


<b>MEDICAL POLICY</b>	<b>Back: Fusion and Decompression Procedures</b>
<b>Effective Date: 10/1/2021</b>   10/1/2021	Medical Policy Number: 10
	Technology Assessment Committee Approved Date: 1/14; 1/15; 5/15  Medical Policy Committee Approved Date: 11/06; 9/07; 7/09; 1/11; 12/11; 2/12; 8/13; 3/16; 6/18; 9/19; 12/19; 2/2020; 8/2020; 10/2020; 9/2021
Medical Officer	Date

**See Policy CPT CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**DOCUMENTATION REQUIREMENTS**

The following information must be submitted in order to determine if medical necessity criteria are met:

- Indication for the requested surgery
- Clinical notes documenting that the individual has been evaluated at least once by the requesting surgeon before submitting a request for surgery.
- Medical records must document that a detailed neurological examination has been performed by, or reviewed by the operating surgeon, within 3 months prior to surgery.
- Clinical documentation of extent and response to conservative care (see [Policy Guidelines](#) for all requirements and exceptions), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes
- Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities

- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms
  - Imaging must be performed and read by an independent radiologist
  - If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede

## POLICY CRITERIA

**Note: Current and/or recent smokers** (i.e. within the past year) must have ceased smoking for at least 4 weeks prior to cervical, lumbar or thoracic fusion and must be willing to refrain from smoking after surgery for 3 months. To ensure compliance, laboratory testing will be required at Medical Director discretion. This requirement may be waived for patients with documented severe or rapidly progressive neurologic abnormalities.

### Cervical

- I. Cervical laminectomy, and/or anterior cervical discectomy with fusion, may be considered **medically necessary and covered** for individuals with herniated discs or other causes of spinal cord or nerve root compression (e.g. osteophytic spurring, ligamentous hypertrophy) when **all** of the following criteria are met (A.-E.):
  - A. **At least one** of the following criteria are met (1. or 2.):
    1. Patient meets both of the following (a. and b.):
      - a. Persistent, debilitating, neck or cervicobrachial radicular pain (see [Policy Guidelines](#)), secondary to spinal cord or nerve root compression; **and**
      - b. Documentation that age-appropriate activities of daily living are moderately or severely impacted (see [Policy Guidelines](#)); **or**
    2. Moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see [Policy Guidelines](#) for complete definition); **and**
  - B. Symptoms have failed to improve after conservative treatment (see [Policy Guidelines](#) for all requirements and exceptions), as part of pre-operative surgery planning unless there is intolerable radicular pain (see [Policy Guidelines](#)), significant motor dysfunction, or progressive neurologic changes; **and**
  - C. Physical and neurological abnormalities documented on physical exam suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, myelopathy (see [Policy Guidelines](#))); **and**
  - D. All other reasonable sources of radicular pain have been formally evaluated and ruled out; **and**
  - E. Imaging studies (e.g., CT or MRI) indicate central/lateral recess or foraminal stenosis (moderate to severe), or nerve root compression, or spinal cord compression at the level corresponding with clinical findings.

- II. Cervical laminectomy/fusion may be considered **medically necessary and covered** for the treatment of spinal instability for **any** of the following (A.-M.) indications:
- A. Criterion I. A-E. above is met and **at least one** of the following is met (1.-4.):
    - 1. There is spinal instability; **or**
    - 2. The surgeon has documented that the therapeutic portion of the surgery will cause instability which requires fusion; **or**
    - 3. Iatrogenic spinal instability due to cervical facetectomy or corpectomy; **or**
    - 4. Cervical pseudarthrosis (non-union of prior fusion); **or**
  - B. Cervical kyphosis causing spinal cord compression; **or**
  - C. Spinal infection; **or**
  - D. Acute spinal fracture and/or dislocation (associated with mechanical instability), locked facets, or displaced fracture fragment confirmed by imaging studies (e.g. CT or MRI); **or**
  - E. Spinal cord compression after spinal fracture; **or**
  - F. Spinal tumor resulting in spinal cord compression, vertebral fracture, or vertebral destruction; **or**
  - G. Adjunct to excision of synovial cysts or arachnoid cysts and **all** of the following are met (1.-4.):
    - 1. Causing spinal cord or nerve root compression with unremitting radicular pain; **and**
    - 2. Confirmed by imaging studies (e.g. CT or MRI); **and**
    - 3. Corresponding neurological deficit; **and**
    - 4. Symptoms have failed to respond to conservative treatment (see [Policy Guidelines](#) for all requirements and exceptions); **or**
  - H. Epidural hematomas confirmed by imaging studies (e.g. CT or MRI); **or**
  - I. Atlantoaxial (C1-C2) subluxation (e.g. associated with congenital anomaly, os odontoideum, or rheumatoid arthritis) noted as widening of the atlantodens interval greater than 3 mm confirmed by imaging studies (e.g. CT or MRI); **or**
  - J. Basilar invagination of the odontoid process into the foramen magnum; **or**
  - K. Subaxial (C2-T1) instability confirmed by imaging studies (e.g. CT or MRI) when **both** of the following are met (1. and 2.):
    - 1. Significant instability (sagittal plane translation of at least 3 mm on flexion and extension views or relative sagittal plane angulation greater than 11 degrees); **and**
    - 2. Symptomatic unremitting radicular pain that has failed conservative management (see [Policy Guidelines](#) for all requirements and exceptions), unless there is evidence of cervical cord compression or other contraindications for conservative management; **or**
  - L. Ossification of the posterior longitudinal ligament (three or more levels) with cord compression, confirmed by imaging studies; **or**
  - M. Clinically significant deformity of the spine (kyphosis, head-drop syndrome, post-laminectomy deformity) that meets **at least one** of the following criteria (1.-3.):
    - 1. The deformity prohibits forward gaze; **or**

2. The deformity is associated with severe, radicular neck pain, difficulty ambulating, and interference with activities of daily living (see [Policy Guidelines](#)); **or**
3. Documented progression of the deformity.

### Thoracic/Lumbar

- III. Thoracic or lumbar laminectomy may be considered **medically necessary and covered** when **all** of the following criteria are met (A.-E.):
  - A. Persistent, debilitating, radicular pain (see [Policy Guidelines](#)) and **at least one** of the following criteria are met (1.-3.):
    1. Documented moderate to severe interference of radicular pain with age-appropriate activities of daily living (see [Policy Guidelines](#)); **or**
    2. Severe disability as measured by the Oswestry Disability Index (see [Policy Guidelines](#)); **or**
    3. Neurological exam abnormalities and symptoms that correlate with spinal cord or nerve root compression that has been identified on neurological imaging studies; **and**
  - B. Symptoms have failed to improve after 3 months of conservative treatment (see [Policy Guidelines](#) for all requirements and exceptions), as part of pre-operative surgery planning, including but not limited to physical therapy (unless there is intolerable radicular pain (see [Policy Guidelines](#)), significant motor dysfunction, or progressive neurologic changes); **and**
  - C. Physical and neurological abnormalities documented on physical exam suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, myelopathy (see [Policy Guidelines](#)); **and**
  - D. Imaging studies (e.g., CT or MRI) indicate stenosis, or nerve root compression, or spinal cord compression at the level corresponding with above clinical findings; **and**
  - E. All other reasonable sources of radicular pain and/or neurological changes have been ruled out.
- IV. Thoracic or lumbar spinal fusion may be considered **medically necessary and covered** for the treatment of spinal instability for **any** of the following indications (A.-I.):
  - A. Criterion III. A-E. above is met **and** there is spinal instability documented by imaging; **or**
  - B. Scoliosis in skeletally immature adolescents when Cobb angle is greater than 40 degrees; **or**
  - C. Scoliosis in skeletally mature adults when **all** of the following (1.-3.) criteria are met:
    1. Spinal instability with disabling radicular pain (see [Policy Guidelines](#)) that interferes with age-appropriate activities of daily living (see [Policy Guidelines](#)); **or**
    2. Severe disability as measured by the Oswestry Disability Index (see [Policy Guidelines](#)); **and**
    3. Symptoms have failed to improve after conservative treatment (see [Policy Guidelines](#) for all requirements and exceptions) as part of surgery planning; **or**

- D. Kyphosis causing spinal cord compression which has failed 6 weeks of conservative treatment (see [Policy Guidelines](#) for all requirements and exceptions); **or**
- E. Spondylolisthesis with spinal instability when **all** of the following (1.-3.) criteria are met:
  - 1. Grade II, III, IV, or V spondylolisthesis (see [Policy Guidelines](#)); **and**
  - 2. Persistent, debilitating radicular back pain (see [Policy Guidelines](#)) that interferes with age-appropriate activities of daily living (see [Policy Guidelines](#)) **or** severe disability as measured by the Oswestry Disability Index (see [Policy Guidelines](#)); **and**
  - 3. Symptoms have failed to improve after 3 months of conservative treatment (see [Policy Guidelines](#) for all requirements and exceptions), as part of pre-operative surgery planning; **or**
- F. Pseudarthrosis when at least 6 months have passed since time of fusion, *unless contraindicated*; **or**
- G. Spinal infection; **or**
- H. Spinal fracture and/or dislocation; **or**
- I. Spinal tumor or cyst resulting in spinal cord compression, vertebral fracture, or vertebral destruction.

#### Vertebral Corpectomy

- V. Corpectomy may be considered **medically necessary and covered** for treatment of **at least one** of the following indications (A.-D.) when confirmed by imaging studies (e.g., CT or MRI):
  - A. Spinal tumor(s); **or**
  - B. Vertebral fractures; **or**
  - C. Symptomatic central spinal stenosis; **or**
  - D. Retropulsed bone fragments.

#### Non-Covered Procedures

- VI. Percutaneous or endoscopic spinal fusion or decompression procedures are considered **investigational and are not covered**, including but not limited to the following procedures (A.-H.):
  - A. Percutaneous endoscopic discectomy
  - B. Automated percutaneous discectomy and disc decompression
  - C. Percutaneous laser discectomy and disc decompression
  - D. Minimally invasive lumbar decompression (MILD procedure)\*
    - \* *note: MILD may be covered for Medicare lines of business when performed in an approved clinical trial. See Billing Guidelines below for details.\**
  - E. Microendoscopic discectomy (MED)
  - F. Endoscopic transforaminal lumbar interbody fusion
  - G. Axial lumbar interbody fusion (AxialLIF)
  - H. Annulus repair devices (e.g. Barricaid®)
  - I. Customized/personalized intervertebral cages

Link to [Policy Summary](#)

## POLICY GUIDELINES

### Definitions

*Activities of daily living:* The activities of daily living (ADLs) is a term used to describe essential skills that are required to independently care for oneself.<sup>1</sup> Examples may include, but are not limited to, the following:

- Ambulating
- Feeding
- Dressing
- Personal hygiene
- Transportation and shopping
- Meal preparation
- Housecleaning and home maintenance

*Conservative treatments:* Conservative care must be recent (within the last year) and include all of the following, unless contraindicated by documentation indicating severe or rapidly progressive neurologic signs:

- Participation in a physical therapy program for the duration of conservative management (i.e. 3 months before surgery depending on the indication for surgery), including at least 3 physical therapy visits
- Oral analgesics (including anti-inflammatory medications, if not contraindicated) or participation in an interdisciplinary pain management program
- Oral corticosteroids (if not contraindicated)

Indications for which conservative care **may be waived** include the following:

- Spinal cord compression with corresponding neurological symptoms
- Stenosis causing cauda equina syndrome
- Stenosis causing myelopathy
- Stenosis causing severe weakness (graded 4 minus or less on Medical Research Council (MRC) Scale\*)
- Severe stenosis associated with instability (dynamic excursion of greater than 1mm translation or greater than 5 degrees angulation at interspace)
- Progressive neurological deficit on serial examinations
- Discharge note from a physical therapist documenting lack of utility of further physical therapy

\*

Medical Research Council (MRC) Scale	
Grade	Description

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0	No contraction
1	Flicker or trace of contraction
2	Active movement with gravity eliminated
3	Active movement against gravity
4 minus	Active movement against gravity and slight resistance
4	Active movement against gravity and moderate resistance
4 plus	Active movement against gravity and strong resistance
5	Normal power

*Low back pain:* Pain of musculoskeletal origin extending from the lowest rib to the gluteal fold, which may at times extend as somatic referred pain/non-radicular pain into the thigh (above the knee).<sup>2</sup>

*Myelopathy:* Myelopathy refers to any neurological deficit related to a spinal cord injury. Corresponding clinical symptoms may include, but are not limited to the following:

- Bowel or bladder incontinence;
- Clumsiness of the hands
- Frequent falls
- Urinary urgency

Corresponding objective neurological signs may include but are not limited to the following:

- Hoffman sign
- Hyperreflexia
- Increased tone or spasticity

*Neck Disability Index:* The Neck Disability Index (NDI) is a modification of the Oswestry Disability Index, and is used by clinicians and researchers to quantify neck pain.<sup>3</sup> Patients self-report scores across 10 categories, including pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. Each section is scored on a 6-point scale ranging from 0 (“no pain”) to 5 (“worst imaginable pain”).

- Scoring
  - 0-4 points (0-8%) no disability,
  - 5-14 points ( 10 – 28%) mild disability,
  - 15-24 points (30-48% ) moderate disability,
  - 25-34 points (50- 64%) severe disability,
  - 35-50 points (70-100%) complete disability

*Persistent, debilitating pain:* Persistent, debilitating (or disabling) pain is defined as significant level of pain on a daily basis defined on a Visual Analog Scale as greater than “5” (moderate). The scale ranges from “0” (no pain) to “10” (as bad as it could be).

*Radiculopathy:* Dysfunction of a nerve root associated with pain, sensory impairment, weakness, or diminished deep tendon reflexes in a nerve root distribution.<sup>2</sup> Signs and symptoms of radiculopathy must be confirmed by imaging studies and may include any of the following:

- Pain that radiates into the distal portion of the extremities following the nerve root distribution for the proposed intervention
- Numbness and tingling in a dermatomal distribution
- Muscular weakness in a pattern associated with spinal nerve root compression
- Increased or abnormal reflexes corresponding to affected nerve root level
- Loss of sensation in a dermatomal pattern.

*Repeat fusion:* Repeat fusion may only be covered in the event that new symptoms have returned following resolution from prior surgery. Residual deficits from prior surgery will not be considered.

*Oswestry Disability Index:* The Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to quantify disability for low back pain.<sup>4</sup> The questionnaire contains ten topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each question is scored by the patient on a scale of 0-5 (least amount of disability to most severe disability). Scores are then added and then doubled to obtain the index (range 0 to 100).

- Scoring
  - 0%–20%: Minimal disability
  - 21%–40%: Moderate disability
  - 41%–60%: Severe disability
  - 61%–80%: Crippling back pain
  - 81%–100%: Patients are either bed-bound or have an exaggeration of their symptoms

*Spondylolisthesis:* Myerding Grading System Percentage of Vertebral Slip Forward:

Grade	Percentage
I	25% of vertebral body has slipped forward
II	25% to 49% of vertebral body has slipped forward
III	50% to 74% of vertebral body has slipped forward
IV	75% to 99% of vertebral body has slipped forward
V	Vertebral body has completely fallen off (i.e. spondyloptosis)

**BILLING GUIDELINES**

- CPT code 22585 is an add-on code that may only be billed in conjunction with 22554, 22556, or 22558.



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- Per the [Billing Guidelines](#)<sup>5</sup> of National Coverage Determination (NCD) for Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis ([150.13](#)),<sup>6</sup> the MILD procedure (CPT code 0275T; HCPCS code G0276) may be considered medically necessary and covered only for Medicare patients currently enrolled in a clinical trial. The procedure must be billed with ICD-9 V70.7 (or ICD-10 Z00.6), Condition Code 30, Modifier Q0 and an 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development [website](#).

**CPT CODES**

All Lines of Business	
Prior Authorization Required	
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)

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22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; each additional interspace and segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
22842	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
22843	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
22844	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)

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22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
22846	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
22847	Anterior instrumentation; 8 or more vertebral segments (List separately in addition to code for primary procedure)
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22852	Removal of posterior segmental instrumentation
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22855	Removal of anterior instrumentation
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; cervical
63003	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; thoracic
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; thoracic

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63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure)
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
63050	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments
63051	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application

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	of bridging bone graft and non-segmental fixation devices [eg, wire, suture, mini-plates], when performed)
63055	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; thoracic
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; single segment
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; each additional segment (List separately in addition to code for primary procedure)
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; cervical, single interspace
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; cervical, each additional interspace (List separately in addition to code for primary procedure)
63077	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; thoracic, single interspace
63078	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophyctomy; thoracic, each additional interspace (List separately in addition to code for primary procedure)
63081	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment
63082	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, each additional segment (List separately in addition to code for primary procedure)
63085	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, single segment
63086	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, each additional segment (List separately in addition to code for primary procedure)
63087	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment
63088	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; each additional segment (List separately in addition to code for primary procedure)

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63090	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment
63091	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; each additional segment (List separately in addition to code for primary procedure)
63101	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (eg, for tumor or retracted bone fragments); thoracic, single segment
63102	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (eg, for tumor or retracted bone fragments); lumbar, single segment
63103	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (eg, for tumor or retracted bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure)
63170	Laminectomy with myelotomy (eg, Bischof or DREZ type), cervical, thoracic, or thoracolumbar
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar

**PA Required (Medicare Only)**

C1831	Personalized, anterior and lateral interbody cage (implantable)
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**No PA Required (Medicare Only)**

Note: The following codes are covered only for Medicare patients currently enrolled in a clinical trial. The procedure must be billed with ICD-9 V70.7 (or ICD-10 Z00.6), Condition Code 30, Modifier Q0 and an 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development [website](#).

0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar
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G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (pild) or placebo-control, performed in an approved coverage with evidence development (ced) clinical trial
Not Covered	
0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
S2348	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar
C2614	Probe, percutaneous lumbar discectomy
Not Covered (All Lines of Business Except Medicare)	
C1831	Personalized, anterior and lateral interbody cage (implantable)
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then <b>prior-authorization is required.</b>	
22899	Unlisted procedure, spine

## DESCRIPTION

### Indications

<i>Atlantoaxial Subluxation</i>	Atlantoaxial subluxation refers to the misalignment of the first and 2 <sup>nd</sup> cervical vertebrae, as a result of either a bony or ligamentous abnormality.
<i>Kyphosis</i>	Kyphosis refers to a condition in which the normal inward curve (lordosis) of the spine reverses, causing an abnormal forward curve (kyphosis).
<i>Pseudarthrosis</i>	Pseudarthrosis refers to the failure of spinal fusion, in which bone formation between fused vertebrae is insufficient to stabilize movement, resulting in continued pain and/or disability.
<i>Scoliosis</i>	Scoliosis is a musculoskeletal disorder in which the spine exhibits abnormal lateral curvature of more than 10 degrees in the coronal plane.



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<i>Iatrogenic or Degenerative Flat-back Syndrome</i>	Flat-back syndrome refers to the loss of normal curvature in the lower spine and may either be iatrogenic – caused by previous medical treatment – or degenerative. The loss of lumbar lordosis may cause chronic pain and make standing upright difficult.
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**Medically Necessary Procedures**

<i>Spinal Fusion</i>	Spinal fusion is surgical procedure in which two or more vertebrae are fused together into a single structure, so as to eliminate painful motion and restore spinal stability. During the procedure, bone graft is inserted between the two vertebrae to help the bones heal together.
<i>Laminectomy</i>	According to Hayes, “laminectomy involves complete removal of the lamina and may also include removal of some of the facet joint and ligaments. Laminectomy creates an opening through which compressed nerves can be relieved, or decompressed, and/or through which a surgeon can remove herniated disc or manipulate other nervous system structures that might be causing pain. An orthopedic surgeon or neurosurgeon typically performs laminectomies and may choose to perform the procedure as a single-stage surgery or in multiple stages.” <sup>7</sup>
<i>Laminoplasty</i>	Laminoplasty is a surgical procedure which removes pressure from the spinal cord. The lamina is surgically thinned out on one side, and a hole is drilled on the lamina’s other side. This creates a “door hinge” on one side of the lamina, which metal plates then fix into an “open” position. This opening enlarges the spinal canal, allowing the spinal cord to move away from the blockages compressing it, thereby relieving pain.
<i>Laminotomy</i>	According to Hayes, “laminotomy refers to partial removal of the lamina—a thin, bony layer that covers the back side of a vertebra and protects the spinal canal and the spinal cord. Unlike laminectomy, laminotomy preserves the midline structures and involves partial removal of the lamina, and may also involve some ligament removal. Since laminotomy preserves the natural support of the lamina, it is hypothesized that, compared with laminectomy, it may lower the incidence of complications, including postoperative spinal instability.” <sup>8</sup>
<i>Foraminotomy</i>	Foraminotomy is a surgical procedure in which blockages (e.g. bone, disc, scar tissue) that narrow the spinal column or intervertebral foramen are removed, thereby relieving pressure compressed nerves.
<i>Facetectomy</i>	Facetectomy is a surgical procedure in which one or both of the facet joints on a set of vertebrae are removed, relieving pressure on a spinal nerve root.
<i>Discectomy</i>	Discectomy involves the surgical removal of the part of the disc that is pressing on nerves or the spinal cord, causing pain. Microdiscectomy is a discectomy in which the surgeon also uses that uses an external operating microscope or headlight loupe.



<b>MEDICAL POLICY</b>	<b>Back: Fusion and Decompression Procedures</b>
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<i>Corpectomy</i>	Corpectomy refers to the removal of damaged vertebrae and intervertebral discs that compress the spinal cord and spinal nerves. Because an implant is inserted to fill the space left behind by the removed vertebrae, spinal fusion is often performed during the same procedure.
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**Non-Covered Procedures**

*Percutaneous/Endoscopic Decompression Procedures*

According to Hayes, “percutaneous disc decompression (PDD) describes a variety of minimally invasive surgical procedures that are used as an alternative to open surgical methods for the treatment of herniated cervical intervertebral discs. The goal of PDD is to remove or destroy herniated disc material that may be pressing on nerve roots and thereby causing pain and other symptoms.”<sup>9</sup> Examples of percutaneous/endoscopic decompression procedures include percutaneous endoscopic discectomy, automated percutaneous discectomy, percutaneous laser discectomy, minimally invasive lumbar decompression (MILD), and microendoscopic discectomy (MED).

*Axial Lumbar Interbody Fusion (AxiaLIF)*

AxiaLIF is a minimally invasive fusion procedure that uses titanium alloy implantable devices and instrumentation to independently distract the L5-S1 or L4-S1 vertebral bodies, while also providing anterior stabilization of the spine during spinal fusion.<sup>10</sup> A small incision is made on the buttock and a tube is inserted to reach the spine; thus, the surgical site is not directly visualized. Following removal of the damaged disc, bone graft is used to fill the space between vertebrae. The graft and vertebrae are then fixed into place with a threaded rod.

*Annulus Repair Devices (e.g. Barricaid®)*

Annulus repair devices are intended to reduce reherniation and reoperation after primary lumbar discectomy procedures (microdiscectomy). Devices are designed to close the annular hole with a polyester fabric, while a titanium bone anchor secures the device in vertebral bone.<sup>11</sup>

**REVIEW OF EVIDENCE**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of cervical, thoracic and lumbar fusion and decompression procedures. Below is a summary of the available evidence identified through June 2020.

Spinal Fusion

**Cervical/Thoracic**

*Systematic Reviews*

- In 2019, Youssef and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of posterior cervical fusion (PCF) and decompression.<sup>12</sup> Independent investigators systematically searched the literature through July 2018, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 31 articles were included for qualitative review and meta-analysis (n=1,238; range 7-166). Follow-up ranged from 1 year to 6 years. Outcomes of interest included patient-reported outcomes of pain and disability, and rates of fusion, revision, and complications or adverse events. Subgroup analyses were also performed on patients with only myelopathy or radiculopathy (or both) and only myelopathy or ossification of the posterior longitudinal ligament (or both).

Improvements were reported across all patient-reported outcomes (visual analog scales for arm pain and neck pain, Neck Disability Index, Japanese Orthopaedic Association (JOA) score, modified JOA score, and Nurick pain scale). Pooled outcome rates with all surgical indications were 98.25% for successful fusion, 1.09% for revision, and 9.02% for complications or adverse events. Commonly reported complications or adverse events included axial pain, C5 palsy, transient neurological worsening, and wound infection. Low rates of revision and of complications and adverse events were also reported. Study limitations included the preponderance of retrospective studies included for review (21 of 31), and moderate to high heterogeneity for almost all variables. Investigators concluded that while additional studies evaluating PCF with decompression are needed, the procedure should nonetheless be considered as a surgical option in selected patients.

- In 2013, the Washington State Health Care Authority conducted a systematic review evaluating the comparative clinical effectiveness and comparative value of spinal fusion and its alternatives in patients with cervical degenerative disc disease (DDD).<sup>13</sup> Outcomes of interest included measures of pain, function, health-related quality of life and employment status. Information was also obtained on standardized or study-specific measures of “treatment success” or “successful clinical outcome.” In total, 21 studies were included for review – 7 comparative cohort studies (n=929) and 14 RCTs (n=1,209), 13 of which focused on patients with symptoms and radiographic evidence of cervical radiculopathy. Samples sizes ranged from 10 to 50 patients per treatment arm. Investigators ultimately conferred a “comparable” rating for spinal fusion versus conservative management of radiculopathic symptoms. On the basis of 1 RCT and 1 comparative cohort study, spinal fusion appeared to provide faster relief than conservative treatment in the short term, although no differences in outcome were observed by 12 months after intervention. Investigators also found that the rate of harm complications from cervical fusion were significantly greater than those from conservative care. Despite these findings, investigators concluded in its “coverage recommendation” that cervical spinal fusion for degenerative disc disease should be covered for patients with signs and symptoms of radiculopathy, provided imaging shows corresponding nerve root compression and failure of conservative (non-operative) care.<sup>14</sup>

#### *Nonrandomized studies*

Three retrospective reviews assessed the safety and efficacy of thoracic fusion for the treatment of adolescent idiopathic scoliosis.<sup>15-17</sup> The combined sample size across the three studies was 271. Follow-up varied from 5 years to 32 years. Each review concluded that patients receiving thoracic fusion experienced improvements in functional outcomes and quality of life.

**Lumbar**

- In 2018, Harris and colleagues conducted a review of systematic reviews evaluating the safety and efficacy of lumbar spinal fusion.<sup>18</sup> Independent investigators systematically searched the literature, identified eligible systematic reviews, assessed study quality and extracted data. In total, 60 systematic reviews were included for review. Systematic reviews assessed low back pain and degenerative disc disease, degenerative scoliosis, lumbar spine stenosis, spondylolisthesis, trauma and metastatic tumors of the spine. Investigators concluded that systematic reviews were uniformly of low quality, and that the risk of bias of RCTs in the reviews was generally high. Investigators concluded that available evidence does not support a clinical benefit from spine fusion compared to non-operative treatment or stabilization without fusion for thoracolumbar burst fractures. Similarly, benefits of spinal fusion compared to non-fusion compared to non-operative treatment for isthmic spondylolisthesis were unclear. Despite calling for additional evidence to better establish the efficacy of spine fusion surgery for the treatment of any indication, investigators acknowledged that fusion surgeries would likely continue to be guided by expert clinical opinion based on low-quality evidence.
- In 2017, Yavin and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of lumbar fusion for the treatment of degenerative disease.<sup>19</sup> Independent investigators systematically searched the literature through June 2016, identified eligible studies, assessed study quality, extracted data and pooled results. Primary outcomes of interest included disability, pain and patient satisfaction following fusion, reoperation rates, mortality, complications and incidence of pseudarthrosis. In total, 70 publications describing 65 individual studies were included for review assessing outcomes in a total of 302,620 patients (19 RCTs, 16 prospective cohort studies, 15 retrospective cohort studies, and 15 registry studies). Disability, pain, and patient satisfaction following fusion, decompression-alone, or nonoperative care were dependent on surgical indications and study methodology. Relative to decompression-alone, the risk of reoperation following fusion was increased for spinal stenosis (RR 1.17, 95% CI 1.06-1.28) and decreased for spondylolisthesis (RR 0.75, 95% CI 0.68-0.83). Among patients with spinal stenosis, complications were more frequent following fusion (RR 1.87, 95% CI 1.18-2.96). Mortality was not significantly associated with any treatment modality. Positive clinical change was greatest in patients undergoing fusion for spondylolisthesis whereas complications and the risk of reoperation limited the benefit of fusion for spinal stenosis. Limitations included significant heterogeneity among the studies included, such that the patients combined in the meta-analysis represent truly different populations. Investigators concluded that “the relative safety and efficacy of fusion for chronic low back pain suggests careful patient selection is required.”<sup>19</sup>
- In 2016, Cochrane conducted a systematic review and meta-analysis evaluating the safety and efficacy of various surgical options for the treatment of lumbar spinal stenosis.<sup>20</sup> Independent investigators systematically searched the literature through June 2016, identified eligible studies, assessed study quality, extracted data and pooled results. Primary outcomes of interest included pain intensity, physical function or disability status, quality of life, and recovery. In total, 24 RCTs were included for review (n=2,352), 5 of which compared the effects of fusion in addition to decompression surgery. None of the included trials compared surgery with no treatment, placebo or sham surgery. The quality of evidence varied from “very low quality” to “high quality.” Results showed no significant differences in pain relief at long-term (MD -0.29, 95% CI -7.32 to 6.74). No

between-group differences in disability reduction in the long-term were identified (MD 3.26, 95% CI -6.12 to 12.63). While patients who received only decompression had significantly less perioperative blood loss and required shorter operations, there was no difference in the number of reoperations compared with patients treated with decompression plus fusion. Investigators concluded that decompression plus fusion and interspinous process spacers have not been shown to be superior to conventional decompression alone. Investigators called for additional, higher quality studies to confirm the validity of results.

### Laminectomy

#### **Cervical/Thoracic**

In 2018 (archived 2019), Hayes conducted a “search and summary” of the available literature evaluating the safety and efficacy of staged cervical laminectomy for the treatment of spinal stenosis and/or disc herniation.<sup>7</sup> Having searched the literature through January 2018, Hayes identified 2 abstracts for retrospective comparative studies, and concluded that published evidence was insufficient to assess staged cervical laminectomy.

#### **Lumbar**

- In 2018 (archived 2019), Hayes conducted a “search and summary” of the available literature evaluating the safety and efficacy of staged lumbar laminectomy for the treatment of spinal stenosis and/or disc herniation.<sup>21</sup> Having searched the literature through March 2018, Hayes identified 6 abstracts (1 RCT; 2 retrospective comparative studies; 1 retrospective uncontrolled study; 1 systematic review; 1 case report), and concluded that published evidence was insufficient to assess staged lumbar laminectomy.
- In 2015, Cochrane conducted a systematic review evaluating the efficacy of posterior decompression techniques compared with conventional laminectomy for the treatment of lumbar stenosis.<sup>22</sup> Independent investigators systematically searched the literature through June 2014, identified eligible studies, assessed study quality and extracted data. The review searched for prospective controlled studies comparing conventional facet-preserving laminectomy versus a posterior decompressive technique that avoids removal of posterior midline structures or a technique involving only partial resection of the vertebral arch. Studies describing techniques of decompression by means of interspinous process devices or concomitant (instrumented) fusion procedures were excluded.

In total, 10 RCTs were included for review (n=733), in which three different posterior decompression techniques compared to conventional laminectomy. Three studies compared unilateral laminotomy for bilateral decompression versus conventional laminectomy; four studies compared bilateral laminotomy versus conventional laminectomy (one study included three treatment groups and compared unilateral and bilateral laminotomy vs conventional laminectomy); four studies compared a split spinous process laminotomy versus conventional laminectomy. Evidence, ranging in quality from “very low” to “low,” suggested that different techniques of posterior decompression and conventional laminectomy have similar effects on functional disability and leg pain. Perceived recovery was better among patients who underwent

bilateral laminotomy compared with conventional laminectomy. Investigators concluded that additional, higher-quality research with long-term follow-up is necessary to establish the safety and efficacy of alternative techniques compared to conventional laminectomy, especially laminotomy compared to laminectomy.

#### Cervical/Thoracic Laminoplasty

Several recent systematic reviews evaluated the safety and efficacy of cervical laminoplasty compared to either laminectomy or anterior decompression and fusion.<sup>23-26</sup> Studies reported mixed results most outcomes assessed, including Japanese Orthopedic Association scores, mean blood loss, complication rates and reoperation rates. Patients receiving anterior decompression and fusion achieved superior neurological improvement compared to laminoplasty patients according to three of the four systematic reviews. Investigators from three of the four systematic reviews called for additional studies to better establish the efficacy and patient selection criteria of laminoplasty.

#### Lumbar Laminotomy

In 2017 (updated 2019; archived 2020), Hayes conducted an evidence review of laminotomy for the treatment of lumbar spinal stenosis.<sup>8</sup> Having searched the literature through March 2017, Hayes included 6 clinical studies for review (n = 120 to 1,531). The body of evidence was assessed as ranging in quality from “very poor” to “poor.” Primary outcomes of interest included pain, disability and safety. Across 2 fair-quality RCTs, laminotomy was associated with significantly greater reductions in pain compared to laminectomy ( $p < 0.05$ ). In a large registry study, laminotomy and laminectomy were significantly less effective at reducing pain than laminectomy plus instrumented fusion. Pain relief was maintained at 12 months’ post-surgery. Across 6 studies, laminotomy was found to improve disability in patients with lumbar spinal stenosis. Results indicated that there were significant improvements from baseline in the laminotomy and laminectomy groups, although with no significant differences in disability or walking distance between these groups. Additionally, laminotomy was either comparable or superior to laminectomy with regard to safety outcomes (i.e. overall complication rates, surgical complication rates, necessity for re-intervention/reoperation, occurrence of dural tears, and spinal instability in the post-operative follow-up period. Results’ validity was limited by small sample sizes, a lack of statistical significance, a lack of prospective, randomized studies, potential for confounding by co-interventions (e.g. fusion, discectomy, foraminotomy) and inadequate follow-up. Hayes ultimately assigned a “C” rating (potential but unproven benefit) for laminotomy for the treatment of lumbar spinal stenosis in adult patients who have failed conservative treatments. Investigators called for additional studies with long-term follow-up to better establish the safety and efficacy of laminotomy.

#### Cervical/Thoracic Foraminotomy

Several recent systematic reviews compared the safety and efficacy of open foraminotomy to either minimally-invasive foraminotomy or cervical discectomy and fusion.<sup>27-32</sup> Results across the studies indicated comparable efficacy between all three techniques, regarding rates of clinical success, complication, pain and disability.

#### Lumbar Facetectomy

Several recent clinical trials (2 prospective, 1 retrospective) evaluated the safety and efficacy of facetectomy, one as part of an interbody fusion<sup>33</sup> procedure and two without fusion.<sup>34,35</sup> Though prospective studies were limited by small sample sizes (n=161) and inadequate follow-up ( $\leq 2$  years), both studies reported significant improvements in patients' pain and disability scores at short-term follow-up. Patients assessed in the retrospective surgeon series (n=222) experienced mixed efficacy at long-term follow-up.<sup>35</sup>

### Discectomy

#### **Cervical/Thoracic**

##### *Systematic Reviews*

No recent systematic reviews were identified addressing the safety and/or efficacy of cervical or thoracic discectomy.

##### *Nonrandomized Studies*

Searches identified several small, retrospective studies evaluating the efficacy of thoracic discectomy.<sup>36-38</sup> Studies' combined sample size was 35; and follow-up ranged from 6 months to 24 months. Studies reported improvements in pain and functionality outcomes. Results' validity was undermined by extremely small sample sizes and the lack of large, prospective studies.

#### **Lumbar**

- In 2019, Arts and colleagues conducted a systematic review and meta-analysis comparing the safety and efficacy of various treatments for lumbar disc herniation.<sup>39</sup> Independent investigators systematically searched the literature through May 2018, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 14 comparative studies were included for discectomy (8 RCTs), all of which evaluated lumbar discectomy as part of at least one treatment arm (n=3,947). Results indicated that lumbar discectomy was more effective than continued conservative care in improving leg pain (mean difference: -10,  $p < 0.001$ ), back pain (MD -7,  $p = 0.02$ ) and disability, although the latter not significantly (MD -5,  $p = 0.09$ ). Lumbar discectomy with bone-anchored annular closure was more effective than LD in reducing risk of reherniation (OR: 0.38,  $p < 0.001$ ) and reoperation (OR: 0.33,  $p < 0.001$ ). Limitations included heterogeneity of outcomes among studies, which confounded data interpretation and was not explained in subgroup analysis. Investigators concluded that lumbar discectomy is more effective than continued conservative care in the treatment of lumbar disc herniation.
- In 2019, Tanavalee and colleagues conducted a systematic review and meta-analysis comparing repeat discectomy versus fusion for the treatment of recurrent lumbar disc herniation.<sup>40</sup> Independent investigators systematically searched the literature through X, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 4 studies were included for review. The combined sample size ranged was 376 (range: 37 to 188). Average follow-up time was 40.3 months. The primary outcome of interest were rates of reoperation between repeat discectomy and fusion treatment. Secondary outcomes included clinical improvement, operative time, blood loss, complications and postoperative hospital stay between repeat discectomy and

fusion treatment. While meta-analysis showed that re-operations were higher among patients receiving discectomy (9.09%) compared to those receiving fusion (2.00%), this difference was not statistically significant. Moreover, operative time and post-operative stay were significantly less in the discectomy group. Limitations included a lack of randomized and prospective studies available for analysis, high heterogeneity, small sample sizes and inadequate follow-up. Investigators concluded that no difference in re-operation rates between the two surgical treatments was found, with both treatment techniques yielding equal improvement and complication rates.

- In 2018, the Washington State Health Care Authority conducted a systematic review evaluating the safety and efficacy of various surgeries for the treatment of lumbar radiculopathy/sciatica.<sup>41</sup> Independent investigators systematically searched the literature through November 2017, identified eligible studies, assessed study quality and extracted data. Studies included for review evaluated surgery for radiculopathy (primarily discectomy or microdiscectomy) to nonsurgical interventions, or that compared alternative surgical procedures (e.g. minimally-invasive procedures) compared with open procedures. Primary outcomes of interest included efficacy outcomes (pain, function and disability, quality of life, neurological symptoms, return to work), safety outcomes (mortality, surgical morbidity, reoperations, persistent opioid us), or cost analyses. In total, 25 RCTs were included for review, 1 of which was assessed as low risk of bias, 12 moderate risk of bias, and 12 high risk of bias. Among these, 7 RCTs compared microdiscectomy or discectomy to nonsurgical interventions (n=1,158).

Results indicate that discectomy and microdiscectomy surgery reduced leg pain by 6 to 26 points more than nonsurgical interventions as measured on a 0 to 100-point visual analog scale of pain at up to 26 weeks' follow-up. These differences disappeared, however, at 1-year follow-up and beyond. Results were mixed for functioning and disability, and surgery and nonsurgical interventions produced similar improvements in quality of life, neurologic symptoms, and return to work. Three RCTs (n=282) compared microdiscectomy to discectomy and reported similar improvements in pain at 26-week follow-up. Four high quality clinical practice guidelines were also identified that generally agreed in recommending discectomy or microdiscectomy (and related decompressive procedures) as acceptable treatment for radiculopathy based on evidence that it improves outcomes in the short- to medium-term. Limitations included small sample sizes, inadequate follow-up imprecise effect estimates and high risk of bias in the majority of RCTs included for review, including extensive participant crossover, lack of participant and outcome assessor blinding, and inadequate randomization and allocation concealment. Despite the low quality of evidence, investigators concluded that surgery improves pain and function at short-term follow-up but not at 1-year or longer. All surgeries (i.e. minimally-invasive surgery, discectomy and microdiscectomy) were found to be generally comparable with respect to efficacy and surgical morbidity.

In its "final findings and decisions" coverage recommendation, investigators recommended open discectomy or microdiscectomy with or without endoscopy (lumbar laminectomy, laminotomy, discectomy, foraminotomy) for patients with lumbar radiculopathy who have failed 6 weeks' conservative care.<sup>42</sup>

- In 2014, Cochrane conducted a systematic review evaluating the safety and efficacy of minimally invasive discectomy (MID) versus microdiscectomy/open discectomy (MD/OD) for the treatment of lumbar disc herniation.<sup>43</sup> Independent investigators systematically searched the literature through

November 2013, identified eligible studies, assessed study quality and extracted data. In total, 11 studies were included for review (n=1,172), 7 of which were assessed as having a high overall risk of bias. Primary outcomes of interest included pain measure by visual analog score (VAS), neurological deficit of lower extremity and functional outcomes.

Low-quality evidence indicated the MD/OD patients experienced reduced VAS-assessed leg pain and low back pain compared to MID patients, at follow-up ranging from 6 months to 2 years, although differences were too small to be clinically meaningful. Additionally, no differences were identified between MID techniques and MD/OD on other primary outcomes related to disability at 6-months and beyond (MD: 0.84, 95% CI -0.21 to 1.88) or in the likelihood of returning to work (OR: 2.07, 95% CI 0.18 to 24.15) and persistence of motor and sensory neurological deficits. MID patients were less likely to experience surgical site infections compared to MD/OD patients, but more likely to be re-hospitalization for recurrent disc herniation. No statistically significant differences were reported in the rate of procedural complications, surgical re-intervention, dural tears, or length of hospital stay.

Limitations include the low level of evidence across outcomes, the small number of trials, and a high degree of heterogeneity a for lower back pain ( $I^2 = 35%$  at 6 months, 90% at 1 year, 65% at 2 years), although there was no/little heterogeneity for other outcomes. Investigators concluded that additional, high-quality research was necessary to define appropriate indications for MID as an alternative to standard MD/OD for the treatment of lumbar disc herniation.

### Cervical/Thoracic Corpectomy

Two recent systematic reviews and meta-analyses compared the safety and efficacy of cervical corpectomy for the treatment of cervical myelopathy.<sup>44,45</sup> One review, comparing corpectomy to laminoplasty, found no significant differences between groups in Japanese Orthopedic Association scores and laminoplasty, although laminoplasty patients experienced a significantly lower reoperation rate, operation time and blood loss.<sup>45</sup> In contrast, corpectomy patients experienced a comparably better post-operative JOA scores and a higher neurological recovery rate. Investigators called for additional, large RCTs with long-term follow-up to better establish both procedures' safety and efficacy. A second systematic review and meta-analysis compared the efficacy of various surgical constructs used in cervical corpectomy and fusion.<sup>44</sup> Investigators concluded that while each construct has varying benefits and shortcomings, corpectomy with fusion in general is a safe and effective procedure for the treatment of cervical myelopathy or ossified posterior longitudinal ligament.

### Percutaneous/Endoscopic Decompression Procedures

#### **Cervical/Thoracic**

In 2014 (updated 2018; archived 2019), Hayes conducted an evidence review assessing the safety and efficacy of percutaneous disc decompression (PDD) for the treatment of cervical disc herniation (CDH).<sup>9</sup> Searching the literature through March 2018, investigators identified eligible studies, assessed study quality and extracted data. Sample sizes ranged from 17 to 176 patients. Follow-up ranged from 4 weeks to 5 years with considerable variation across studies. Outcomes of interest included patient-rated pain and disability scores, and clinician-rated clinical improvement. In total, 14 studies were included for review (9 retrospectives, 3 prospective and 2 RCTs). Results from evidence assessed as being of "very



low” quality indicated that, compared to patients receiving conservative care, PDD patients experienced significant reductions in pain (average reduction of 75.5%) and disability (66% average improvement from baseline), consistent clinical improvement (85% average improvement from baseline) and no significant complications. Evidence was insufficient to establish definitive patient selection criteria. Despite positive results, Hayes ultimately assigned a “D2” rating (insufficient evidence) for PDD in the treatment of CDH. Limitations included a lack of prospective and controlled studies with large sample sizes. Investigators called for additional, high-quality studies comparing PDD to established treatments for CDH (e.g. discectomy). Hayes also assigned a “D1” rating (no proven benefit) for PDD for the treatment of CDH in patients with a sequestered or free disc fragment, vertebral disease (e.g., degenerative spinal stenosis, spondylolisthesis, or spondylitis), and previous surgical treatment of the disc.

## Lumbar

### Percutaneous Endoscopic Discectomy

#### *Systematic Reviews*

- In 2018, the Washington State Health Care Authority conducted a systematic review evaluating the safety and efficacy of various surgeries for the treatment of lumbar radiculopathy/sciatica.<sup>41</sup> Independent investigators systematically searched the literature through November 2017, identified eligible studies, assessed study quality and extracted results. In total, 25 RCT’s were included for review, of which 13 (n=1,288) compared various minimally-invasive surgeries to microdiscectomy or discectomy. Follow-up ranged from 12 weeks to 2 years. Evidence ranging in quality from “very low” to “low” indicated that minimally-invasive surgeries and discectomy procedures produced similar improvements in patients’ pain, function/disability, quality of life and neurologic symptoms. Surgical morbidity and reoperation rates between groups were also comparable. Patients undergoing minimally invasive surgeries returned to work 4 to 15 weeks sooner than patients receiving discectomy, however, numerous limitations undermine the validity of this finding. Given the lack of high-quality evidence with long-term follow-up, investigators concluded that “minimally invasive procedures that do not include laminectomy, laminotomy, or foraminotomy including but not limited to energy ablation techniques. Automated percutaneous lumbar discectomy, percutaneous laser, nucleoplasty, etc. are not covered.”<sup>42</sup>
- In 2017 (archived 2019), Hayes conducted an evidence review evaluating the safety and efficacy of percutaneous endoscopic lumbar discectomy (PELD) for the treatment of primary lumbar disc herniation (LDH).<sup>46,47</sup> Searching the literature through January 2019, Hayes identified 8 clinical studies for review (1 RCT, 1 prospective cohort study, 4 retrospective cohort study, 2 comparative registry-analyses). Sample sizes ranged from 20 to 15,817. Follow-up ranged from 6 months to 11 years, with all studies conducted in either China and Korea. Outcomes of interest included treatment success, pain, disability, quality of life, recurrence and reoperation, safety and patient selection criteria. Hayes assessed the overall body of evidence as “low-quality.”

Results indicated that PELD performed similarly to other surgical alternatives in adults with LDH that has failed conservative management. Patients undergoing PELD experienced statistically significant improvements in pain, disability, and quality life. Treatment success rates ranged from 85% to 97%,

defined as patient-reported MacNab criteria of excellent or good results. Visual analog scores for back and leg pain also demonstrated clinically significant improvements ranging from 43% to 76%. Clinically relevant improvement in disability was noted in PELD patients (30.1% - 93%), with no significant differences in comparison with microendoscopic discectomy (MED) or open lumbar microdiscectomy (OLM). Reoperation rates in patients undergoing PELD ranged from 3% to 12% at up to 5-year follow-up. Recurrence rates ranged from 3.1% to 6.4% in patients treated with PELD, with no great difference between treatment groups. Complication rates ranged from 0% to 12.5% in patients with PELD, with complications including dural tear, dysesthesia, discitis, bowel violation, headache during and after procedure, nerve numbness, and symptomatic pseudocyst. Patient selection criteria had also not been clearly identified.

Limitations across included studies included observational study designs, retrospective data collection, and a high potential for selection bias. Hayes ultimately assigned a “C” rating (potential but unproven benefit) for PELD as a primary surgical intervention for the treatment of LDH that is refractory to conservative medical management. Consistent results from low-quality evidence demonstrates that PELD is efficacious comparable to other surgical treatments, although substantial uncertainty remains regarding appropriate patient-selection criteria.

- In 2017 (updated 2019; archived 2020), Hayes conducted an evidence review evaluating the safety and efficacy of percutaneous endoscopic lumbar discectomy (PELD) for the treatment of recurrent lumbar disc herniation (rLDH).<sup>48</sup> Searching the literature through January 2019, Hayes identified 6 clinical studies for review (1 nonrandomized controlled trial; 3 retrospective cohort studies; 2 retrospective pretest/posttest studies). Sample sizes ranged from 41-401 patients. Follow-up ranged from 1-4 years, with all studies conducted in either China or Korea. Hayes assess the overall body of evidence as “low-quality.”

Results indicated that PELD may be inferior to comparable treatments for reducing back pain, but comparably higher rates of recurrence. No significant difference was noted between PELD and other treatments for a majority of key outcomes, including leg pain, treatment success, disability, quality of life or associated complications. Results assessing back pain were mixed, and no definitive patient selection criteria were identified. Limitations across studies included a lack of prospective and randomized trials, retrospective data collection, small sample sizes, undefined endpoints and inadequate follow up. Hayes ultimately assigned a “D1” rating (“no proven benefit” for the use of PELD for the treatment of rLDH, given consistent findings from low-quality evidence of inferior outcomes for PELD patients comparable to other procedures.

- Three recent systematic reviews compared the safety and efficacy of endoscopic discectomy compared to open discectomy for the treatment of lumbar disc herniation.<sup>49-52</sup> Each systematic review concluded that full- and microendoscopic discectomy were at least as effective as open discectomy, with either comparable or superior outcomes of back and leg pain, disability, estimated blood loss, and complication rates. Each systematic review concluded by calling for additional, large RCTs to further validate findings.

#### *Randomized Controlled Trials*

In 2017, Gibson and colleagues conducted a randomized controlled trial comparing the efficacy of endoscopic discectomy (ED) to microdiscectomy for the treatment of single level lumbar prolapse and radiculopathy.<sup>53</sup> In total, 143 patients were randomized to receive either TED or microdiscectomy. Outcomes of interest were disability, visual analogue scores of back and leg pain and quality of life. Patients were assessed at 3, 12 and 24-months' follow-up. Patients in both groups experienced significant improvements from baseline, with comparable improvements in each patient-reported outcome. While TED patients' risk of revision was slightly higher for ED patients, side leg pain and length of hospital stays were significantly lower in the ED group at 2-years' follow-up. While ED may be a comparably effective to microdiscectomy, the validity of findings' was nonetheless limited by the study's small sample size, lack of blinding and lack of long-term follow-up.

#### Automated Percutaneous Discectomy and Disc Decompression

In 2019 (archived 2020), Hayes conducted a "search and summary" of the available literature evaluating the safety and efficacy of automated percutaneous lumbar discectomy (APD).<sup>54</sup> Searching the literature through January 2019, Hayes identified 2 articles for review and found conflicting findings presented in the abstracts. As a result, Hayes judged the evidence to be insufficient to conclude that APD conferred a health benefit for patients with lumbar disc disease.

#### Percutaneous Laser Discectomy and Disc Decompression

In 2018 (updated 2019), Hayes conducted an evidence review evaluating the safety and efficacy of percutaneous laser disc decompression (PLDD) for lumbar disc herniation (LDH).<sup>47</sup> Searching the literature through March 2019, Hayes identified 5 studies eligible for review (1 RCT and 4 retrospective comparative studies). Sample sizes ranged from 61 to 100 patients; follow-up ranged from post-treatment to 2 years. Outcomes of interest were pain, MacNab criteria, disability and quality of life. For these outcomes, PLDD was associated with similar efficacy compared to alternative treatments (i.e. microdiscectomy, or radiofrequency ablation). Across studies, PLDD patients experienced a mean of 50% to 80.5% pain relief with follow-up of up to 2 years. Four of 5 studies included information related to safety and adverse events, finding that complication rates ranged from 0% to 5.5% for PLDD group and from 0% to 10.5% for control groups.

While PLDD may be associated with clinical improvements comparable to alternative treatments at up to 2 years, Hayes assessed the overall body of evidence as "very low quality." As such, Hayes concluded that evidence was insufficient to support definitive conclusions regarding PLDD's safety and efficacy. Limitations included the small number of studies, retrospective study design, heterogeneity, small sample sizes and the lack of power analyses. Hayes ultimately assigned a "D2" rating (insufficient evidence) for PLDD for the treatment of lumbar disc herniation refractory to conservative treatment; and called for additional, large and randomized studies to better establish PLDD's safety and comparative efficacy.

#### Minimally Invasive Decompression (MILD)

- In 2019 (updated 2020), Hayes conducted an evidence review evaluating the safety and efficacy of minimally invasive lumbar decompression (MILD) device kit for treatment of lumbar spinal stenosis.<sup>55</sup> Searching the literature through March 2019, Hayes identified 6 studies for review (1

RCT, 3 pretest/posttest prospective studies, 1 retrospective database study). Sample sizes ranged from 38 to 302; follow-up ranged from 3 months to 2 years. Primary outcomes of interest included pain, disability, patient satisfaction, quality of life, medication use, retreatment, procedural outcomes and complications. Across 2 studies, MILD patients experienced significantly superior outcomes relative to both baseline, as well outcomes experienced by patients receiving epidural steroid injections. Hayes assessed the overall body of evidence as “low-quality,” due to a lack of comparisons between MILD with other minimally invasive surgical techniques. Other limitations included small sample sizes, inadequate follow-up, a lack of blinding, high attrition, missing data and heterogeneity across patient groups’ baseline characteristics. Hayes ultimately assigned a “C” rating (potential but unproven benefit) for use of MILD in patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophied ligamentum flavum. Investigators called for additional studies to clarify patient selection criteria.

- In 2011 (updated 2018), ECRI conducted a systematic review of the evidence to evaluate the mild<sup>®</sup> Device Kit for treating lumbar spinal stenosis.<sup>56</sup> Independent reviewers identified relevant evidence, extracted data, and assessed quality. A total of three systematic reviews, one randomized controlled trial, and two nonrandomized studies were selected for review.

The three systematic reviews evaluated pain and functional status up to one year compared to baseline. The RCT (miDAS ENCORE trial, n=301) compared mild to epidural steroid injections and reported pain and functional status at 1-year follow-up. The nonrandomized studies (n=178) evaluated pain and functional status in patients treated with mild or laminectomy up to 59 months. The findings suggest that the mild procedure improves pain and functional outcomes for up to one year. Additionally, the one RCT found that mild is superior to epidural steroid injections at one-year follow-up. However, the ECRI review concluded that “(a)dditional RCTs are needed to verify findings and assess *mild*'s effectiveness compared with other decompression procedures.”<sup>56</sup>

In terms of evidence limitations, ECRI stated “(d)espite the large amount of available data, some evidence gaps remain. The RCT (MiDAS ENCORE) lacks blinding, assesses subjective outcomes, and only 66% of patients completed 24-month follow-up. Nonrandomized comparative studies are at high risk of bias from lack of controls and randomization.”<sup>56</sup> The ECRI Evidence Bar™ concluded that the “balance of evidence is somewhat favorable.”<sup>56</sup>

### Microendoscopic Discectomy

#### *Systematic Reviews*

Three recent systematic reviews compared the safety and efficacy of endoscopic discectomy compared to open discectomy for the treatment of lumbar disc herniation.<sup>49-51</sup> Each systematic review concluded that full- and microendoscopic discectomy were at least as effective as open discectomy, with either comparable or superior outcomes of back and leg pain, disability, estimated blood loss, and complication rates. Each systematic review concluded by calling for additional, large RCTs to further validate findings.

#### *Randomized Controlled Trials*

Four recent randomized controlled trials evaluated the safety and efficacy of microendoscopic discectomy relative to either endoscopic discectomy or open discectomy, for the treatment of lumbar disc herniation.<sup>57-60</sup> Results across studies were mixed, with microendoscopic patients experiencing treatment success at rates comparable to other treatment groups. Nonetheless, studies were limited by small sample sizes of individual studies (n = 32 to 185), a lack of blinding and patient selection criteria.

### Lumbar Interbody Fusion Procedures

#### AxiaLIF

- In 2015 (updated 2018), ECRI conducted an evidence review of AxiaLIF (lumbar interbody fusion) Plus System for the treatment of patients with lumbar degenerative disc disease (DDD).<sup>10</sup> ECRI systematically searched relevant databases through October 2018, identified eligible studies, assessed quality and extracted data. In total 2 studies (1 systematic review (n=700) and 1 case series (n=23)) were included for review.

The systematic review pooled results from 15 uncontrolled, largely retrospective case series conducted by authors with conflict of interests. These studies evaluated the fusion rate of L5-S1 and the safety profile of axial interbody arthrodesis. Study authors reported overall pseudoarthrosis rates at L5-S1 at 6.9% and the rate of all other complications at 12.9%. However, deformity studies reported significantly higher complications rate (46.3%) and prospectively collected data demonstrated significantly high complication and revision rates (36.8% and 22.6% respectively.) Investigators concluded that axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%). Given the systematic review's limitations, study investigators concluded that the actual fusion rate may be lower and the complication rate may be higher than results indicate.

ECRI assessed results to be at high risk of bias due to studies' retrospective design, lack of comparator groups, lack of blinding, lack of randomization and financial conflicts of interests among study investigators. ECRI concluded that multicenter RCTs remained necessary to establish AxiaLIF's efficacy compared to other interbody fusion surgical approaches in patients requiring 1- and 2-level lumbar fusion. However, no current ongoing studies meeting these design parameters were identified.

- In 2018, Anand and colleagues evaluated the fate of the lumbosacral junction in axial lumbar interbody fusion (ALIF) versus AxiaLIF patients in terms of clinical and radiographic outcomes.<sup>61</sup> Adults with spinal deformities were separated into two groups – AxiaLIF (n=56) and ALIF (n=38). Follow-up was 2 years. ALIF patients experienced significant improvements compared to AxiaLIF patients in segmental lordosis, sagittal vertical alignment, lumbar lordosis (LL), pelvic incidence-LL mismatch, AxiaLIF patients experience significantly higher rates of pseudoarthrosis, major complications and revision surgery rates. Investigators concluded that ALIF should privilege ALIF over AxiaLIF for fusion at L5-S1 distal to a long-segment construct, but called for additional studies to further elucidate differences between the two surgical techniques.

### Annulus Repair Devices (e.g. Barricaid®)

In 2020, Miller and colleagues conducted an expert review with meta-analysis of randomized and nonrandomized controlled studies assessing the safety and efficacy of Barricaid annular closure in patients at high risk for lumbar disc reherniation.<sup>62</sup> Independent investigators systematically searched the literature through October 2019, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 4 controlled studies were included for review and included in the meta-analysis, assessing a total of 801 patients - 381 treated with lumbar discectomy and the Barricaid device and 420 treated with lumbar discectomy only. Follow-up duration was 2 years in 3 studies and 4 years in one study. Meta-analysis reported a 55% reduced reherniation rate among Barricaid patients compared to lumbar discectomy at 2-year follow-up. Reoperation risk was reported to be 48% lower among Barricaid patients compared to patients without the device. Limitations include authorial financial conflicts of interest, a lack of long-term follow-up, and the inclusion of 2 nonrandomized and unblinded studies for meta-analysis. Moreover, none of the included studies were conducted the United States.

In 2020, ECRI conducted an evidence review of the Barricaid Annular Closure Device for preventing recurrent vertebral disc herniation after lumbar discectomy.<sup>11</sup> In total, 1 systematic review and 2 publications of 1 RCT were included for review.<sup>62-64</sup> The systematic review with meta-analysis examined 2 RCTs and 2 nonrandomized comparison studies (n=801) comparing limited lumbar discectomy using the Barricaid device to limited lumbar discectomy alone and reported reherniation risk and reoperation risk at 2 years. Additional publications of an RCT (n = 550) assessed 3-year data on serious adverse events; and reoperation rates at 4-year follow-up (i.e., for reherniation and/or leg and back pain). One prospective, multicenter, nonrandomized study (Parker et al. 2016; n = 76) compared lumbar discectomy with Barricaid ACD to lumbar discectomy without Barricaid ACD and reported reherniation at 2 years and pain and disability at 1 year.

The systematic review reported 55% lower reherniation rates at 2-year follow-up in patients receiving lumbar discectomy and Barricaid ACD than in patients receiving lumbar discectomy without the Barricaid ACD. The reoperation risk was reported as 48% lower with than without the Barricaid ACD. At 4-year follow-up, 1 of the RCTs in the meta-analysis reported reoperation risk at 14.4% in patients receiving Barricaid ACD procedure and 21.1% in those that did not receive the device (p = 0.03). At 3 year follow-up, 1 RCT in the meta-analysis reported that serious AEs related to the device or procedure occurred in 10.7% of the Barricaid ACD group and in 18.7% of controls. Investigators concluded that evidence supporting the safety and efficacy of Barricaid was “somewhat favorable.” Limitations included the lack of long-term follow-up, lack of blinding, lack of randomization, the lack of studies conducted in the United States, and manufacturer conflicts of interest.

### **Effects of Smoking on Cervical Fusion**

#### *Systematic Reviews*

In 2016, Jackson et al. conducted a systematic review of the literature to assess the effects of smoking and smoking cessation on spine surgery.<sup>65</sup> Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The outcomes of interest were: increased risks of nonunion, postoperative wound complications, and diminishment of both objective and subjective postoperative outcomes.

The authors found that smoking increases the risk of nonunion in both lumbar and cervical spine procedures. Additionally, current smokers were at significantly increased risk for pseudoarthrosis, postoperative infection, and lower clinical outcomes after surgery. The review found that smoking cessation can reduce these risks and complications, dependent on the duration and timing of tobacco abstinence. Overall, preoperative smoking cessation for 4 weeks was associated with a decreased risk of infection, respiratory, and wound complications. Furthermore, investigators have also shown improved outcomes in patients who ceased smoking for more than 6 months after surgery.

Strengths of this study include the systematic review of evidence using independent reviewers, assessment of quality, and inclusion of a large number of studies. Limitations are seen in the lack of meta-analysis and the lack of high quality studies included in the review. The authors concluded that “(s)moking negatively affects both the objective and subjective outcomes of surgery in the lumbar and cervical spine. Current literature supports smoking cessation as an effective tool in potentially mitigating these unwanted outcomes.”<sup>65</sup>

#### *Non-randomized Controlled Trials*

Across several cohort studies, smokers were shown to experience worse response rates to cervical fusion compared to non-smokers.<sup>66-68</sup> Evidence suggests that smokers are significantly more likely to experience pseudarthrosis and postoperative infection and to report lower clinical outcomes after surgery in cervical spines.<sup>65</sup> Smoking was also associated with a higher rate of delayed fusions and pseudarthrosis, greater interspace collapse, and increased pain and decreased activity in multilevel anterior interbody grafting.<sup>66-68</sup>

## CLINICAL PRACTICE GUIDELINES

### Cervical Spinal Fusion

#### North American Spine Society (NASS)

- In 2013, the NASS issued an clinical practice guideline addressing appropriate use criteria for cervical fusion.<sup>69</sup> On the basis of a non-systematic literature review and expert opinion, investigators stated that it was appropriate to offer cervical fusion to patients who were actively smoking.
- In 2011, the NASS issued an evidence-based clinical practice guideline on the diagnosis and treatment of cervical radiculopathy from degenerative disorders.<sup>70</sup> On the basis of “fair evidence,” NASS recommended anterior cervical discectomy with fusion for the treatment of single level degenerative cervical radiculopathy secondary to foraminal soft disc herniation.

### Lumbar Spinal Fusion

#### North American Spine Society (NASS)

- In 2014, NASS issued an evidence-based guideline for the treatment of lumbar spondylolisthesis.<sup>71</sup> The NASS issued a grade “B” (fair evidence) recommendation for the use of fusion with

decompression for the treatment of stenosis and lumbar spondylolisthesis. On the basis of “poor evidence,” investigators stated that decompression and fusion may provide long-term results for the treatment of patients with spinal stenosis and lumbar spondylolisthesis.

- In 2014, NASS issued an evidence-based guideline for the treatment of isthmic spondylolisthesis (IS).<sup>72</sup> The NASS found no evidence addressing whether fusion with decompression improves surgical outcomes in the treatment of adult IS compared with decompression alone. The body issues a grade “A” recommendation (strong evidence) supporting the use of posterolateral fusion and 360° fusion to improve the clinical outcomes in adult patients with low grade isthmic spondylolisthesis. NASS issued a grade “C” recommendation (“may be considered”) for anterior lumbar interbody fusion (ALIF) in the treatment of adults with low grade isthmic spondylolisthesis.<sup>72</sup>

#### American Association of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS)

In 2014, the American Association of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS) issued a joint guidance addressing fusion procedures for the lumbar spine.<sup>73</sup> Investigators issued grade “B” recommendations (fair evidence) supporting the use of fusion for the treatment of LBP refractory to conservative treatment, and decompression with fusion for the treatment of lumbar stenosis both with and without spondylolisthesis. Investigators issued a grade “B” recommendation (moderate quality evidence) for the addition of an interbody fusion to enhance the fusion rate in patients undergoing lumbar fusion. Based on a lack of conclusive evidence, the body made no recommendation regarding which interbody fusion technique should be employed.<sup>74</sup>

#### National Institute for Health and Care Excellence (NICE)

In 2017, NICE issued a guidance addressing lateral interbody fusion in the lumbar spine.<sup>75</sup> The report concluded that the surgery carries “serious but well-recognized complications” and that “evidence on efficacy is adequate in quality and quantity.

#### U.S. Preventive Services Task Force (USPSTF)/American Academy of Family Physicians (AAFP)

In 2014, the USPSTF and AAFP issued an evidence-based clinical practice guideline for the diagnosis and management of adolescent idiopathic scoliosis.<sup>76</sup> The guideline recommends surgery in scoliosis patients whose Cobb angle is >40 degrees and whose Risser grade is 0 to 4.

#### American Academy of Orthopedic Surgeons (AAOS)

In 2012, the AAOS issued an evidence-based clinical practice guideline on the etiology and management of adult scoliosis. The guideline recommends surgery “for patients who are refractory to nonsurgical management and/or have severe debilitation.”<sup>77</sup>

### **Cervical Discectomy**

#### North American Spine Society (NASS)

In 2011, the North American Spine Society (NASS) issued an evidence-based clinical practice guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders.<sup>70</sup> NASS made a



grade “B” recommendation that anterior cervical discectomy with fusion could provide rapid relief of symptoms when compared to medical/interventional treatment in the short-term, although only poor-quality evidence supported the procedure’s long-term efficacy.

American Academy of Neurological Surgeons (AANS)

In 2009, the American Academy of Neurological Surgeons (AANS) issued an evidence-based clinical practice guideline addressing anterior cervical decompression for the treatment of cervical degenerative radiculopathy.<sup>78</sup> Investigators concluded that anterior cervical discectomy may rapidly improve symptoms of cervical radiculopathy at up to 4 months’ follow-up compared to conservative treatment. Weaker evidence supported the efficacy of cervical discectomy at 12-months, with improvements declining to levels comparable to those attained by physical therapy or cervical immobilization.

**Lumbar Discectomy**

Oregon Health Evidence Review Commission (HERC)

In 2018, HERC issued an evidence-based coverage guidance on the use of minimally invasive and non-corticosteroid percutaneous interventions for the treatment of low back pain.<sup>79</sup> Based largely on the findings of the Cochrane review discussed above,<sup>43</sup> HERC issued a “weak” coverage recommendation for minimally invasive discectomy as an alternative to microdiscectomy or open discectomy, when discectomy is indicated.

North American Spine Society (NASS)

In 2014, NASS issued an evidence-based clinical practice guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy.<sup>80</sup> The body issued a grade “B” recommendation (fair-quality evidence), the body concluded that discectomy and medical/interventional care appear to be effective in short and long-term relief.

**Percutaneous/Endoscopic Decompression Procedures**

*Percutaneous Endoscopic Lumbar Discectomy*

National Institute for Health and Care Excellence (NICE)

In 2016, NICE issued guidance on the use of transforminal<sup>81</sup> and interlaminar<sup>82</sup> percutaneous endoscopic lumbar discectomy for the treatment of sciatica. Both reports concluded that current evidence was “adequate” to support the use of PED for sciatica, depending on the patient’s symptoms and location and size of prolapsed disc.

North American Spine Society (NASS)

In 2014, NASS issued a guidance on the diagnosis and treatment of lumbar disc herniation with radiculopathy.<sup>80</sup> The body issued a grade “C” recommendation (poor evidence) for the use of endoscopic percutaneous discectomy for the treatment of LDH with radiculopathy. The body also issued a grade “B” recommendation (fair evidence) stating that endoscopic percutaneous discectomy be used for “carefully

selected patients” to reduce early postoperative disability and reduce opioid use compared with open discectomy.

#### *Automated Percutaneous Discectomy and Disc Decompression*

##### North American Spine Society (NASS)

In 2014, NASS issued a guidance on the diagnosis and treatment of lumbar disc herniation with radiculopathy.<sup>80</sup> The body issued a grade “C” recommendation (poor evidence) for the use of automated percutaneous discectomy (APD) for the treatment of lumbar disc herniation with radiculopathy. Investigators stated that evidence was insufficient to recommend for or against the use of APD over open discectomy.

##### American Society of Interventional Pain Physicians (ASIPP)

In 2013, ASIPP issued a clinical practice guideline, stating that “evidence for automated percutaneous lumbar discectomy, percutaneous disc decompression, and decompressor use is limited.”<sup>83</sup> Investigators nonetheless recommended the procedures for use in select cases.

#### *Percutaneous Laser Discectomy and Disc Decompression*

##### Oregon Health Evidence Review Commission (HERC)

In 2018, HERC issued a coverage guidance addressing minimally invasive and non-corticosteroid percutaneous interventions for the treatment of low back pain.<sup>79</sup> HERC issued a strong recommendation against percutaneous laser disc decompression for the treatment of low back pain.

##### National Institute for Health and Care Excellence (NICE)

In 2016, NICE issued a guidance addressing epiduroscopic lumbar discectomy through the sacral hiatus for sciatica.<sup>84</sup> Investigators concluded that current evidence on the safety and efficacy of epiduroscopic lumbar discectomy through the sacral hiatus for sciatica is limited in quantity and quality, and thus the procedure should only be used in the context of research. NICE also called for additional, long-term studies evaluating patient selection criteria and complications.

#### **Axial Lumbar Interbody Fusion (AxialIF)**

##### National Institute for Health and Care Excellence (NICE)

In 2018, NICE issued a guidance addressing transaxial interbody lumbosacral fusion (AxialIF) for the treatment of low back pain.<sup>85</sup> The report concluded that the surgery carries “serious but well-recognized complications” and that “evidence on efficacy is adequate in quality and quantity.

#### **Annulus Repair Devices (e.g. Barricaid®)**

##### International Society for the Advancement of Spine Surgery (ISASS)

In 2019, the ISASS published a policy guideline addressing surgical treatment of lumbar disc herniation with radiculopathy.<sup>86</sup> On the basis of a non-systematic review of evidence, investigators concluded that implantation of a bone-anchored annular closure devices reduces the risk of symptom recurrence and revision surgery compared to discectomy alone.

### **Revision Surgery**

#### North American Spine Society (NASS)

In 2013, the NASS issued a clinical practice guideline addressing appropriate use criteria for cervical fusion.<sup>69</sup> On the basis of a non-systematic literature review and expert opinion, investigators stated that patients with a history of prior cervical fusion with persistent axial pain and symptomatic pseudarthrosis were appropriate for revision of the fusion, but that fusion for asymptomatic pseudarthrosis was rarely appropriate. Authors also stated that patients with a history of prior cervical fusion and pseudarthrosis and foraminal stenosis at that level with either concordant radiculopathy or axial pain were also appropriate for revision of the fusion.

### **Functional Impairment**

#### North American Spine Society (NASS)

In 2020, the NASS issued an evidence-based clinical practice guideline addressing the diagnosis and treatment of low back pain.<sup>2</sup> On the basis of level I evidence, investigators recommended that pain severity and functional impairment be used to stratify risk of conversion from acute to chronic pain.

## **CENTERS FOR MEDICARE & MEDICAID**

As of 7/10/2020, one Medicare coverage guidance was identified which addresses cervical, thoracic, or lumbar fusion and decompression procedures. National Coverage Determination 150.13: Percutaneous Image-Guided Lumbar Decompression addresses CPT code 0275T.<sup>87</sup> According to the NCD, percutaneous lumbar decompression may only be covered by Medicare when provided in a clinical study through Coverage with Evidence Development (CED).

## **POLICY SUMMARY**

Professional clinical organizations as well as consistent evidence from clinical trials support the use of spinal fusion, laminectomy, discectomy and corpectomy in the cervical, thoracic, and lumbar spinal regions. Evidence does not support, however, the efficacy of percutaneous/endoscopic decompression procedures. Systematic reviews evaluating the efficacy of these procedures noted a lack of long-term evidence from controlled, prospective trials, and called for additional studies to establish safety and efficacy.

## **INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

## REGULATORY STATUS

### U.S. Food and Drug Administration (FDA)

In February 2019, the FDA granted Premarket Approval for the Barricaid ACD<sup>88</sup>. The device is indicated for the following:

The Barricaid<sup>®</sup> ACD is indicated for reducing the incidence of reherniation, and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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