
Spinal Fusion and Decompression Procedures

MEDICAL POLICY NUMBER: 10

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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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP 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.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Spinal fusion and decompression procedures:

Guideline Note 37 - Line 346

Guideline Note 100 - Lines 47, 150, 200, 254, 346, 361, 401, 478, 530, 559

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Notes:

- Single-level spinal fusion procedures are reviewed for both medical necessity (criteria below) and inpatient site of service (see criteria in “[Surgical Site of Service](#)” policy.)
- **Current and/or recent smokers** (i.e., within the past year) (see [Policy Guidelines](#) for definition of smoker) 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.
- Please refer to [Medical Policy References](#) for other medical policies addressing back procedures.

Cervical

- I. Cervical laminectomy, and/or anterior cervical discectomy with fusion, may be considered **medically necessary** 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.-F.):

- 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. Medical records document that a detailed, physical examination (which includes a neurological exam) has been performed by, or reviewed by the operating surgeon, within 3 months prior to surgery; **and**
- D. Physical and neurological abnormalities are well documented and suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, radicular pain, hyperreflexia, reflex changes, myelopathy (see [Policy Guidelines](#))); **and**
- E. All other reasonable sources of radicular pain have been formally evaluated and ruled out; **and**
- F. 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** for the treatment of spinal instability for **any** of the following (A.-M.) indications:

- A. Criterion I. A-F. 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** when **all** of the following criteria are met (A.-F.):
- 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. Medical records document that a detailed, physical examination (which includes a neurological exam) has been performed by, or reviewed by the operating surgeon, within 3 months prior to surgery; **and**
 - D. Physical and neurological abnormalities are well documented and suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, radicular pain, hyperreflexia, reflex changes, myelopathy (see [Policy Guidelines](#)); **and**
 - E. 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**
 - F. 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** for the treatment of spinal instability for **any** of the following indications (A.-I.):
- A. Criterion III. A-F. 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](#)); **and**
 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 (i.e. medically necessary fusion is needed more urgently)*; **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** 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. Lumbar fusion for the treatment of facet syndrome is considered **not medically necessary**.

VII. Percutaneous or endoscopic spinal fusion or decompression procedures are considered **not medically necessary**, including but not limited to the following procedures:

- 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)
- E. Microendoscopic discectomy (MED)
- F. Endoscopic transforaminal lumbar interbody fusion
- G. Axial lumbar interbody fusion (AxialLIF)
- H. OptiLIF with Optimesh
- I. Annulus repair devices (e.g. Barricaid®)
- J. Customized/personalized intervertebral cages

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

- [Ablative Procedures to Treat Back and Neck Pain](#)
- [Artificial Intervertebral Discs](#)
- [Discography](#)
- [Spinal Epidural Steroid Injections](#)
- [Implantable Spinal Cord and Dorsal Root Ganglion Stimulation](#)
- [Back: Intradiscal Procedures for Low Back Pain](#)
- [Back: Percutaneous Vertebroplasty and Sacroplasty](#)
- [Sacroiliac Joint Fusion or Stabilization](#)
- [Stabilization Devices and Interspinous Spacers](#)
- [Surgical Site of Service](#)

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

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
 - 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

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.¹ 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)

Smoker: Includes smoking cigarettes, cigars, and pipe smoking of tobacco.

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 neurogenic claudication
- 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	
<i>Grade</i>	<i>Description</i>
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).²

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.³ 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.² 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.⁴ 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)

BACKGROUND

Indications

<i>Atlantoaxial Subluxation</i>	Atlantoaxial subluxation refers to the misalignment of the first and 2 nd cervical vertebrae, as a result of either a bony or ligamentous abnormality.
<i>Facet Syndrome</i>	Facet syndrome refers to pain stemming from the level of the posterior facet joints of the spine.
<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.
<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.

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.” ⁵
<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.” ⁶
<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.
<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.

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.”⁷ 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.⁸ 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.

OptiLIF Procedure with the Optimesh Expandable Interbody Fusion System

The Optimesh® expandable interbody fusion system is a surgical system intended for use in a minimally invasive transforaminal lumbar interbody fusion (TLIF) procedure known as OptiLIF®. The system consists of an expandable interbody cage made of knitted polyester yarn and instrumentation for implanting the cage. TLIF is intended to relieve pain and restore mobility in patients with spine compression resulting from degenerative disc disease. Because the Optimesh insert is introduced through the same working channel used to prepare the target site, the OptiLIF procedure does not require removal of the facet joint and may reduce complication and sequelae risks.

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.⁹

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

- In September 2020, the FDA granted De Novo clearance to the Spineology interbody fusion system (the original name of the Optimesh system).
- In February 2019, the FDA granted Premarket Approval for the Barricaid Annular Closure Device.¹⁰

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 September 2023.

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.¹¹ 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).¹² 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.¹³

Nonrandomized studies

Three retrospective reviews assessed the safety and efficacy of thoracic fusion for the treatment of adolescent idiopathic scoliosis.¹⁴⁻¹⁶ 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.¹⁷ 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.¹⁸ 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.”¹⁸
- 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.¹⁹ 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

No prospective studies were identified examining cervical or thoracic laminectomy.

Lumbar

- In 2015, Cochrane conducted a systematic review evaluating the efficacy of posterior decompression techniques compared with conventional laminectomy for the treatment of lumbar stenosis.²⁰ 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.²¹⁻²⁴ 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.⁶ 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.²⁵⁻³⁰ 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 fusion³¹ procedure and two without fusion.^{32,33} Though prospective studies were limited by small sample sizes (n=161) and inadequate follow-up (≤ 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.³³

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.³⁴⁻³⁶ 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.³⁷ 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.³⁸ 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.³⁹ 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 use), 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.⁴⁰

- 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.⁴¹ 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 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.

Nonrandomized Studies

- In 2021, Austevoll and colleagues conducted an open-label, multicenter, noninferiority trial involving patients with symptomatic lumbar stenosis that had not responded to conservative management and who had single-level spondylolisthesis of 3 mm or more.⁴² The primary outcome was a reduction of at least 30% in the score on the Oswestry Disability Index (ODI; range, 0 to 100, with higher scores indicating more impairment) during the 2 years after surgery, with a noninferiority margin of -15 percentage points. The mean change from baseline to 2 years in the ODI score was -20.6 in the decompression-alone group and -21.3 in the fusion group in the modified intention-to-treat analysis, 95 of 133 patients (71.4%) in the decompression-alone group and 94 of 129 patients (72.9%) in the fusion group had a reduction of at least 30% in the ODI score, showing the noninferiority of decompression alone. Authors concluded that decompression alone was noninferior to decompression with instrumented fusion over a period of 2 years. Limitations included the study's lack of blinding and lack of established patient selection criteria.
- In 2020, Austevoll and colleagues comparative effectiveness study evaluating microdecompression alone versus decompression plus instrumented fusion in lumbar degenerative spondylolisthesis.⁴³ In total, 1376 patients at 35 Norwegian orthopedic and neurosurgical departments underwent surgery for lumbar spinal stenosis with degenerative spondylolisthesis without scoliosis. After excluding patients undergoing laminectomy alone, fusion without instrumentation, or surgery in more than 2 levels and those with a former operation at the index level, 794 patients were included in the analyses, regardless of missing or incomplete follow-up data, before propensity score matching. The proportion of patients with improvement in the Oswestry Disability Index of at least 30% was 150 of 219 (68%) in the microdecompression group and 155 of 215 (72%) in the instrumentation group. Microdecompression alone was associated with shorter operation time and shorter hospital stay. Authors concluded that microdecompression alone was noninferior to that of decompression with instrumented fusion. Limitations included the study's short follow-up (i.e. 1 year), nonrandomized design, and heterogeneous treatment parameters.

Cervical/Thoracic Corpectomy

Two recent systematic reviews and meta-analyses compared the safety and efficacy of cervical corpectomy for the treatment of cervical myelopathy.^{44,45} 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.⁴⁵ 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.⁴⁴ 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).⁷ 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.³⁹ 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.”⁴⁰

- 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).^{46,47} 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).⁴⁸ 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.⁴⁹⁻⁵² 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.⁵³ 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).⁵⁴ 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 2022 (archived 2023), Hayes conducted an evidence review evaluating the safety and efficacy of percutaneous laser disc decompression (PLDD) for lumbar disc herniation (LDH).⁴⁷ 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 associate 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)

Systematic Reviews

- In 2023, Hayes conducted an evidence review evaluating the safety and efficacy of minimally invasive lumbar decompression (MILD) device kit for treatment of lumbar spinal stenosis.⁵⁵ 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 2021, ECRI conducted a systematic review of the evidence to evaluate the mild® Device Kit for treating lumbar spinal stenosis.⁵⁶ 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.

Limitations in the MiDAS ENCORE RCT included a lack of 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."⁵⁶ Investigators concluded that while evidence supporting the mild® system is "somewhat favorable" that "(a)dditional RCTs are needed to verify findings and assess *mild's* effectiveness compared with other decompression procedures."⁵⁶

Nonrandomized Studies

In 2020, Mekhail and colleagues published a retrospective longitudinal observational cohort study, assessing the durability of the mild® system among 75 patients.⁵⁷ Patients reports significant pain relief and reduction of opioid medication at 12-month follow-up. Limitations included the study's small sample size, lack of long-term follow-up for all outcomes of interest, retrospective design and author conflicts of interest with the device manufacturer.

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.⁴⁹⁻⁵¹ 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.⁵⁸⁻⁶¹ 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 2020, ECRI conducted an evidence review of AxiaLIF (lumbar interbody fusion) Plus System for the treatment of patients with lumbar degenerative disc disease (DDD).⁸ 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.⁶² 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 pseudarthrosis, 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.

OptiLIF Procedure

In 2021, ECRI published a systematic review assessing the safety and efficacy of OptiLIF procedure with the Optimesh expandable interbody fusion system (spineology, inc.) for percutaneous lumbar interbody fusion.⁶³ Evidence from four before-and-after treatment studies, all at high risk of bias, suggests OptiLIF with Optimesh may improve short-term functional status in patients with discopathy, but how well it works to improve patient outcomes compared with other methods of lumbar interbody fusion cannot be determined because available studies do not assess OptiLIF's comparative safety and effectiveness. No studies compared OptiLIF with conventional or minimally invasive TLIF. The included before-and-after-treatment studies are at high risk of bias due to two or more of the following: small sample size, single-center focus, retrospective design, and lack of control groups and randomization. Also, findings may not generalize across all studies because of differences in clinical procedure and eligibility criteria for study participation. Authors called for additional randomized controlled trials comparing the Optimesh system with other devices for performing TLIF and reporting long-term clinical outcomes.

Annular Repair Devices (e.g. Barricaid®)

Systematic Reviews

- In 2023, Wang and colleagues conducted a meta-analysis of clinical outcomes from controlled studies evaluating the Barricaid device.⁶⁴ In total, 7 randomized controlled studies and 8 observational studies with a total of 2161 participants met the inclusion criteria. The pooled data analysis showed that adding the annular repair technique reduced postoperative recurrence rate, reoperation rate, and loss of intervertebral height compared with lumbar discectomy alone. Subgroup analysis based on different annular repair techniques showed that the Barricaid Annular Closure Device (ACD) was effective in preventing re-protrusion and reducing reoperation rates, while there was no significant difference between the other subgroups. The annulus fibrosus suture (AFS) did not improve the postoperative Oswestry Disability Index (ODI). No statistically significant difference was observed in the incidence of adverse events between the annular repair and control groups. Authors concluded that lumbar discectomy combined with ACD can effectively reduce

postoperative recurrence and reoperation rates in patients with LDH. AFS alone was less effective in reducing recurrence and reoperation rates and did not improve postoperative pain and function. Limitations include the lack of high-quality randomized controlled trials available for review and heterogeneous in some of the pooled results.

- In 2023, Hayes conducted a systematic review assessing the safety and efficacy of annular closure for prevention of lumbar disc reherniation.⁶⁵ In total, 9 eligible studies (reported in 21 publications) were included for review, including 2 RCTs. Outcomes of interest included back pain, leg pain, disability scores, quality of life scores, reoperation rate, reherniation rate and complication rates. Follow-up ranged from 1 to 5 years. Sample sizes across studies ranged from 30 to 276 patients. Across the studies, annular closure consistently led to statistically significant improvement of patient symptoms and disability. Comparative analyses of patients treated with stand-alone LD or with annular closure found mixed results for VAS-back pain, VAS-leg pain, and ODI scores, generally finding no between-group statistical differences between the intervention groups, but occasionally concluding that annular closure led to statistically superior results. Results suggested that adjunct annular closure may improve patient outcomes compared with LD/sequestrectomy. Comparative studies generally found mixed results for efficacy outcomes, with some studies concluding annular closure was favored over LD/sequestrectomy, but other studies finding no statistically significant differences between treatment groups. Safety outcomes also appeared to favor annular closure, although the safety data were too sparse to draw reliable conclusions.

Authors assessed the overall quality of evidence as “low.” The body of evidence was primarily limited by inconsistency in the findings of the comparative analyses, variability in reporting of recurrence outcomes, sparse safety data, and poor quality study designs. Limitations of the individual studies included retrospective and/or observational study design, use of historical controls, small sample sizes or lack of power analyses, and insufficient follow-up time to determine the long-term outcomes.

Investigators assigned a “C” rating (potential but unproven benefit) for use of annular closure device (ACD) implantation as an adjunct procedure to lumbar discectomy (LD) to close sizable annular defects (usually ≥ 6 mm) with the goal of reducing the risk of recurrent lumbar disc herniation (LDH) in adult patients with LDH refractory to conservative treatment. Investigators concluded that “larger, well-designed studies, including RCTs, with a focus on safety data and long-term outcomes needed to determine the efficacy and safety of annular closure with greater reliability and precision.”⁶⁵

- 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.⁶⁶ 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 2023, ECRI conducted an evidence review of the Barricaid Annular Closure Device for preventing recurrent vertebral disc herniation after lumbar discectomy.⁹ In total, 1 systematic review and 2 publications of 1 RCT were included for review.⁶⁶⁻⁶⁸ 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.

Randomized Controlled Trials

In 2022, Thomé and colleagues reported on the effectiveness of an annular closure device to prevent recurrent lumbar disc herniation.⁶⁹ This secondary analysis of a multicenter randomized clinical trial reports 5-year follow-up for enrolled patients between December 2010 and October 2014 at 21 clinical sites. Patients in this study had a large annular defect (6-10mmwidth) following lumbar microdiscectomy for treatment of lumbar disc herniation. Statistical analysis was performed from November to December 2020. The incidence of symptomatic reherniation, reoperation, and adverse events as well as changes in leg pain, Oswestry Disability Index, and health-related quality of life when comparing the device and control groups over 5 years of follow-up. Among 554 randomized participants, 550 were included in the modified intent-to-treat efficacy population; control group: n = 278; 273 [98%] were White) and 550 were included in as-treated safety population (device group: n = 267; control group: n = 283). The risk of symptomatic reherniation and reoperation was lower in the device group. There were 53 reoperations in 40 patients in the device group and 82 reoperations in 58 patients in the control group. Scores for leg pain severity, Oswestry Disability Index, and health-related quality of life significantly improved over 5 years of follow-up with no clinically relevant differences between groups. The frequency of serious adverse events was comparable between the treatment groups. Serious adverse events associated with the device or procedure were less frequent in the device group. Limitations included manufacturer funding, a lack of patients with non-large defects in the annulus fibrosus following lumbar discectomy, lack of blinding, a lack of control group receiving aggressive disc resection, and significant attrition at 5-year follow-up (27 percent).

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.⁷⁰ 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.”⁷⁰

Non-randomized Controlled Trials

Across several cohort studies, smokers were shown to experience worse response rates to cervical fusion compared to non-smokers.⁷¹⁻⁷³ 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.⁷⁰ 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.⁷¹⁻⁷³

Facet Syndrome

Facet syndrome is not a clearly identified source of back pain. Facet joints are the articulations or connections between the vertebrae. It is hypothesized that increased motion and instability of the motion segments stress the facet joint capsule, generating pain. While lumbar fusion has been proposed as a treatment for facet syndrome, inconsistent outcomes have been reported and no studies have been published recently.⁷⁴

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.⁷⁵ 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.⁷⁶ 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.⁷⁷ 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).⁷⁸ 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.⁷⁸

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.⁷⁹ 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.⁸⁰

National Institute for Health and Care Excellence (NICE)

In 2017, NICE issued a guidance addressing lateral interbody fusion in the lumbar spine.⁸¹ 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.⁸² The guideline recommends surgery in scoliosis patients whose Cobb angle is >40 degrees and whose Risser grade is 0 to 4.

International Society for the Advancement of Spine Surgery (ISASS)

In 2011, the ISASS published an evidence-based policy statement addressing lumbar spinal fusion. On the basis of a non-systematic review of evidence, authors stated that “lumbar fusion surgery for facet syndrome is no longer commonly supported and should only be performed in the context of a prospective clinical research study.”⁸³

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.⁷⁶ 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.⁸⁴ 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.⁸⁵ Based largely on the findings of the Cochrane review discussed above,⁴¹ 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.⁸⁶ 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 transforminal⁸⁷ and interlaminar⁸⁸ 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.⁸⁶ 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.⁸⁶ 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.”⁸⁹ 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.⁸⁵ 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.⁹⁰ 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 (AxialLIF)

National Institute for Health and Care Excellence (NICE)

In 2018, NICE issued a guidance addressing transaxial interbody lumbosacral fusion (AxialLIF) for the treatment of low back pain.⁹¹ 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.⁹² 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.

National Institute for Health and Care Excellence (NICE)

In 2014, the NICE published guidelines addressing the use of annular disc implants at lumbar discectomy.⁹³ Authors determined that the evidence base surrounding annular closure is too sparse, recommending that annular disc implantation only occur under special arrangements for governance, consent, and audit or research.

Revision Surgery

North American Spine Society (NASS)

In 2013, the NASS issued a clinical practice guideline addressing appropriate use criteria for cervical fusion.⁷⁵ 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.² 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.

EVIDENCE 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, axial lumbar interbody fusions and annular closure devices. 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.

BILLING GUIDELINES AND CODING

- CPT code 22585 is an add-on code that may only be billed in conjunction with 22554, 22556, or 22558.
- According to the Company Coding Policy (Bundled or Adjunct Services, 13.0), CPT code 22841 is not separately payable. While this service may be considered medically necessary when the primary spinal procedure is determined to be medically necessary, separate payment for CPT 22841 is not provided.
- HCPCS code S2348 is not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy (*HCPCS S-Codes and H-Codes*, 22.0). Providers need to use alternate available CPT or HCPCS codes to report for this service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

CODES*		
CPT	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
	0275T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment
	0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment
	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, osteophyctomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy 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 interspace; thoracic (with lateral transverse technique, when performed)
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (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; 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; 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)
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)
22899	Unlisted procedure, spine
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
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
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
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 vertebral 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 of bridging bone graft and non-segmental fixation devices [eg, wire, suture, mini-plates], when performed)
63052		Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053		Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)
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 osteophytectomy; cervical, single interspace
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; 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 osteophytectomy; thoracic, single interspace
63078	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; 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)
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 retropulsed 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 retropulsed 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 retropulsed 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
HCPCS	C1831	Interbody cage, anterior, lateral or posterior, personalized (implantable)
	C2614	Probe, percutaneous lumbar discectomy
	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
	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.
	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

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy](#), [Reimbursement Policy](#), [Pharmacy Policy and Provider Information website](#) for additional information.

- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
4/2023	Changed denial of percutaneous and endoscopic procedures from “investigational” to “not medically necessary.”
2/2023	Converted to new policy template.
11/2023	Annual update. Policy title change. No changes to criteria or codes.