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.
Policy Coverage Criteria

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>
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<td></td>
<td>OR</td>
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<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>
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<td>AND</td>
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<td></td>
<td>• Either one of the following:</td>
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<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>
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<td></td>
<td>OR</td>
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<td></td>
<td>o Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome</td>
</tr>
<tr>
<td>Severe progressive juvenile idiopathic scoliosis</td>
<td>Lumbar spinal fusion may be considered medically necessary for severe progressive juvenile idiopathic scoliosis with one of</td>
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<tr>
<td>Condition</td>
<td>Medical Necessity</td>
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</tbody>
</table>
| **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  
- Significant sagittal imbalance (eg, sagittal vertical axis > 5 cm), and with ONE of the following:  
  - 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  
  - 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  
  - 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:  
- Congenital (Wiltse type I) or acquired pars defect (Wiltse II), |
<table>
<thead>
<tr>
<th>Condition</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| 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) or 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  
  **AND**  
  • With persistent axial back pain, with or without neurogenic |

- **Condition**
- **Medical Necessity**
  - 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) or 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
  - **AND**
  - With persistent axial back pain, with or without neurogenic
<table>
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<th>Condition</th>
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<td>Condition</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>symptoms OR with severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome AND • Impairment or loss of function, in a patient who had experienced significant interval relief of prior symptoms</td>
<td></td>
</tr>
<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>
<tr>
<td>Adjacent level disease after prior fusion</td>
<td>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</td>
</tr>
<tr>
<td>Multiple level lumbar spinal fusions</td>
<td>Multiple level lumbar spinal fusions are considered not medically necessary when the criteria in this policy are not met for all levels that will be surgically fused.</td>
</tr>
<tr>
<td>Conditions other than those listed in this policy</td>
<td>Lumbar spinal fusion is considered not medically necessary for any indication not addressed in this policy.</td>
</tr>
<tr>
<td>Condition</td>
<td>Investigational</td>
</tr>
<tr>
<td>As listed</td>
<td>Lumbar spinal fusion is considered investigational if the sole</td>
</tr>
</tbody>
</table>
**Condition**

Investigational indication is any one of the following conditions:
- Chronic nonspecific low back pain without radiculopathy
- Degenerative disc disease
- Disc herniation
- Facet syndrome
- Initial discectomy/laminectomy for neural structure decompression

**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 that document the requesting surgeon personally evaluated the individual at least twice 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).

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**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.

**Pseudoarthrosis:** 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 fusion of 2 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 (PLF) 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 (2 adjacent vertebrae and the disc between them) that is 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 1 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 that is 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 operations 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.

**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. Four large retrospective comparative studies were included; 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), but fusion success improved with postoperative smoking cessation.

**Summary of Evidence**

For individuals who have spinal stenosis undergoing decompressive surgery who receive lumbar spinal fusion, the evidence includes RCTs with mixed results. 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 on 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 SSSS found no benefit of surgery related to clinical outcomes, while the SLIP trial reported a
small benefit in clinical outcomes and a reduction in the number of subsequent surgeries when fusion was added to decompression. In the earlier SPORT trial, decompression surgery plus fusion was compared with conservative, nonsurgical treatment. Ninety-five percent of patients in the surgical group underwent decompression with fusion and had better outcomes than patients receiving non-operative therapy. This trial, however, did not isolate the impact of fusion apart from that of decompression surgery. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have juvenile idiopathic scoliosis who receive lumbar spinal fusion, the evidence includes a large comparative cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Long-term follow-up of a large comparative cohort indicates that spinal fusion can reduce curve progression compared with bracing in patients with large Cobb angles. In this study the populations were not comparable, because curves less than 60° were treated with a brace and curves of 60° or greater were treated with spinal fusion. Although existing evidence supports the use of spinal fusion in juveniles with large Cobb angles and remaining growth, studies are needed that compare curve progression after fusion or bracing in a comparable populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have adult degenerative scoliosis who receive lumbar spinal fusion, the evidence includes a nonrandomized comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. No RCTs were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. Evidence includes a prospective comparative cohort study, which evaluated outcomes in adults with symptomatic scoliosis who were treated with spinal fusion surgery or nonoperatively. 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 receive lumbar spinal fusion, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. One 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 who receive 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 randomized trial have 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 an RCT and a nonrandomized comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Current evidence, which includes the large SPORT RCT, supports surgical treatment with discectomy for lumbar disc herniation. The evidence does not support a conclusion that the addition of fusion to discectomy improves outcomes in patients with lumbar disc herniation without instability. 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 receive 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. Meta-analysis of results from 4 RCTs found no clinically significant advantage of lumbar fusion over conservative therapy in patients with nonspecific chronic low back pain unresponsive to conservative management. While some trials have reported a benefit, others have not. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in March 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

**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 3 additional reviewers identified through a third physician specialty society, as well as 2 academic medical centers when this policy was created 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. Specific criteria were described for infection, tumor, traumatic injuries, deformity (eg, scoliosis), stenosis, disc herniations, synovial facet cysts, discogenic low back pain, and pseudoarthrosis. 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 has addressed the diagnosis and treatment of degenerative lumbar spondylolisthesis. 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. 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.\(^{30,31}\) 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 (AANS) 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.\(^{32}\) 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 1.

**Table 1. Guidelines on Fusion Procedures for the Lumbar Spine**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>GOR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>One- or 2-level degenerative disease without stenosis or spondylolisthesis (part 7)(^33)</td>
<td>B</td>
<td>Multiple level II studies</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></td>
<td></td>
</tr>
<tr>
<td><strong>Discography degenerative disease of the lumbar spine (part 6)(^34)</strong></td>
<td>C</td>
<td>Single level II study</td>
</tr>
<tr>
<td>Discoblock “(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)” 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></td>
<td></td>
</tr>
<tr>
<td><strong>Disc herniation and radiculopathy (part 8)(^35)</strong></td>
<td>C</td>
<td>IV</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></td>
<td></td>
</tr>
<tr>
<td>Lumbar spinal fusion is recommended as a potential option in patients with</td>
<td>C</td>
<td>IV</td>
</tr>
</tbody>
</table>
Recommendation | GOR | LOE
---|---|---
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. |  |  
Reoperative discectomy combined with fusion is recommended as a treatment option in patients with a recurrent disc herniations associated with lumbar instability or chronic axial low back pain. | C | III

**Stenosis and spondylolisthesis (part 9)**\(^{36}\)

Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with degenerative spondylolisthesis in patients who desire surgical treatment.

There was insufficient evidence to recommend a standard fusion technique.

**Stenosis without spondylolisthesis (part 10)**\(^{37}\)

Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who undergo surgical intervention.

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.

DDD: degenerative disc disease; GOR: grade of recommendation; LOE: level of evidence.

- The 2 associations also provided recommendations on\(^{32}\):
  - 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)
- 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.38

- Observation is appropriate when the curve is mild (<25 degrees) 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 degrees and 45 degrees. There are several types of braces, most being the underarm type.

- Surgery may be recommended if the curve is greater than 45 degrees and the child is still growing. If the patient has reached skeletal maturity, surgery may still be recommended for scoliotic curves that exceed 50 degrees to 55 degrees. 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 Clinical Excellence**

The National Institute for Health and Care Excellence (NICE; 2017) provided guidance on lateral interbody fusion for lumbar spine low back pain.39 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.40 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.
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.\(^\text{41}\)

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 (FDA). Various instruments used in lumbar spinal fusion have been cleared for marketing by the Food and Drug Administration such as, INFUSE (recombinant human bone morphogenetic protein-2), OP-1 (recombinant human bone morphogenetic protein-7 for specified indications).

References


Appendix
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, minimally invasive, 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 minimally invasive</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 minimally invasive</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>Minimally invasive</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>
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</tr>
</tbody>
</table>

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 $360^\circ$ 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<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>
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<td>12/2/11</td>
<td>Related Policies updated; 7.01.115 removed.</td>
</tr>
<tr>
<td>01/11/12</td>
<td>Codes 22633 and 22634 added.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
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<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>
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<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>
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<td>12/19/12</td>
<td>Update Related Policies – Add 7.01.85.</td>
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<td>01/10/13</td>
<td>Coding update. CPT codes 22586 and 0309T, effective 1/1/13, added to policy.</td>
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<tr>
<td>04/08/13</td>
<td>Clarification only. “Acute” 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>
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<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>
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<tr>
<td>02/03/15</td>
<td>Update Related Policies. Add 7.01.130.</td>
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<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>
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<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>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</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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</tr>
<tr>
<td>10/11/16</td>
<td>Definition of Terms for neurogenic claudication. Policy statements unchanged. 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>
</tbody>
</table>

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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