Lack of evidence for disc-related pain or facet joint pain as the main pain generators (Manchikanti, 2009; Manchikanti, 2013a).

2) **For the treatment of spondyloarthropathy** (ACR 2012):

   **All** of the following must be met:

   a) The patient has experienced ≥ 3 months of low back pain; **AND**

   b) Age of onset < 45 years; **AND**

   c) Comprehensive pain management program including physical therapy, home exercise, patient education, psychosocial support and/or oral medication is in place; **AND**

   d) Prior history of evidence of sacroiliitis on imaging (i.e., active inflammation on magnetic resonance imaging [MRI] or definite radiographic sacroiliitis grade > 2 bilaterally or grade 3-4 unilaterally); **AND**

   e) **1 or more** spondyloarthropathy features:

      a. Inflammatory back pain with **at least 4** of the following criteria present:

         (1) Age at onset < 45 years
         (2) Insidious onset
         (3) Improvement with exercise
         (4) No improvement with rest
         (5) Pain at night (with improvement upon getting up)

   f) Arthritis

   g) Enthesitis of the heel (irritability of muscles, tendons, or ligaments where they enter the bone)

   h) Uveitis (inflammation of the uvea, the middle layer of the eye)

   i) Dactylitis (inflammation of a finger or toe)

   j) Psoriasis

   k) Crohn’s/colitis

   l) Good response to NSAIDs

   m) Family history of spondyloarthropathy

   n) Positive testing for HLA-B27

   o) Elevated C-reactive protein (CRP)

II. **FREQUENCY OF REPEAT THERAPEUTIC INJECTIONS**

1) SIJ injections may be repeated up to 2 times in the initial treatment phase no sooner than 2 weeks apart provided that at least 50% relief is obtained (Manchikanti, 2013a); **AND**
2) SIJ injections may only be repeated after the initial treatment phase if symptoms recur and the patient has had at least a 50% improvement for a minimum of 6 weeks after each therapeutic injection (Manchikanti, 2013a); **AND**
3) The patient is actively engaged in other forms of active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy (AHRQ, 2013; Qassem, 2017; Summers, 2013); **AND**
4) Repeat injections should not be done more frequently than every two months for a total of 4 injections in a 12 month period (Manchikanti, 2013a); **AND**
5) Pain causing functional limitations or average pain levels of ≥ 6 on a scale of 0 to 10 (AHRQ, 2013; Manchikanti, 2009; Manchikanti, 2013a; Summers, 2013).

### III. CONTRAINDICATIONS FOR SACROILIAC JOINT INJECTIONS

1) Active systemic infection
2) Skin infection at the site of needle puncture
3) Bleeding disorder or anticoagulation therapy
4) Uncontrolled high blood pressure
5) Uncontrolled diabetes
6) Unstable angina
7) Congestive heart failure
8) Allergies to contrast, anesthetics, or steroids (AAOS, 2009)

### IV. ADDITIONAL INFORMATION

1) **Conservative Therapy:** (Musculoskeletal) includes a combination of modalities, such as rest, ice, heat, modified activities, medical devices, (such as crutches, immobilizer, metal braces, orthotics, rigid stabilizer or splints, etc and not to include neoprene sleeves), medications, diathermy, chiropractic treatments, or physician supervised home exercise program. Part of this combination may include the physician instructing patient to rest the area or stay off the injured part (AHRQ, 2013; Qassem, 2017; Summers, 2013).

2) **Home Exercise Program - (HEP)** – the following two elements are required to meet guidelines for completion of conservative therapy:
   a) Information provided on exercise prescription/plan and may include yoga, Tai chi, or supervised aerobic exercise (Qassem, 2017; Sculpo, 2001); **AND**
   b) Follow up with member with information provided regarding completion of HEP (after suitable 6 week period), or inability to complete HEP due to physical reason - i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete” HEP).

Low back pain is one of the most common of all spinal pain problems. According to the Centers for Disease Control and Prevention (CDC), the prevalence of low back pain in adults 18 years of age and older is 28.4% and may range as high as 32.1% in adults ≥ 75 years (CDC, 2012). Symptoms of low back pain may arise from multiple sites, including lumbar intervertebral discs, facet joints, sacroiliac joints, ligaments, fascia, muscles, and nerve root dura. The sacroiliac joint has been shown to be a source of pain in 10% to 27% of chronic low back pain (Hansen et al, 2007; Simopoulos et al, 2012; Manchikanti et al, 2013a).
The sacroiliac joint (SIJ) is located between the sacrum (located at the base of the spine) and the pelvis, and supports the weight of the upper body in the standing position. There are SIJs in both the right and left side of the lower back. Strong ligaments hold the joints in place. The SIJ is well innervated and has been shown to be capable of being a source of low back pain and referred pain in the lower extremity. Low back pain originating from the SIJ can result from inflammatory conditions such as sacroiliitis, spondyloarthropathy (ankylosing spondylitis; rheumatoid spondylitis), or from postsurgical or traumatic injury, degeneration (wear and tear), or pregnancy. SIJ pain most often occurs in the buttocks and lower back, and may radiate down through the buttocks and the leg. Physical examination and radiographic techniques may confirm a diagnosis related to spondyloarthropathy. Physical examination, including provocative maneuvers to elicit pain response, and controlled SIJ injections can help diagnose noninflammatory pain arising from the SIJ (Hansen et al, 2007; Medline Plus, 2012; Mayo Clinic, 2013).

In order to confirm correct placement of the injectable medication into the intra-articular space, fluoroscopic or computed tomography (CT) guidance is used. A periarticular injection into the soft tissue may be used if ligamentous or muscular attachments are suspected to be involved. The goal of the therapeutic injection is to reduce inflammation and/or pain and provide longer pain relief. Long-term relief is generally defined as 6 weeks or longer, but positive responders generally have a much longer duration of response: serial injections may be required in order to maintain therapeutic effectiveness (Hansen et al, 2007; AAOS, 2009; Luukkainen et al, 2002; Hawkins et al, 2009).

Spinal injections for the treatment of SIJ pain syndrome are typically performed as one part of a comprehensive treatment program, which will nearly always include an exercise program to improve or maintain spinal mobility. Potential candidates for SIJ injections include those with low back pain originating from the SIJ that is unresponsive to conservative treatments.

Treatment for SIJ pain depends upon the signs and symptoms, as well as the underlying cause for the pain. Medications, such as over-the-counter analgesics, a short course of narcotics, muscle relaxants or tumor necrosis factor (TNF) inhibitors, such as etanercept (Enbrel), adalimumab (Humira), or infliximab (Remicade), may be prescribed. Therapy sessions with a physical therapist involving range-of-motion, stretching, and strengthening exercises may be used to maintain joint flexibility and strengthen the muscles. Other interventional procedures used to treat SIJ pain include corticosteroid injections to reduce inflammation and pain, radiofrequency denervation, electrical stimulation, or in rare cases, joint fusion (Mayo Clinic, 2013).

The indications for coverage for the treatment of spondyloarthropathy have been established through use of the reviewed clinical studies and through criteria developed by the Assessment of SpondyloArthritis International Society (ASAS) for the classification of axial spondyloarthritis (Sieper et al, 2009). They are in keeping with the benefit guidelines developed by the Centers for Medicare & Medicaid Services (CMS).

While evidence supports that SIJ injection is an effective method of determining the source of pain, evidence supporting the efficacy of SIJ in the treatment of SIJ pain syndrome is considerably limited. There are limited controlled or prospective clinical studies to support SIJ injection for therapeutic purposes. Despite the limited quality of the clinical studies
supporting SIJ injection for the treatment of SIJ pain, the procedure is recommended by the American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Management (ASRPM) Practice Guidelines. The indications for coverage have been established from the 2009 Comprehensive Evidence-Based Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain, and updated with the 2013 An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations.

REFERENCES


