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Lumbar Spinal Fusion

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
SUR705.038: Bone Morphogenetic Protein
THE803.010: Physical Therapy (PT) and Occupational Therapy (OT) Services

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Coverage

NOTE 1: Conservative non-surgical therapy for the duration specified should include the following:

a. Use of analgesics for several weeks at a dose sufficient to induce a therapeutic response, AND
b. Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants or documentation of why the individual could not tolerate anti-inflammatory medications with or without adjunctive medications, AND
c. Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the individual could not tolerate physical therapy, AND
d. Evaluation and appropriate management of associated cognitive, behavioral or addiction issues; AND
e. Documentation of the individual's compliance with the preceding criteria.

NOTE 2: "Severely restricted functional ability" should generally include loss of function and/or documentation of inability or significantly decreased ability, to perform normal daily activities of work, school, or at-home duties.

NOTE 3: Persistent debilitating pain is defined as:

a. Significant level of pain on a daily basis defined on a Visual Analog Scale as greater than 4; AND
b. Pain on a daily basis that has a documented impact on activities of daily living despite optimal conservative non-surgical therapy as outlined above and appropriate for the individual.

NOTE 4: On individual consideration, conservative therapy and/or a waiting period may be waived in the presence of "red flag" symptoms or signs, e.g., severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome.

Lumbar spinal fusion **may be considered medically necessary** for any one of the following conditions:

1. Spinal stenosis with:
   a. Any one of the following:
      - Associated spondylolisthesis demonstrated on plain x-rays; OR
      - Spinal instability demonstrated on imaging studies; OR
      - Spinal instability is anticipated due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis; **AND**
   b. Either:
      - Neurogenic claudication or radicular pain that results in significant functional impairment in an individual who has failed at least 6 weeks of conservative care and has documentation of central/lateral recess/or foraminal stenosis on magnetic resonance imaging or other imaging, OR
      - Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome.
2. Juvenile, neuromuscular, congenital scoliosis when either of the following is present:
   a. Documented significant progression of the deformity as measured on consecutive radiographs; OR
   b. Neurologic compromise.
3. Severe, progressive idiopathic scoliosis with either of the following:
   a. Cobb angle greater than 40°; OR
   b. Spinal cord compression with neurogenic claudication or radicular pain that results in significant functional impairment in an individual who has failed at least 3 months of conservative care.
4. Severe degenerative scoliosis (i.e., lumbar or thoracolumbar) with a minimum Cobb angle of 30°, or significant sagittal imbalance (e.g., sagittal vertical axis >5 cm), and with any one of the following:

a. Documented progression of deformity with persistent axial (nonradiating) pain and impairment or loss of function unresponsive to at least 3 months of conservative therapy; OR
b. Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to at least 3 months of conservative nonsurgical care; OR
c. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome.

5. Isthmic spondylolisthesis, when **all** of the following are present:
   a. Congenital (Wiltse type I) or acquired pars defect (Wiltse type II), documented on x-ray, AND
   b. Persistent back pain (with or without neurogenic symptoms), with impairment or loss of function, AND
   c. Either 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.
6. Recurrent, same-level disc herniation, at least 3 months after previous disc surgery, when **all** of the following are present:
   a. 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
   b. Impairment or loss of function, AND
   c. 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
   d. Neural structure compression and instability documented by imaging at a level and side corresponding to the clinical symptoms.

NOTE 5: Fusion for same-level disc herniation without instability may be considered following two (2) prior discectomies at that level.

7. Pseudarthrosis, documented radiologically, when **all** of the following are present:
   a. No less than 6 months after initial fusion, AND
   b. With persistent axial back pain, with or without neurogenic symptoms, or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome, AND
   c. Impairment or loss of function, in an individual who had experienced significant interval relief of prior symptoms.
8. Instability due to fracture, dislocation, infection, abscess, or tumor when extensive surgery is required that could create an unstable spine.
9. Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy or interbody spacers when **all** of the following are present:
   a. Presence of intractable back pain, neurogenic claudication or neurological deficit, AND

b. Failure of 6 months of conservative management

10. Adjacent-level disease when **all** of the following are present:
    a. Persistent back pain (with or without neurogenic symptoms) with impairment or loss of function that is unresponsive to at least 3 months of conservative therapy, AND
    b. Eccentric disc space collapse, spondylolisthesis, acute single-level scoliosis, or lateral listhesis on imaging, AND
    c. Symptoms and functional measures correlate with imaging findings, AND
11. Lumbar synovial cyst when **all** of the following conditions have been met:
    a. Radicular pain (with or without demonstrable neurologic deficits) or neurogenic claudication which has not responded to at least 6 weeks of conservative management, AND
    b. Documentation of a synovial cyst on CT or MRI performed within the past 6 months which correlates with symptoms and exam findings.

Lumbar spinal fusion **is considered not medically necessary** if the sole indication is any one of the following conditions:

1. Disc herniation,
2. Chronic nonspecific low back pain without radiculopathy,
3. Degenerative disc disease,
4. Facet syndrome.

Lumbar spinal fusion **is considered not medically necessary** for any indication not addressed above.

NOTE 6: For additional information on physical therapy please refer to medical policy THE803.010 Physical Therapy (PT) and Occupational Therapy (OT) Services and for specified indications for Bone Morphogenetic Protein refer to medical policy SUR705.038.

Policy Guidelines

CPT codes 22853, 22854, and 22859 are not specific to the Coflex-F device or any other devices mentioned on medical policy SUR712.040 Interspinous Fixation (Fusion) Devices and could be used for cages/mesh.

For procedure codes 27279 and 27280 please refer to medical policy SUR705.033 Sacroiliac Joint Fusion or Stabilization.

Description

Lumbar spinal fusion (arthrodesis) is a surgical technique that involves fusing 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 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 decompression surgery of the spinal canal for spinal stenosis.

Lumbar Spinal Fusion

Fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction. 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 (2 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 used to stabilize an unstable spine or to correct deformity. Decompression surgery is indicated for patients 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 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 1 vertebra over the subjacent vertebra, associated with degenerative changes, without an associated disruption or defect in the vertebral ring." (1) 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. 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 Owestry Disability Index (ODI) score 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.

Patient 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 patients may choose to prolong conservative treatments even if it means they have additional pain and functional limitation. Conversely, some patients will accept long-term outcomes of surgery similar to those of conservative therapy to get faster relief of symptoms and improvement in function.

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

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

Measure	Outcome Evaluated	Description	MDD and MCID
Oswestry Disability Score (ODI) Score	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 to 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 to 24 (higher scores are worse).	MCID: 30% reduction.
Visual analog scale for leg pain	Degree of leg pain.	Patients indicate the degree of pain on a 0 to 100 scale.	MDD: 5 points.
Visual analog scale for back pain	Degree of back pain.	Patients indicate the degree of pain on a 0 to 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. (Refer to Clinical Context sections for those indications).

Smoking within the previous 3 months has been shown to reduce fusion rates. (Jackson & Devine, 2016)

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 FDA (e.g., INFUSE [recombinant human bone morphogenetic protein-2], OP-1 [recombinant human bone morphogenetic protein-7]) for specified indications.

Rationale

This medical policy was created in May 2013 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 15, 2022.

This medical policy reviews the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Spinal Stenosis

Clinical Context and Therapy Purpose

The purpose of lumbar spinal fusion in patients who have spinal stenosis and are undergoing decompression surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies such as decompression surgery alone.

The question addressed in this medical policy is: Does use of lumbar spinal fusion improve the net health outcome patients who have spinal stenosis and are undergoing decompression surgery compared to decompression alone?

The following PICO was used to select literature to inform this policy.

Populations

The relevant populations of interest are individuals who have spinal stenosis undergoing decompression surgery.

Interventions

The therapy being considered is lumbar spinal fusion.

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. Spinal fusion is not a primary treatment for spinal stenosis but can be performed in addition to decompression surgery with the intent of decreasing spinal instability. The primary surgical intervention for spinal stenosis is decompression surgery (i.e., laminectomy or related procedures). Therefore, the most relevant comparison for patients with spinal stenosis is decompression surgery alone compared with decompression surgery plus fusion.

Spinal surgeries typically require an inpatient hospital stay, ranging from a few days to a week.

Comparators
The following therapies and practices are currently being used: Comparators of interest include decompression surgery alone.

Outcomes
The general outcomes of interest are symptoms (back and leg pain measures), functional outcomes, quality of life, resource utilization, and treatment-related morbidity, quality of life (e.g., improvements in function, reductions in pain) and post-procedural-related adverse events. (perioperative complications and secondary operations).

Both short-term and long-term outcomes are important in evaluating spinal fusion. 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 Owestry Disability Index (ODI) score, SF-36, Zurich Claudication Questionnaire, or visual analog scale (VAS) measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence
Laminectomy has often been accompanied by fusion based on the argument that this will save patients a second surgery or neurological catastrophe when instability eventually presents. Studies that appear to show a preponderance of future instability among patients treated with laminectomy alone have buttressed this argument.

Three recent randomized trials have attempted to resolve this question. Characteristics of these trials are summarized in Table 2. Below, discussed separately is the evidence from these trials for individuals with lumbar spinal stenosis and no spondylolisthesis undergoing decompression

and for individuals with lumbar spinal stenosis and grade 1 spondylolisthesis undergoing decompression.

Table 2. Recent Trials of Decompression Plus Fusion vs. Decompression Alone for Stenotic Patients With No or Low-grade Spondylolisthesis

Study	Countries	Dates	Participants	Interventions	
				Decompression plus Fusion	Decompression alone
Försth et al. (2016) (6) (SSSS)	Sweden	2006-2012	Patients aged 50 to 80 years of age with spinal stenosis and up to grade 1 spondylolisthesis, 1 or 2 levels (N=247).	n=123, 111 analyzed.	n=124, 117 analyze.
Ghogawala et al. (2016) (7)	US	2002-2009	Patients with spinal stenosis and grade 1 spondylolisthesis, 1 level, and no instability (N=66).	n=31, 19 analyzed.	n=35, 26 analyzed.
Inose et al. (2018) (8)	Japan	2003-2012	Patients with spinal stenosis and grade 1 spondylolisthesis, 1 level, (N=85 [54 in relevant groups]).	N=31, 28 analyzed.	N=29, 23 analyzed.

SSSS: Swedish Spinal Stenosis Study.

Patients with No or Low-Grade Spondylolisthesis

Only one of the trials shown in Table 2, the Swedish Spinal Stenosis Study (SSSS), included patients who did not have spondylolisthesis. (9) The primary outcome measure was ODI score at two years analyzed on a per protocol basis (see Table 3). The addition of fusion to laminectomy resulted in similar patient-reported outcomes, longer operating time, more bleeding, higher surgical costs, and longer hospitalization but did not result in better ODI scores.

Table 3. Summary of Key RCT Outcomes* for Patients With No Spondylolisthesis

Study	Change in EQ-5D	Change in ODI Score	ZCQ score (post-treatment)	Reoperation
2-year follow-up				
Försth et al. (2016) (6) (SSSS)				
Fusion (n=46)	+0.22	-14	2.6	11(24%)
Decompression alone	+0.22	-14	2.5	10(19%)
% Δ (95% CI)	.85	NR		P<0.01

CI: confidence interval; EQ-5D: European Quality of life scale; NR: not reported; ODI: Oswestry Disability Index; RCT: randomized controlled trial; SSSS: Swedish Spinal Stenosis Study; ZCQ: Zurich Claudication Questionnaire.
*These are per protocol outcomes that do not include patients who did not receive the assigned treatment.

Several features of SSSS suggest that its results for patients who do not have spondylolisthesis are valid. Although the primary outcome analysis was underpowered for the subgroup analysis, the fact that patient outcomes and reoperation rates were similar to those of patients with spondylolisthesis increases the likelihood that decompression alone was safe and effective. Patients with dynamic instability were included which, if anything, would bias the study in favor of fusion.

Observational studies tend to support the finding that decompression alone can result in improvements in back pain as well as leg pain (10) and that fusion does not result in better outcomes in practice. (11, 12) A large, prospective observational study based on national spine surgery registries in Sweden, Norway, and Denmark found no difference in mean ODI improvement for laminectomy alone vs laminectomy plus fusion for spinal stenosis without spondylolisthesis. (13) After adjustment for age, gender, body mass index, smoking, any comorbidity, and baseline ODI scores, the ODI improvement was 17 (95% confidence interval [CI] 17 to 18) in the decompression alone group and 19 (95% CI, 18 to 20) in the fusion group. This study has several important limitations, including 1) the registries do not provide information about why some patients were selected to have fusion—it is also possible that patients who underwent fusion had clinical features that surgeons felt made laminectomy alone less likely to be effective or safe. 2) One-year follow-up is not adequate to assess the need for reoperations, which is a key outcome. Nevertheless, the results of this and other observational studies add weight to the findings of the SSSS in patients.

Patients with Grade 1 Spondylolisthesis and Without Instability

Spinal fusion is combined with laminectomy when instability of the spine is present preoperatively, or if the procedure is sufficiently extensive to expect postoperative spinal instability. With spinal stenosis and spondylolisthesis greater than grade 1, pairing decompression with fusion should be expected. However, routine use of fusion in patients who have grade 1 spondylolisthesis remains controversial. The preference for adding fusion to decompression was based on small, frequently cited observational studies and a quasi-randomized study. (14-18) The validity of early studies advocating routine additional fusion is

low because of small sample sizes, weak designs, and emphasis on radiological results rather than on clinical outcomes.

Arguments for a conservative approach—either nonsurgical treatment or decompression alone—are based on concerns that fusion, particularly instrumented fusion, had high rates of complications and secondary surgeries, and that the natural history of spinal stenosis was more favorable than was generally appreciated. (19-21) On the other hand, most studies of patients treated with decompression alone were also small and had important limitations.

All three trials described in Table 2 above have examined this issue. Two of these—randomized trials published in 2016—and subsequent observational studies and systematic reviews provide the best evidence regarding the value of lumbar spinal fusion in stenotic patients with low-grade spondylolisthesis or instability. Results from these trials are summarized in Table 4.

Table 4. Summary of Key RCT Outcomes* For Patients with Spinal Stenosis and Spondylolisthesis

Study	Change in EQ-5D	Change in ODI Score	Reoperation	Mean Blood Loss
2-year follow-up				
Försth et al. (2016) (6) (no spondylolisthesis) (SSSS)				
Fusion (n=46)	+0.24	-16		686±434
Decompression alone	+0.33	-20		311±314
% Δ (95% CI) or p value	.20	0.11		<0.01
Ghogawala et al. (2016) (7) (SLIP)				
Fusion	15.2	-26.3		513.7±334.2
Laminectomy	9.5	-17.9		83.4±63.5
% Δ (95% CI) or p value	6.4 (1.1 to 11.7)	8.5 (-17.5 to 0.5)		0.0001
4-year follow-up				
Ghogawala et al. (2016) (7)				
Fusion	14.1	-23.7	14%	513.7±334.2
Laminectomy	7.4	-14.7	34%	83.4±63.5
% Δ (95% CI) or p value	6.7 (1.2 to 12.3)	9 (-18 to 0.1)	NR	0.0001
5-year follow-up				
Inose et al. (2018) (8)				
Fusion				334.8 ±206.3
Laminectomy				80.3 +62.5
% Δ (95% CI) or p value				<0.0001
6-year follow-up				

Försth et al. (2016) (6)				
Fusion			22%	
Laminectomy			21%	

CI: confidence interval; EQ-5D: European Quality of Life Scale; NR: not reported; ODI: Oswestry Disability Index; RCT: randomized controlled trial; SLIP: Spinal Laminectomy vs Instrumental Pedicle Screw trial; SSSS: Swedish Spinal Stenosis Study; ZCQ: Zurich Claudication Questionnaire.
*These are per protocol outcomes that do not include patients who did not receive the assigned treatment.

In SSSS, about half of the patients had spondylolisthesis. (6) The protocol specified that a separate analysis of these patients would be done. The SSSS found no benefit of fusion plus decompression compared with decompression alone in patients who had spinal stenosis with degenerative spondylolisthesis, and reoperation rates were comparable in the two groups.

The Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial randomized patients who had spinal stenosis, grade 1 spondylolisthesis (3-14mm), and no evidence of spinal instability to decompression alone or to decompression plus posterolateral fusion with instrumentation. (7) Decompression was performed by laminectomy with partial removal of the medial facet joint. Initially, 2 primary outcome measures were specified in the protocol—1) change in SF-36 Physical Component Summary score at 2 years and 2) the ODI score. Later, ODI was changed to a secondary outcome measure. Mean SF-36 Physical Component Summary scores were higher in the fusion group (15.2) than in the decompression-only group (9.5; p=0.046). The minimally important difference for an SF-36 score was prespecified at 5 points and was achieved in 86% of the fusion group and 69% of the decompression group. At 1 year, SF-36 scores had increased 11.3 in the decompression group and 15.3 in the fusion group; between 1 and 2 years, the decompression group's scores worsened while the fusion group's scores remained stable. At 2 years, ODI scores had improved by 26.3 points in the fusion group and by 17.9 points in the decompression alone group (p=0.06). The prespecified minimally important difference for ODI score was ten points, but the percentages of patients who achieved the minimally important difference were not reported. The fusion group also had more blood loss and longer hospital stays.

Comparing SSSS and SLIP, ODI improvement in the two trials was similar for the decompression groups in the two trials but was better for the SLIP fusion patients than for the SSSS fusion patients. The most striking difference is that the rate of reoperations after laminectomy alone was much higher in SLIP than in other trials. In SLIP, the rate of reoperation in the fusion group was 14% compared with 34% in the decompression alone group (p=0.05), although only 68% of patients were available for follow-up at 4 years. All reoperations in the fusion group were for adjacent-level degeneration, while reoperations in the decompression alone group were performed for instability at the index level.

The third trial, a small trial conducted in Japan, Inose et al. (2018), also found no difference in Visual Analogue Scale (VAS) lower back pain or leg pain scores between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1

spondylolisthesis; about 40% of the patients also had dynamic instability. (8) Postoperative slip progression was 26.1% in the decompression group and 26.3% in the fusion group and was not associated with baseline instability. Certainty in the findings of this trial is limited because of its size. In a post-hoc analysis of 5-year outcomes published by Inose et al. (2021), the intervertebral angle at L4/5 and the presence of translation were associated with poor recovery. (22) Inose et al. (2022) published a follow-up study and reported that fusion surgery provided clinically meaningful improvements in patient-reported vitality, social functioning, role limitations due to personal or emotional problems, and overall mental health compared with decompression alone, although low back pain at mean follow-up was not significantly different. (23)

Table 5. Study Design and Conduct Limitations in Trials of Fusion vs Laminectomy Alone

Study	Allocation [a]	Blinding [b]	Selective Reporting [c]	Data Completeness [d]	Power [e]	Stat-istical [f]
Försth et al. (2016) (6)		1, 2, 3, 4		3. Crossovers excluded from analysis.	3. Small study, spondylo-listhesis and nonspondylo-listhesis subgroups not adequately powered adequately for ODI comparison.	
Ghogawala et al. (2016) (7)		1, 2, 3, 4		1. High loss to follow-up	Small study.	
Inose et al. (2018) (8)		1, 2			Small study.	

ODI: Oswestry Disability Index.

The study limitations noted in this table are those most pertinent in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician; 4. No independent adjudication or preset criteria for subsequent intervention.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Important limitations of the SSSS and SLIP trials are summarized in Table 5. The most concerning issue is that SLIP had an unusually high reoperation rate for laminectomy alone that could reflect surgeon bias. The unusually high rate of reoperation may have negatively influenced patient-reported outcomes in the decompression-only group.

Surgeons diagnosed instability on the basis of radiological findings but did not use explicit criteria to select patients for reoperation. SLIP patients with certain radiographic findings (motion at spondylolisthesis > 1.25 mm, disc height > 6.5 mm, and facet angle > 50 degrees) were most likely to undergo reoperation for instability, (24) but it is not clear that patient-reported outcomes prior to reoperation or the results of reoperation justified the use of fusion. Explanations for the high reoperation rate include the lack of a prespecified protocol for reoperation, "national practice patterns," and the choice of decompression procedure. Others argue that methods to diagnose instability are inaccurate and that data linking radiological instability to pain and impaired function in the individual patient is lacking. This can lead to high, surgeon-dependent variation in diagnosis and in the therapeutic impact of the diagnosis.

Recent prospective cohort studies and large database analyses strengthen the concern that the reoperation rate in the SLIP decompression-only group does not represent results of decompression alone in actual practice. Most (but not all) studies (25, 26) found no difference in back pain outcomes for decompression alone and decompression plus fusion. (27-29) Importantly, reoperation rates were similar to those observed in the SSSS; the high rate of reoperation for instability observed in the SLIP trial has not been confirmed in any other setting, including studies conducted in the U.S. For example, a large, well-conducted retrospective analysis of U.S. data found no difference in reoperation rates between patients treated with or without fusion. (29) A recent analysis of the American College of Surgeons National Surgical Quality Improvement Program database compared 30-day outcomes for decompression alone (N=907) vs decompression with fusion (N=8699) in 9606 patients with lumbar spondylolisthesis. (30) The fusion group tended to be younger ($P < 0.001$) and were more likely to be smokers ($P = 0.01$). Unplanned return to surgery was 3.02% in the fusion group compared with 1.02% ($P = 0.011$). Major and minor adverse events occurred in 4.5% and 12.8% of the fusion group compared to 3.1% ($P = 0.0498$) and 4.9% ($P < 0.001$) in the decompression alone group, respectively. There were no differences in 30-day mortality, prolonged admission, or 30-day readmission.

The SSSS and SLIP trials have led to the proliferation of systematic reviews and meta-analyses of the value of fusion and instrumentation in this population. For the most part, these systematic reviews combine data from disparate, small, and sometimes very old clinical trials, and their findings are driven primarily by how they incorporate the SLIP and SSSS trials. (31-36)

Study Relevance Limitations
None of the trials specifically looked at whether patients with spinal stenosis who have dynamic instability in the setting of grade 0 to 1 spondylolisthesis benefit from routine use of fusion with decompression.

Section Summary: Spinal Stenosis
In patients with spinal stenosis and no spondylolisthesis who receive decompression, the evidence is sufficient to conclude that routine fusion is not better than decompression alone in patients with spinal stenosis and no spondylolisthesis. Evidence comes from a small randomized trial and recent observational studies. This finding does not apply to patients who were excluded from SSSS because of technical or surgical factors that make it likely that laminectomy alone will cause instability. These factors are described in the North American Spine Society recommendations for lumbar fusion.

In patients with spinal stenosis and grade 1 spondylolisthesis and without instability, the current evidence does not support routine addition of fusion to decompression surgery for patients with spinal stenosis and grade 1 spondylolisthesis and no instability. This conclusion does not apply to patients who have technical or surgical factors that make it likely that laminectomy alone will cause instability. These factors are described in the North American Spine Society recommendations for lumbar fusion.

Juvenile or Adolescent Idiopathic Scoliosis
Clinical Context and Therapy Purpose
The purpose of lumbar spinal fusion is to provide a treatment option that is an alternative to or an improvement on existing therapies such as conservative, nonsurgical therapy, or no treatment, in patients with juvenile or adolescent idiopathic scoliosis.

The question addressed in this medical policy: Does lumbar spinal fusion improve the net health outcome in individuals with juvenile or adolescent idiopathic scoliosis?

The following PICO was used to select literature to inform this policy.

Populations
The population of interest is individuals with juvenile or adolescent idiopathic scoliosis.

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of the curve), and the remaining growth expected for the patient at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered at high risk of curve progression. Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications. Large curves may be associated with adverse long-term health outcomes in later adulthood, including an increased

risk for shortness of breath with curves greater than 50º, diminished lung volumes with curves greater than 70º, and more impaired pulmonary function with curves greater than 100º. Surgery is typically recommended to correct a curve or stop it from progressing when the patient is still growing and has a curve greater than 50 degrees, although this is controversial. (37)

Interventions
The therapy being considered is lumbar spinal fusion.

Comparators
Comparators of interest include conservative, nonsurgical therapy, and observation. Conservative treatment includes back braces, physical exercise, and stretching regimens.

Outcomes
The general outcomes of interest are symptoms (including appearance, back pain, and curve progression), functional outcomes, disability, quality of life, resource utilization, and treatment-related morbidity.

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence
Observational studies have reported outcomes in adulthood for individuals who received spinal fusion or other interventions for scoliosis as adolescents. (38, 39)

Danielsson and Nachemson (2001) reported on long-term follow-up on 283 consecutive patients who had been treated with a brace or with surgical treatment for adolescent idiopathic scoliosis in Sweden. (39) Lumbar curves of less than 60° were treated with a brace worn for an average of 2.7 years. Curves of 60° or more were treated with fusion using bone grafts from the iliac crest. On average, 9.5 vertebrae were fused. Clinical and radiologic follow-up data were obtained in 89% of patients at a mean of 22 years (range, 20 to 28 years). Curve progression was 3.5° for surgically treated curves and 7.9° for brace-treated curves. Five (4%) patients

treated surgically and 39 (36%) treated with bracing had an increase in the Cobb angle of more than 10°.

More recently, Diarbakerli et al. (2018) reported health-related quality of life outcomes in adults (mean age 38.8 years, SD 12.7 years) with idiopathic scoliosis diagnosed before maturity. (38) Among the sample of 1187 adults, 347 were untreated, 459 had been treated with bracing, and 341 had received surgery. Patients who had surgery had lower quality of life scores than those who were untreated and those who were treated with bracing (mean SRS-22, 4.15 ± 0.59 points for the untreated group, 4.10 ± 0.57 points for the previously braced group, and 4.01 ± 0.64 points for the surgically treated group; p = 0.007 adjusted for age and sex). Surgically treated patients had statistically significantly worse scores than the brace-treated and untreated groups on the domains mobility and usual activities, but 87% to 90% of adults reported "no problem" in these areas. There were no significant differences between groups on the domains self-care, pain, or anxiety.

It is important to note that 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. (40, 16) They do suggest that, among patients who are referred for surgery, outcomes in adulthood are similar to those observed in patients who received bracing or no treatment. Limitations of this evidence include recall bias, and the use of procedures that are not currently used.

Dunn et al. (2017) conducted a systematic review of screening for adolescent idiopathic scoliosis for the US Preventive Services Task Force. (41), The review included an evaluation of treatments, but was limited to studies in children and adolescents with a Cobb angle of 10 to 50 degrees at detection, since children with curves greater than 50 degrees are likely to be detected clinically, not through screening. No studies of surgery met inclusion criteria.

Section Summary: Juvenile or Adolescent Idiopathic Scoliosis

Observational studies have reported outcomes in adults who received lumbar spinal fusion as adolescents. These observational studies do not provide evidence of the comparative effectiveness of spinal fusion to other interventions. Furthermore, because a goal of conservative treatment is to avoid fusion surgery, such comparisons would not be appropriate. They do suggest that, among patients who are referred for surgery, outcomes in adulthood are similar to those observed in patients who received bracing or no treatment. Limitations of this evidence include recall bias and the use of procedures that are not currently used.

Adult Degenerative Scoliosis

Clinical Context and Therapy Purpose

The purpose of lumbar spinal fusion is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative, nonsurgical therapy, in patients with adult degenerative scoliosis.

The question addressed in this medical policy: Does lumbar spinal fusion improve the net health outcome in individuals with adult degenerative scoliosis?

The following PICO was used to select literature to inform this policy.

Populations
The population of interest is individuals with adult degenerative scoliosis.

Interventions
The therapy being considered is lumbar spinal fusion.

Comparators
Comparators of interest include conservative, nonsurgical therapy. Treatment includes back braces, physical exercise, and stretching regimens.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Long-term outcomes (2 years) are important.

Table 6. Outcomes of Interest for Individuals With Adult Degenerative Scoliosis

Outcome	Details
Symptoms	Minimum Cobb angle of 30° [Timing: 2-year follow-up]
Functional outcomes	Owestry Disability Index (ODI) score [Timing: 2-year follow-up]
Quality of life	Scoliosis Research Society Questionnaire Numeric rating scale for back pain [Timing: 2-year follow-up]

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence
Bridwell et al. (2009) reported on a prospective multicenter comparative cohort study that compared operative with nonoperative treatment of adult symptomatic lumbar scoliosis (defined as a minimum Cobb angle of 30°) in 160 consecutively enrolled patients. (16) Operative vs nonoperative treatment was decided by the patient and medical team. Nonoperative treatment included observation (21%), medications (26%), medications plus physical therapy and/or injections (40%), and other treatment without medications (13%). For

analysis, patients were matched using propensity scores that included baseline Cobb angle, ODI score, Scoliosis Research Society (SRS) score, and a numeric rating scale for back and leg pain. The percentage of patients who returned for follow-up at 2 years was higher for operative (95%) than for nonoperative (45%) patients, although baseline measures for patients lost to follow-up were similar to those who were followed for 2 years. At the 2-year follow-up, nonoperative treatment did not improve quality of life or any other outcome measures, while the operative treatment showed significant improvement in all outcomes.

The potential complications of spinal fusion for adult degenerative scoliosis include the risks of any type of spinal surgery, including infection, nerve damage, blood loss, and bowel or bladder problems. Sciubba et al. (2015) conducted a review of complication rates after surgery for adult spinal deformity. (42) Across 93 articles, the overall mean complication rate was 55%. Major perioperative complications occurred at a mean rate of 18.5%, minor perioperative complications occurred at a mean rate of 15.7%, and long-term complications at a mean rate of 20.5%.

Section Summary: Adult Degenerative Scoliosis

Evidence includes a prospective comparative cohort study, which evaluated outcomes in adults with symptomatic scoliosis who received spinal fusion surgery or nonoperative treatment. Using propensity matching, the study found that nonoperative treatment did not improve outcomes whereas surgical treatment improved all outcome measures. The surgical outcomes in this study must be considered in light of the potential for bias due to the self-selection of treatment and high loss to follow-up in the conservatively managed group.

Isthmic Spondylolisthesis

Clinical Context and Therapy Purpose

The purpose of lumbar spinal fusion is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative, nonsurgical therapy, in patients with isthmic spondylolisthesis.

The question addressed in this medical policy is: Does lumbar spinal fusion improve the net health outcome in individuals with isthmic spondylolisthesis?

The following PICO was used to select literature to inform this policy.

Populations

The population of interest is individuals with isthmic spondylolisthesis.

Interventions

The therapy being considered is lumbar spinal fusion.

Comparators

Comparators of interest include conservative, nonsurgical therapy. Treatment includes back braces, analgesics and nonsteroidal anti-inflammatory drugs, epidural steroid injections, physical therapists, and stretching regimens.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Studies assessed outcomes between 1 and 2 years.

Table 7. Outcomes of Interest for Individuals With Isthmic Spondylolisthesis

Outcomes	Details
Symptoms	Low back pain Sciatica Severely restricted functional ability [Timing: ≥1 year]
Functional outcomes	Disability Rating Index score [Timing: 1 and 2 years post-treatment]
Quality of life	Back pain [Timing: 1 and 2 years post-treatment]

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Moller and Hedlund (2000) reported on a study of 111 adults with isthmic spondylolisthesis who were randomized to posterolateral fusion (with or without instrumentation, n=77) or to an exercise program (n=34). (43) Inclusion criteria were lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and severely restricted functional ability. Mean age of patients was 39 years, with a mean age at onset of symptoms of 26 years. At 1- and 2-year follow-ups, functional outcomes (assessed by the Disability Rating Index) had improved in the surgery group but not in the exercise group. Pain scores improved in both groups but were significantly lower in the surgically treated group.

Section Summary: Isthmic Spondylolisthesis

One RCT has compared fusion with an exercise program for adults who had 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.

Spinal Fracture

Clinical Context and Therapy Purpose

The purpose of lumbar spinal fusion is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative, nonsurgical therapy, in patients with spinal fracture.

The question addressed in this medical policy: Does lumbar spinal fusion improve the net health outcome in individuals with spinal fracture?

The following PICO was used to select literature to inform this policy.

Populations

The population of interest is individuals with spinal fracture.

Interventions

The therapy being considered is lumbar spinal fusion.

Comparators

Comparators of interest include conservative, nonsurgical therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Studies assessed outcomes up to 44 months.

Table 8. Outcomes of Interest for Individuals With Spinal Fracture

Outcomes	Details
Functional outcomes	Fracture kyphosis angle Canal compromise Owestry Disability Index (ODI) score Short-form survey (SF)-36 Physical Functioning Scale score [Timing: Up to 44 months follow-up]
Quality of life	Return to work Pain scores [Up to 44 months follow-up]

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

A qualitative systematic review by Thomas et al. (2006) identified 2 RCTs that compared operative with nonoperative treatment for thoracolumbar burst fractures in patients without neurologic deficit. (44) The larger trial, by Wood et al. (2003), is described next. The other trial identified in the systematic review only evaluated 20 patients.

Wood et al. (2003) randomized 53 consecutive patients with a stable burst fracture and no neurologic deficit or loss of structural integrity to fusion with instrumentation or to nonoperative treatment with application of a body cast or orthosis for approximately 16 weeks. (45) At an average follow-up of 44 months (24-month minimum), patients completed pain and function assessments. At follow-up, the 2 groups were similar in average fracture kyphosis angle, canal compromise, and return to work. Patients treated nonoperatively reported less disability on the ODI and SF-36 physical function, lower pain scores, and had fewer complications.

Section Summary: Spinal Fracture

Results of a small RCT have indicated that, compared with conservative care, spinal fusion may be associated with worse outcomes in patients with spinal fracture without instability or neural compression.

Lumbar Disc Herniation With Radiculopathy

Clinical Context and Therapy Purpose

The purpose of lumbar spinal fusion is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as discectomy alone, in patients with lumbar disc herniation with radiculopathy who are undergoing discectomy.

The question addressed in this medical policy: Does lumbar spinal fusion improve the net health outcome in individuals with lumbar disc herniation with radiculopathy who are undergoing discectomy?

The following PICO was used to select literature to inform this Policy.

Populations

The population of interest is individuals with lumbar disc herniation with radiculopathy who are undergoing discectomy.

Interventions

The therapy being considered is lumbar spinal fusion.

Spinal fusion can be performed in addition to discectomy for a herniated disc. Therefore, the most relevant comparison is discectomy plus fusion to discectomy alone. Discectomy can destabilize the spine when there is primary extraforaminal disc herniation at L5-S1; primary foraminal disc herniation for which facet resection is necessary; low-lying conus medullaris, and recurrent disc herniation. As is the case for spinal stenosis, however, the rate of fusion

procedures accompanying treatment for disc herniation is higher than can be accounted for by these situations.

Comparators
The comparator of interest is discectomy alone.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

Both short-term and long-term outcomes are important in evaluating spinal fusion. 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.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence
There are no randomized trials or prospective cohort studies of fusion plus discectomy vs discectomy alone. Low-quality retrospective studies have had mixed results. (46, 47)

The likelihood of instability following discectomy is too low to justify routine stabilization at the time of discectomy. Reoperation rates are one indicator of the incidence of instability, which itself has not been evaluated systematically after discectomy. In a large study based on billing data, the rate of reoperation was 12.2% within 4 years; lumbar fusion was performed on 5.9% of patients in this time period and was related to re-exploration discectomies for recurrence; (48) 38.4% of re-explorations led to a spinal fusion. A large, well-conducted population-based study found that the ten-year rate of spinal fusion surgery following discectomy was 8.5%. (49) In the Spine Patient Outcomes Research Trial (SPORT), the 8-year reoperation rates following discectomy or laminectomy for the herniated disc was 15%, but the proportion of fusion surgeries was not reported. (50) However, the most common reason was recurrence (62%), which is associated with higher fusion rates. Older patients and those who presented with asymmetric motor weakness were more likely to undergo a reoperation. In a secondary analysis of data from another randomized trial, female patients with large annular defects (width, ≥6 mm), who were ≤50 years of age had the highest risk (up to ~10 times higher) of recurrent lumbar disc herniation. (51) A meta-analysis of outcomes from repeat discectomy vs fusion for

the treatment of recurrent lumbar disc herniation published by Tanavalee et al. (2019) found a higher reoperation rate in the discectomy group (9.09%) compared to the fusion group (2.00%), but this difference was not statistically significant. (52) The primary cause of reoperation in the discectomy group was recurrent disc herniation, whereas the causes in the fusion group were adjacent segmental degeneration and implant removal. There was no difference in the rate of improvement between the 2 groups.

Section Summary: Lumbar Disc Herniation With Radiculopathy

In patients with lumbar radiculopathy with herniated disc who receive discectomy, the evidence does not support the routine use of fusion as an adjunct to discectomy. The evidence is insufficient to determine who might benefit from spinal fusion at the time of initial discectomy for a herniated disc.

Chronic Low Back Pain Without Radiculopathy

Clinical Context and Therapy Purpose

The purpose of lumbar spinal fusion is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative therapy, in patients with chronic low back pain without radiculopathy.

The question addressed in this medical policy: Does lumbar spinal fusion improve the net health outcome in individuals with chronic low back pain without radiculopathy?

The following PICO was used to select literature to inform this policy.

Populations

The population of interest is individuals with chronic low back pain without radiculopathy.

Interventions

The therapy being considered is lumbar spinal fusion.

Comparators

Comparators of interest include conservative therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity.

Both short-term and long-term outcomes are important in evaluating spinal fusion. 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

For patients with chronic or persistent low back pain without radiculopathy, fusion, disc replacement, dynamic stabilization, and inter-spinous posterior devices have been used to relieve symptoms. Most randomized trials of surgery in chronic low back pain without radiculopathy have evaluated different technical approaches, not who does and does not benefit from surgery. (53) In four European trials, patients who underwent fusion had a small improvement in disability compared with nonstandardized conservative care, (40) but in a well-done UK trial, outcomes were similar to those of an intensive rehabilitation program incorporating cognitive behavior therapy. (54, 15)

A systematic review of 4 trials (total n=666 patients) published in 2014 reported a reduction in ODI scores that was -2.91 favoring lumbar fusion over usual care. (11) However, this improvement was not statistically significant, nor did it reach the minimal clinically significant 10-point difference in ODI score. Reviewers concluded there was strong evidence that lumbar fusion does not lead to a clinically significant reduction in perceived disability compared with conservative treatment in patients who had chronic low back pain and degenerative spinal disease. Reviewers also noted it is unlikely that further research on the subject would alter this conclusion. A recent meta-analysis of 6 trials (N = 834) concluded that fusion surgery was no better than nonoperative treatment for pain and disability outcomes at either short- or long-term follow-up. (55)

Fusion may be somewhat more effective than usual care in the short-term, but the effect is small, and fusion is not superior to organized rehabilitation either in the short-term or in the long-term. A good-quality prospective observational study of 495 patients with discogenic back pain conducted in the U.S. confirmed that surgery had a slight advantage over nonstandardized nonsurgical treatment at 1 year, but both groups did poorly. Because of the short follow-up period, reoperations and failed low back syndrome were not taken into account. (56) A small, short-term Japanese trial also showed a small advantage for surgery. (57) A more definitive study found that, after four years of follow-up, fusion had no advantage over cognitive intervention and exercises at relieving back pain, improving function and return to work at four years. (58)

Patients with intractable pain, radiological evidence of advanced disc disease, and temporary relief of pain with a diagnostic injection of the disc who have exhausted all other options including a multimodal rehabilitation program are sometimes considered for fusion surgery. There is little systematically collected evidence about this group.

Section Summary: Chronic Low Back Pain Without Radiculopathy

In most patients with chronic or persistent low back pain who do not have neurogenic leg pain, fusion surgery has little or no net benefit. Clinical trials have not used clear criteria for diagnosing "discogenic" pain, which may contribute to mixed results.

Summary of Evidence

For individuals with spinal stenosis who are undergoing decompression surgery and receive lumbar spinal fusion, the evidence includes three small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Two RCTs published in 2016 compared decompression surgery plus fusion with decompression surgery alone. These trials reached different conclusions about the benefit of adding fusion to decompression, one specifically in patients with low-grade (0%-25% slippage) spondylolisthesis and one in patients with lumbar stenosis with or without spondylolisthesis. Both trials reported a larger number of operative and perioperative adverse outcomes with the addition of fusion. The third trial, a small trial conducted in Japan, also found no difference in lower back pain or leg pain scores between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1 spondylolisthesis. About 40% of the patients also had dynamic instability. In patients with spinal stenosis and grade 1 spondylolisthesis and without instability, the evidence does not support routine addition of fusion to decompression surgery. The Swedish Spinal Stenosis Study (SSSS), included patients who did not have spondylolisthesis. The addition of fusion to laminectomy resulted in similar patient-reported outcomes, longer operating time, more bleeding, higher surgical costs, and longer hospitalization but did not result in better functional disability and pain scores. In patients with spinal stenosis and no spondylolisthesis who receive decompression, the evidence suggests that routine fusion is not better than decompression alone. The evidence is insufficient to determine 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. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. These observational studies do not provide evidence of the comparative effectiveness of spinal fusion to other interventions. Furthermore, because a goal of conservative treatment is to avoid fusion surgery, such comparisons would not be appropriate. They do suggest that, among patients who are referred for surgery, outcomes in adulthood are similar to those observed in patients who received bracing or no treatment. Limitations of this evidence include recall bias and the use of procedures that are not currently used. The evidence is insufficient to determine 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.

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. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The RCT identified compared fusion with an exercise program for patients 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 patients. 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. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Results of a small RCT indicated that spinal fusion for patients with spinal fracture without instability or neural compression might result in worse outcomes than nonsurgical management. The evidence is insufficient to determine 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. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. In patients with lumbar radiculopathy with herniated disc who receive discectomy, the evidence does not support the routine use of fusion as an adjunct to discectomy. The evidence is insufficient to determine 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. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. In most patients with chronic or persistent low back pain who do not have neurogenic leg pain, fusion surgery has little or no net benefit. Clinical trials have not used clear criteria for diagnosing "discogenic" pain, which may contribute to mixed results. The evidence is insufficient to that the technology results in an improvement in the net health outcome.

Clinical Input From Physician Specialty Societies and Academic Medical Centers
Clinical input was received in 2014 on the indications for lumbar spinal fusion. Input supported the use of lumbar spinal fusion under conditions of spinal deformity or instability, including stenosis with spondylolisthesis and recurrent disc herniation. Based on the results of clinical

vetting, spinal fusion combined with decompression surgery may be considered medically necessary when conservative treatment has failed in patients with severe scoliosis, stenosis plus spondylolisthesis, or recurrent disc herniation.

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society (NASS; 2021) published coverage policy recommendations for lumbar fusion and made the following recommendations. (59)

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 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 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 non-destabilizing 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 through 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. Nonoperative care for at least 6 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:
        - Lack of bridging bone;
        - 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 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 addressed the diagnosis and treatment of degenerative lumbar spondylolisthesis. (60) 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, 61) 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. The 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. (62, 63) 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: (64)

- "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)"

American Association of Neurological Surgeons and Congress of Neurological Surgeons

The 2014 guidelines from American Association of Neurological Surgeons and Congress of Neurological Surgeons addressed fusion procedures for the lumbar spine. (65) 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 9).

Table 9. Guidelines on Fusion Procedures for the Lumbar Spine

Recommendation	GOR	LOE
One- or 2-level degenerative disease without stenosis or spondylolisthesis (part 7) (66)		
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) (67)		
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) (68)		

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 herniations associated with lumbar instability or chronic axial low back pain.	C	III
Stenosis and spondylolisthesis (part 9) (69)		
Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with degenerative spondylolisthesis in patients who desire surgical treatment.	B	II
There was insufficient evidence to recommend a standard fusion technique.		Insufficient
Stenosis without spondylolisthesis (part 10) (70)		
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 2 associations also provided recommendations on the following (65):

- 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).

<u>American Academy of Orthopaedic Surgeons</u>

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. (71)

- 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 an investigation into genetic factors as a cause of scoliosis.

Additional information

The American Academy of Orthopaedic Surgeons website includes information on Neuromuscular Scoliosis. (72) Both surgical and nonsurgical treatments are addressed. The information noted under the Surgical Treatment section notes the most common indications for surgery include:

- Curves greater than 50 degrees (in patients who are still growing).
- Curves greater than 50 degrees that have progressed more than 10 degrees (in patients who have reached skeletal maturity).
- Difficulty sitting and functional deterioration.
- Pain.
- Problems with heart or lung function.

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. (73) 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.

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

The International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) updated their guidelines on treatment of idiopathic scoliosis in 2018. (74) In these guidelines, fusion is discussed in the context of other treatments, as an outcome measure indicating treatment failure.

U.S. Preventive Services Task Force Recommendations

Adolescent Idiopathic Scoliosis: The US Preventive Services Task Force updated their recommendations on screening for adolescent idiopathic scoliosis in 2018 and concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for adolescent idiopathic scoliosis in children and adolescents aged 10 to 18 years (I statement). (75) The Task Force found no studies of surgical treatment in screening-relevant populations that met inclusion criteria.

Other indications: Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 10.

Table 10. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03570801	SLIP II Registry: Spinal Laminectomy to Laminectomy with Instrumented Pedicle Screw Fusion for Lumbar Stenosis With Grade I Spondylolisthesis	1000	Nov 2026 (recruiting)
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 (recruiting)

NCT03439228[a]	To Brace or Not to Brace for Single Level Lumbar Fusion: A Pilot Prospective Randomized Controlled Trial (BRACE Pilot)	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)
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	130	Sep 2022
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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	20930, 20931, 20936, 20937, 20938, 22533, 22534, 22558, 22585, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22848, 22853, 22854, 22859
HCPCS Codes	C1831

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Reviewed. No changes.
11/01/2023	Document updated with literature review. The following changes were made to the Coverage: 1) Removed from NOTE 1: “prescription strength” from the following statement: Use of prescription strength analgesics for several

	weeks at a dose sufficient to induce a therapeutic response; 2) Added Juvenile, neuromuscular, congenital scoliosis when either of the following is present: Documented significant progression of the deformity as measured on consecutive radiographs; OR Neurologic compromise; 3) Removed from "not medically necessary" section: Anterior lumbar interbody fusion for indirect decompression of foraminal stenosis in the absence of spinal instability or other indication for fusion as listed above. References 22, 23, 26, 34-36, 55, 64 and 72 were added, other references updated or removed.
04/15/2022	Reviewed. No changes.
10/01/2021	Document updated with literature review. The following changes were made to Coverage: 1) Changed time limits for conservative non-surgical therapy for some indications; 2) Clarified NOTE 1; 3) Added information to NOTE 6; 4) Added NOTE 5; 5) Renumbered other NOTEs; 6) Added additional criteria for indication 8. Iatrogenic or degenerative flatback syndrome; 7) Removed criteria d. from indication 9. Adjacent-level disease; 8) Added indication and criteria for 10. Lumbar synovial cyst; and 9) Replaced indication 4. Under lumbar fusion is considered not medically necessary section with the following: 4. Anterior lumbar interbody fusion for indirect decompression of foraminal stenosis in the absence of spinal instability or other indication for fusion as listed above. References 12, 19-30 and 46 were added.
06/01/2020	Document updated with literature review. The following Coverage changes were made: 1) Note 1 had duration and documentation criteria added; and 2) Additional criteria were added to the following conditions: spinal stenosis, severe progressive idiopathic scoliosis, severe degenerative scoliosis, isthmic spondylolisthesis, recurrent same-level disc herniation, pseudarthrosis, iatrogenic or degenerative flatback syndrome and adjacent-level disease. The following references were added: 2-5, 8, 10, 12; 14; 16-19; 22-23; 27-28; 33; 37; 48-50; and 52-56.
07/15/2017	Reviewed. No changes.
03/01/2017	Document updated with literature review. Chronic nonspecific low back pain without radiculopathy was added to the following coverage statement: Lumbar spinal fusion surgical procedures are considered not medically necessary if the sole indication is any one or more of the following: Chronic nonspecific low back pain without radiculopathy.
04/15/2015	Reviewed. No changes.
08/15/2014	Document updated with literature review. The following changes were made to Coverage: 1) Spinal repair surgery for dislocation, tumor, or infection may be considered medically necessary when extensive surgery is required that could create an unstable spine; 2) Any criteria that stated 6 months of conservative treatment or waiting period now states 3 months. In addition, the Description and Rationale were completely revised.
05/01/2013	New medical document. Lumbar spinal fusion may be considered medically necessary when stated criteria are met, and is considered not medically

	necessary when criteria are not met if the sole indication is any one or more of the following: a) Disc herniation; b) Degenerative disc disease (DDD); c) Initial discectomy/laminectomy for neural structure decompression; or d) Facet syndrome.