National Imaging Associates, Inc.*

2024 Evolent Clinical Guidelines For Medical Necessity Review - HMSA

MUSCULOSKELETAL SURGERY GUIDELINES - SPINE SURGERY

Effective January 1, 2024 – June 30, 2024

**National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health, LLC.*

Guidelines for Clinical Review Determination

Preamble

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

Guideline Development Process

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

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Clinical guidelines: **CERVICAL SPINE SURGERY**	**Original Date: July 2008**
CPT Codes:** - **Anterior Cervical Decompression with Fusion (ACDF) - Single Level: 22548, 22551, 22554** - **Anterior Cervical Decompression with Fusion (ACDF) - Multiple Levels: +22552, +22585** - **Cervical Posterior Decompression with Fusion - Single Level: 22590, 22595, 22600** - **Cervical Posterior Decompression with Fusion - Multiple Levels: 22595, +22614** - **Cervical Artificial Disc Replacement - Single Level: 22856, 22861, 22864** - **Cervical Artificial Disc Replacement - Two Levels: +22858, +0098T, +0095T** - **Cervical Posterior Decompression (without fusion): 63001, 63015, 63020, +63035, 63040, +63043, 63045, +63048, 63050, 63051** - **Cervical Anterior Decompression (without fusion): 63075, +63076** ***See Utilization Review Matrix for allowable billed groupings and additional covered codes*	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_307	**Implementation Date: January 2024**

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

INDICATIONS FOR CERVICAL SPINE SURGERY

Anterior Cervical Decompression with Fusion (ACDF) - Single Level

The following criteria must be met*:

- Positive clinical findings of myelopathy with evidence of progressive neurologic deficits consistent with **spinal cord compression -** immediate surgical evaluation is indicated.[1-16] Symptoms may include:
    - Upper extremity weakness
    - Unsteady gait related to myelopathy/balance or generalized lower extremity weakness
    - Disturbance with coordination
    - Hyperreflexia
    - Hoffmann sign
    - Positive Babinski sign and/or clonus; **OR**
- 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 (Tetreault, 2013)[2, 6, 10, 14]; **OR**

When ALL of the following criteria are met[2, 17]

- Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity
- 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 in the last 6 months of **any 2** of the following physician-directed conservative treatments:
    - Analgesics, steroids, and/or NSAIDs
    - Structured program of physical therapy
    - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
    - Epidural steroid injections and or selective nerve root block
- 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**.[2] Imaging studies may include:
    - MRI (preferred study for assessing cervical spine soft tissue); **OR**
    - CT with or without myelography— indicated in individuals in whom MRI is contraindicated; preferred for examining bony structures, or in individuals presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI).

***Cervical spine decompression with fusion as first-line treatment without conservative care measures in the following clinical cases[6, 10, 11, 14, 16, 18, 19]**

- As outlined above for myelopathy or progressive neurological deficit scenarios
- Significant spinal cord or nerve root compression due to tumor, infection, or trauma

- Fracture or instability on radiographic films measuring:
    - Sagittal plane angulation of greater than 11 degrees at a single interspace or greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction; **OR**
    - Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child

Not Recommended[17, 20]

- In asymptomatic or mildly symptomatic cases of cervical spinal stenosis
- 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 Cervical Fusion for Treatment of Axial Neck Pain Criteria*

Anterior Cervical Decompression with Fusion (ACDF) – Multiple Levels

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.[1-16] Symptoms may include:
    - Upper extremity weakness
    - Unsteady gait related to myelopathy/balance or generalized lower extremity weakness
    - Disturbance with coordination
    - Hyperreflexia
    - Hoffmann sign
    - Positive Babinski sign and/or clonus; **OR**
- 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[2, 6, 10, 14]; **OR**

When ALL of the following criteria are met[2, 17]

- Cervical radiculopathy or myelopathy due to ruptured disc, spondylosis, spinal instability, or deformity
- 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 in the last 6 months of **any 2** of the following physician-directed conservative treatments:
    - Analgesics, steroids, and/or NSAIDs
    - Structured program of physical therapy
    - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
    - Epidural steroid injections and or selective nerve root block
- 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[2]:
    - MRI (preferred study for assessing cervical spine soft tissue); **OR**

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

Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases[6, 10, 11, 14, 16, 18, 19]

- As outlined above for myelopathy or progressive neurological deficit scenarios
- Significant spinal cord or nerve root compression due to tumor, infection, or trauma
- Fracture or instability on radiographic films measuring:
  - Sagittal plane angulation of greater than 11 degrees at a single interspace or greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction; **OR**
  - Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child

Not Recommended[17, 20]

- In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
- 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 Cervical Fusion for Treatment of Axial Neck Pain Criteria.*

<u>Cervical Posterior Decompression with Fusion - Single Level</u>

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**.**[1, 3, 4, 7, 9-16, 21] Symptoms may include:
  - Upper extremity weakness
  - Unsteady gait related to myelopathy/balance or generalized lower extremity weakness
  - Disturbance with coordination
  - Hyperreflexia
  - Hoffmann sign
  - Positive Babinski sign and/or clonus; **OR**
- 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[2, 6, 10, 14]; **OR**

When **<u>ALL</u> of the following** criteria are met[2, 17]

- Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity
- Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at least **6 weeks of conservative treatment**

- Documented failure of at least 6 consecutive weeks in the last 6 months of **any 2** of the following physician-directed conservative treatments:
    - Analgesics, steroids, and/or NSAIDs
    - Structured program of physical therapy
    - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
    - Epidural steroid injections and or selective nerve root block
- 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**.[2] Imaging studies may include:
    - MRI (preferred study for assessing cervical spine soft tissue); **OR**
    - CT with or without myelography – indicated in individuals in whom MRI is contraindicated; preferred for examining bony structures, or in individuals presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI); **AND**

Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases[10, 11, 14, 16, 18, 19, 21]

- As outlined above for myelopathy or progressive neurological deficit scenarios
- Significant spinal cord or nerve root compression due to tumor, infection, or trauma.
- Fracture or instability on radiographic films measuring:
    - Sagittal plane angulation of greater than 11 degrees at a single interspace or greater than 3.5 mm anterior subluxation in association with radicular/cord dysfunction; **OR**
    - Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child

Not Recommended[17, 22, 23]:

- In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
- 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 Cervical Fusion for Treatment of Axial Neck Pain Criteria.*

Cervical Posterior Decompression with Fusion – Multiple Levels
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.[1, 3, 4, 7, 9-16, 21] Symptoms may include:
    - Upper extremity weakness
    - Unsteady gait related to myelopathy/balance or generalized lower extremity weakness
    - Disturbance with coordination
    - Hyperreflexia
    - Hoffmann sign

- Positive Babinski sign and/or clonus; **OR**
- 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[2, 6, 10, 14]; **OR**

When ALL of the following criteria are met[2, 17]

- Cervical radiculopathy or myelopathy from ruptured disc, spondylosis, spinal instability, or deformity
- Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to at **least 6 weeks of conservative treatment**
- Documented failure of at least 6 consecutive weeks in the last 6 months of **any 2** of the following physician-directed conservative treatments:
  - Analgesics, steroids, and/or NSAIDs
  - Structured program of physical therapy
  - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
  - Epidural steroid injections and or facet injections/selective nerve root block; **AND**
- Imaging studies indicate significant spinal cord or spinal nerve root compression at multiple levels **corresponding with the clinical findings**. Imaging studies may include[2]:
  - MRI (preferred study for assessing cervical spine soft tissue); **OR**
  - CT with or without myelography - indicated in individuals in whom MRI is contraindicated; preferred for examining bony structures, or in individuals presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI); **AND**

***Cervical spine decompression with fusion performed as first-line treatment without conservative care measures in the following clinical cases[10, 11, 18 14, 16, 19, 21]**

- As outlined above for myelopathy or progressive neurological deficit scenarios
- Significant spinal cord or nerve root compression due to tumor, infection, or trauma
- Fracture or instability on radiographic films measuring:
  - Sagittal plane angulation of greater than 11 degrees at a single interspace or greater than 3.5mm anterior subluxation in association with radicular/cord dysfunction; **OR**
  - Subluxation at the (C1) level of the atlantodental interval of more than 3 mm in an adult and 5 mm in a child

Not Recommended[17, 22, 23]

- In asymptomatic or mildly symptomatic cases of cervical spinal stenosis.
- 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: Cervical Fusion for Treatment of Axial Neck Pain Criteria.*

Cervical Fusion for Treatment of Axial Neck Pain

In individuals with non-radicular cervical pain for whom fusion is being considered, **ALL of the following criteria must be met**[24]

- 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 those debilitated with complex problems [**NOTE:** Mere passage of time with poorly guided treatment is not considered an active treatment program]
- All pain generators are adequately defined and treated
- All physical medicine and manual therapy interventions are completed
- X-ray, MRI, or CT demonstrating disc pathology or spinal instability
- Spine pathology limited to one or two levels unless other complicating factors are involved
- Psychosocial evaluation for confounding issues addressed

NOTE: The effectiveness of three-level or greater cervical fusion for non-radicular pain has not been established.[20]

Cervical Posterior Decompression

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.[1, 2, 9-11, 13-16, 25-27] Symptoms may include:
    - Upper extremity weakness
    - Unsteady gait related to myelopathy/balance or generalized lower extremity weakness
    - Disturbance with coordination
    - Hyperreflexia
    - Hoffmann sign
    - Positive Babinski sign and/or clonus; **OR**
- 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[10, 14, 26]; **OR**

When **ALL of the following criteria are met**[2]

- Cervical radiculopathy from ruptured disc, spondylosis, or deformity
- 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 in the last 6 months of **any 2** of the following physician-directed conservative treatments:
    - Analgesics, steroids, and/or NSAIDs
    - Structured program of physical therapy
    - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician

    - Epidural steroid injections and or facet injections/selective nerve root block
- Imaging studies confirm the presence of spinal cord or spinal nerve root compression at the level(s) **corresponding with the clinical findings.**[2, 28] Imaging studies may include **any** of the following:
    - MRI (preferred study for assessing cervical spine soft tissue); **OR**
    - CT with or without myelography— indicated in individuals in whom MRI is contraindicated; preferred for examining bony structures, or in individuals presenting with clinical symptoms or signs inconsistent with MRI findings (e.g., foraminal compression not seen on MRI)

Cervical decompression performed as first-line treatment without conservative care in the following clinical cases[10, 11, 14, 16, 26, 27]

- As outlined above for myelopathy or progressive neurological deficit scenarios.
- Spinal cord or nerve root compression due to tumor, infection, or trauma.

Not Recommended[17, 22, 23]

- In asymptomatic or mildly symptomatic cases.
- In cases of neck pain alone, without neurological deficits and abnormal imaging findings. *See Cervical Fusion for Treatment of Axial Neck Pain Criteria.*
- In individuals with kyphosis or at risk for development of postoperative kyphosis.

<u>Cervical Artificial Disc Replacement (Single or Two Level)</u>

Indications for cervical artificial disc replacement are as follows:[2, 8, 29-31]

- Skeletally mature individual; **AND**
- Intractable radiculopathy caused by one-or-two-level disease (either herniated disc or spondolytic osteophyte) located at C3-C7; **AND**
- Persistent or recurrent symptoms/pain with functional limitations that are unresponsive to **at least 6 weeks** of appropriate conservative treatment; **AND**
- Documented failure of at least 6 consecutive weeks in the last 6 months of **any 2** of the following physician-directed conservative treatments:
    - Analgesics, steroids, and/or NSAIDs
    - Structured program of physical therapy
    - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
    - Epidural steroid injections and or facet injections /selective nerve root block; **AND**
- Imaging studies confirm the presence of compression at the level**(s) corresponding with the clinical findings** (MRI or CT); **AND**
- Use of an FDA-approved prosthetic intervertebral discs.

Cervical Artificial Disc Replacement is **NOT** indicated when **any of the following** clinical scenarios exists[31]

- Symptomatic multiple level disease affecting 3 or more levels
- Infection (at site of implantation or systemic)

- Osteoporosis or osteopenia
- Instability
    - Translation greater than 3mm difference between lateral flexion-extension views at the symptomatic levels
    - 11 degrees of angular difference between lateral flexion-extension views at the symptomatic levels
- Sensitivity or allergy to implant materials
- Severe spondylosis defined as[31]:
    - > 50% disc-height loss compared to minimally or non-degenerated levels; **OR**
    - Bridging osteophytes; **OR**
    - Absence of motion on lateral flexion-extension views at the symptomatic site
- Severe facet arthropathy
- Ankylosing spondylitis
- Rheumatoid arthritis
- Previous fracture with anatomical deformity
- Ossification of the posterior longitudinal ligament (OPLL)
- Active cervical spine malignancy

Cervical Fusion without Decompression

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.[32]

Cervical Anterior Decompression (without fusion)

All requests for anterior decompression without fusion will be reviewed on a **case-by-case basis**.[2, 5, 8, 33]

BACKGROUND

This guideline outlines the key surgical treatments and indications for common cervical spinal disorders and is 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, 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.

OVERVIEW

***Conservative Therapy:** (Musculoskeletal) includes primarily physical therapy and/or injections and a combination of modalities; rest, ice, heat, modified activities, medical devices (e.g., cervical collar), medications, diathermy, chiropractic treatments, or physician supervised home exercise program.

****Home Exercise Program** (HEP) –two elements are required to meet guidelines for completion of conservative therapy:

- Exercise prescription/plan; **AND**
- Follow-up with member providing documentation regarding completion of HEP, (after 4–6-weeks) or inability to complete HEP due to physical reason (i.e., increased pain, inability to physically perform exercises). Inconvenience or noncompliance without explanation does not constitute "inability to complete" HEP.

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

- Early intervention may be required in acute incapacitating pain or with progressive neurological deficits.
- Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.
- Individuals may present with pain, numbness, extremity weakness, loss of coordination, gait issues, or bowel and bladder complaints. Non-operative treatment is an important role in the care of individuals with degenerative cervical spine disorders. If these symptoms progress to neurological deficits, from corresponding spinal cord or nerve root compression, surgical intervention may be warranted.
- All individuals being considered for surgical intervention should receive a comprehensive neuromusculoskeletal examination to identify pain generators that may either respond to non-surgical techniques or may be refractory to surgical intervention.
- Obesity is an identified risk factor for surgical site infection. For individuals undergoing posterior cervical decompression with or without fusion for a diagnosis other than myelopathy, BMI should be less than 40. These cases will be reviewed on a case-by-case basis and may be denied given the increased risk of infection.[34]
- If operative intervention is being considered, especially procedures that require a fusion, it is required the person refrain from smoking/nicotine for **at least six weeks** prior to surgery and **during the time of healing**.[35-40]
- Situations requiring possible need for an operation, a second opinion may be necessary. Psychological evaluation is strongly encouraged before surgery is performed for isolated axial pain to determine if the individual will likely benefit from the treatment.
- 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.

Anterior Approaches:

Anterior surgical approaches to cervical spine decompression emerged in the 1950s. The first literature reports 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.[5, 6, 20, 33, 41-43]

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.[44]

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 individuals with symptomatic radiculopathy. Discectomy is most often combined with fusion to stabilize the spine.

Cervical Artificial Disc Replacement - 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 is based on the surgeon's preference and training; only FDA-approved artificial discs are appropriate.

Posterior Approaches

Laminectomy – removal of the bone between the spinal process and facet pedicle junction to expose the neural elements of the spine.

Laminoplasty – opening of the lamina to enlarge the spinal canal. There are several laminoplasty techniques to alleviate cord compression by reconstructing the spinal canal. Laminoplasty is performed to decompress the spinal cord in individuals with multilevel degenerative spinal stenosis and neutral or lordotic alignment.

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.

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POLICY HISTORY

Date	Summary
May 2023	• Updated references • Moved General Information phrase to top of GL
May 2022	• Reference added • Background updated (added obesity as a risk factor)

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guidelines: **LUMBAR SPINE SURGERY**	**Original Date: June 2013**
CPT Codes:** - **Lumbar Microdiscectomy: 62380, 63030, +63035** - **Lumbar Decompression: 63005, 63012, 63017, 63042, +63044, 63047, +63048, 63056, +63057** - **Lumbar Fusion - Single Level: 22533, 22558, 22612, 22630, 22633, +63052, +63053** - **Lumbar Fusion - Multiple Levels: +22534, +22585, +22614, +22632, +22634, +63052, +63053** ***See UM Matrix for allowable billed groupings and additional covered codes*	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_304	**Implementation Date: January 2024**

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

INDICATIONS FOR LUMBAR SPINE SURGERY[1]

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

- When **ALL of the following** are present:
  - Primary radicular symptoms noted upon clinical exam that significantly hinders daily activities[2-7]
  - Failure to improve with at least 6 consecutive weeks in the last 6 months of documented, physician directed appropriate conservative treatment to include at least 2 of the following[3, 7, 8]:
    - Analgesics, steroids, and/or NSAIDs
    - Structured program of physical therapy

        - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
        - Epidural steroid injections and or selective nerve root block **AND**
    - Imaging studies showing evidence of inter-vertebral disc herniation that correlate exactly with the individual's symptoms/signs[3, 7, 9, 10] **OR**

***Other Indications:** Microdiscectomy may be used as the first line of treatment (*no conservative treatment required*) in the following clinical scenarios[3]:

- Progressive nerve compression resulting in an acute neurologic deficit (motor) due to herniated disc. The neurological deficits should 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 **OR**
- 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.

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*:

- When **ALL of the following** are present:
    - Neurogenic claudication, and/or radicular leg pain that impairs daily activities[2-7, 9-14]
    - Failure to improve with at least 6 consecutive weeks in the last 6 months of documented, physician directed appropriate conservative therapy to include **at least two (2) of the following[3, 8]**:
        - Analgesics, steroids, and/or NSAIDs
        - Structured program of physical therapy
        - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
        - Epidural steroid injections and or selective nerve root block
    - Imaging findings demonstrating moderate to severe stenosis consistent with clinical signs/symptoms[3, 13, 14] **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[3, 7]:

- Progressive nerve compression resulting in an acute neurologic (motor) deficit. The neurological deficits should 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 **OR**
- Cauda equina syndrome (loss of bowel or bladder control) **OR**

- 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 microdecompression via laminectomy or laminotomy are the gold standards.[3, 7]

Lumbar Spine Fusion

Single Level Fusion with or without Decompression

Because of variable outcomes with fusion surgery, individuals should be actively involved in the decision-making process and provided appropriate decision-support materials explaining potential risks/benefits and treatment alternatives when considering this intervention.

- When **ALL of the following** are present*:
    - Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities **for at least 6 months**[2-7, 12, 13, 15-22]
    - Failure to improve with at least 6 consecutive weeks in the last 6 months of documented, physician directed appropriate conservative therapy (6 months for isolated low back pain to include **at least two (2) of the following**[2, 3, 5, 7, 8, 15, 18-21]:
        - Analgesics, steroids, and/or NSAIDs
        - Structured program of physical therapy
        - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
        - Epidural steroid injections and or facet injections/selective nerve root block
    - Imaging studies corresponding to the clinical findings[3, 13-15, 18, 19, 21]
    - **At least ONE of the following** clinical conditions:
        - Spondylolisthesis (neural arch defect - spondylolytic spondylolisthesis, degenerative spondylolisthesis, and congenital unilateral neural arch hypoplasia)[13, 18, 19, 21-25]
        - Evidence of segmental instability - Excessive motion, as in degenerative spondylolisthesis, segmental instability, and surgically induced segmental instability[13, 18, 19, 21-25]
        - 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[26]
        - 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)[3]
        - Fusion for the treatment of spinal tumor, cancer, or infection[26]
        - 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[2, 5, 7, 9, 10, 16, 17, 20, 23, 25]

NOTE: The results of several randomized trials suggests that in many degenerative cases un-instrumented 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)[22, 23, 25, 27-29] **OR**

***Other Indications:** Lumbar spinal fusion may be used as the first line of treatment (*no conservative treatment required*) in the following clinical scenarios[3, 7]:

- Progressive nerve compression resulting in an acute neurologic deficit (motor) **AND**
    - One of the aforementioned clinical conditions, <u>except</u> 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.
- Cauda equina syndrome (loss of bowel or bladder control) **AND**
    - One of the aforementioned clinical conditions, <u>except</u> chronic low back pain or degenerative disc disease.

**** REPEAT LUMBAR SPINE FUSION OPERATIONS**: Repeat lumbar fusion operations will be reviewed on a <u>case-by-case</u> 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[2, 5, 7, 17, 20, 23, 25]:

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

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, individuals should be actively involved in the decision-making process and provided appropriate decision-support materials explaining potential risks/benefits and treatment alternatives when considering this intervention.

- When **ALL of the following** are present*:

- Lumbar back pain, neurogenic claudication, and/or radicular leg pain without sensory or motor deficit that impairs daily activities for **at least 6 months**[2, 4-7, 12, 13, 16, 17, 20]
- Failure to improve with at least 6 consecutive weeks in the last 6 months of documented, physician directed appropriate conservative therapy to include **at least two** (2) of the following[8, 18-21]:
  - Analgesics, steroids, and/or NSAIDs
  - Structured program of physical therapy
  - Structured home exercise program prescribed by a physical therapist, chiropractic provider or physician
  - Epidural steroid injections and or facet injections/selective nerve root block
- Imaging studies corresponding to the clinical findings[3, 13-15, 18, 19, 21]
- **At least ONE of the following** clinical conditions[18, 19, 21-25]:
  - Multiple level spondylolisthesis (Note: Fusions in cases with single level spondylolisthesis should be limited to the unstable level)
  - Fusion for the treatment of spinal tumor, trauma, cancer, or infection affecting multiple levels
  - 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[3, 7]:

- 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**
- 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.

RELATIVE CONTRAINDICATIONS FOR SPINE SURGERY (NOTE: Cases may not be approved if the below contraindications exist):

- **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).[30, 31]
- **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.[3, 7] Individuals 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.
- **Active Tobacco or Nicotine** use prior to fusion surgery. Individuals 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.[32-37]
- **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.[38] These cases will be reviewed on a case-by-case basis and may be denied given the risk of failure.

BACKGROUND

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.

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.

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.

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 below for procedures considered not medically necessary.

- **Spinal surgeries should be performed only by those with extensive surgical training (neurosurgery, orthopedic surgery)**
- **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; and pre-sacral fusion.
    - *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. Its only indication is to obtain diagnostic tissue, such as, for a biopsy for discitis. Its effectiveness has not been fully established.
    - *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.
    - *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.
    - *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.
- **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 braces), medications, diathermy, chiropractic treatments, or physician supervised home exercise program.
- **Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:
    - Documentation provided of an exercise prescription/plan **AND**
    - 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. (Inconvenience or noncompliance without explanation does not constitute "inability to complete" HEP).

- **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.
- **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:
    - Intertransverse fusion or posterolateral fusion
    - Anterior interbody fusion (ALIF)
    - Lateral or transpsoas interbody fusion (XLIF)
    - Posterior or trans-foraminal interbody fusion (PLIF or TLIF)
    - Anterior/posterior fusion (360-degree)
    - Pre-sacral, axial lumbar interbody fusion (AxiaLIF) is still being investigated and is not recommended.
        - 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).
        - 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, orthopedic 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.
        - Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.
            - All individuals 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.

        - 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).
- In general, if the program of non-operative treatment fails, operative treatment is indicated when:
    - 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 individuals with complex problems; and/or
    - 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.

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POLICY HISTORY

Date	Summary
May 2023	• Updated references • Removed Claims Billing/Coding from background
May 2022	Replaced “patients” with “individuals” where appropriate
January 2022	Added CPT Codes +63052, +63053

Reviewed / Approved by NIA Clinical Guideline Committee

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