Guidelines for Clinical Review Determination

Preamble
Magellen 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 Healthcare 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 and other specialty groups. They were developed following a literature search pertaining to established clinical guidelines and accepted diagnostic imaging practices.

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CPT Codes:
Anterior Cervical Decompression with Fusion - Single Level** (ACDF) 22548, 22551, 22554
Anterior Cervical Decompression with Fusion - Multiple Level** (ACDF) 22548, 22551, 22554, +22552, +22585
Cervical Posterior Decompression with Fusion - Multiple Levels** 22590, 22595, 22600, +22614
Cervical Posterior Decompression with Fusion - Single Level** 22590, 22595, 22600
Cervical Artificial Disc – Single Level 22856, 22861, 22864
Cervical Artificial Disc – Two Levels (**0375T is not a covered service and is not reimbursable) 22858, 0098T, 0095T
Cervical Posterior Decompression (without fusion) 63001, 63015, 63020, 63040, 63045, 63050, 63051, +63035, +63043, +63048,
Cervical Anterior Decompression (without fusion) 63075, +63076

OVERVIEW:
This guideline outlines the key surgical treatments and indications for common cervical 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 clinical indications by surgical type. Operative treatment is indicated only when the natural history of an operatively treatable problem is better than the natural history of the problem without operative treatment. Choice of surgical approach is based on anatomy, the patient's pathology, and the surgeon's experience and preference. All operative interventions must be based on a positive correlation with clinical findings, the natural history of the disease, the clinical course, and diagnostic tests or imaging 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.

INDICATIONS FOR CERVICAL SPINE SURGERY:
A. Anterior Cervical Decompression with Fusion (ACDF) - Single Level
   1) Anterior cervical discectomy and fusion with either a bone bank allograft or autograft with or without plating is the standard approach anteriorly and is most commonly used for disc herniation. The following criteria must be met*:
      a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with spinal cord compression - immediate surgical evaluation is indicated. Symptoms may include:
         i) upper extremity weakness
         ii) unsteady gait related to myelopathy/balance or generalized lower extremity weakness
         iii) disturbance with coordination
         iv) hyperreflexia
v) Hoffmann sign
vi) positive Babinski sign and/or clonus

OR

b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with evidence of spinal cord or nerve root compression on Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) imaging - immediate surgical evaluation is indicated.

OR

c) When All of the following criteria are met:
   i) Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity; **AND**
   ii) Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least **6 weeks of appropriate conservative treatment**. Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:
      i) Analgesics, steroids, and/or NSAIDs
      ii) Structured program of physical therapy
      iii) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
      iv) Epidural steroid injections and or facet injections /selective nerve root block; **AND**

d) **Imaging studies** confirm the presence of spinal cord or spinal nerve root compression (disc herniation or foraminal stenosis) at the level corresponding with the clinical findings. Imaging studies may include:
   i) MRI (preferred study for assessing cervical spine soft tissue); **OR**
   ii) CT with or without myelography— indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI).

2) **Cervical spine decompression with fusion as first-line treatment without conservative care measures** in the following clinical cases:
   a) As outlined above for myelopathy or progressive neurological deficit scenarios.
   b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.
   c) Fracture or instability on radiographic films measuring:
      i) Sagittal plan angulation of greater than 11 degrees at a single interspace greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction **OR**
      ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

3) **Not Recommended:**
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
b) In cases of neck pain alone, without neurological deficits, and no evidence of significant spinal nerve root or cord compression on MRI or CT. See V. Cervical Fusion for Treatment of Axial Neck Pain Criteria

B. **Anterior Cervical Decompression with Fusion (ACDF) - Multiple Level**

1) Anterior cervical discectomy and fusion with either a bone bank allograft or autograft with or without plating is the standard approach anteriorly and is most commonly used for disc herniation. **The following criteria must be met***:

   a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with worsening **spinal cord compression** - immediate surgical evaluation is indicated. Symptoms may include:
      
      i) upper extremity weakness
      ii) unsteady gait related to myelopathy/balance or generalized lower extremity weakness
      iii) disturbance with coordination
      iv) hyperreflexia
      v) Hoffmann sign
      vi) positive Babinski sign and or clonus

   OR

   b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated.

   OR

   c) **When ALL of the following criteria are met:**
      
      i) Cervical radiculopathy or myelopathy due to ruptured disc, spondylosis, spinal instability, or deformity; **AND**
      
      ii) Persistent or recurrent pain/symptoms with functional limitations that are unresponsive to **at least 6 weeks** of conservative treatment. Documented failure of at least 6 consecutive weeks of **any 2** of the following physician-directed conservative treatments:
         
         (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**

   d) Imaging studies confirm the presence of spinal cord or spinal nerve root compression (disc herniation or foraminal stenosis) **at multiple levels corresponding with the clinical findings**. Imaging studies may include any of the following:
      
      i) MRI (preferred study for assessing cervical spine soft tissue); OR
ii) CT with or without myelography - indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI)

2) **Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases:**
   a) As outlined above for myelopathy or progressive neurological deficit scenarios.
   b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.
   c) Fracture or instability on radiographic films measuring:
      i) Sagittal plan angulation of greater than 11 degrees at a single interspace greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction: **OR**
      ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

3) **Not Recommended:**
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
   b) In cases of neck pain alone, without neurological deficits, and no evidence of significant spinal nerve root or cord compression on MRI or CT. **See V. Cervical Fusion for Treatment of Axial Neck Pain Criteria.**

C. **Cervical Posterior Decompression with Fusion - Single Level**

Surgical indications for cervical spine stenosis/cervical spondylotic myelopathy (CSM) must meet the following criteria:

1) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with worsening **spinal cord compression** - immediate surgical evaluation is indicated. Symptoms may include:
   a) upper extremity weakness
   b) unsteady gait related to myelopathy/balance or generalized lower extremity weakness
   c) disturbance with coordination
   d) hyperreflexia
   e) Hoffmann sign
   f) positive Babinski sign and / or clonus

**OR**

2) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated.

**OR**

3) **When ALL of the following criteria are met:**
   a) Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity; **AND**
b) Persistent or recurrent symptoms/pain with functional limitations that is unresponsive to at least 6 weeks of conservative treatment; AND Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:
   i) Analgesics, steroids, and/or NSAIDs
   ii) Structured program of physical therapy
   iii) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
   iv) Epidural steroid injections and or facet injections/selective nerve root block: AND

c) Imaging studies confirm the presence of spinal cord or spinal nerve root compression (disc herniation or foraminal stenosis) at single level corresponding with the clinical findings. Imaging studies may include:
   i) MRI (preferred study for assessing cervical spine soft tissue); OR
   ii) CT with or without myelography - indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI); AND

d) Single level symptomatic cervical disease as evidence by:
   i) cervical spinal stenosis due to cervical spondylotic myelopathy (CSM); or
   ii) cervical spinal stenosis due to ossification of the posterior longitudinal ligament (OPLL); or
   iii) single level spinal cord or nerve root compression due to herniated disc.

4) Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases:
   a) As outlined above for myelopathy or progressive neurological deficit scenarios.
   b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.
   c) Fracture or instability on radiographic films measuring:
      i) Sagittal plan angulation of greater than 11 degrees at a single interspace greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction: OR
      ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

5) Not Recommended:
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
   b) In cases of neck pain alone, without neurological deficits, and no evidence of significant spinal nerve root or cord compression on MRI or CT. See V. Cervical Fusion for Treatment of Axial Neck Pain Criteria.
   c) In patients with kyphosis or at risk for development of postoperative kyphosis.

D. Cervical Posterior Decompression with Fusion - Multiple Levels
   1) Surgical indications for cervical spine stenosis/cervical spondylotic myelopathy (CSM) must meet the following criteria*:
a) Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with worsening **spinal cord compression** - immediate surgical evaluation is indicated. Symptoms may include:

i) upper extremity weakness  
ii) unsteady gait related to myelopathy/balance or generalized lower extremity weakness  
iii) disturbance with coordination  
iv) hyperreflexia  
v) Hoffmann sign  
vi) positive Babinski sign and/or clonus

**OR**

b) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated.

**OR**

c) When **ALL** of the following criteria are met:

i) Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity; **AND**

ii) Persistent or recurrent symptoms/pain with functional limitations that is unresponsive to at least **6 weeks of conservative treatment**; **AND** Documented failure of at least 6 consecutive weeks of **any 2** of the following physician-directed conservative treatments:

   (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**

d) Imaging studies indicate significant spinal cord or spinal nerve root compression at **multiple levels corresponding with the clinical findings**. Imaging studies may include:

i) MRI (preferred study for assessing cervical spine soft tissue); OR

ii) CT with or without myelography - indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI); **AND**

e) Multilevel (>=2) symptomatic cervical disease as evidence by:

i) cervical spinal stenosis due to cervical spondylotic myelopathy (CSM); **or**

ii) cervical spinal stenosis due to ossification of the posterior longitudinal ligament (OPLL); **or**
iii) Evidence of significant spinal cord or nerve root compression from herniated discs at two or more levels.

2) *Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases:
   a) As outlined above for myelopathy or progressive neurological deficit scenarios.
   b) Significant spinal cord or nerve root compression due to tumor, infection or trauma.
   c) Fracture or instability on radiographic films measuring:
      i) Sagittal plan angulation of greater than 11 degrees at a single interspace greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction; **OR**
      ii) Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child.

3) **Not Recommended:**
   a) In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
   b) In cases of neck pain alone, without neurological deficits, and no evidence of significant spinal nerve root or cord compression on MRI or CT. **See V. Cervical Fusion for Treatment of Axial Neck Pain Criteria.**
   c) In patients with kyphosis or at risk for development of postoperative kyphosis.

**Cervical Fusion for Treatment of Axial Neck Pain:**

In patients with non-radicular cervical pain for whom fusion is being considered, **ALL of the following criteria must be met:**

1) Improvement of the symptoms has failed or plateaued, and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 consecutive months of appropriate, active treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems [NOTE: Mere passage of time with poorly guided treatment is not considered an active treatment program]; **AND**

2) All pain generators are adequately defined and treated; **AND**

3) All physical medicine and manual therapy interventions are completed; **AND**

4) X-ray, MRI, or CT demonstrating disc pathology or spinal instability; **AND**

5) Spine pathology limited to one or two levels unless other complicating factors are involved; **AND**

6) Psychosocial evaluation for confounding issues addressed.

**NOTE:** The effectiveness of three-level or greater cervical fusion for non-radicular pain has not been established.

VI. **Cervical Posterior Decompression**

1) Surgical indications for cervical nerve root decompression due to radiculopathy, disc herniation or foraminal stenosis. A posterior laminotomy and discectomy is occasionally used for patients with specific lateral disc herniations when the surgeon's preference is that the individual would respond better with a posterior approach than an anterior one.

**The following criteria must be met:**
Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with worsening **spinal cord compression** - immediate surgical evaluation is indicated. Symptoms may include:

a) upper extremity weakness  
b) unsteady gait related to myelopathy/balance or generalized lower extremity weakness  
c) disturbance with coordination  
d) hyperreflexia  
e) Hoffmann sign  
f) positive Babinski sign and/or clonus

**OR**

2) Progressive neurological deficit (motor deficit, bowel or bladder dysfunction) with corresponding evidence of spinal cord or nerve root compression on an MRI or CT scan images - immediate surgical evaluation is indicated.

**OR**

3) When ALL of the following criteria are met:

a) Cervical radiculopathy from ruptured disc, spondylosis, or deformity: **AND**

b) Persistent or recurrent symptoms/pain with functional limitations that is unresponsive to at least 6 weeks of appropriate conservative treatment; **AND** Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:

i) Analgesics, steroids, and/or NSAIDs  
ii) Structured program of physical therapy  
iii) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician  
v) Epidural steroid injections and or facet injections/selective nerve root block: **AND**

c) Imaging studies confirm the presence of spinal cord or spinal nerve root compression at the level(s) corresponding with the clinical findings. Imaging studies may include any of the following:

i) MRI (preferred study for assessing cervical spine soft tissue); **OR**

ii) CT with or without myelography—indicated in patients in whom MRI is contraindicated; preferred for examining bony structures, or in patients presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI):

**4) Cervical decompression performed as first-line treatment without conservative care in the following clinical cases:**

a) As outlined above for myelopathy or progressive neurological deficit scenarios.

b) Spinal cord or nerve root compression due to tumor, infection or trauma.

**5) Not Recommended:**
a) In asymptomatic or mildly symptomatic cases.

b) In cases of pain alone, without neurological deficits and abnormal imaging findings. See E. Cervical Fusion for Treatment of Axial Neck Pain Criteria.

VII. Cervical Artificial Disc Replacement (Single or Two Level)

This involves the insertion of a prosthetic device into the cervical intervertebral space with the goal of maintaining physiologic motion at the treated cervical segment. The use of artificial discs in motion-preserving technology is based on the surgeon’s preference and training. Only FDA-approved artificial discs are appropriate.

1) Indications for artificial cervical disc replacement are as follows:

a) Skeletally mature patient: AND

b) Patient has intractable radiculopathy caused by one or two level disease (either herniated disc or spondolytic osteophyte) located at C3-C7: AND

c) Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least 6 weeks of appropriate conservative treatment. Documented failure of at least 6 consecutive weeks of any of the following physician-directed conservative treatments:

i) Analgesics, steroids, and/or NSAIDs

ii) Structured program of physical therapy

iii) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician

iv) Epidural steroid injections and or facet injections /selective nerve root block: AND

d) Imaging studies confirm the presence of compression at the level(s) corresponding with the clinical findings (MRI or CT): AND

e) No prior neck surgery: AND

f) Use of an FDA-approved prosthetic intervertebral discs

2) Cervical Artificial Disc Replacement is NOT indicated when any of the following clinical scenarios exists:

a) Symptomatic multiple level disease affecting 3 or more levels

b) Adjacent level disease: degenerative disease adjacent to a previous cervical fusion

c) Infection (at site of implantation or systemic)

d) Osteoporosis or osteopenia

e) Instability

i) Translation greater than 3mm difference between lateral flexion-extension views at the symptomatic levels;

ii) 11 degrees of angular difference between lateral flexion-extension views at the symptomatic levels

f) Sensitivity or allergy to implant materials

g) Severe spondylosis defined as:

i) > 50% disc height loss compared to minimally or non-degenerated levels; OR
ii) Bridging osteophytes: OR

iii) Absence of motion on lateral flexion-extension views at the symptomatic site

h) Severe facet arthropathy

i) Ankylosing spondylitis

j) Rheumatoid arthritis

k) Previous fracture with anatomical deformity

l) Ossification of the posterior longitudinal ligament (OPLL)

m) Active cervical spine malignancy

VIII. Cervical Fusion without Decompression

1) Cervical fusion without decompression will be reviewed on a case-by-case basis. Atraumatic instability due to Down Syndrome-related spinal deformity, rheumatoid arthritis, or basilar invagination are uncommon, but may require cervical fusion.

IX. Cervical Anterior Decompression (without fusion)

2) All requests for anterior decompression without fusion will be reviewed on a case-by-case basis.

X. ADDITIONAL INFORMATION:

1) CPT Codes:

a) Anterior Cervical Decompression with Fusion - Single Level** (ACDF) 22548, 22551, 22554

b) Anterior Cervical Decompression with Fusion - Multiple Level** (ACDF) 22548, 22551, 22554, +22552, +22585

c) Cervical Posterior Decompression with Fusion - Multiple Levels** 22590, 22595, 22600, +22614

d) Cervical Posterior Decompression with Fusion - Single Level** 22590, 22595, 22600

e) Cervical Artificial Disc – Single Level 22856, 22861, 22864

f) Cervical Artificial Disc – Two Levels (**0375T is not a covered service and is not reimbursable) 22858, 0098T, 0095T

g) Cervical Posterior Decompression (without fusion) 63001, 63015, 63020, 63040, 63045, 63050, 63051, +63035, +63043, +63048,

h) Cervical Anterior Decompression (without fusion) 63075, +63076

2) *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.

3) **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 documentation provided regarding completion of HEP, (after 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).

4) A comprehensive assimilation of factors should lead to a specific diagnosis with positive identification of the pathologic condition(s).

a) Early intervention may be required in acute incapacitating pain or in the presence of progressive neurological deficits.

b) Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.

c) Patients may present with localized pain or severe pain in combination with numbness, extremity weakness, loss of coordination, gait issues, or bowel and bladder complaints. Nonoperative treatment continues to play an important role in the care of patients with degenerative cervical spine disorders. If these symptoms progress to neurological deficits, from corresponding spinal cord or nerve root compression, than surgical intervention may be warranted.

d) All patients being considered for surgical intervention should first undergo a comprehensive neuromusculoskeletal examination to identify those pain generators that may either respond to non-surgical techniques, or may be refractory to surgical intervention.

e) If operative intervention is being considered, particularly those procedures that require a fusion, it is recommended that the person refrain from smoking for at least six weeks prior to surgery and during the time of healing.

f) In situations requiring the possible need for operation, a second opinion may be necessary. Psychological evaluation is strongly encouraged when surgery is being performed for isolated axial pain to determine if the patient will likely benefit from the treatment.

g) It is imperative for the clinician to rule out non-physiologic modifiers of pain presentation, or non-operative conditions mimicking radiculopathy, myelopathy or spinal instability (peripheral compressive neuropathy, chronic soft tissue injuries, and psychological conditions), prior to consideration of elective surgical intervention.

5) Degenerative cervical spine disorders, while often benign and episodic in nature, can become debilitating, resulting in axial pain and neurological damage to the spinal cord or roots. Compression on the nerve root and / or spinal cord may be caused by (1) a herniated disc with or without extrusion of disc fragments and/or (2) degenerative cervical spondylosis.

XI. **Anterior Approaches – Additional Information:**

1) Anterior surgical approaches to cervical spine decompression emerged in the 1950s in response to technical limitations experienced with posterior approaches, including restricted access to and exposure of midline bony spurs and disc fragments.

2) The first reports in the literature describe anterior cervical discectomy combined with a spinal fusion procedure (ACDF). Fusion was added to address concerns about potential for loss of spinal stability and disc space height, leading to late postoperative complications such as kyphosis and radicular pain (Sonntag and Klara, 1996; Dowd and Wirth, 1999; Matz et al.,
3) Anterior cervical fusion (ACF) accounted for approximately 80% of cervical spine procedures performed in the United States between 2002 and 2009, while posterior cervical fusion (PCF) accounted for 8.5% of these procedures (Oglesby et al., 2013).

4) **Anterior Cervical Discectomy and Fusion (ACDF)** — removal of all or part of a herniated or ruptured disc or spondolytic bony spur to alleviate pressure on the nerve roots or on the spinal cord in patients with symptomatic radiculopathy. Discectomy is most often combined with fusion to stabilize the spine.

XII. **Posterior Approaches**

1) **Laminectomy** — removal of the bone between the spinal process and facet pedicle junction to expose the neural elements of the spine; this allows for the inspection of the spinal canal, identification and removal of pathological tissue, and decompression of the cord and roots.

2) **Laminoplasty** — the opening of the lamina to enlarge the spinal canal. There are several laminoplasty techniques; all aim to alleviate cord compression by reconstructing the spinal canal. Laminoplasty is commonly performed to decompress the spinal cord in patients with multilevel degenerative spinal stenosis and neutral or lordotic alignment.

3) **Laminoforaminotomy (also known as posterior discectomy)** — the creation of a small window in the lamina to facilitate removal of arthritic bone spurs and herniated disc material pressing on the nerve root as it exits through the foramen. The procedure widens the opening of the foramen so that the nerve exits without being compressed.

XIII. **REFERENCES**


XIV. **Fusion References**


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 level) Plus Decompression
Lumbar Decompression = 63030, +63035, 63005, 63012, 63017, 63042, +63044, 63047, +63048, 63056, +63057
Lumbar Microdiscectomy = 63030, +63035

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

- Indications for Lumbar Discectomy/Microdiscectomy - Surgical indications for inter-vertebral disc herniation*:
  
  a) Primary radicular symptoms noted upon clinical exam that significantly hinders daily activities; AND
  
  b) Failure to improve with at least six (6) consecutive weeks of appropriate conservative treatment; And Documented failure of at least six (6) consecutive weeks of any 2 of the following physician-directed conservative treatments:
  
  i) Analgesics, steroids, and/or NSAIDs
  
  ii) Structured program of physical therapy
  
  iii) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
  
  iv) Epidural steroid injections and or facet injections/selective nerve root block; AND
  
  c) Imaging studies showing evidence of inter-vertebral disc herniation that correlate exactly with the patients symptoms / signs

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

  a) 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

  b) 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*:

  1) Neurogenic claudication, and/or radicular leg pain that impairs daily activities for at least twelve (12) weeks; AND

  2) Failure to improve with at least 6 weeks of appropriate conservative therapy. Documented failure of at least 6 consecutive weeks of any 2 of the following physician-directed conservative treatments:

  a) Analgesics, steroids, and/or NSAIDs

  b) Structured program of physical therapy
c) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician

d) Epidural steroid injections and or facet injections /selective nerve root block; AND

3) Imaging findings demonstrating moderate to severe stenosis consistent with clinical signs/symptoms.

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

a) 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.

b) Cauda equina syndrome (loss of bowel or bladder control)

c) 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.

III. **Indications for Lumbar Spine Fusion: Single Level with or without decompression**

i) 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. The following indicators must be 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; AND*

b) Failure to improve with at least 6 weeks of appropriate conservative therapy (six months for isolated LBP). Documented failure of at least 6 consecutive weeks of *any 2* of the following physician-directed conservative treatments:

i) Analgesics, steroids, and/or NSAIDs

ii) Structured program of physical therapy

iii) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician

iv) Epidural steroid injections and or facet injections /selective nerve root block; AND

c) Imaging studies corresponding to the clinical findings; **AND**

d) At least **one of the following** clinical conditions:

i) Spondylolisthesis [Neural Arch Defect -Spondylolytic spondylolisthesis, degenerative spondylolisthesis, and congenital unilateral neural arch hypoplasia]; OR

ii) Evidence of segmental instability -Excessive motion, as in degenerative spondylolisthesis, segmental instability, and surgically induced segmental instability; OR
iii) 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; OR

iv) 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); OR

v) Fusion for the treatment of spinal tumor, cancer, or infection; OR

vi) *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.

**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).

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

a) Progressive nerve compression resulting in an acute neurologic deficit (motor) **AND**

i) 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 conservative treatment and are not considered an indication for early surgery.

b) Cauda equina syndrome (loss of bowel or bladder control)

IV. **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:

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.
V. **Indications for multi-level fusions 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. The following clinical indications must be present*:

1) Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for **at least 6 months; AND**

2) Failure to improve with at least 6 weeks of appropriate conservative therapy. Documented failure of 6 consecutive weeks of **any 2** of the following physician-directed conservative treatments:
   a) Analgesics, steroids, and/or NSAIDs
   b) Structured program of physical therapy
   c) Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
   d) Epidural steroid injections and or facet injections /selective nerve root block; **AND**

3) Imaging studies corresponding to the clinical findings; **AND**

4) At least one of the following clinical conditions:
   a) Multiple level spondylolisthesis (Note: Fusions in cases with single level spondylolisthesis should be limited to the unstable level); **OR**
   b) Fusion for the treatment of spinal tumor, trauma, cancer, or infection affecting multiple levels; **OR**
   c) Intra-operative segmental instability

5) **Other Indications:** Lumbar spinal fusion may be used as the first line of treatment (**no conservative treatment required**) in the following clinical scenarios:
   a) Progressive nerve compression resulting in an acute neurologic deficit (motor), **AND** one of the aforementioned clinical conditions. 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 appropriate conservative treatment and are not considered an indication for early surgery.
   b) 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.
   c) This lumbar surgery guideline does not address spinal deformity surgeries or the clinical indications for spinal deformity surgery [CPT codes 22800-22812].

**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.
VI. 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

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. 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.

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. These cases will be reviewed on a case-by-case basis and may be denied given the risk of failure.

VII. 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 trocar 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) NIA uses a combination of internally developed edits in addition to an enhanced set of industry standard editing. NIA’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 NIA custom edits developed specifically for spine surgery. The following describes each of the edits NIA 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. NIA 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. NIA 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. NIA 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, NIA 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.

VIII. REFERENCES


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

CPT codes for procedures performed with ultrasound guidance are not a covered service and are not reimbursable: 0213T, +0214T, +0215T, 0216T, +0217T, +0218T, 0228T, +0229T, 0230T, +0231T.

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:

- **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. Interlaminar epidural injections are the most common type of epidural injection.

- **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.

- **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. 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.

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

- Acute pain or exacerbation of chronic radicular pain with the following clinical timeframes:
  - Neck or Back Pain with acute radicular pain:
    - after 2 weeks or more of acute radicular pain that has failed to respond or poorly responded to active conservative (including medication) management unless the medical reason this conservative treatment cannot be done is clearly documented; OR
  - Failed back surgery syndrome or epidural fibrosis causing radicular pain:
    - typically not done immediately post-surgery. Documentation requires a medical reason that clearly indicates why an injection is needed.
    - patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented; OR
  - Spinal stenosis (foraminal, central or disc disease) causing radicular pain
    - patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months prior to epidural injections unless the medical reason this conservative treatment cannot be done is clearly documented.

AND

- Average pain levels of ≥ 6 on a scale of 0 to 10 or intermittent or continuous pain causing functional disability.

**FREQUENCY OF REPEAT THERAPEUTIC INJECTIONS:**

- 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:
  - Documented proof that the prior injection had a positive response by significantly decreasing the patient’s pain (at least 30-50% reduction in pain after initial injections or significant documented functional improvement). 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; AND
  - The patient continues to have ongoing pain or documented functional disability (≥ 6 on a scale of 0 to 10); AND
The patient is actively engaged in other forms of active conservative non-operative treatment (unless pain prevents the patient from participating in conservative therapy*); AND

Injections meet the following criteria:

- There must be at least 14 days between injections;
- No more than 3 procedures in a 12-week period of time per region;
- Limited to a maximum total of 6 procedures per region per 12 months.

Course of treatment, up to three epidural injections, regardless of approach must provide at least:

- At least 50% or more cumulative pain relief obtained for a minimum of 6 weeks to be considered a positive and effective response.
- NOTE: Each epidural injection requires an authorization.

If the neural blockade is applied for different regions, injections may be administered at intervals of no sooner than 14 days for most types of procedures.

Injecting multiple regions or performing multiple procedures during the same visit may be deemed medically unnecessary unless documentation is provided outlining an unusual situation.

No more than 2 levels of transforaminal blocks should be done in one day.

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

CONTRAINDICATIONS FOR EPIDURAL INJECTIONS

- Bleeding diathesis and full anticoagulation (risk of epidural hematoma);
- Severe spinal stenosis resulting in intraspinal obstruction;
- Local infection at injection site;
- Predominantly psychogenic pain;
- Sepsis;
- Hypovolemia;
- Uncontrolled diabetes;
- Uncontrolled glaucoma;
- High concentrations of local anesthetics in patients with multiple sclerosis;
- For diagnosis or treatment of facet mediated pain;
- Known or suspected allergic reaction to steroid medications;
- Spinal infection;
- Malignancy; OR
- Acute fracture.

ADDITIONAL INFORMATION:

*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 (epidural, facet, not 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.
**Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:

- Information provided on exercise prescription/plan AND
- 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).

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

**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.

**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.

**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.

**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.

**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.

**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 discectomy. The
inflammation resulting from the surgical procedure may start the process of fibrosis and cause pain. Epidural steroid injections are administered to reduce pain.

**Discogenic pain** - Discogenic pain is predominant low back pain without disc herniation. 80% to 90% of low back pain is commonly believed to be of unknown etiology. The term, discogenic disc disease, may refer to degenerative disc disease or to internal disc disruption syndrome. Patients with the latter condition may have painful invertebral discs despite minimal degenerative changes. In the U.S., discogenic pain accounts for 25% of cases of chronic low back pain. Evidence has shown that epidural steroid injections are effective for short-term improvement of discogenic pain.

**REFERENCES**


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: AND
   b) Lack of evidence, either for discogenic or sacroiliac joint pain: AND
   c) Lack of disc herniation or evidence of radiculitis: AND
   d) Facet blocks should not be performed at same levels as previous surgical fusion: AND
   e) Intermittent or continuous pain with average pain levels of ≥ 6 on a scale of 0 to 10 or functional disability prior to each injection, including each unilateral facet block: AND
   f) Duration of pain of at least 2 months: 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.

h) All procedures must be performed using fluoroscopic or CT guidance.

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 injections.

2) There must be a positive response of ≥ 50% pain relief or improved ability to function or a change in technique 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. 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*

3) 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.)

4) If the procedures are applied for different regions, they may be performed at intervals of no sooner than 2 weeks for most types of procedures.

5) Maximum of 3 levels injected on same date of service.

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).

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.

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
   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.

V. REFERENCES


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. Used most often for facet joint pain, radiofrequency neurolysis is recently emerging for sacroiliac joint pain. However, it has been shown to have limited evidence in treating sacroiliac joint pain and is considered investigational and not medically necessary.

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, 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: OR

2) Positive response to prior radiofrequency neurolysis procedures with at least 50% pain relief and/or improved ability to function for at least 6 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*): 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;
   b) Intermittent or continuous facet-mediated pain [average pain levels of ≥ 6 on a scale of 0 to 10] causing functional disability prior to each radiofrequency procedure including radiofrequency procedures done unilaterally on different days;
   c) Duration of pain of at least 3 months.
   d) Maximum of 3 spinal levels performed on same date of service.

II. FREQUENCY:

1) Relief typically lasts between 6 and 12 months and sometimes provides relief for greater than 2 years.
2) Limit to 2 facet neurolysis procedures every 12 months, per region (cervical, thoracic and lumbar are each considered one region). 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.

III. CONTRAINDICATIONS FOR PARAVERTEBRAL 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.

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
   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).


V. REFERENCES


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Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer

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