MEDICAL POLICY – 7.01.551

Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotom, Laminectomy in Adults

BCBSA Ref. Policies: 7.01.145 & 7.01.146

Effective Date: May 1, 2023
Last Revised: April 11, 2023
Replaces: N/A

RELATED MEDICAL POLICIES:

7.01.18 Automated Percutaneous and Percutaneous Endoscopic Discectomy
7.01.72 Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty, and Intraosseous Basivertebral Nerve Ablation
7.01.87 Artificial Intervertebral Disc: Lumbar Spine
7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.126 Image-Guided Minimally Invasive Decompression for Spinal Stenosis
7.01.130 Axial Lumbosacral Interbody Fusion
7.01.542 Lumbar Spinal Fusion
7.01.560 Cervical Spine Surgeries: Discectomy, Laminectomy, and Fusion in Adults
8.03.09 Vertebral Axial Decompression
8.03.501 Chiropractic Services
11.01.524 Site of Service: Select Surgical Procedures

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | APPENDIX | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

The spine is a complex combination of tissues, bones, and nerves. The small bones of the back (vertebrae) surround and protect the spinal cord. Disease or injury can affect these bones and tissues, causing them to shift or bulge. This can put pressure on the spinal cord or nerves and cause symptoms like pain, numbness, weakness, or tingling. Physical therapy, chiropractic adjustments, or steroid injections often relieve these symptoms. Surgery may be needed if these treatments don’t work. Decompression surgery is a general term meaning the removal of bone and/or tissue that is pressing on the nerves or spinal cord. These surgeries include removing all or part of a disc that’s pressing on a nerve (discectomy), enlarging the passageway where nerves branch out from the spinal cord (foraminotomy), or removing all or part of the vertebra known
as the lamina (laminotomy or laminectomy). This policy describes when decompression surgery on the lower back may be medically necessary and covered by the health plan.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

### Policy Coverage Criteria

We will review for medical necessity these elective surgical procedures.

This includes lumbar spine decompression surgeries performed with/without single level lumbar fusion.

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medically necessary sites of service:</td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.</td>
</tr>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
<td></td>
</tr>
<tr>
<td>• On campus-outpatient hospital/medical center</td>
<td></td>
</tr>
<tr>
<td>• Ambulatory Surgical Center</td>
<td></td>
</tr>
<tr>
<td>Inpatient hospital/medical center</td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):</td>
</tr>
<tr>
<td>Site of Service for Elective Surgical Procedures</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>• Anesthesia Risk</td>
<td>o ASA classification III or higher (see definition)</td>
</tr>
<tr>
<td></td>
<td>o Personal history of complication of anesthesia</td>
</tr>
<tr>
<td></td>
<td>o Documentation of alcohol dependence or history of cocaine use</td>
</tr>
<tr>
<td></td>
<td>o Prolonged surgery (&gt;3 hours)</td>
</tr>
<tr>
<td>• Cardiovascular Risk</td>
<td>o Uncompensated chronic heart failure (NYHA class III or IV)</td>
</tr>
<tr>
<td></td>
<td>o Recent history of myocardial infarction (MI) (&lt;3 months)</td>
</tr>
<tr>
<td></td>
<td>o Poorly controlled, resistant hypertension*</td>
</tr>
<tr>
<td></td>
<td>o Recent history of cerebrovascular accident (&lt; 3 months)</td>
</tr>
<tr>
<td></td>
<td>o Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt;90 days)</td>
</tr>
<tr>
<td></td>
<td>o Symptomatic cardiac arrhythmia despite medication</td>
</tr>
<tr>
<td></td>
<td>o Significant valvular heart disease</td>
</tr>
<tr>
<td>• Liver Risk</td>
<td>o Advance liver disease (MELD Score &gt; 8)**</td>
</tr>
<tr>
<td>• Pulmonary Risk</td>
<td>o Chronic obstructive pulmonary disease (COPD) (FEV1 &lt;50%)</td>
</tr>
<tr>
<td></td>
<td>o Poorly controlled asthma (FEV1 &lt;80% despite treatment)</td>
</tr>
<tr>
<td></td>
<td>o Moderate to severe obstructive sleep apnea (OSA)***</td>
</tr>
<tr>
<td>• Renal Risk</td>
<td>o End stage renal disease (on dialysis)</td>
</tr>
<tr>
<td>• Other</td>
<td>o Morbid obesity (BMI ≥ 50)</td>
</tr>
<tr>
<td></td>
<td>o Pregnancy</td>
</tr>
<tr>
<td></td>
<td>o Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion])</td>
</tr>
<tr>
<td></td>
<td>o Anticipated need for transfusion(s)</td>
</tr>
</tbody>
</table>

Note:  
*3 or more drugs to control blood pressure  
<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient hospital/medical center</strong></td>
<td>This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.</td>
</tr>
</tbody>
</table>

**Note:** This policy only applies to adults aged 19 and older.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Lumbar discectomy (diskectomy), foraminotomy, laminotomy | Lumbar discectomy (diskectomy)*, foraminotomy, or laminotomy surgery may be considered medically necessary for the rapid (48 hours or less) progression of neurologic impairment (e.g., cauda equina syndrome, foot drop, extremity weakness, saddle anesthesia, sudden onset of bladder or bowel dysfunction). If there is not rapid progression of neurologic impairment, lumbar discectomy (diskectomy)*, foraminotomy, or laminotomy may be considered medically necessary when ALL the following criteria are met:  
  • All other sources of low back pain have been ruled out AND  
  • A lumbar spine magnetic resonance image (MRI) or lumbar spine computerized tomography (CT) scan with myelogram done within the past 12 months shows nerve root compression that corresponds to symptoms and physical examination findings or there is definitive neurological localization by other means (e.g., selective nerve root injections) AND  
  • Persistent, debilitating pain radiating from the low back down to the lower extremity is present on a daily basis and limits activities of daily living (ADLs) AND  
  • Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30  
  • DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin) |

---

---

---

---
### Procedure vs. Medical Necessity

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Neurological deficits (e.g., reflex change in the legs, dermatomal sensory loss, motor weakness) or alternative signs of lumbar root irritation (e.g., positive leg raising test) are present on physical examination</td>
</tr>
</tbody>
</table>
|                      | **AND**                                                                IAL of the following:  
|                      | • Symptoms have been unresponsive to at least 6 weeks of conservative nonsurgical care, including **ALL** of the following:  
|                      |   o Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response  
|                      |     ▪ Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants (if not contraindicated)  
|                      |   o Physical therapy  
|                      |   o Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present                                                                                               |
| **Note:**            | *See Related Information for further description of lumbar discectomy                                                                                                                                            |

#### Lumbar laminectomy

**Lumbar laminectomy may be considered medically necessary for the rapid (48 hours or less) progression of neurologic impairment (e.g., cauda equina syndrome, foot drop, extremity weakness, saddle anesthesia, sudden onset of bowel or bladder dysfunction).**

**If there is not rapid progression of neurologic impairment, lumbar laminectomy for spinal stenosis may be considered medically necessary when ALL of the following criteria are met:**

- All other sources of low back pain have been ruled out

**AND**

- Persistent, progressive, debilitating symptoms of neurogenic claudication (numbness, tingling, muscle weakness with or without back pain) are present on a daily basis that limits activities of daily living

**AND**
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• A lumbar spine MRI or lumbar spine CT scan with myelogram within the past 12 months shows lumbar spine stenosis that corresponds to the clinical findings on physical examination AND • Symptoms have been unresponsive to at least 6 weeks of conservative nonsurgical care, including <strong>ALL</strong> of the following: o Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response ▪ Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants (if not contraindicated) o Physical therapy o Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present</td>
</tr>
<tr>
<td>Lumbar laminectomy may also be considered medically necessary for <strong>ANY</strong> of the following:</td>
<td>• Dorsal rhizotomy for spasticity in cerebral palsy</td>
</tr>
<tr>
<td></td>
<td>• Lumbar spondylolisthesis confirmed by a lumbar MRI study</td>
</tr>
<tr>
<td></td>
<td>• Metastatic neoplasm of the spine, non-cancerous spinal tumor, or cysts that cause nerve root or spinal cord compression with corresponding neurological deficit, confirmed by a lumbar MRI study</td>
</tr>
<tr>
<td></td>
<td>• Spinal infection confirmed by a lumbar MRI study</td>
</tr>
<tr>
<td></td>
<td>• Spinal injury confirmed by a lumbar MRI study (e.g., epidural hematoma or foreign body)</td>
</tr>
<tr>
<td></td>
<td>• Spinal trauma confirmed by a lumbar MRI study (e.g., spinal fracture, displaced fragment from a spinal fracture, vertebral dislocation together with instability, locked facets)</td>
</tr>
<tr>
<td>Lumbar spine decompression surgery</td>
<td><strong>Lumbar spine decompression surgery is considered not medically necessary when no clinical indication is documented and there are no confirmatory physical and radiologic findings that meet the relevant criteria listed above in this policy.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>The provider’s choice of interventional surgery depends on the specific member’s symptoms and imaging findings.</strong></td>
</tr>
<tr>
<td>Procedure</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Note:</strong>  <em>See Related Policies for other spinal procedures not addressed in this policy.</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annular defect repair with ACD following lumbar discectomy</td>
<td>The use of a bone anchored annular closure device (ACD) to repair an annular defect is considered investigational (e.g., Barricaid®)</td>
</tr>
</tbody>
</table>

**Documentation Requirements**

Documentation in the medical record must clearly support the medical necessity of the surgery and include the following information:

- **Medical History**
  - Co-morbid physical and psychological health conditions
  - History of back surgery, including minimally invasive back procedures
  - Prior trial, failure, or contraindication to conservative medical/non-operative interventions that may include but are not limited to the following:
    - Activity modification for at least 6 weeks
    - Oral analgesics and/or anti-inflammatory medications
    - Physical therapy
    - Chiropractic manipulation
    - Epidural steroid injections

- **Physical Examination**
  - Clinical findings, including the patient’s stated symptoms and duration

- **Diagnostic Test**
  - Radiologist’s report of a magnetic resonance image (MRI) or computerized tomography (CT) scan with myelogram of the lumbar spine within the past 12 months showing a lumbar spine abnormality. Report of the selective nerve root injection results, if applicable, to the patient’s diagnostic workup.

**Coding**
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22899</td>
<td>Unlisted procedure, spine (when used for repair of annular defect with implantation of bone anchored annular closure device, following lumbar discectomy)</td>
</tr>
<tr>
<td>63005</td>
<td>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</td>
</tr>
<tr>
<td>63012</td>
<td>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)</td>
</tr>
<tr>
<td>63017</td>
<td>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</td>
</tr>
<tr>
<td>63030</td>
<td>Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar</td>
</tr>
<tr>
<td>63035</td>
<td>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)</td>
</tr>
<tr>
<td>63042</td>
<td>Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar</td>
</tr>
<tr>
<td>63044</td>
<td>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)</td>
</tr>
<tr>
<td>63047</td>
<td>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</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>63185</td>
<td>Laminectomy with rhizotomy; 1 or 2 segments</td>
</tr>
<tr>
<td>63190</td>
<td>Laminectomy with rhizotomy; more than 2 segments</td>
</tr>
<tr>
<td>63191</td>
<td>Laminectomy with section of spinal accessory nerve</td>
</tr>
<tr>
<td>63267</td>
<td>Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar</td>
</tr>
<tr>
<td>63272</td>
<td>Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; lumbar</td>
</tr>
</tbody>
</table>

**HCPCS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9757</td>
<td>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</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

**Lumbar Discectomy**

Lumbar discectomy refers to standard open discectomy or minimally invasive microdiscectomy. Microdiscectomy will be defined for the purpose of this policy as having the following features: (1) uses a small surgical incision (as opposed to an endoscopic “port”), (2) uses a specially designed microscope to achieve direct visualization of the vertebral column (as opposed to indirect visualization with an endoscope or other type of cameras), and (3) removes disc and other surgical products by direct visualization through the surgical incision. Microdiscectomy may be done with adjunctive devices, such as tubular retractors to improve visualization, or endoscopy to localize the correct areas to operate. However, removal of the disc itself must be done under direct visualization to be considered microdiscectomy.
Radiculopathy

Radiculopathy presents with a characteristic set of signs and symptoms based on history and physical exam.

History:

• Pain that radiates down the back of the leg to below the knee
• Numbness and tingling in a dermatomal distribution
• Muscular weakness in a pattern associated with spinal nerve root compression.

Physical exam:

• Positive straight leg raise test
• Loss of deep tendon reflexes corresponding to affected nerve root level
• Loss of sensation in a dermatomal pattern.

Conservative Nonsurgical Therapy Should Include the Following:

• Use of prescription-strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
  o Analgesics should include anti-inflammatory medications with or without adjunctive medications, such as nerve membrane stabilizers or muscle relaxants, AND
• Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND
• Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues AND
• Documentation of patient compliance with the preceding criteria
**Medical History**

- Assessment of comorbid physical and psychological health conditions (e.g., morbid obesity, current smoking, diabetes, renal disease, osteoporosis, severe physical deconditioning)

- History of back surgery, including minimally invasive back procedures

- Prior trial, failure, or contraindication to conservative medical/nonoperative interventions that may include but are not limited to the following:
  - Activity modification for at least 6 weeks
  - Oral analgesics and/or anti-inflammatory medications
  - Physical therapy
  - Chiropractic manipulation
  - Epidural steroid injections

**Persistent Debilitating Pain Is Defined As:**

- Significant level of pain on a daily basis, defined on a visual analog scale score as greater than 4; AND

- Pain on a daily basis that has a documented impact on activities of daily living despite optimal conservative nonsurgical therapy, as outlined above, and appropriate for the patient.

**Diagnostic Testing**

- Radiologically confirmed lumbar spine abnormality based on a magnetic resonance image or computerized tomography scan with myelogram of the lumbar spine within the past 6 months

- Report of the selective nerve root injection results, if applicable to the patient's diagnostic workup
Definition of Terms

American Society of Anesthesiologists (ASA) Score:

- **ASA 1** A normal healthy patient.
- **ASA 2** A patient with mild systemic disease.
- **ASA 3** A patient with severe systemic disease.
- **ASA 4** A patient with severe systemic disease that is a constant threat to life.
- **ASA 5** A moribund patient who is not expected to survive

**Cauda equina**: The nerve roots resembling a horse’s tail that hang from the tip of the spinal cord where it ends in the lower back. These nerve roots dangle in the spinal canal before exiting through the vertebral foramen and go to out to the lower part of the body. (Cauda equina is Latin for horse’s tail).

**Cauda equina syndrome**: Cauda Equina Syndrome (CES) is a serious condition caused by compression of the cauda equina nerves of the lower spine; it is considered a surgical emergency. CES may be caused by a herniated disk, infection, cancer, trauma, or spinal stenosis. A rapid progression of neurologic symptoms is seen that may include but are not limited to severe sharp/stabbing debilitating low back pain that starts in the buttocks and travels down one or both legs. It is often accompanied by severe muscle weakness, inability to start/stop urine flow, inability to start/stop bowel movement, loss of sensation below the waist and absence of lower extremity reflexes.

**Disc (intervertebral)**: Round flat “cushions” between each vertebra of the spine.

**Discectomy (diskectomy)**: The removal of herniated disc material/disc fragments that are compressing a nerve root or the spinal cord. A discectomy may be done to treat a ruptured disc. (Percutaneous discectomy is addressed in a separate policy; see Related Policies).

**Dorsal rhizotomy**: The cutting of selected nerves in the lower spine to reduce leg spasticity in patients with cerebral palsy.

**Foraminotomy (foraminectomy)**: The removal of bone and tissue to enlarge the opening (foramen) where a spinal nerve root exits the spinal canal.

**Hemilaminectomy**: The removal of only one side (left or right) of the posterior arch (lamina) of a vertebra.

**Lamina**: Bony arch of the vertebra that helps to cover and protect the spinal cord running through the spinal canal. Each spinal vertebra has two laminae (left and right).

**Laminectomy**: The removal of the whole posterior arch (lamina) of a vertebra.
**Laminotomy:** The removal of a small portion of a lamina of a vertebra.

**Lumbar spinal stenosis:** Abnormal narrowing of the spinal canal which puts pressure on the spinal cord and the nerve roots leaving the spinal cord. Spinal stenosis may cause pain, numbness or weakness in the legs, feet, or buttocks.

**Lumbar spondylolisthesis:** A condition where one of the vertebrae slips out of place by moving forward or backward on an adjacent vertebra. Usually occurs in the lumbar spine. Isthmic spondylolisthesis is the most common form of spondylolisthesis due to a defect or fracture of the bone that connects the upper and lower facet joints (the pars interarticularis). The disorder may be congenital when the bone fails to form properly or acquired due to a stress fracture and slippage of part of the spinal column. (Some athletes, such as gymnasts, football players, and weightlifters may suffer from this disorder.)

**Myelopathy:** Refers to any neurologic deficit related to the spinal cord. It could be caused by trauma, inflammation, vascular issues, arthritis in the spine, or other causes.

**Neurogenic claudication (or pseudoclaudication):** Symptoms of pain, paresthesia (numbness, tingling, burning sensation) in the back, buttocks and lower limbs and possible muscle tension, limping or leg weakness that worsens with standing/walking and is relieved by rest, sitting, or leaning forward – usually associated with lumbar spinal stenosis.

**New York Heart Association (NYHA) Classification:**

- **Class I** No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
- **Class II** Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
- **Class III** Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
- **Class IV** Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

**Paresthesia:** Abnormal sensations of the skin including burning, prickling, pricking, tickling, or tingling, and are often described as “pins and needles.”

**Radicular pain:** Pain that radiates down a compressed or irritated nerve root that connects to the spinal cord, also known as radiculitis. A common form is sciatica.

**Radiculopathy:** A progressive neurologic deficit caused by compression or irritation of a nerve root as it leaves the spinal column. The compression may be caused by disc material or boney
changes like spurs. Symptoms may include pain radiating from the spine, a motor deficit, reflex changes, or EMG changes.

**Saddle anesthesia:** A loss of feeling in the buttocks, perineum and inner thighs frequently related to cauda equina syndrome.

**Spinal cord/nerve roots:** The spinal cord runs down through the spinal canal in the vertebral column. The spinal cord gives off pairs of nerve roots that extend from the cord, pass through spaces in between the vertebrae, and go out to the body.

**Vertebrae:** The individual bones of the spinal column that consist of the cervical, thoracic, and lumbar regions. The vertebrae in the spinal column surround and protect the spinal cord.

---

**Evidence Review**

**Description**

Back pain, with and without radicular symptoms, is one of the most common medical reasons that members seek medical care and may affect 8 out of 10 people during their lifetime. Most back pain will improve over 2 months with minimal intervention. The pain can vary from mild to disabling. Back pain is considered to be chronic if it lasts more than three months. Age-related disc degeneration, facet joint arthrosis and segmental instability are leading causes of chronic back pain.

The most common symptoms of spinal disorders are regional pain and range of motion limitations. A small subset of patients may experience radiating pain in addition to decreased range of motion and low back discomfort. For the majority of patients, pain characteristics depend on activity levels. For example, the pain intensity changes with increased physical activity, certain movements or postures and decreases with rest. However, night-time back pain may be present in the absence of serious specific spinal disorders. The precise location and originating point of back pain is often difficult for patients to describe.

There are many potential causes for low back pain. Several conditions may cause pinched or compressed nerves in the low back area putting pressure on the spinal cord that may cause tingling, muscle weakness and sudden loss or impairment of bowel and bladder function. Intervertebral disc herniation, spinal stenosis, and degenerative spondylolisthesis with stenosis are the most common conditions that have low back pain and leg symptoms and may require
surgery to relieve the compression according to the findings in the Spine Patient Outcomes Research Trial (SPORT).

Normally, the spinal cord is protected by the back bones (vertebrae) that form the spine, but certain injuries to and disorders of the spine may cause cord compression, affecting its normal function. The spinal cord may be compressed by bone, the collection of blood outside a blood vessel (hematomas), pus (abscesses), tumors (both noncancerous and cancerous), or a herniated/ruptured or malformed disc. These injuries and disorders may also compress the spinal nerve roots that pass through the spaces between the back bones or the bundle of nerves that extend downward from the spinal cord (cauda equina). The spinal cord may be compressed suddenly, causing symptoms in minutes or over a few hours or days, or slowly, causing symptoms that worsen over many weeks or months.

Lumbar spine decompression is a broad definition of surgical procedures performed on the bones in the lower (lumbar) spine to relieve the pinched or compressed spinal cord and/or nerve(s). The goal is to “decompress” the spinal cord and/or nerve root(s) that are causing disabling pain and/or weakness due to damage to the spinal cord (myelopathy).

During a lumbar decompression surgery, the surgeon removes portions of the intervertebral disc and/or adjacent bone and tissue in the lower spine to give the nerve root more space. Surgical procedures for spinal decompression include lumbar discectomy, foraminotomy, laminotomy, and lumbar laminectomy.

Background

Lumbar Discectomy (Diskectomy)

Discectomy is a surgical procedure in which one or more intervertebral discs are removed. Extrusion of an intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in pain, numbness, and weakness. Discectomy is intended to treat symptoms by relieving pressure on the affected nerve root(s). Discectomy can be performed by a variety of surgical approaches, with either open surgery or minimally invasive techniques.

Disc Herniation

Extrusion of an intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in symptoms of pain, numbness, and weakness.
The natural history of untreated disc herniations is not well-characterized, but most herniations will decrease in size over time due to shrinking and/or regression of the disc. Clinical symptoms will also tend to improve over time in conjunction with shrinkage or regression of the herniation.

**Treatment**

Because most disc herniations improve over time, initial care is conservative, consisting of analgesics and a prescribed activity program tailored to patient considerations. Other potential nonsurgical interventions include opioid analgesics and chiropractic manipulation. Epidural steroid injections can also be used as a second-line intervention and are associated with short-term relief of symptoms.

However, some disc herniations will not improve over time with conservative care. A small proportion of patients will have rapidly progressive signs and symptoms, thus putting them at risk for irreversible neurologic deficits. These patients are considered to be surgical emergencies, and expedient surgery is intended to prevent further neurologic deterioration and allow for nerve recovery.

Other patients will not progress but will have the persistence of symptoms that require further intervention. It is estimated that up to 30% of patients with sciatica will continue to have pain for more than 1 year. For these patients, there is a high degree of morbidity and functional disability associated with chronic back pain, and there is a tendency for recurrent pain despite treatment. Therefore, treatments that have more uniform efficacy for patients with a herniated disc and chronic back pain are needed. In particular, decreased chronic pain and decreased disability are the goals of treatment of chronic low back pain due to a herniated disc.

**Surgical Treatment**

Discectomy is a surgical procedure in which one or more intervertebral discs are removed. The primary indication for discectomy is herniation (extrusion) of an intervertebral disc. Discectomy is intended to treat symptoms by relieving pressure on the affected nerve(s).

**Lumbar Discectomy**

Lumbar discectomy can be performed by a variety of surgical approaches. Open discectomy is the traditional approach. In open discectomy, a 2- to 3-cm incision is made over the area to be
repaired. The spinal muscles are dissected, and a portion of the lamina may be removed to allow access to the vertebral space. The extruded disc is removed either entirely or partially using direct visualization. Osteophytes that are protruding into the vertebral space can also be removed if deemed necessary.

The main alternative to open discectomy is microdiscectomy, which has gained popularity. Microdiscectomy is a minimally invasive procedure that involves a smaller incision, visualization of the disc through a special camera, and removal of disc fragments using special instruments. Because less resection can be performed in a microdiscectomy, it is usually reserved for smaller herniations, in which a smaller amount of tissue needs to be removed. A few controlled trials comparing open discectomy with microdiscectomy have been published and reported that neither procedure is clearly superior to the other, but that microdiscectomy is associated with more rapid recovery. Systematic reviews and meta-analyses have also concluded that the evidence does not support the superiority of one procedure over another.

Adverse Events

Complications of discectomy generally include bleeding, infections, and inadvertent nerve injuries. Dural puncture occurs in a small percentage of patients, leading to leakage of cerebrospinal fluid that can be accompanied by headaches and/or neck stiffness. In a small percentage of cases, worsening of neurologic symptoms can occur post-surgery.

Other Surgical Alternatives

Other variations on discectomy include the following. These procedures do not have high-quality comparative trials versus standard discectomy, and will therefore not be considered as true alternatives to discectomy for this policy:

- Laser discectomy
- Radiofrequency coblation (nucleoplasty)
- Automated percutaneous discectomy
- Automated endoscopic discectomy
- Intradiscal electrothermal annuloplasty
- Intradiscal radiofrequency therapy
• Vertebral axial decompression
• Chemonucleolysis.

**Annular Defect Repair with Annular Closure Device Following Lumbar Discectomy**

Annular closure is a surgical procedure that involves the fluoroscopic guided implantation of a bone anchored annular closure device at the site of an annular defect following a lumbar discectomy. This surgery is performed to try to prevent reherniation and reoperation. The Barricaid annular closure device is currently the only FDA approved ACD. The Barricaid is “U” shaped with a titanium component on one side that is secured to an adjacent healthy vertebral body and a flexible polymer mesh occlusion component on the other side that is used to fill the annular defect (the damaged annulus fibrosus) to prevent future expulsion or migration of disc material. The ACD is generally used to close annular defects $\geq 6$ mm. This surgical procedure is to be performed only at a single level between L4 and S1.

**Lumbar Laminectomy**

Lumbar laminectomy is a surgical procedure in which a portion of the vertebra (the lamina) is removed to decompress the spinal cord. Removal of the lamina creates greater space for the spinal cord and the nerve roots, thus relieving compression on these structures. Lumbar laminectomy is typically performed to alleviate compression due to lumbar spinal stenosis or a space-occupying lesion.

**Associated Disorders**

The most common diagnosis treated with laminectomy is spinal stenosis. In spinal stenosis, the spinal canal (vertebral foramen) is narrowed, thus compressing the spinal cord. Narrowing of the spinal canal may be congenital or degenerative in origin. Other conditions that cause pressure on the spine and spinal nerve roots include those where a mass lesion is present (e.g., tumor, abscess, other localized infection).
**Surgical Techniques**

Laminectomy is an inpatient procedure performed under general anesthesia. An incision is made in the back over the affected region, and the back muscles are dissected to expose the spinal cord. The lamina is then removed from the vertebral body, along with any inflamed or thickened ligaments that may be contributing to compression. Following resection, the muscles are reapproximated and the soft tissues sutured back into place. The extent of laminectomy varies, but most commonly extends 2 levels above and below the site of maximal cord compression.20

There are numerous variations on the basic laminectomy procedure. It can be performed by minimally invasive techniques, which minimizes the extent of resection. Laminoplasty is a more limited procedure in which the lamina is cut but not removed, thus allowing expansion of the spinal cord. Foraminotomy and/or foramenectomy, which involve partial or complete removal of the facet joints, may be combined with laminectomy when the spinal nerve roots are compressed at the foramen. Spinal fusion is combined with laminectomy when instability of the spine is present preoperatively, or if the procedure is sufficiently extensive to expect postoperative spinal instability.

**Surgical Variations**

Hemilaminotomy and laminotomy, sometimes called laminoforaminotomy, are less invasive than a laminectomy. These procedures focus on the interlaminar space, where most of the pathologic changes are concentrated, minimizing resection of the stabilizing posterior spine. A laminotomy typically removes the inferior aspect of the cranial lamina, the superior aspect of the subjacent lamina, the ligamentum flavum, and the medial aspect of the facet joint. Unlike laminectomy, laminotomy does not disrupt the facet joints, supra- and interspinous ligaments, a major portion of the lamina, or the muscular attachments. Muscular dissection and retraction are required to achieve adequate surgical visualization.

Microendoscopic decompressive laminotomy is similar to laminotomy but uses endoscopic visualization. The position of the tubular working channel is confirmed by fluoroscopic guidance, and serial dilators (METRx™ lumbar endoscopic system, Medtronic) are used to dilate the musculature and expand the fascia. For microendoscopic decompressive laminotomy, an endoscopic curette, rongeur, and drill are used for the laminotomy, facetectomy, and foraminotomy. The working channel may be repositioned from a single incision for multilevel and bilateral dissections.
Adverse Events

Complications of laminectomy can include spinal cord and nerve root injuries, which occur at rates from 0% to 10%. Worsening myelopathy and/or radiculopathy can occur in a small percentage of patients independent of surgical injuries. Worsening of symptoms is usually temporary, but in some cases has been permanent. Infection and bleeding can occur; hematomas following surgery often require reoperation if they are close to critical structures. Leakage of spinal fluid may occur and occasionally be persistent requiring treatment. Instability of the spine can result from extensive laminectomy involving multiple levels. This is usually an indication for spinal fusion as an adjunct to laminectomy, but if fusion is not performed, the instability may lead to progressive symptoms and additional surgery. Specific complication rates depend on the indication and location treated, surgical approach, and extent of surgery.

Summary of Evidence

Lumbar Discectomy (Diskectomy)

For individuals who have lumbar herniated disc(s) and symptoms of radiculopathy rapidly progressing or refractory to conservative care who receive lumbar discectomy, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. In patients with lumbar radiculopathy with disc herniation who receive discectomy, there is sufficient evidence to support the use of discectomy in patients who have not responded to “usual care” for six weeks. The evidence is limited by a lack of high-quality trials. In most trials, a high percentage of patients in the conservative care group crossed over to surgery. This high degree of crossover reduced the power to detect differences when assessed by intention-to-treat analysis. Analysis by treatment received was also flawed because of the potential noncomparability of groups resulting from the high crossover rate. Despite the methodologic limitations, the evidence has consistently demonstrated a probable short-term benefit for surgery and a more rapid resolution of pain and disability. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Lumbar Laminectomy

For individuals who have lumbar spinal stenosis and spinal cord or nerve root compression who receive lumbar laminectomy, the evidence includes RCTs and a systematic review of RCTs.
Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. In patients with spinal stenosis, there is sufficient evidence that laminectomy is more effective than nonoperative “usual care” in individuals with spinal stenosis who do not improve after eight weeks of conservative treatment. The superiority of laminectomy is sustained through eight years of follow-up. This conclusion applies best to individuals who do not want to undergo intensive, organized conservative treatment, or who do not have access to such a program. For individuals who want to delay surgery and participate in an organized program of physical therapy and exercise, early surgery with the combination of conservative initial treatment and delayed surgery in selected patients have similar outcomes at two years. From a policy perspective, this means that immediate laminectomy and intensive conservative care are both viable options. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have space-occupying lesion(s) of the spinal canal or nerve root compression who receive lumbar laminectomy, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Most case series are small and retrospective. They have reported that most patients with myelopathy experience improvements in symptoms or abatement of symptom progression after laminectomy. However, this uncontrolled evidence does not provide a basis to determine the efficacy of the procedure compared with alternatives. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The current standard of care, clinical input obtained in 2015, clinical practice guidelines, and the absence of alternative treatments all support the use of laminectomy for space-occupying lesions of the spinal canal. As a result, laminectomy may be considered medically necessary for patients with space-occupying lesions of the spinal cord.

For individuals who have a repair of an annular defect with the implantation of a bone anchored annular closure device following a lumbar discectomy, the evidence includes 2 meta-analyses, 2 RCTs, and multiple prospective and retrospective observational studies. In 2018 (Choy, et.al). performed a meta-analysis of clinical outcomes and complications of annular closure devices for disc herniation reviewing three studies (one randomized, 2 nonrandomized) related to the use of the Barricaid® ACD and one study related to Anulex X-close for annular repair (AR). A total of 24 symptomatic reherniation were reported among 811 discectomies with ACD/AR versus 51 out of 645 in the control group. (OR: 0.34, 95% CI: 0.20,0.56; I² =0%, P< 0.0001) demonstrating a significant reduction in symptomatic disc reherniation compared to individuals without ACD/AR. The meta-regressions comparing improvements in ODI and VAS pain scores (both back and legs) for the ACD/AR cohort were similar when compared to the control cohort. The results were
statistically insignificant without either group being superior to the other at both 90 days and 2-year follow-up. The authors concluded that additional research is needed to explore the efficacy of ACD with longer-term follow-up needed beyond 2 years to determine any potential delayed or late complications of the device. (Miller, et. al) in 2020 performed a meta-analysis of four studies (two randomized, two nonrandomized) of the Barricaid® ACD which included 801 individuals, 381 treated with lumbar discectomy and the Barricaid® ACD and 420 treated with lumbar discectomy alone. Results showed a 55% lower risk of reherniation with the Barricaid® ACD (9.3% vs. 20.3%, risk ratio= 0.45, p < 0.001) over a 2-year follow-up. The results were similar for reoperation, which was 48% lower with the Barricaid® ACD (7.7% vs. 14.5%, risk ratio= 0.52, p=0.003). Similar results were achieved when the analysis was isolated to only the randomized trials, which demonstrated a 53% reduction in symptomatic reherniation and reoperation risk. (each risk ratio =0.47). This meta-analysis was funded by Intrinsic Therapeutics, Inc., as well as the primary author received personal fees from Intrinsic Therapeutics, Inc.

(Kienzler, et. al), in 2019 published results of a multicenter (21 European hospitals), RCT of 574 individuals with sciatica due to lumbar intervertebral disc herniation who failed conservative treatment. 272 individuals were intraoperatively randomly assigned after lumbar limited microdiscectomy to receive ACD (5 individuals had unsuccessful implantation of the ACD) or 278 to control and followed for 3 years. Patients, surgeons, outcome assessors, nor imaging core laboratory readers were blinded to group allocation. There was approximately 25 % attrition in both groups at the 3-year follow-up. Results demonstrated that symptom recurrence was lower in individuals treated with ACD vs. controls through 3 years (14.8% vs. 29.5%, log-rank P < 0.001 at 3 years). Reoperation rates were also less frequent in the ACD group (11.0% vs. 19.3%, log-rank P< 0.001 at 3 years). There were 38 reoperations in 29 ACD individuals and 70 reoperations in 51 control individuals with repeat discectomy the most frequent surgery performed. Better long-term pain and disability relief were achieved with the ACD group vs. control. 21 vs 30 (mean difference = -8, 95% CI= -2 to -15, P < 0.01) for leg pain, 23 vs. 30 (mean difference = - 7, 95% CI = − 1 to − 12, P = 0.01) for back pain, and 18 vs. 23 (mean difference = − 5, 95% CI = − 1 to − 9, P = 0.02) for ODI, Device failures noted on follow-up imaging included: mesh detachment, device migration, and anchor fracture. Limitations of this study are the lack of blinding to treatment allocation which poses a risk for bias. Longer follow-up is needed to determine the durability of the treatment effect of the ACD to ensure there are no late-onset safety or device-related complications. This trial was also funded by Intrinsic Therapeutics, Inc. and 4 of the 7 authors disclosed consultancy with Intrinsic Therapeutics, Inc.

Thomé, et.al (2021) published a secondary analysis of the above RCT with 5 years of follow-up and found the addition of an ACD reduced the risk of symptomatic reherniation (18.8% vs. 31.6%) and reoperation (16.0% vs. 22.6%) versus lumbar microdiscectomy alone over 5 years of follow-up. A total of 40 individuals underwent 53 reoperations in the ACD group and 58
individuals underwent 82 reoperations in the control group. Scores for leg pain severity, ODI and health-related quality of life showed no clinically important differences between the two groups. Serious adverse events were less frequent in the ACD group (12.0% vs 20.5%; difference −8.5%; 95% CI, −14.6% to −2.3%; P = .008). However, the incidence of any adverse event was comparable between the two groups, (45.3% vs 37.1%; difference, 8.2%; 95% CI, 0.0% to 16.3%; P = .06). Vertebral end plate changes were more commonly reported in the ACD group (20.2% vs 1.4%; difference 18.8%; 95% CI, 13.9% to 24.1%; P < .001). There was a 73% follow-up visit rate through 5 years. Similar limitations of this secondary analysis are noted as for the above clinical trial. It was funded by Intrinsic Therapeutics, Inc. and most of the authors had some form of conflict of interest through receiving personal and consulting fees, grants, or royalties.

In 2019 (Cho, et.al) published a prospective, RCT comparing conventional lumbar discectomy (CLD) with lumbar discectomy with the Barricaid ® ACD with 2 year follow-up. Sixty patients (30 CLD, 30 ACD) were enrolled in this study using computer generated randomization with double-blinded allocation. The same neurosurgeon performed all the surgeries. At 2-year follow-up, the disc height in the ACD group was greater than that in the CLD group (11.4±1.5 vs. 10.2±1.2 mm, p=0.006). Re-herniation occurred in one patient in the ACD group versus six patients in the CLD group (χ² =4.04, p=0.044). Back and leg VAS scores, ODI scores, and SF-12 scores improved in both groups compared with preoperative scores in the first 7 days following surgery and remained at improved levels at the 2-year follow-up. 19 patients were lost to follow-up and so at 2 years, data was available for 20 individuals in the ACD group and 21 in the CLD group. Limitations of this study include small sample size with approximately 30% attrition, and short-term follow-up.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trails

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from two specialty societies and four academic medical centers when this policy was in development in 2015. Input informed criteria for medical necessity for the indications of mass lesions.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.
North American Spine Society (NASS)

In 2014, the North American Spine Society published evidence-based clinical guidelines on the diagnosis and treatment of lumbar disc herniation with radiculopathy.¹ Table 2 summarizes the recommendations specific to open discectomy or microdiscectomy.

**Table 2. Recommendations for Treating Lumbar Disc Herniation with Radiculopathy**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>GOR&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy.</td>
<td>B</td>
</tr>
<tr>
<td>There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy.</td>
<td>I</td>
</tr>
<tr>
<td>Discectomy is suggested to provide more effective symptom relief than medical/interventional care for patients whose symptoms warrant surgical care. In patients with less severe symptoms, both surgery and medical/interventional care appear to be effective in short and long-term relief.</td>
<td>B</td>
</tr>
<tr>
<td>Use of an operative microscope is suggested to obtain comparable outcomes to open discectomy for patients whose symptoms warrant surgery.</td>
<td>B</td>
</tr>
<tr>
<td>There is insufficient evidence to make a recommendation for or against the use of tubular discectomy compared with open discectomy.</td>
<td>I</td>
</tr>
</tbody>
</table>

GOR: grade of recommendation.
<sup>a</sup> Grade B: fair evidence (level II or III studies with consistent findings); grade I: insufficient evidence.

In 2011, the North American Spine Society issued evidence-based guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis.⁴⁹ The guidelines stated that patients with mild symptoms of lumbar spinal stenosis are not considered surgical candidates; however, decompressive surgery was suggested to improve outcomes in patients with moderate-to-severe symptoms of lumbar spinal stenosis (grade B recommendation). The Society also indicated that current evidence was insufficient to recommend for or against the placement of interspinous process spacing devices to treat spinal stenosis. A 2013 update of this guideline from the Degenerative Lumbar Spinal Stenosis Work Group of the NASS notes the same recommendation.⁵⁰
International Society for the Advancement of Spine Surgery

In 2019, the International Society for the Advancement of Spine Surgery published a policy on the surgical treatment of lumbar disc herniation with radiculopathy.19 This policy contained a review of available clinical evidence and concluded that discectomy (open, microtubular, or endoscopic) is a medically necessary procedure for the treatment of patients who do not respond to nonsurgical care or have severe and deteriorating symptoms. Per the policy, documentation requirements include confirmation of radiculopathy based on history/physical examination AND either the presence of disabling leg or back pain refractory to six weeks of conservative care or progressive neurologic deficit AND level appropriate documentation of nerve root compression on imaging and/or nerve conduction velocity/electromyogram.

The ISASS in this same publication concluded that the available evidence supports the usage of implanted bone anchored ACDs to improve the efficacy of stand-alone discectomy and to prevent recurrent lumbar disc herniation.19

National Institute for Health and Care Excellence (NICE)

In 2014, NICE in their interventional procedure guidance (IPG506)52 recommended that the current evidence on the safety and efficacy of insertion of an annular disc implant at lumbar discectomy is limited in quantity and quality. They recommend that the procedure only be performed with special arrangements for clinical governance, consent, and audit or research.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Discectomy and laminectomy are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA). Some instrumentation used during laminectomy may be subject to FDA approval.

In 2019, the FDA granted premarket approval for the Barricaid implantable annular closure device (ACD) (Intrinsic Therapeutics, Inc.) (P160050). It is “indicated for reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy attributed to a
posterior or posterolateral herniation... It is used to treat a large annular defect between 4-6 mm tall and between 6-10 mm wide following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

FDA Product code: QES

References


Figure 1. Lumbosacral dermatome innervations

Labels indicate the innervation of each lumbosacral dermatome. L=lumbar, S=sacral

<p>| L1, 2, 3, 4 | L4 – inner (medial) side of the great toe |
| L4, 5, S1 | foot |
| S1 – outer (lateral) margin of foot and little toe | L5, S1, S2 – back and outer surfaces of legs, buttocks |
| S2, 3, 4 – perineum (urogenital and anal areas of pelvis) |</p>
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/13/14</td>
<td>New policy. Lumbar decompression surgery may be considered medically necessary when applicable criteria are met. Effective May 18, 2014 with 90-day hold for provider notification.</td>
</tr>
<tr>
<td>01/14/14</td>
<td>Replace policy. Policy criteria revised for lumbar disectomy MRI sub-bullet to add &quot;nerve root compression that corresponds to symptoms and physical examination findings or there is definitive neurological localization by other means (e.g., selective nerve root injections)&quot; and the neurological deficits sub-bullet add &quot;to include alternative signs of lumbar root irritation (e.g., positive leg raising test)&quot;. ICD-10 CM and ICD-10 PCS codes removed. Policy statements changed as noted.</td>
</tr>
<tr>
<td>02/10/14</td>
<td>Replace policy. Policy statement revised: deleted cauda equina syndrome (CES) as an indication since &quot;the rapid progression of symptoms&quot; includes CES, added lumbar spine CT myelogram to diagnostic imaging criteria, minor edits for readability. Related policies list revised. In the Policy Guidelines, added information about pre-service requests, added selective nerve root injections to the diagnostic test reports, expanded definition of CES. Reference 16 added for Figure 1, second graphic removed. Policy statements changed as noted.</td>
</tr>
<tr>
<td>02/27/14</td>
<td>Updated Related Policies. Add 8.03.501.</td>
</tr>
<tr>
<td>04/04/14</td>
<td>Minor rewording of not medically necessary policy statement for clarity, intent is unchanged.</td>
</tr>
<tr>
<td>05/02/14</td>
<td>Update Related Policies. Add 7.01.537 and 8.03.503.</td>
</tr>
<tr>
<td>05/20/14</td>
<td>Update Related Policies. Remove 7.01.116 as it was deleted, and replace with 7.01.555.</td>
</tr>
<tr>
<td>06/26/14</td>
<td>Update Related Policies. Add 7.01.18.</td>
</tr>
<tr>
<td>09/11/14</td>
<td>Update Related Policies. Add 8.03.502.</td>
</tr>
<tr>
<td>09/25/14</td>
<td>Update Related Policies. Add 7.01.93.</td>
</tr>
<tr>
<td>12/22/14</td>
<td>Interim Update. Updated Related Policies added 8.03.09. Reference 7 removed from the additional resources and websites section; others renumbered. Policy statement unchanged.</td>
</tr>
<tr>
<td>01/06/15</td>
<td>Update Related Policies. Add 8.01.40.</td>
</tr>
<tr>
<td>09/24/15</td>
<td>Coding update; ICD-9 diagnosis and procedure codes removed. These were for informational purposes only.</td>
</tr>
<tr>
<td>10/13/15</td>
<td>Annual update. Reference 8 added. Policy statements unchanged. Coding update: Removed CPT codes 63200, 63252, 63277, 63282, 63287 and 63290; these are not specific to the procedures addressed in this policy.</td>
</tr>
<tr>
<td>11/10/15</td>
<td>Interim Review. Policy guidelines update to reflect imaging timeline of 12 from 6 to be consistent with all policies within documentation requirements.</td>
</tr>
<tr>
<td>03/21/16</td>
<td>Interim Update. Removed related policy 8.01.40 as it was archived.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Policy updated with literature review; references added. Policy statements unchanged but added clarification that “rapid” progression is defined as 48 hours or less.</td>
</tr>
<tr>
<td>11/24/16</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update; added new CPT 62380 effective 1/1/17.</td>
</tr>
<tr>
<td>07/01/17</td>
<td>Annual review, approved June 22, 2017. Minor language update in policy statement for clarification purposes. No major change to policy statements.</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Note added that this policy has been revised. Added link to revised policy that will become effective June 1, 2018. Added Documentation Requirements section.</td>
</tr>
<tr>
<td>06/01/8</td>
<td>Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.</td>
</tr>
<tr>
<td>02/01/19</td>
<td>Minor update, added 7.01.560 to related policies.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Minor update, clarified Site of Service requirements.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.</td>
</tr>
<tr>
<td>06/10/20</td>
<td>Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.</td>
</tr>
<tr>
<td>12/01/20</td>
<td>Interim Review, approved November 19, 2020. Edits made to conservative care policy statements for greater clarity and consistency.</td>
</tr>
<tr>
<td>09/01/22</td>
<td>Annual Review, approved August 8, 2022. Policy updated with literature review through April 19, 2022; no references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>04/01/23</td>
<td>Coding update. Removed HCPC code C9757 as this was moved to the E&amp;I policy.</td>
</tr>
</tbody>
</table>
Interim Review, approved April 11, 2023. Added policy statement that the use of a bone anchored annular closure device (ACD) to repair an annular defect is considered investigational. References added.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2023 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 505F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.


Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).


注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY: 711)。

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

WHEN YOU SPEAK ON A RUSSIAN PHONE, YOU ARE ENTITLED TO FREE TRANSLATION SERVICES. CALL 800-722-1471 (TTY: 711).


MO LOU SILAFIA: Afai e te tautala Gagan a fa’a Sāmoa, o lo iai auanauga fesoasoan, e fai fua e leaie to tetogia, mo oe. Telefonia mai: 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

WHEN YOU SPEAK ON A RUSSIAN PHONE, YOU ARE ENTITLED TO FREE TRANSLATION SERVICES. CALL 800-722-1471 (TTY: 711).


УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мової підтримки. Інформуйте за номером 800-722-1471 (телетайп: 711).

1471 (TTY: 711).


시리아 리바인 아랍어로 연락해 주시려고 하시는 분들께는, 722-1471 (TTY: 711) 번으로 전화해 주십시오.


ATTACYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).


Premera Blue Cross is an independent licensee of the Blue Cross Blue Shield Association serving businesses and residents of Alaska and Washington State, excluding Clark County. 052493 (07-01-2021)