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MEDICAL POLICY – 7.01.542

Lumbar Spinal Fusion in Adults

BCBSA Ref. Policy: 7.01.141

Effective Date:	Mar. 1, 2024
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RELATED MEDICAL POLICIES:

7.01.85	Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
7.01.87	Artificial Intervertebral Disc: Lumbar Spine
7.01.130	Axial Lumbosacral Interbody Fusion
7.01.138	Interspinous Fixation (Fusion) Devices
7.01.551	Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy
11.01.524	Site of Service: Select Surgical Procedures

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | APPENDIX | HISTORY

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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 do not 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

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

We will review for medical necessity this elective surgical procedure.

The surgical procedure subject to medical necessity review for site of service addressed in this policy is limited to:

- **Single-level lumbar fusion (this includes lumbar spine decompression surgeries performed with single level lumbar fusion)**

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

Site of Service for Elective Surgical Procedures	Medical Necessity
Medically necessary sites of service: • **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center** • **Ambulatory surgical center**	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.**
Inpatient hospital/medical center	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk for**

Site of Service for Elective Surgical Procedures	Medical Necessity

	complications including any of the following (this list may not be all inclusive):
	• **Anesthesia Risk**
	  ○ American Society of Anesthesiologists (ASA) classification III or higher (see **definition**)
	  ○ Personal history of complication of anesthesia
	  ○ Documentation of alcohol dependence or history of cocaine use
	  ○ Prolonged surgery (> 3 hours)
	• **Cardiovascular Risk**
	  ○ Uncompensated chronic heart failure (New York Heart Association [**NYHA] class** III or IV)
	  ○ Recent history of myocardial infarction (MI) (< 3 months)
	  ○ Poorly controlled, resistant hypertension*
	  ○ Recent history of cerebrovascular accident (< 3 months)
	  ○ Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty < 90 days)
	  ○ Symptomatic cardiac arrhythmia despite medication
	  ○ Significant valvular heart disease
	• **Liver Risk**
	  ○ Advanced liver disease (Model for End-Stage Liver Disease Score > 8)**
	• **Pulmonary Risk**
	  ○ Chronic obstructive pulmonary disease (COPD) (FEV1 <50%)
	  ○ Poorly controlled asthma (FEV1 <80% despite treatment)
	  ○ Moderate to severe obstructive sleep apnea (OSA)***
	• **Renal Risk**
	  ○ End stage renal disease (on dialysis)
	• **Other**
	  ○ Morbid obesity (body mass index ≥ 50 kg/m^2)
	  ○ Pregnancy

Site of Service for Elective Surgical Procedures	Medical Necessity
	○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion) ○ Anticipated need for transfusion(s) **Note:** * 3 or more drugs to control blood pressure ** https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease *** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30 ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)
Inpatient hospital/medical center	**This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above in this policy are not met.**

Note: 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.

Condition	Medical Necessity
Spinal stenosis	**Lumbar spinal fusion may be considered medically necessary for spinal stenosis when both of the following criteria are met:** • Either one of the following: ○ Associated spondylolisthesis demonstrated by at least a 4 millimeter (mm) shift in the sagittal plane on flexion/extension plain X-rays **OR** ○ Spinal instability will be created due to need for bilateral or wide decompression with facetectomy or resection of pars

Condition	Medical Necessity

	interarticularis; imaging studies must document encroachment on the nerve root channel (neural foramen)
	AND
	• Either one of the following:
	  ○ Neurogenic claudication or radicular pain that results in significant functional impairment in an individual who has failed at least 3 months of conservative care (see **Related Information**) and has documentation of central/lateral recess/or foraminal stenosis on magnetic resonance imaging (MRI) or other imaging
	OR
	  ○ Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome

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 (e.g., sagittal vertical axis > 5 centimeters [cm]) with any 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 (see **Related Information**)
	OR
	  ○ 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 (see **Related Information**)
	OR
	  ○ 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

Condition	Medical Necessity
	• Persistent back pain (radicular pain or neurogenic claudication) • Impairment or loss of function that is unresponsive to at least 3 months of conservative therapy (see **Related Information**)

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) 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 (see **Related Information**)
	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:** • Rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome **OR** • 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 (see Related Information) AND**

Condition	Medical Necessity
	• 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:** • With severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome **OR** • No less than 6 months after initial fusion **AND** • With persistent axial back pain, with or without neurogenic symptoms **AND** • Impairment or loss of function, in an individual who had experienced significant interval relief of prior symptoms
Revision surgery for implant/instrumentation failure	**Revision lumbar spine surgery may be medically necessary for implant/instrumentation failure demonstrated on imaging showing malposition or other evidence of failure (e.g., dislocation/subluxation, vertebral body fracture, hardware breakage, surrounding radiolucency)**
Instability	**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.**
Iatrogenic or degenerative flatback syndrome	**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.**
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 (see **Related Information**)

Condition	Medical Necessity
	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
Multiple-level lumbar spinal fusion	**Multiple-level lumbar spinal fusion is considered not medically necessary when the criteria listed above are not met for all levels.**
Conditions other than those listed in this policy	**Lumbar spinal fusion is considered not medically necessary for any indication not addressed in this policy.**

Condition	Investigational
As listed	**Lumbar spinal fusion is considered investigational if the sole 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 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)

Documentation Requirements

- 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 individual 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

Code	Description
CPT	
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression; thoracic or lumbar, each additional vertebral segment
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar

Code	Description
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace and segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22853	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., 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)
22859	Insertion of intervertebral biomechanical device(s) (e.g., 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)
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)

Code	Description
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)

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: 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 six weeks of physical therapy (including active exercise) or documentation of why the individual could not tolerate physical therapy
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present
- Documentation of individual 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 individual.

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 six 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 one 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 individual, 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 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 (e.g., 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 (e.g., 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. Decompression surgery is indicated for individuals with persistent symptoms

despite conservative treatment. Spinal fusion is frequently performed in combination with decompression surgery with the intent of decreasing instability of the spine. One potential marker of instability is spondylolisthesis, and many surgeons target individuals 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 1 vertebra over the subjacent vertebra, associated with degenerative changes, without an associated disruption or defect in the vertebral ring."[1] Most individuals with symptomatic degenerative lumbar spondylolisthesis and an absence of neurologic deficits do well with conservative care. Individuals 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 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.[2] 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.

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 (e.g., 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 greater 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 Short-Form Survey (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.[3] For these reasons, some investigators prefer to calculate a minimum detectable difference (MDD).[4]

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.

Individual preferences are important in decision-making about elective back surgery.[5] In particular, to avoid the morbidity and risk of complications of the surgery, some individuals may choose to prolong conservative treatments even if it means they have additional pain and functional limitation. Conversely, some individuals 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. Individual-reported Outcome Measures for Back and Leg Pain

Measure	Outcome Evaluated	Description	MDD and MCID
Oswestry Disability Score (ODI)	Functional disability and pain related to back conditions	Ten 5-point items; scores 0 (no disability) to 50 (totally disabled) or 0-100% of maximum score	MDD: 8-10 points MCID varies; often 15 points (30 percentage points)
Zurich Claudication Questionnaire (ZCQ)	Pain, numbness, weakness, walking tolerance, and (if applicable) satisfaction with treatment results	Eighteen items; three subscales. Total score is expressed in points or as a percentage of maximum score (higher scores are worse)	MDD: 5 points. MCID: Varies; sometimes defined as a detectable improvement on 2 of 3 subscales

RMDQ	Disability from back problems	Twenty-four items; scored 0-24 (higher scores are worse)	MCID: 30% reduction
Visual analog scale for leg pain	Degree of leg pain	Individuals indicate the degree of pain on a 0-100 scale	MDD: 5 points
Visual analog scale for back pain	Degree of back pain	Individuals indicate the degree of pain on a 0-100 scale	MDD: 2 points

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.

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.[75] 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 individuals by Brown et al (1986) with a 32% difference in fusion rates between smokers and nonsmokers (*P*=0.001).[76] 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).[77] A retrospective analysis by Andersen et al (2001) of 232 smokers and 194 nonsmokers found that individuals who smoked more than 10 cigarettes per day within 3 months of surgery had a 9% decrease in fusion rates [78] 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.[79]

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). The 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 individuals with low-grade (0%-25% slippage) spondylolisthesis and one in individuals 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 individuals with 1-level spinal stenosis and grade 1 spondylolisthesis. About 40% of the individuals also had dynamic instability. In individuals 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 included individuals who did not have spondylolisthesis. The addition of fusion to laminectomy resulted in similar individual-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 individuals 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 that the technology results in an improvement in the net health outcome.

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. The 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 individuals who are referred for surgery, outcomes in adulthood are similar to those observed in individuals 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 that the technology results in an improvement in the net health outcome.

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. The 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 that the technology results in an improvement in the net health outcome.

For individuals who have isthmic spondylolisthesis who undergo lumbar spinal fusion, the evidence includes an RCT. The 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 individuals who had symptomatic isthmic spondylolisthesis. Functional outcomes and pain relief were significantly better after fusion surgery. Results of this trial support the use of fusion for this condition but should be corroborated in a larger number of individuals. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spinal fracture and undergo lumbar spinal fusion, the evidence includes RCTs and meta-analyses of RCTs. The 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 individuals with spinal fracture without instability or neural compression might result in worse outcomes than nonsurgical management. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lumbar disc herniation with radiculopathy who are undergoing discectomy who receive lumbar spinal fusion, the evidence includes observational studies. The relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. In individuals 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 that the technology results in an improvement in the net health outcome.

For individuals who have chronic low back pain without radiculopathy who undergo lumbar spinal fusion, the evidence includes RCTs and meta-analyses of RCTs. The relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. In most individuals 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 that the technology results in an improvement in the net health outcome.

Additional Information

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 individuals with severe scoliosis, stenosis plus spondylolisthesis, or recurrent disc herniation.

Ongoing and Unpublished Clinical Trials

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

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03115983[a]	A Concurrently Controlled Study of the LimiFlex Paraspinous Tension Band in the Treatment of Lumbar Degenerative Spondylolisthesis With Spinal Stenosis	315	Jul 2025
NCT04318795	Minimally Invasive Spinal Decompression (MIS-D) Versus Minimally Invasive Spinal Decompression and Fusion (MIS-TLIF) for the Treatment of Lumbar Spinal Stenosis (LSS): A Prospective Randomized Controlled Trial	80	Dec 2025 (not yet recruiting)
NCT01455805[a]	Efficacy and Quality of Life Following Treatment of Lumbar Spinal Stenosis, Spondylolisthesis or Degenerative Disc Disease With the Minuteman Interspinous Interlaminar Fusion Implant Versus Surgical Decompression	50	Mar 2024
NCT04094220	A Randomized, Controlled Trial of Lateral Lumbar Interbody Fusion Plus Posterior Decompression or Not for Severe Lumbar Spinal Stenosis	60	Dec 2022
NCT03439228[a]	To Brace or Not to Brace for Single Level Lumbar Fusion: A Pilot Prospective Randomized Controlled Trial	50	Apr 2023 (recruiting)
NCT02385695	A Prospective Comparative Study to Evaluate Safety and Effectiveness of Dynamic Stabilization Versus Lumbar Fusion in Treatment of Multilevel Lumbar Disc Degeneration Disease	102	Aug 2021 (Unknown)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04893720	The SPINUS II Study: Spinal Fusion for Multilevel SPECT/CT Positive Lumbar Degeneration	30	Jun 2024
NCT02348645	Decompression Alone vs. Decompression and Instrumented Fusion for the Management of Lumbar Spinal Stenosis Associated With Stable Degenerative Spondylolisthesis: A Pragmatic Randomized Clinical Pilot Trial	70	Sep 2023
Unpublished			
NCT01549366[a]	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)	64	Jan 2016
NCT00758719[a]	A Prospective Multicenter Lumbar Spine Fusion Study to Evaluate the Effectiveness of the Biomet Lumbar Spinal Fusion System	53	Aug 2012

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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

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

American Academy of Orthopaedic Surgeons

Information updated in 2021 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.[58]

- 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.

American Association of Neurological Surgeons and Congress of Neurological Surgeons

The 2014 guidelines from the American Association of Neurological Surgeons and Congress of Neurological Surgeons addressed fusion procedures for the lumbar spine.[59] 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 3. Guidelines on Fusion Procedures for the Lumbar Spine

Recommendation	GOR	LOE
One or two level degenerative disease without stenosis or spondylolisthesis (part 7)[60]		
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	B	Multiple level II studies
Discography degenerative disease of the lumbar spine (part 6)[61]		
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.	C	Single level II study
Disc herniation and radiculopathy (part 8)[62]		
Lumbar spinal fusion is not recommended as routine treatment following primary disc excision in patients with a herniated lumbar disc causing radiculopathy.	C	IV
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.	C	IV
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.	C	III
Stenosis and spondylolisthesis (part 9)[63]		
Surgical decompression and fusion are recommended as an effective treatment alternative for symptomatic stenosis associated with degenerative spondylolisthesis in patients who desire surgical treatment.	B	II

Recommendation	GOR	LOE
There was insufficient evidence to recommend a standard fusion technique.		Insufficient
Stenosis without spondylolisthesis (part 10)[64]		
Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who undergo surgical intervention.	B	II/III
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.	C	IV

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

The two associations also provided recommendations on the following:[59]

- 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)

International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment

The International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment updated their guidelines on treatment of idiopathic scoliosis in 2018.[65] In these guidelines,

fusion is discussed in the context of other treatments, as an outcome measure indicating treatment failure.

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.[66] 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.[3] 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.

North American Spine Society

The North American Spine Society (NASS; 2021) published coverage policy recommendations for lumbar fusion and made the following recommendations:[67]

1. In disc herniation who fulfill criteria for discectomy. 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 (i.e., 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 3 millimeters (mm) between views

b. Spondylolisthesis (defined as at least 3 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%of the facet joint will be removed to adequately decompress the exiting nerve root.* or in which disc space distraction is intended (e.g., interbody fusion) to achieve indirect central or foraminal decompression in lieu of direct decompression via aggressive resection of the facet joints and lamina*

d. Adjacent level disease, (e.g., stenosis) that has developed above or below a previous fusion

e. Recurrent stenosis (e.g., that which developed at a level that has been previously operated)

f. Lumbar spinal fusion is not recommended as an adjunct to primary decompression of central and/or lateral recess stenosis, or spondylolisthesis and when greater than 50% bilateral facet resection is not required to achieve neurologic decompression.

*For cases in which there is severe foraminal stenosis, adequate decompression often can require aggressive resection of 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. A period of time following the index surgery during which the patient had symptomatic relief

c. Presence of symptoms for at least six months

d. Failure of nonoperative treatment

e. Computed tomography (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 (e.g., 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.[68] 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.[2,69] 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.[70,71] 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)."

In 2020, the NASS published guidelines on the diagnosis and treatment of low back pain. The guidelines included the following recommendations regarding the use of spinal fusion surgery:[72]

- "There is insufficient evidence to make a recommendation for or against a particular fusion technique for the treatment of low back pain. (Grade of Recommendation: I)
- There is insufficient evidence to make a recommendation regarding whether radiographic evidence of fusion correlates with better clinical outcomes in patients with low back pain. (Grade of Recommendation: I)"

US 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).[73] The Task Force found no studies of surgical treatment in screening-relevant populations that met inclusion criteria.

Other indications: Not applicable.

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.[74]

Regulatory Status

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

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Appendix

Procedures for Lumbar Interbody Fusion

Procedures used for lumbar interbody fusion differ primarily in the direction of approach to the spine, i.e., 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

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

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

Date	Comments
03/08/11	Add to Surgery Section - New Policy held for provider notification. The effective and publication date will be 9/1/2011.
05/18/11	Policy Published - The policy was published on the internal and external sites with an effective date of September 1, 2011.
12/2/11	Related Policies updated; 7.01.115 removed.
01/11/12	CPT codes 22633 and 22634 added.
09/11/12	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.
10/09/12	Replace policy - Added definitions for truncal imbalance. Added clarity to spondylolisthesis statement – It is measured in the sagittal plane on functional flexion

Date	Comments
	and extension views on upright x-ray. MRI and CT removed from bullet. Added references 17 and 18.
12/19/12	Update Related Policies – Add 7.01.85.
01/10/13	Coding update. CPT codes 22586 and 0309T, effective 1/1/13, added to policy.
04/08/13	Clarification only. "Acute" added to describe spinal fracture within the Policy section. Literature reviewed.
12/06/13	Update Related Policies. Add 7.01.138.
01/21/14	Update Related Policies. Add 7.01.551.
07/14/14	Annual review. Policy updated with literature review through October 23, 2013; considered medically necessary under specified conditions. Policy rewritten and reorganized.
01/13/15	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 & ICD-10 diagnosis; CPT codes 20930-20938, 22840-22847 & 22851.
02/03/15	Update Related Policies. Add 7.01.130.
04/14/15	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.
10/13/15	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.
12/08/15	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.
10/11/16	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

Date	Comments
	in Rationale/Reference section. CPT code 22586 removed from policy; it applies to a separate medical policy.
01/01/17	Coding update, added new CPT codes 22853, 22854, and 22859 with effective date 01/01/17.
01/13/17	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.
02/10/17	Policy moved to new format. No changes to policy statement.
10/01/17	Annual Review, approved September 12, 2017. Policy updated with literature review through February 23, 2017. References added: 22-26, reference 42 updated, some references removed. Removed CPT code 62290. Clarifications made to policy statements. BCBSA references added.
01/01/18	Removed CPT code 22851 as this code was terminated on 1/1/17 and replaced with 22853, 22854, and 22859.
09/01/18	Annual Review, approved August 23, 2018. Policy updated with literature review through May 2018; reference 40 added; reference 2 updated. Policy statements unchanged.
01/01/19	Coding update, removed CPT code 0309T as it was terminated 1/1/18.
09/01/19	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.
03/01/20	Interim Review, approved February 4, 2020. Removed multiple level fusion statement.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
12/01/20	Annual Review, approved November 3, 2020. Policy updated with literature review through June, 2020; references added. Policy statements unchanged.
10/01/21	Interim Review, approved September 14, 2021. Review for site of service added to single-level lumbar fusion procedure after 90-day provider notification. Site of service review added to CPT codes 22553, 22558, 22612, 22630 and 22633. This addition is effective for dates of service January 7, 2022 and after. Added HCPCS code C1831.
12/01/21	Annual Review, approved November 9, 2021. Policy title changed to Lumbar Spinal Fusion in Adults. Policy updated with literature review through August 5, 2021; references added. Policy criteria for progressive juvenile or adolescent idiopathic scoliosis removed. Otherwise, policy statements unchanged.

Date	Comments
01/01/22	Coding update, updated coding description for CPT codes 22612, 22614, 22630, 22632, 22633, 22634. Added new CPT codes 63052 & 63053.
06/01/22	Interim Review, approved May 10, 2022. Added medically necessary statement for revision surgery for implant/instrumentation failure. Change becomes effective for dates of service on or after September 2, 2022.
08/18/22	Minor edit to policy criteria. Corrected “age” to “aged”.
12/01/22	Annual Review, approved November 7, 2022. Policy updated with literature review through July 15, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
12/01/23	Annual Review, approved November 6, 2023. Policy updated with literature review through July 21, 2023; no references added. Added clarifying policy statement that multiple-level lumbar spinal fusion is considered not medically necessary when the criteria listed are not met for all levels.
03/01/24	Interim Review, approved February 12, 2024. Reorganized criteria under recurrent (same level) disc herniation to call out that rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome is a stand-alone criterion for meeting medical necessity for this condition.
08/01/24	Coding update. Removed HCPCS code C1831, since we do not have the policy criteria to manage this code.

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