Introduction

Lumbar fusion is a surgery that joins or fuses bones (vertebrae) in the low back. It is performed when the bones or the discs between the bones are damaged, leading to pressure on the spinal cord or nerves and instability. The goal of this surgery is to make the spine more stable and help relieve symptoms such as pain or weakness. During the surgery itself, the bones are not fused. Instead, the surgeon places small pieces of bone that grow together over time. Sometimes metal plates or cages are used in the surgery. Prior to having this surgery for most conditions, most experts recommend a trial of nonsurgical care. It is important to note that not all lumbar fusions are successful. And for those who smoke, the chance of an unsuccessful fusion is higher than for those who don’t smoke. Published studies bear this out, and expert medical organizations recommend quitting smoking for several weeks before spinal lumbar fusion.

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.
Smoking within the 6 weeks just prior to scheduled surgery is a contraindication for lumbar spinal fusion (see documentation requirements for smoking cessation).

This policy does not address the pre-operative cessation of smokeless/chewing/dipping/snuff tobacco or nicotine replacements such as electronic cigarettes (e-cigs), nicotine gum, nicotine lozenges and nicotine patches. No studies or literature were found that report the effect of these products on orthopedic surgical outcomes (see documentation requirements for smoking cessation).

See Documentation Requirements section for information that must be submitted for review.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal stenosis</td>
<td>Lumbar spinal fusion may be considered medically necessary for spinal stenosis when both of the following criteria are met:</td>
</tr>
<tr>
<td></td>
<td>• Either one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Associated spondylolisthesis demonstrated by at least a 4mm shift in the sagittal plane on flexion/extension plain x-rays</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>o Spinal instability will be created due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis; imaging studies must document encroachment on the nerve root channel (neural foramen)</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>• Either one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative care and has documentation of central/lateral recess/or foraminal stenosis on MRI or other imaging</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>o Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome</td>
</tr>
<tr>
<td>Condition</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Severe progressive juvenile or adolescent idiopathic scoliosis  | Lumbar spinal fusion may be considered medically necessary for individuals with severe, progressive juvenile or adolescent idiopathic scoliosis with one of the following:  
  • Cobb angle greater than 40 degrees  
  OR  
  • Spinal cord compression with neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative care |
| Severe degenerative scoliosis in adults                         | Lumbar spinal fusion may be considered medically necessary for severe degenerative scoliosis in adults with ONE of the following:  
  • A minimum Cobb angle of 30 degrees  
  OR  
  • Significant sagittal imbalance (eg, sagittal vertical axis > 5 cm), and with any ONE of the following:  
    o Documented progression of deformity with persistent axial (non-radiating) pain and impairment or loss of function unresponsive to at least 1 year of conservative therapy  
    OR  
    o Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to at least 1 year of conservative nonsurgical care  
    OR  
    o Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome |
| Spondylolisthesis (except isthmic)                               | Lumbar spinal fusion may be considered medically necessary for severe spondylolisthesis when ALL of the following are present:  
  • At least a 4 mm shift in the sagittal plane measured on functional flexion/extension plain x-rays  
  • Persistent back pain (radicular pain or neurogenic claudication)  
  • Impairment or loss of function that is unresponsive to at least 3 months of conservative therapy |
| Isthmic spondylolisthesis                                       | Lumbar spinal fusion may be considered medically necessary for isthmic spondylolisthesis when ALL of the following are present:  
  • At least a 4 mm shift in the sagittal plane measured on functional flexion/extension plain x-rays  
  • Persistent back pain (radicular pain or neurogenic claudication)  
  • Impairment or loss of function that is unresponsive to at least 3 months of conservative therapy |
### Condition | Medical Necessity
--- | ---
**Condition**<br>Medical Necessity present:  
- Congenital (Wiltse type I) or acquired pars defect (Wiltse II), documented on x-ray  
**AND**  
- Persistent back pain (with or without neurogenic symptoms), with impairment or loss of function  
**AND**  
- Either ONE of the following:  
  - Condition is unresponsive to at least 3 months of conservative nonsurgical care  
  **OR**  
  - Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome are present  
--- | ---
Recurrent, same level, disc herniation | Lumbar spinal fusion may be considered medically necessary for recurrent, same level, disc herniation when ALL of the following are present:  
- At least 3 months have passed since the original disc surgery  
**AND**  
- Recurrent neurogenic symptoms (radicular pain or claudication) and evidence of nerve-root irritation, as demonstrated by a positive nerve-root tension sign or positive femoral tension sign or a corresponding neurologic deficit  
**AND**  
- Impairment or loss of function  
**AND**  
- Unresponsive to at least 3 months of conservative nonsurgical care OR with severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome  
**AND**  
- Neural structure compression or instability documented by imaging at a level and side corresponding to the clinical symptoms  
--- | ---
Pseudarthrosis | Lumbar spinal fusion may be considered medically necessary for pseudarthrosis, documented radiologically, when ALL of the following are present:  
- No less than 6 months after initial fusion
<table>
<thead>
<tr>
<th>Condition</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instability</td>
<td>Lumbar spinal fusion may be considered medically necessary for instability due to fracture, dislocation, infection, abscess, or tumor when extensive surgery is required that could create an unstable spine.</td>
</tr>
<tr>
<td>Iatrogenic or degenerative flatback syndrome</td>
<td>Lumbar spinal fusion may be considered medically necessary for iatrogenic or degenerative flatback syndrome with significant sagittal imbalance when fusion is performed with spinal osteotomy or interbody spacers.</td>
</tr>
</tbody>
</table>
| Adjacent level disease after prior fusion | Lumbar spinal fusion may be considered medically necessary for adjacent level disease when ALL of the following are present:  
  • Persistent back pain (radicular pain or neurogenic claudication) with impairment or loss of function that is unresponsive to at least 3 months of conservative therapy  
  AND  
  • Eccentric disc space collapse, spondylolisthesis, acute single level scoliosis, or lateral listhesis on imaging  
  AND  
  • Symptoms and functional measures correlate with imaging findings  
  AND  
  • The previous fusion resulted in significant relief for at least 6 months                                                                                                                                                                                                                           |
<p>| Conditions other than those listed in this policy | Lumbar spinal fusion is considered not medically necessary for any indication not addressed in this policy.                                                                                                                                                                                                 |</p>
<table>
<thead>
<tr>
<th>Condition</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chronic nonspecific low back pain</td>
<td>• Chronic nonspecific low back pain without radiculopathy</td>
</tr>
<tr>
<td>• Degenerative disc disease</td>
<td>• Degenerative disc disease</td>
</tr>
<tr>
<td>• Disc herniation</td>
<td>• Disc herniation</td>
</tr>
<tr>
<td>• Facet syndrome</td>
<td>• Facet syndrome</td>
</tr>
<tr>
<td>• Initial discectomy/laminectomy</td>
<td>• Initial discectomy/laminectomy for neural structure decompression</td>
</tr>
<tr>
<td>• Lumbar spinal fusion</td>
<td></td>
</tr>
</tbody>
</table>

**Documentation Requirements**

The following information must be submitted to ensure an accurate, expeditious and complete review for lumbar spinal fusion surgery:

- Specific procedures requested with related procedure/diagnosis codes and identification of the disc levels for surgery
- Office notes that include a current history and physical exam
- Clinical notes document individual has been evaluated at least twice by a physician(s) before submitting a request for surgery (except in cases of malignancy, trauma, infection or rapidly progressive neurologic symptoms)
- Detailed documentation of the extent and response to conservative therapy, including outcomes of any procedural interventions, medication use and physical therapy/physiatrist notes
- Documentation of current smoking status, and a written statement that the patient was non-smoking for the 6 weeks prior to scheduled (non-emergent) surgery (not applicable to emergent surgery). See smoking cessation definition.
- Copy of the radiologist’s report for diagnostic imaging (MRI, CT, etc.) done within the past 12 months prior to surgery. Imaging must be performed and read by an independent radiologist. If there are discrepancies in the interpretation of the imaging, the radiologist’s report will supersede.
- Copy of most recent x-ray report of flexion-extension films that demonstrate the presence of lumbar spine instability

**Coding**
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22533</td>
<td>Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
</tr>
<tr>
<td>22534</td>
<td>Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression; thoracic or lumbar, each additional vertebral segment</td>
</tr>
<tr>
<td>22558</td>
<td>Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
</tr>
<tr>
<td>22585</td>
<td>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)</td>
</tr>
<tr>
<td>22612</td>
<td>Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)</td>
</tr>
<tr>
<td>22614</td>
<td>Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22630</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar</td>
</tr>
<tr>
<td>22632</td>
<td>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)</td>
</tr>
<tr>
<td>22633</td>
<td>Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar</td>
</tr>
<tr>
<td>22634</td>
<td>Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; each additional interspace and segment (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22800</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments</td>
</tr>
<tr>
<td>22802</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments</td>
</tr>
<tr>
<td>22804</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments</td>
</tr>
<tr>
<td>22808</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments</td>
</tr>
<tr>
<td>22810</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>22812</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments</td>
</tr>
<tr>
<td>22853</td>
<td>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)</td>
</tr>
<tr>
<td>22854</td>
<td>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)</td>
</tr>
<tr>
<td>22859</td>
<td>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)</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, including open and endoscopically-assisted approaches; 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**

**Definition of Terms**

**Cauda equina syndrome (CES):** Cauda equina are the nerve roots, resembling a horse’s tail, that continue from where the spinal cord ends and branch down to the lower part of the body. (Cauda equina is Latin for horse’s tail.)

- Cauda Equina Syndrome (CES): Considered a surgical emergency with a rapid progression of neurologic symptoms 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, with severe muscle weakness
  - Inability to start/stop urine flow
  - Inability to start/stop bowel movement
- Loss of sensation below the waist
- Absence of lower extremity reflexes

CES is caused by compression of the cauda equina nerves of the lower spine by a herniated disk, infection, cancer, trauma, or spinal stenosis.

**Conservative nonsurgical therapy:** For the duration specified should include all of the following:

- 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)
- Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present
- Documentation of patient compliance with preceding criteria

**Isthmic spondylolisthesis:** Spondylolisthesis caused by a fracture in the pars interarticularis. Note that many people have fractures of the pars and do not have symptoms.

**Neurogenic claudication (also known as pseudoclaudication):** A common indicator of lumbar spinal stenosis. The problem is caused by an inflamed nerve coming from the spinal column. Symptoms include the sensation of pain or weakness in the legs that is relieved with a change in position or leaning forward.

**Persistent debilitating pain:** Defined as:

- Significant level of pain on a daily basis defined on a visual analog scale (VAS) as greater than 4; AND
- Pain on a daily basis that has a documented impact on activities of daily living in spite of optimal conservative nonsurgical therapy as outlined above and appropriate for the patient.

**Pseudarthrosis:** When bones fail to fuse with one another after spinal fusion surgery. Lack of union at the fused location.
Radicular pain: Pain that radiates along a dermatome of a nerve due to inflammation/irritation/compression of the nerve root that connects to the spinal column, also known as radiculitis. A common form is sciatica.

Restricted functional ability: Severely restricted functional ability generally includes loss of function and/or documentation of inability or significantly decreased ability to perform normal daily activities of work, school or at-home duties.

Smoking cessation: Smoking cessation for at least 6 weeks prior to scheduled (non-emergent) surgery applies to smoking cigarettes, cigars, and pipe smoking of tobacco.

Spondylolisthesis: North American Spine Society defines lumbar degenerative spondylolisthesis as an acquired anterior displacement (slip) of 1 vertebra over the subjacent vertebra, associated with degenerative changes, but without an associated disruption or defect in the vertebral ring.

Evidence Review

Description

Lumbar spinal fusion (arthrodesis) is a surgical technique that involves fusing two or more lumbar vertebrae using local bone, autologous bone taken from the iliac crest of the patient, allogeneic donor bone, or bone graft substitutes. There are numerous potential indications for lumbar spinal fusion. Spinal fusion can be performed as a single procedure or can be performed in conjunction with other spinal surgeries. For example, lumbar spinal fusion can be performed in combination with discectomy for either herniated discs or degenerative disc disease, or in combination with decompressive surgery of the spinal canal for spinal stenosis.

Background

Fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction (see Appendix). Anterior lumbar interbody fusion or posterior lumbar interbody fusion are usually performed with an open approach (long incision with wide retraction of the musculature) but can also be performed using minimally invasive/minimal access procedures. Minimally invasive approaches that use specialized retractors include lateral interbody fusion (eg, lateral transpsoas interbody fusion, extreme lateral interbody fusion, direct lateral lumbar interbody fusion), and transforaminal interbody fusion. Posterolateral fusion fuses the transverse processes
alone and should be differentiated from the interbody procedures (eg, posterior lumbar interbody fusion) just described. Interbody cages, instrumentation such as plates, pedicle screws, or rods, and osteoinductive agents, such as recombinant human bone morphogenetic protein, may be used to stabilize the spine during the months that fusion is taking place and to improve fusion success rates.

The objective of interbody fusion is to permanently immobilize the functional spinal unit (two adjacent vertebrae and the disc between them) believed to be causing pain and/or neurologic impingement. An alternative or supplemental approach is fusion of the transverse processes. Lumbar fusion is most commonly accepted when it is used to stabilize an unstable spine or to correct deformity. For example, lumbar spondylolisthesis is an acquired anterior displacement (slip) of one vertebra over the subjacent vertebra that is associated with degenerative changes. Patients who do not have neurologic deficits will typically do well with conservative care. However, patients who present with sensory changes, muscle weakness or cauda equina syndrome are more likely to develop progressive functional decline without surgery. Scoliosis, an abnormal lateral and rotational curvature of the vertebral column, can result in severe deformity associated with back pain in adulthood and may lead to compromised respiratory function if it is not corrected. Scoliosis with severe deformity is also an accepted indication for spinal fusion.

Lumbar spinal fusion is more controversial when the conditions previously described are not present. Spinal stenosis is one such condition. A 2011 consensus statement from the North American Spine Society defined degenerative lumbar spinal stenosis as a condition in which there is diminished space available for the neural and vascular elements in the lumbar spine secondary to degenerative changes in the spinal canal. When symptomatic, this causes a variable clinical syndrome of gluteal and/or lower-extremity pain and/or muscle fatigue, which may occur with or without back pain. Decompression surgery is indicated for patients with persistent symptoms despite conservative treatment, and spinal fusion is frequently performed in combination with decompression surgery for this purpose, with the intent of decreasing instability of the spine. One potential marker of instability is spondylolisthesis, and many surgeons target patients with spinal stenosis and spondylolisthesis for the combined decompression plus fusion procedure. The North American Spine Society has defined lumbar degenerative spondylolisthesis as “an acquired anterior displacement of one vertebra over the subjacent vertebra, associated with degenerative changes, without an associated disruption or defect in the vertebral ring.” Most patients with symptomatic degenerative lumbar spondylolisthesis and an absence of neurologic deficits do well with conservative care. Patients who present with sensory changes, muscle weakness, or cauda equina syndrome are more likely to develop progressive functional decline without surgery.
Fusion has also been performed for degenerative disc disease. Degenerative disc disease is a universal age-related condition consisting of morphologic changes in the lumbar motion segment. Because many degenerative changes seen on imaging are asymptomatic, and invasive provocative discography has variable accuracy in the ability to localize the pain generator, identifying the source of low back pain can be difficult. A large number of fusion procedures are also performed for nonspecific low back pain unresponsive to nonsurgical measures (eg, nonsteroidal anti-inflammatory drugs, analgesics, physical therapy), when definitive indications for fusion are not present. Across the United States, there is wide variation in the rates of lumbar spinal fusion, and many experts consider lumbar fusion to be overused, indicating a need for better standardization and uniformity in the application of this procedure.

**Outcomes**

Outcome measures for back surgery are relatively well-established (see Table 1). Most studies used back and leg visual analog scores or the Zurich Claudication Questionnaire to assess pain and the Oswestry Disability Score (ODI) to assess functional limitations related to back pain. Most studies also use a broader functional status index such as the SF-12 or SF-36, particularly the physical function subscale of SF-36. Determining the minimal clinically important differences (MCID) for these measures is complex. The MCID for a given measure can depend on the baseline score or severity of illness, the method used to calculate MCID, and the times at which the scores are measured. For these reasons, some investigators prefer to calculate a minimum detectable difference (MDD).

Both short-term and long-term outcomes are important in evaluating back treatments. For example, for definitive back surgery, net benefit should take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36, Zurich Claudication Questionnaire, or visual analog scale measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures.

Patient preferences are important in decision-making about elective back surgery. In particular, to avoid the morbidity and risk of complications of the surgery, some patients may choose to prolong conservative treatments even if it means they have additional pain and functional limitation. Conversely, some patients will accept long-term outcomes of surgery similar to those of conservative therapy to get faster relief of symptoms and improvement in function.

Group means are commonly designated as primary outcome measures in spine studies. Variation in the calculation and definition of MCIDs makes it difficult to compare response rates
across studies. Nevertheless, clinical trials should prespecify an MCID for ODI and, when used, the other measures in the table and report response rates in addition to group means.

Table 1. Patient-reported Outcome Measures for Back and Leg Pain

<table>
<thead>
<tr>
<th>Measure</th>
<th>Outcome Evaluated</th>
<th>Description</th>
<th>MDD and MCID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oswestry Disability Score (ODI)</td>
<td>Functional disability and pain related to back conditions.</td>
<td>Ten 5-point items; scores 0 (no disability) to 50 (totally disabled) or 0-100% of maximum score</td>
<td>MDD: 8-10 points MCID varies; often 15 points (30 percentage points).</td>
</tr>
<tr>
<td>Zurich Claudication Questionnaire (ZCQ)</td>
<td>Pain, numbness, weakness, walking tolerance, and (if applicable) satisfaction with treatment results.</td>
<td>Eighteen items; three subscales. Total score is expressed in points or as a percentage of maximum score (higher scores are worse)</td>
<td>MDD: 5 points. MCID: Varies; sometimes defined as a detectable improvement on 2 of 3 subscales.</td>
</tr>
<tr>
<td>RMDQ</td>
<td>Disability from back problems.</td>
<td>Twenty-four items; scored 0-24 (higher scores are worse).</td>
<td>MCID: 30% reduction</td>
</tr>
<tr>
<td>Visual analog scale for leg pain</td>
<td>Degree of leg pain.</td>
<td>Patients indicate the degree of pain on a 0-100 scale.</td>
<td>MDD: 5 points</td>
</tr>
<tr>
<td>Visual analog scale for back pain</td>
<td>Degree of back pain.</td>
<td>Patients indicate the degree of pain on a 0-100 scale.</td>
<td>MDD: 2 points</td>
</tr>
</tbody>
</table>

MDD: minimal detectable difference; MCID: Minimal clinically important difference; RMDQ: Roland and Morris Disability Questionnaire.

Additional outcome measures are used for juvenile or adolescent idiopathic scoliosis and adult degenerative scoliosis.

Validated outcome measures of symptoms and quality of life include the Scoliosis Research Society-22 (SRS-22) questionnaire and the Pediatric Quality of Life Inventory (PedsQL). The long-term outcomes of interest are respiratory dysfunction, spinal pain and growth. Outcomes are generally measured from 1 to 3 years following skeletal maturity and into adulthood.

**Effect of Smoking on Spinal Fusion Rates**

A systematic review of the effects of smoking on spine surgery was published by Jackson and Devine in 2016. They included four large retrospective comparative studies; they evaluated fusion rates in smokers and nonsmokers. The greatest difference in fusion rates was observed in a study of 100 patients by Brown et al (1986) with a 32% difference in fusion rates between...
smokers and nonsmokers (p=0.001). Bydon et al (2014) found no significant difference in fusion rates between smokers and nonsmokers for single-level fusion, but an 18% lower fusion rate in smokers for 2-level fusions (p=0.019). A retrospective analysis by Andersen et al (2001) of 232 smokers and 194 nonsmokers found that patients who smoked more than 10 cigarettes per day within 3 months of surgery had a 9% decrease in fusion rates and a fourth study (Glassman et al, 2000) of 188 nonsmokers and 169 smokers found that smokers had a 7% reduction in fusion rates (p=0.05), and that fusion success improved with postoperative smoking cessation.

Summary of Evidence

For individuals with spinal stenosis who are undergoing decompression surgery and receive lumbar spinal fusion, the evidence includes three small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Two RCTs published in 2016 compared decompression surgery plus fusion with decompression surgery alone. These trials reached different conclusions about the benefit of adding fusion to decompression, one specifically in patients with low-grade (0%-25% slippage) spondylolisthesis and one in patients with lumbar stenosis with or without spondylolisthesis. Both trials reported a larger number of operative and perioperative adverse outcomes with the addition of fusion. The third trial, a small trial conducted in Japan, also found no difference in lower back pain or leg pain scores between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1 spondylolisthesis. About 40% of the patients also had dynamic instability. In patients with spinal stenosis and grade 1 spondylolisthesis and without instability, the evidence does not support routine addition of fusion to decompression surgery. The Swedish Spinal Stenosis Study (SSSS) included patients who did not have spondylolisthesis. The addition of fusion to laminectomy resulted in similar patient-reported outcomes, longer operating time, more bleeding, higher surgical costs, and longer hospitalization but did not result in better functional disability and pain scores. In patients with spinal stenosis and no spondylolisthesis who receive decompression, the evidence suggests that routine fusion is not better than decompression alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with juvenile or adolescent idiopathic scoliosis who undergo lumbar spinal fusion, the evidence includes observational studies reporting outcomes in adults who received lumbar spinal fusion as adolescents. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. These observational studies
do not provide evidence of the comparative effectiveness of spinal fusion to other interventions. Furthermore, because a goal of conservative treatment is to avoid fusion surgery, such comparisons would not be appropriate. They do suggest that, among patients who are referred for surgery, outcomes in adulthood are similar to those observed in patients who received bracing or no treatment. Limitations of this evidence include recall bias and the use of procedures that are not currently used. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have adult degenerative scoliosis who undergo lumbar spinal fusion, the evidence includes a prospective comparative cohort study, which evaluated outcomes in adults with symptomatic scoliosis who were treated with spinal fusion surgery or nonoperatively. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Although the surgically treated group had better outcomes than the conservatively managed group, there was potential bias in this study due to the self-selection of treatment and high loss to follow-up in the conservatively managed group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have isthmic spondylolisthesis who undergo lumbar spinal fusion, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The RCT identified compared fusion with an exercise program for patients with symptomatic isthmic spondylolisthesis. Functional outcomes and pain relief were significantly better following fusion surgery. Results of this trial support the use of fusion for this condition but should be corroborated in a larger number of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spinal fracture and undergo lumbar spinal fusion, the evidence includes RCTs and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Results of a small RCT indicated that spinal fusion for patients with spinal fracture without instability or neural compression might result in worse outcomes than nonsurgical management. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lumbar disc herniation with radiculopathy who are undergoing discectomy who receive lumbar spinal fusion, the evidence includes observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. In patients with lumbar radiculopathy with herniated disc who receive discectomy, the evidence does not support the routine use of fusion as an adjunct to discectomy. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have chronic low back pain without radiculopathy who undergo lumbar spinal fusion, the evidence includes RCTs and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. In most patients with chronic or persistent low back pain who do not have neurogenic leg pain, fusion surgery has little or no net benefit. Clinical trials have not used clear criteria for diagnosing discogenic pain, which may contribute to mixed results. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input on the indications for lumbar spinal fusion was obtained when this policy was created in 2014. Input supported the use of lumbar spinal fusion under conditions of spinal deformity or instability, including stenosis with spondylolisthesis and recurrent disc herniation. Based on the results of clinical vetting, spinal fusion combined with decompression surgery may be considered medically necessary when conservative treatment has failed in patients with severe scoliosis, stenosis plus spondylolisthesis, or recurrent disc herniation.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.

**Table 2. Summary of Key Trials**

<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>
<tr>
<td>NCT01455805</td>
<td>Minuteman Spinal Fusion Implant Versus Surgical Decompression for Lumbar Spinal Stenosis</td>
<td>50</td>
<td>Mar 2024</td>
</tr>
<tr>
<td>NCT03439228</td>
<td>To Brace or Not to Brace for Single Level Lumbar Fusion: A Pilot Prospective Randomized Controlled Trial</td>
<td>50</td>
<td>Apr 2020</td>
</tr>
<tr>
<td>NCT02466048</td>
<td>Clinical Trial to Evaluate the Efficacy and Safety of SurgiFill™, on Spinal Fusion—Comparison Between Autograft Mixed with SurgiFill™ and Autograft in Spinal Fusion—</td>
<td>20</td>
<td>Jan 2016</td>
</tr>
<tr>
<td>NCT03176303</td>
<td>A Multi-Center, Open-Label, Prospective Study of SpinalStim™ (MOP-SS) as Adjunctive Care Following Lumbar Fusion Surgery</td>
<td>500</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT02385695</td>
<td>A Prospective Comparative Study to Evaluate Safety and Effectiveness of Dynamic Stabilization Versus Lumbar Fusion in Treatment of Multilevel Lumbar Disc</td>
<td>102</td>
<td>Aug 2021</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT03793530</td>
<td>The Use of Bone Marrow Concentrate in Elective Transforaminal Lumbar Interbody Fusion Surgery: A Randomized Control Trial</td>
<td>40</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT01560273a</td>
<td>Aspen Spinous Process Fixation System for Use in PLF in Patients with Spondylolisthesis</td>
<td>25</td>
<td>Terminated</td>
</tr>
<tr>
<td>NCT01549366a</td>
<td>A Multi-Center Prospective Randomized Study Comparing Supplemental Posterior Instrumentation, Aspen™ Spinous Process System Versus Pedicle Screw Fixation, in Lateral Lumbar Interbody Fusion (LLIF) or Anterior Lumbar Interbody Fusion (ALIF)</td>
<td>64</td>
<td>Jan 2016</td>
</tr>
<tr>
<td>NCT00758719a</td>
<td>A Prospective Multicenter Lumbar Spine Fusion Study to Evaluate the Effectiveness of the Biomet Lumbar Spinal Fusion System</td>
<td>53</td>
<td>Aug 2012</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Clinical Input Received 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.

2014 Input

In response to requests, input was received from the North American Spine Society, American Association of Neurological Surgeons, and Congress of Neurological Surgeons, with three additional reviewers identified through a third physician specialty society, as well as two academic medical centers in 2014. Input addressed specific criteria to determine the medical necessity of lumbar spinal fusion.
Practice Guidelines and Position Statements

**North American Spine Society**

The North American Spine Society (NASS; 2014) published coverage policy recommendations for lumbar fusion and made the following recommendations.\(^{36}\)

1. In disc herniation who fulfill criteria for disectomy. The NASS recommends fusion for patients who meet any of the following criteria:
   
   a. primary extraforaminal disc herniation is present at L5-S1, in which a far lateral approach is not feasible because of the presence of the iliac wings
   
   b. primary foraminal disc herniation for which facet resection is necessary to retrieve the disc, which will result in iatrogenic instability
   
   c. recurrent disc herniation
   
   d. primary disc herniation in the lumbar spine that is at the level of the spinal cord (ie, low lying conus medullaris)
   
   e. Lumbar spinal fusion is not recommended as an adjunct to primary excision of a central or posterolateral disc herniation at any level in the absence of instability or spondylolisthesis.

2. In lumbar spinal stenosis who fulfill criteria for decompression. The NASS recommends fusion for patients who meet any of the following criteria:
   
   a. dynamic instability is present, as documented by flexion-extension radiographs or comparison of a supine and upright image, defined as a difference in translational alignment between vertebrae greater than 2 mm between views
   
   b. spondylolisthesis (defined as at least 1-2 mm of anterolisthesis of the upper vertebra in relation to the lower vertebra) is present, either isthmic (i.e., secondary to a posterior arch stress fracture) or degenerative type
   
   c. cases in which decompression will likely result in iatrogenic instability, such as foraminal stenosis, during which greater than 50 percent of the facet joint will be removed to adequately decompress the exiting nerve root.*
   
   d. adjacent level disease, (eg, stenosis) that has developed above or below a previous fusion
e. recurrent stenosis (eg, that which developed at a level that has been previously operated)

*For cases in which there is severe foraminal stenosis, adequate decompression often can require aggressive resection one or both facet joints at a particular level. Removal of an entire facet joint, even unilaterally, is generally thought to be a destabilizing event in the lumbar spine. While most cases of unilateral foraminal stenosis can be adequately decompressed with a nondestabilizing procedure, such as a foraminotomy, there are some cases in which the compression can be so severe and the orientation of the joint is such that achieving adequate decompression without producing iatrogenic instability can be difficult, if not dangerous to the underlying nerve root. This is a particular clinical scenario that would be exceedingly difficult to study that will likely not be addressed by a prospective, randomized trial (or other comparative trial for that matter). Recognizing this limitation in the evidence, that will likely persist, evidence-based medicine surgeons have made it clear that this should be reserved as a potential indication for fusion in the setting of stenosis without obvious signs of preoperative spondylolisthesis or instability.

3. In patients with pseudarthrosis in the lumbar spine. The NASS recommends fusion for patients who meet all of the following criteria (a-d) or demonstrate presence of a gross failure of the instrumentation (e.g., pedicle screw breakage, screw loosening, curve/correction decompensation):

   a. mechanical low back pain that is approximately at the level of the pseudarthrosis, qualified as pain that can be somewhat positionally abated
   
   b. period of time following the index surgery during which the patient had symptomatic relief
   
   c. nonoperative care for at least 6 months
   
   d. CT or plain films that are highly suggestive of nonunion at a lumbar segment at which a fusion had been previous attempted. These criteria include:

       i. lack of bridging bone

       ii. dynamic motion noted on flexion-extension radiographs

Specific criteria were described for infection, tumor, traumatic injuries, deformity (eg, scoliosis), stenosis, disc herniations, synovial facet cysts, discogenic low back pain, and pseudarthrosis. NASS isolated situations where lumbar fusion would not be indicated: disc herniation in the absence of instability or spondylolisthesis; stenosis in the absence of instability; foraminal stenosis or spondylolisthesis; and discogenic low back pain.
Other 2014 guidelines from NASS addressed the diagnosis and treatment of *degenerative lumbar spondylolisthesis*.\(^{37}\) NASS gave a grade B recommendation to surgical decompression with fusion for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone. A grade C recommendation was given to decompression and fusion as a means to provide satisfactory long-term results for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

The 2011 NASS guidelines (updated in 2013) addressed multidisciplinary spine care for adults with a chief complaint of degenerative lumbar spinal stenosis.\(^{1,38}\) The guidelines indicated that the nature of the pain and associated patient characteristics should be more typical of a diagnosis of spinal stenosis than a herniated disc. NASS addressed whether the addition of lumbar fusion to surgical decompression improved surgical outcomes in the treatment of spinal stenosis compared with treatment by decompression alone. NASS gave a grade B recommendation (fair evidence) to decompression alone for patients with leg predominant symptoms without instability.

The 2012 NASS guidelines (updated in 2014) addressed multidisciplinary spine care for the diagnosis and treatment of lumbar disc herniation with radiculopathy.\(^{39,40}\) The guidelines indicated that “there is insufficient evidence to make a recommendation for or against fusion for specific patient populations with lumbar disc herniation with radiculopathy whose symptoms warrant surgery. Recommendation: I (Insufficient Evidence).”

**American Association of Neurological Surgeons and Congress of Neurological Surgeons**

The 2014 guidelines from American Association of Neurological Surgeons and Congress of Neurological Surgeons addressed fusion procedures for the lumbar spine.\(^{41}\) These guidelines indicated that there was no evidence that conflicted with the recommendations formulated in the 2005 guidelines for fusion procedures for the lumbar spine. See Table 3.
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>GOR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>One- or two-level degenerative disease without stenosis or spondylolisthesis (part 7)</strong>&lt;sup&gt;42&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumbar fusion should be performed for patients whose low back pain refractory to conservative treatment (physical therapy or other nonoperative measures) and is due to 1- or 2-level DDD without stenosis or spondylolisthesis</td>
<td>B</td>
<td>Multiple level II studies</td>
</tr>
<tr>
<td><strong>Discography degenerative disease of the lumbar spine (part 6)</strong>&lt;sup&gt;43&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discoblock &quot;(a procedure that involves injecting the disc with an anesthetic agent instead of a contrast agent in an effort to eliminate as opposed to reproducing a patient’s pain)&quot; is considered as a diagnostic option during the evaluation of a patient presenting with chronic low back pain, but that the potential for acceleration of the degenerative process be included in the discussion of potential risks.</td>
<td>C</td>
<td>Single level II study</td>
</tr>
<tr>
<td><strong>Disc herniation and radiculopathy (part 8)</strong>&lt;sup&gt;44&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumbar spinal fusion is not recommended as routine treatment following primary disc excision in patients with a herniated lumbar disc causing radiculopathy.</td>
<td>C</td>
<td>IV</td>
</tr>
<tr>
<td>Lumbar spinal fusion is recommended as a potential option in patients with herniated discs who have evidence of significant chronic axial back pain, work as manual laborers, have severe degenerative changes, or have instability associated with radiculopathy caused by herniated lumbar discs.</td>
<td>C</td>
<td>IV</td>
</tr>
<tr>
<td>Reoperative discectomy combined with fusion is recommended as a treatment option in patients with a recurrent disc herniation associated with lumbar instability or chronic axial low back pain.</td>
<td>C</td>
<td>III</td>
</tr>
<tr>
<td><strong>Stenosis and spondylolisthesis (part 9)</strong>&lt;sup&gt;45&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with degenerative spondylolisthesis in patients who desire surgical treatment.</td>
<td>B</td>
<td>II</td>
</tr>
<tr>
<td>There was insufficient evidence to recommend a standard fusion technique.</td>
<td></td>
<td>Insufficient</td>
</tr>
<tr>
<td><strong>Stenosis without spondylolisthesis (part 10)</strong>&lt;sup&gt;46&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who undergo surgical intervention.</td>
<td>B</td>
<td>II/III</td>
</tr>
<tr>
<td>In the absence of deformity or instability, lumbar fusion is not recommended because it has not been shown to improve outcomes in patients with isolated stenosis.</td>
<td>C</td>
<td>IV</td>
</tr>
</tbody>
</table>

DDD: degenerative disc disease; GOR: grade of recommendation; LOE: level of evidence.
The two associations also provided recommendations on:

- Assessment of functional outcome following lumbar fusion (part 2)
- Assessment of economic outcome (part 3)
- Radiographic assessment of fusion status (part 4)
- Correlation between radiographic outcome and function (part 5)
- Interbody techniques for lumbar fusion (part 11)
- Pedicle screw fixation as an adjunct to posterolateral fusion (part 12)
- Injection therapies (part 13)
- Brace therapy (part 14)
- Electrophysiologic monitoring (part 15)
- Bone growth extenders and substitutes (part 16), and
- Bone growth stimulators (part 17)

**American Academy of Orthopaedic Surgeons**

Information updated in 2015 by the American Academy of Orthopaedic Surgeons has indicated that the type of treatment required for idiopathic scoliosis in children and adolescents depends on the type and degree of the curve, child's age, and number of remaining growth years until the child reaches skeletal maturity.47

Observation is appropriate when the curve is mild (<25°) or if the child is near skeletal maturity.

The goal of bracing is to prevent scoliotic curves from worsening. Bracing can be effective if the child is still growing and has a spinal curvature between 25° and 45°. There are several types of braces, most being the underarm type.

Surgery may be recommended if the curve is greater than 45° and the child is still growing. If the patient has reached skeletal maturity, surgery may still be recommended for scoliotic curves that exceed 50° to 55°. An implant made up of rods, hooks, screws, and/or wires is used to straighten the spine. Bone graft from the bone bank, or from the patient's hip region, is also used to help the operated portion of the spine heal solid.
At present, the main research focus in idiopathic scoliosis is investigation into genetic factors as a cause of scoliosis.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE; 2017) provided guidance on lateral interbody fusion for lumbar spine low back pain. NICE stated that lumbar fusion may be appropriate for “people with severe, life-limiting, chronic low back pain that does not respond to conservative treatments.” The evidence on lateral interbody fusion was considered “adequate in quality and quantity.” Also in 2017, NICE reexamined lumbar disc replacement and reported higher complication rates were found in patients who underwent fusion. The conclusion was that disc replacement was not warranted and spinal fusion for nonspecific low back pain should only be performed as part of a randomized controlled trial.

International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT)

The International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) updated their guidelines on treatment of idiopathic scoliosis in 2018. In these guidelines, fusion is discussed in the context of other treatments, as an outcome measure indicating treatment failure.

U.S. Preventive Services Task Force Recommendations

Adolescent Idiopathic Scoliosis: The US Preventive Services Task Force updated their recommendations on screening for adolescent idiopathic scoliosis in 2018 and concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for adolescent idiopathic scoliosis in children and adolescents aged 10 to 18 years (I statement). The Task Force found no studies of surgical treatment in screening-relevant populations that met inclusion criteria.
Medicare National Coverage

In 2006, the Medicare Coverage Advisory Committee provided recommendations on the quality and strength of evidence for the benefits and risks of spinal fusion surgery for chronic low back pain from lumbar degenerative disc disease.1

Regulatory Status

Lumbar spinal fusion is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration. Various instruments used in lumbar spinal fusion have been cleared for marketing by the Food and Drug Administration (eg, INFUSE [recombinant human bone morphogenetic protein-2], OP-1 [recombinant human bone morphogenetic protein-7]) for specified indications.

References


Procedures for Lumbar Interbody Fusion

Procedures used for lumbar interbody fusion differ primarily in the direction of approach to the spine, ie, from the front (anterior), from the back (posterior or transforaminal), or from the side (lateral). An alternative approach to interbody fusion is arthrodesis of the transverse processes alone (posterolateral), which does not fuse the adjoining vertebral bodies. Circumferential fusion fuses both the adjacent vertebral bodies and the transverse processes, typically using both an anterior and posterior approach to the spine. See Appendix Table 1 for various approaches.

Appendix Table 1. Open and Minimally Invasive Approaches to Lumbar Interbody Fusion

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Access</th>
<th>Approach</th>
<th>Visualization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior lumbar interbody fusion</td>
<td>Open, MI, or laparoscopic</td>
<td>Transperitoneal or retroperitoneal</td>
<td>Direct, endoscopic or laparoscopic with fluoroscopic guidance</td>
</tr>
<tr>
<td>Posterior lumbar interbody fusion</td>
<td>Open or MI</td>
<td>Incision centered over spine with laminectomy / laminotomy and retraction of nerve</td>
<td>Direct, endoscopic or microscopic, with fluoroscopic guidance</td>
</tr>
<tr>
<td>Transforaminal lumbar interbody fusion</td>
<td>Open or MI</td>
<td>Offset from spine, through the intervertebral foramen via unilateral facetectomy</td>
<td>Direct, endoscopic or microscopic, with fluoroscopic guidance</td>
</tr>
<tr>
<td>Lateral interbody fusion</td>
<td>MI</td>
<td>Retroperitoneal through transpsoas</td>
<td>Direct, with neurologic monitoring and fluoroscopic guidance</td>
</tr>
<tr>
<td>Extreme lateral interbody fusion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct lateral interbody fusion</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MI: minimally invasive.

Anterior Lumbar Interbody Fusion

Anterior lumbar interbody fusion (ALIF) approaches the anterior side of the spinal column through a transperitoneal or retroperitoneal approach and provides direct visualization of the disc space, potentially allowing a more complete discectomy and better fusion than lateral or
posterior approaches. An anterior approach avoids trauma to the paraspinal musculature, epidural scarring, traction on nerve roots, and dural tears. However, the retraction of the great vessels, peritoneal contents, and superior hypogastric sympathetic plexus with a peritoneal or retroperitoneal approach place these structures at risk of iatrogenic injury. Access to the posterior space for the treatment of nerve compression is also limited. Laparoscopic ALIF has also been investigated.

**Posterior Lumbar Interbody Fusion**

Posterior lumbar interbody fusion (PLIF) approaches the posterior side of the spine and can be performed through either a traditional open procedure with a midline incision or a minimally invasive approach using bilateral paramedian incisions. In the open procedure, the midline muscle attachments are divided along the central incision to facilitate wide muscle retraction and laminectomy. In minimally invasive PLIF, tubular retractors may be used to open smaller central bilateral working channels to access the pedicles and foramen. Minimally invasive PLIF typically involves partial laminotomies and facetectomies. The decompression allows treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum), as well as stabilization of the spine through interbody fusion.

**Transforaminal Lumbar Interbody Fusion**

Transforaminal lumbar interbody fusion (TLIF) is differentiated from the more traditional bilateral PLIF by a unilateral approach to the disc space through the intervertebral foramen. In minimally invasive TLIF, a single incision about 2-3 cm in length is made approximately 3 cm lateral to the midline. A tubular retractor is docked on the facet joint complex and a facetectomy with partial laminectomy is performed. Less dural retraction is needed with access through the foramen via unilateral facetectomy, and contralateral scar formation is eliminated. TLIF provides access to the posterior elements along with the intervertebral disc space.

**Lateral Lumbar Interbody Fusion**

Lateral interbody fusion (e.g., extreme lateral interbody fusion or direct lateral interbody fusion) uses specialized retractors in a minimally invasive, lateral approach to the anterior spine through the psoas. Compared with ALIF, the lateral approach does not risk injury to the peritoneum or
great vessels. However, exposure to the spine may be more limited, and dissection of the psoas major places the nerves of the lumbar plexus at risk. Electromyographic monitoring and dissection predominantly within the anterior psoas major may be used to reduce the risk of nerve root injury. These factors decrease the ability to perform a complete discectomy and address the pathology of the posterior elements.

Oblique Lateral Interbody Fusion

Oblique lateral interbody fusion is a more recently developed technique that uses retroperitoneal access to the spine. This minimally invasive approach is designed to reduce complications from the stripping of muscles and soft tissue from a posterior approach. It approaches the disc through the Kambin triangle and uses bilateral fluoroscopy.

Circumferential Fusion

Circumferential fusion is 360° fusion that joins vertebrae by their entire bodies and transverse processes, typically through an anterior and posterior approach.

Posterolateral Fusion

Posterolateral fusion is a procedure where the transverse processes of the involved segments are decorticated and covered with a mixture of bone autograft or allograft.

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/08/11</td>
<td>Add to Surgery Section - New Policy held for provider notification. The effective and publication date will be 9/1/2011.</td>
</tr>
<tr>
<td>05/18/11</td>
<td>Policy Published - The policy was published on the internal and external sites with an effective date of September 1, 2011.</td>
</tr>
<tr>
<td>12/2/11</td>
<td>Related Policies updated; 7.01.115 removed.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>01/11/12</td>
<td>Codes 22633 and 22634 added.</td>
</tr>
<tr>
<td>09/11/12</td>
<td>Replace policy - Policy statements extensively revised for clarification. Instability clarified by adding 4 mm of translational instability. Spinal stenosis criteria clarified. Pseudoarthrosis criteria clarified by adding lucency around the hardware per x-ray or CT scan. Failure of 6 months of nonsurgical care removed from all policy statements. Added reference 16.</td>
</tr>
<tr>
<td>10/09/12</td>
<td>Replace policy - Added definitions for truncal imbalance. Added clarity to spondylolisthesis statement – It is measured in the sagittal plane on functional flexion and extension views on upright x-ray. MRI and CT removed from bullet. Added references 17 and 18.</td>
</tr>
<tr>
<td>12/19/12</td>
<td>Update Related Policies – Add 7.01.85.</td>
</tr>
<tr>
<td>01/10/13</td>
<td>Coding update. CPT codes 22586 and 0309T, effective 1/1/13, added to policy.</td>
</tr>
<tr>
<td>04/08/13</td>
<td>Clarification only. &quot;Acute&quot; added to describe spinal fracture within the Policy section. Literature reviewed.</td>
</tr>
<tr>
<td>12/06/13</td>
<td>Update Related Policies. Add 7.01.138.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
</tr>
<tr>
<td>07/14/14</td>
<td>Annual review. Policy updated with literature review through October 23, 2013; considered medically necessary under specified conditions. Policy rewritten and reorganized.</td>
</tr>
<tr>
<td>01/13/15</td>
<td>Annual Review. Policy updated with literature review through September 2014; no change in policy statements. References 18 and 28-34 added. The following codes were removed from the policy as they do not facilitate adjudication: ICD-9 &amp; ICD-10 diagnosis; CPT 20930-20938, 22840-22847 &amp; 22851.</td>
</tr>
<tr>
<td>02/03/15</td>
<td>Update Related Policies. Add 7.01.130.</td>
</tr>
<tr>
<td>04/14/15</td>
<td>Interim Update. Policy updated within the Policy Guidelines section to state that smoking within the previous 6 weeks (previously stated 3 months) is a contraindication for lumbar spinal fusion; supportive Rationale added within said section and references 14-21 added (others renumbered). An additional bullet has been added within the same section within the minimal documentation requirement to document proof of smoking cessation for 6 weeks prior to surgery.</td>
</tr>
<tr>
<td>10/13/15</td>
<td>Interim Update. Clarified medically necessary policy criteria to state that presence of both spondylolisthesis and instability must be met for spinal stenosis (previously stated or instability). Added Definition of Terms subheading with definition of smoking cessation. Added Documentation requirement that medical record include a written statement that patient was non-smoking the 6-weeks prior to scheduled surgery (previously stated “proof/evidence” without specificity). Added statement about documentation that must be submitted for review including copy of radiologist’s MRI/CT report. Policy statements revised as noted.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12/08/15</td>
<td>Interim Update. Added clarification to Documentation requirement that the diagnostic imaging (CT, MRI) must be done within 12 months prior to the surgery. Clarified the Definition of Terms for neurogenic claudication. Policy statements unchanged.</td>
</tr>
<tr>
<td>10/11/16</td>
<td>Annual Review. Policy updated with literature review through February 22, 2016; references 3-4, 18, 23, and 38-40 added. Policy statements revised: Spondylolisthesis added as its own condition, rapidly progressive symptoms and CES removed from pseudoarthrosis section. Definitions of spondylolisthesis and pseudoarthrosis added. Study descriptions and references regarding Tobacco Use and Spinal Fusion retained in Rationale/Reference section. CPT code 22586 removed from policy; it applies to a separate medical policy.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update, added new CPT codes 22853, 22854, and 22859 with effective date 01/01/17.</td>
</tr>
<tr>
<td>01/13/17</td>
<td>Clarified and corrected coding update. Note was added that CPT code 22851 was deleted as of 01/01/17 and replaced with three new CPT codes (22853, 22854, and 22859) effective 01/01/17.</td>
</tr>
<tr>
<td>02/10/17</td>
<td>Policy moved to new format. No changes to policy statement.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Removed CPT code 22851 as this code was terminated on 1/1/17 and replaced with 22853, 22854, and 22859.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Coding update, removed code 0309T as it was terminated 1/1/18.</td>
</tr>
<tr>
<td>09/01/19</td>
<td>Annual Review, approved August 22, 2019. Policy updated with literature review through April 2019; References added. Edited statement to “individuals with juvenile or adolescent idiopathic scoliosis” to more accurately reflect current terminology. Otherwise, policy statements unchanged.</td>
</tr>
</tbody>
</table>

**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). ©2020 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 complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
• Qualified sign language interpreters
• Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
• Qualified interpreters
• 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, or sex, 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 800-842-5357
Email AppealsDepartmentinquines@Premera.com

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 Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):
Lakkoofsa biliibila 800-722-1471 (TTY: 800-842-5357) ti biliibila.

Français (French):
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan Idayann. Avi sila a kapab genyen enfòmasyon enpòtan konsèn kapas yon kweyisyen yon kweyisyen asinsan lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksoyan avan sèten dat limit pou ka jenbe kweyisyen asinsan sante w la osa pou yo ka ede w akav depans yo. Se dwa w pou resesva enfòmasyon sa a ak asisans lan ou pangal ni ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilokó (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasyon. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasyon maipanggep iti aplikasyon wu coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaar. Mabalin nga adda rumbgeng a nan turlud nga aramyedeng nga adda sacking dagiti partikular a naituding nga aldaw tapo napagatinalayid ti coverag ti salun-atyo wu tungol kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasyon ken tungol iti bukoddy a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero essere date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamà 800-722-1471 (TTY: 800-842-5357).
Este Aviso contiene información importante. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Fa’samaso (Samoa): Atonu ua i ai i lelei fa’asialisiaga ni fa’amatala e sili ona taua e tatau ona e malamalama i ai. O lelei fa’asialisiaga o se fesoasoani e fa’amatala ona taua i ai. Fa’amolemoa, ia i folio fa’alae o i lelei fa’asialisiaga tava. Masoale o lelei fa’alae o iai ona ona e fai a le’a e a fi’a le’a e lelei fa’asialisiaga ina ia e ia e lelei fa’asialisiaga tava. Le iatapalama e le Malo olo’o i ai e iai. Olo’o i iate iai le’a e lelei fa’asialisiaga tava, ona e fai a le’a e iai ona e fai a le’a e iai.


Vietnamese (Vietnamese): Thông báo này cung cấp thông tin quan trọng. Thông báo này có thể thay đổi trong thời gian tới và thông báo này không cung cấp thông tin quan trọng về bệnh viện hoặc cung cấp thông tin quan trọng về bảo hiểm. Để biết thêm thông tin, vui lòng liên hệ với Premera Blue Cross tại 800-722-1471 (TTY: 800-842-5357).

Ukrainian (Ukrainian): Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує можливість того, що Вам треба буде здійснити певні кроки в конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Premera Blue Cross, 800-722-1471 (TTY: 800-842-5357) has your rights to obtain this information and assistance at no charge.