

Medical Policy



Title: Lumbar Spinal Fusion

See Also: Interspinous Fixation (Fusion) Devices
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Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With spinal stenosis undergoing decompression surgery 	Interventions of interest are: <ul style="list-style-type: none"> Lumbar spinal fusion 	Comparators of interest are: <ul style="list-style-type: none"> Decompression surgery alone 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Functional outcomes Quality of life Resource utilization Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With juvenile idiopathic scoliosis	Interventions of interest are: • Lumbar spinal fusion	Comparators of interest are: • Conservative, nonsurgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity
Individuals: • With adult degenerative scoliosis	Interventions of interest are: • Lumbar spinal fusion	Comparators of interest are: • Conservative, nonsurgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity
Individuals: • With isthmic spondylolisthesis	Interventions of interest are: • Lumbar spinal fusion	Comparators of interest are: • Conservative, nonsurgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity
Individuals: • With spinal fracture	Interventions of interest are: • Lumbar spinal fusion	Comparators of interest are: • Conservative, nonsurgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity
Individuals: • With lumbar disc herniation with radiculopathy undergoing discectomy	Interventions of interest are: • Lumbar spinal fusion	Comparators of interest are: • Discectomy alone	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity
Individuals: • With chronic low back pain without radiculopathy	Interventions of interest are: • Lumbar spinal fusion	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Resource utilization • Treatment-related morbidity

DESCRIPTION

Lumbar spinal fusion (arthrodesis) is a surgical technique that involves fusion of 2 or more lumbar vertebrae using local bone, autologous bone taken from the iliac crest of the patient, allogeneic donor bone, or bone graft substitutes. There are numerous potential indications for lumbar spinal fusion. Spinal fusion can be performed as a single procedure, or can be performed in conjunction with other spinal surgeries. For example, lumbar spinal fusion can be performed in combination with discectomy for either herniated discs or degenerative disc disease, or in combination with decompression surgery of the spinal canal for spinal stenosis.

OBJECTIVE

The objective of this policy is to determine whether lumbar spinal fusion improves health outcomes in individuals with spinal stenosis, scoliosis, spondylolisthesis, spinal fracture, or chronic low back pain.

BACKGROUND

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

The objective of interbody fusion is to permanently immobilize the functional spinal unit (2 adjacent vertebrae and the disc between them) that is believed to be causing pain and/or neurologic impingement. An alternative or supplemental approach is fusion of the transverse processes. Lumbar fusion is most commonly accepted when it is used to stabilize an unstable spine or to correct deformity. For example, lumbar spondylolisthesis is an acquired anterior displacement (slip) of 1 vertebra over the subjacent vertebra that is associated with degenerative changes. Patients who do not have neurologic deficits will typically do well with conservative care. However, patients who present with sensory changes, muscle weakness or cauda equina syndrome are more likely to develop progressive functional decline without surgery. Scoliosis, an abnormal lateral and rotational curvature of the vertebral column, can result in severe deformity that is associated with back pain in adulthood and may lead to compromised respiratory function if it is not corrected. Scoliosis with severe deformity is also an accepted indication for spinal fusion.

Lumbar spinal fusion is more controversial when the conditions previously described are not present. Spinal stenosis is 1 such condition. A 2011 consensus statement from the North American Spine Society (NASS) defines 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.¹ 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. Decompressive surgery is indicated for patients with persistent symptoms despite conservative treatment, and spinal fusion is frequently performed in combination with decompressive surgery for this purpose, with the intent 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 / fusion procedure. NASS defines lumbar degenerative spondylolisthesis as an acquired anterior displacement of 1 vertebra over the subjacent vertebra, associated with degenerative changes, but without an associated disruption or defect in the vertebral ring.² Most patients with symptomatic degenerative lumbar spondylolisthesis and an absence of neurologic deficits do well with conservative care. Patients who present with sensory changes, muscle weakness, or cauda equina syndrome are more likely to develop progressive functional decline without surgery.

Fusion has also been performed for degenerative disc disease (DDD). DDD is a universal age-related condition consisting of morphologic changes in the lumbar motion segment. Because many degenerative changes seen on imaging are asymptomatic, and invasive provocative discography has variable accuracy in the ability to localize the pain generator, identifying the source of low back pain can be difficult. A large number of fusion operations are also performed for nonspecific low back pain not responsive to nonsurgical measures (eg, nonsteroidal anti-inflammatory drugs, analgesics, physical therapy), when definite indications for fusion are not present. Across the United States, there is wide variation in the rates of lumbar spinal fusion, and many experts consider lumbar fusion to be overused, indicating a need for better standardization and uniformity in the application of this procedure.

Effect of Smoking On Spinal Fusion Rates

A systematic review of the effects of smoking on spine surgery was published by Jackson and Devine (2016).³ Four large retrospective comparative studies were included; they evaluated fusion rates in smokers and nonsmokers. The greatest difference in fusion rates was observed in a study of 100 patients by Brown et al (1986), with a 32% difference in fusion rates between smokers and nonsmokers ($p=0.001$).⁴ Bydon et al (2014) found no significant difference in fusion rates between smokers and nonsmokers for single-level fusion, but an 18% lower fusion rate in smokers for 2-level fusions ($p=0.019$).⁵ A retrospective analysis by Andersen et al (2001) of 232 smokers and 194 nonsmokers found that patients who smoked more than 10 cigarettes per day within 3 months of surgery had a 9% decrease in fusion rates⁶ and a fourth study (Glassman et al [2000]) of 188 nonsmokers and 169 smokers found that smokers had a 7% reduction in fusion rates ($p=0.05$), and that fusion success improved with postoperative smoking cessation.⁷

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

POLICY

- A. Lumbar spinal fusion may be considered **medically necessary** for any one of the following conditions:
1. Spinal stenosis with **both** of the following:
 - a. Any **one** of the following
 - 1) Associated spondylolisthesis demonstrated on plain x-rays
OR
 - 2) Spinal instability demonstrated on imaging studies
OR
 - 3) Spinal instability is anticipated due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis
AND
 - b. **Either** of the following
 - 1) Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative care and has documentation of central/lateral recess/or foraminal stenosis on MRI or other imaging
OR
 - 2) Severely restricted functional ability or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome
 2. 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 a patient who has failed at least 3 months of conservative care
 3. Severe degenerative scoliosis (ie, lumbar or thoracolumbar) with a minimum Cobb angle of 30°, or significant sagittal imbalance (eg, 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 1 year of conservative therapy
OR
 - b. Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to at least 1 year of conservative nonsurgical care
OR
 - c. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome

4. Isthmic spondylolisthesis, when **all** of the following are present:
 - a. Congenital (Wiltse type I) or acquired pars defect (Wiltse 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
5. 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
6. Pseudarthrosis, documented radiologically (by the presence of hardware failure after solid fusion), 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 a patient who had experienced significant interval relief of prior symptoms
7. Instability due to fracture, dislocation, infection, abscess, or tumor when extensive surgery is required that could create an unstable spine
8. Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy or interbody spacers

9. 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, lateral listhesis on imaging, or severe stenosis at that level requiring decompression
AND
 - c. Symptoms and functional measures correlate with imaging findings
AND
 - d. The previous fusion resulted in significant relief for at least 6 months

10. Discogenic low back pain secondary to a degenerated disc that meet **ALL** of the following criteria:
 - a. Advanced single level disease noted on an MRI and plain radiographs of the lumbar spine, characterized by moderate to severe degeneration of the disc with Modic changes (defined as peridiscal bone signal above and below disc space in question) as compared to other normal or mildly degenerative levels (characterized by normal plain radiographic appearance and no or mild degeneration on MRI)
AND
 - b. Presence of symptoms for at least one year AND that are not responsive to multi-modal therapy / rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavioral therapy, and active exercise programs.
AND
 - c. Absence of active, significant psychiatric disorders, such as major depression, requiring pharmaceutical treatment
AND
 - d. Absence of tobacco use or nicotine replacement products for 6 weeks prior to surgery date
AND
 - e. Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain

- B. Lumbar spinal fusion is considered **experimental / investigational** if the sole indication is any one of the following conditions:
 1. Disc herniation
 - a. As an adjunct to primary excision of a central or posterolateral disc herniation at any level in the absence of instability or spondylolisthesis
 2. Chronic nonspecific low back pain without radiculopathy

3. Discogenic low back pain
 - a. Any case that does not fulfill ALL of the above criteria
 - b. Presence of advanced multi-level degeneration (2 or more levels) on a preoperative MRI and plain radiographs
 - c. Significant psychiatric disorder
 - d. Tobacco use or nicotine replacement products
 4. Stenosis
 - a. As an adjunct to primary decompression of central and/or lateral recess stenosis in the absence of instability, foraminal stenosis, spondylolisthesis
 5. Facet syndrome
 6. Initial discectomy/laminectomy for neural structure decompression
- C. Lumbar spinal fusion is considered **not medically necessary** for any indication not addressed above.
- D. Multiple level lumbar spinal fusion is considered **not medically necessary** when the criteria listed above are not met for all levels.

Policy Guidelines

1. Tobacco use or nicotine replacement products within the previous 6 weeks is a contraindication for lumbar spinal fusion.
2. Conservative nonsurgical therapy for the duration specified should include the following:
 - a. Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
 - Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, AND
 - b. Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND
 - c. Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues
 - d. Documentation of patient compliance with the preceding criteria.
3. "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.
4. Persistent debilitating pain is defined as:
 - a. Significant level of pain on a daily basis defined on a visual analog scale (VAS) as greater than 4; AND
 - b. Pain on a daily basis that has a documented impact on activities of daily living in spite of optimal conservative nonsurgical therapy as outlined above and appropriate for the patient.

RATIONALE

This policy was created with a literature review of the MEDLINE database. The most recent literature update was performed through May 15, 2018. Key studies are described next.

Evidence reviews assess 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.

Lumbar Spine Disorders

Clinical Context and Therapy Purpose

The purpose of lumbar spinal fusion in patients who have a range of lumbar spine disorders (eg, spinal stenosis, scoliosis, spondylolisthesis, fracture, disc herniation, chronic low back pain [CLBP]) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does use of lumbar spinal fusion improve the net health outcome patients who have spinal stenosis, juvenile idiopathic scoliosis, adult degenerative scoliosis, isthmic spondylolisthesis, spinal fracture, lumbar disc herniation with radiculopathy, or CLBP without radiculopathy?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant populations of interest are individuals who have spinal stenosis undergoing decompression surgery, juvenile idiopathic scoliosis, adult degenerative scoliosis, isthmic spondylolisthesis, spinal fracture, lumbar disc herniation with radiculopathy who are undergoing discectomy, or CLBP without radiculopathy.

Interventions

The therapy being considered is lumbar spinal fusion.

Comparators

The following therapies and practices are currently being used and range from: decompression surgery alone (spinal stenosis undergoing decompression surgery), to conservative, nonsurgical therapy (juvenile idiopathic scoliosis, adult degenerative scoliosis, isthmic spondylolisthesis, spinal fracture), to discectomy alone (lumbar disc herniation with radiculopathy who are undergoing discectomy), and to conservative therapy (CLBP without radiculopathy).

Outcomes

The general outcomes of interest are quality of life (eg, improvements in function, reductions in pain) and post-procedural-related adverse events.

Timing

Spinal fusion may be recommended after failure of conservative therapies. The time frame for postprocedural follow-up ranges from 3 to 12 months.

Setting

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

Spinal Stenosis

The primary surgical intervention for spinal stenosis is decompression surgery (ie, laminectomy or related procedures). 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. Therefore, the most relevant comparison for patients with spinal stenosis is decompression surgery alone compared with decompression surgery plus fusion.

Two published RCTs have assessed the benefit of adding fusion to laminectomy (ie, decompression surgery alone vs decompression surgery plus fusion), both of which were published in 2016. These trials reported different results on the benefit for the combined procedure.^{8,9}

In the Swedish Spinal Stenosis Study (SSSS), 247 patients between 50 and 80 years of age who had lumbar spinal stenosis at 1 or 2 levels were randomized to decompression plus fusion surgery or decompression surgery alone.⁸ The specific surgical method for decompression and fusion was determined by the surgeon. Randomization was stratified by the presence of degenerative spondylolisthesis, which was present in about half of the patients. The analysis was prespecified to be per-protocol. The addition of fusion to laminectomy resulted in longer operating time, more bleeding, higher surgical costs, and longer hospitalization. The primary outcome measure, the Oswestry Disability Index (ODI) score (range, 0-100; with higher scores indicating severe disability), did not differ significantly between groups at the 2- or 5-year follow-ups. At 2 years, the difference in change in ODI score did not differ significantly between fusion and decompression-only groups (-2; 95% confidence interval, -7 to 3; p=0.36). Mean scores were also analyzed separately for patients with or without spondylolisthesis. In patients with degenerative spondylolisthesis (range, 7.4-14.3 mm), the mean ODI score at 2 years was 25 in the fusion group and 21 in the decompression-alone group. The distance walked in 6 minutes (6-minute walk test) did not differ significantly between groups. Additional lumbar spine surgery during 6.5 years of follow-up was performed in a similar percentage of patients in the fusion group (22%) and the decompression-alone group (21%). Of the 153 patients who had enrolled early enough to have 5 years of follow-up, there were no significant differences in ODI results.

In the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial, all 66 patients randomized to decompression plus fusion or decompression alone had stable degenerative spondylolisthesis (grade 1, 3-14 mm) and symptomatic lumbar spinal stenosis.⁹ Decompression was performed by laminectomy with partial removal of the medial facet joint. The fusion group, which underwent posterolateral fusion with instrumentation, had more blood loss and longer hospital stays. The primary outcome measure, change in 36-Item Short-Form Health Survey (SF-36; scoring range, 0-100; with higher scores indicating more favorable health status) Physical Component Summary score at 2 years, was significantly greater in the fusion group (15.2) than in the decompression-alone 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 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 minimally important difference for ODI score was prespecified as a 10-point improvement, but the percentages of patients who achieved the minimally important difference were not reported. 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. In addition to the low follow-up rate, there were questions about the risk of surgeon bias in the recommendation for additional fusion surgery in patients who had undergone decompression alone.

A quasi-randomized study by Herkowitz and Kurz (1991) evaluated decompression, with or without fusion, in 50 patients with spondylolisthesis and spinal stenosis.¹⁰ All patients had failed nonoperative treatment. This study used alternating assignment to the 2 treatment groups. At a mean follow-up of 3 years (range, 2.4-4.0 years), patients who had posterolateral fusion together with limited decompression had significantly improved outcomes, as measured by overall outcomes and numeric rating scales, compared with the patients who underwent decompression alone. An increase in postoperativeolisthesis was also observed in the decompression-alone group.

Weinstein et al (2007, 2009) reported on findings from the widely cited multicenter controlled trial (Spine Patient Outcomes Research Trial [SPORT]).^{11,12} The primary comparison in this trial was decompression surgery plus fusion with nonsurgical treatment for patients who had lumbar spinal stenosis and degenerative spondylolisthesis. All patients had neurogenic claudication or radicular leg pain associated with neurologic signs, spinal stenosis shown on cross-sectional imaging, and degenerative spondylolisthesis shown on lateral radiographs with symptoms persisting for at least 12 weeks. There were 304 patients in a randomized cohort and 303 patients in an observational cohort. About 40% of the randomized cohort crossed over in each direction by 2 years of follow-up. At the 4-year follow-up, 54% of patients randomized to nonoperative care had undergone surgery. Five percent of the surgically treated patients received decompression only and 95% underwent decompression with fusion. Analysis by treatment received was used due to the high percentage of crossovers. This analysis, controlled for baseline factors, showed a significant advantage for surgery at up to 4 years of follow-up for all primary and secondary outcome measures.

Section Summary: Spinal Stenosis

Two RCTs that specifically assessed the benefit of adding fusion to decompression in patients with grade 1 spondylolisthesis reached different conclusions. Both trials reported more frequent

operative and perioperative adverse outcomes with the addition of fusion. The SSSS trial found no benefit of surgery on clinical outcomes measured by ODI score, while the SLIP trial reported a small benefit measured by an SF-36 score, a difference in the ODI score that was not statistically significant, and a reduction in subsequent surgeries when fusion was added to decompression. In SPORT, 95% of patients in the surgical group underwent decompression with fusion and had improved outcomes compared with nonoperative therapy. Although this is an important trial of surgical therapy in patients with spinal stenosis, it evaluated whether the combination of decompression surgery plus fusion is superior to nonsurgical therapy. It did not isolate the effect of the fusion, therefore, it is not possible to determine whether the benefit of surgery derived from decompression, fusion, or both. An earlier quasi-randomized study reported that lumbar spinal fusion improved outcomes in patients with spinal stenosis associated with spondylolisthesis. Methodologic limitations of this evidence base include high loss to follow-up in the SLIP and SPORT trials, lack of information on the surgical procedures in the SSSS trial, and variation in outcome measures used. The current evidence does not permit conclusions whether the addition of fusion to decompression surgery for patients with spinal stenosis improves outcomes.

Juvenile 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. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, in the United States, surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.¹³ For further discussion, see evidence review 2.01.83 (interventions for progressive scoliosis).

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.¹⁴ 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, 20-28 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°.

Section Summary: Juvenile Idiopathic Scoliosis

Long-term follow-up of a large comparative cohort has indicated that spinal fusion can reduce curve progression compared with bracing in patients who had large Cobb angles. In this study, the populations were not comparable, because spinal curves less than 60° were treated with bracing and curves 60° or greater were treated with spinal fusion. Although supportive of the use of spinal fusion in juveniles with large Cobb angles and remaining growth, studies comparing curve progression following fusion or bracing are needed in comparable populations.

Adult Degenerative Scoliosis

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.¹⁵ 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 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.

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

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).¹⁶ 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

A qualitative systematic review by Thomas et al (2006) identified 2 RCTs that compared operative who nonoperative treatment for thoracolumbar burst fractures in patients without neurologic deficit.¹⁷ 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.¹⁸ 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

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. No RCTs were identified with that specific comparison.

The largest trial on surgery for a herniated disc is SPORT, which reported on randomized (n=501) and observational (n=743) cohorts with lumbar disc herniation and radiculopathy that received discectomy or nonoperative care.^{19,20} Intention-to-treat analysis for the randomized cohort found a small advantage for patients assigned to discectomy, with no significant differences between groups for the primary outcome measures (bodily pain, physical function, ODI score). Analysis by treatment received indicated significant advantages for discectomy on the primary outcome measures, but there was no mention of any patient undergoing fusion following discectomy.

Section Summary: Lumbar Disc Herniation with Radiculopathy

Current evidence is lacking on whether the addition of fusion to discectomy improves outcomes compared with discectomy alone. One large RCT has indicated that surgical treatment with discectomy improves outcomes for lumbar disc herniation with radiculopathy compared with nonsurgical care. However, there is no evidence that the addition of spinal fusion to discectomy improves outcomes in patients with lumbar disc herniation undergoing discectomy.

Chronic Low Back Pain Without Radiculopathy

Nonspecific chronic low back pain (CLBP) is a persistent low back pain not attributable to a known specific pathology such as infection, tumor, osteoporosis, fracture, structural deformity (eg, spondylolisthesis, scoliosis), an inflammatory disorder, radiculitis, or cauda equine syndrome. Surgical interventions, including fusion and disc arthroplasty, have been used on the assumption that abnormal intersegmental movement or degenerative pathology may be the cause of CLBP.²¹

A systematic review by Andrade et al (2013) assessed trials on surgical fusion for CLBP.²² As of September 2012, 4 RCTs (total N=981 patients) had compared surgical with nonsurgical approaches for CLBP. In contrast, 33 RCTs (total N=3790 patients) had compared variations of surgical techniques. A systematic review by Hart et al (2015) identified many of the same RCTs that evaluated fusion for CLBP attributed to degenerative disc disease; a number of the included studies compared fusion with total disc replacement for presumed degenerative disc disease.²³

A meta-analysis by Saltychev et al (2014) compared lumbar fusion with conservative treatment in patients who had CLBP.²⁴ Meta-analysis of 4 trials (total N=666 patients) reported a reduction in ODI scores that was -2.91 in favor of lumbar fusion. However, this improvement was not statistically significant nor did it reach the minimal clinically significant 10-point difference in ODI score. There was evidence of publication bias that favored placebo. Reviewers concluded that 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 CLBP and degenerative spinal disease. Reviewers also noted it is unlikely that further research on the subject would alter this conclusion.

One study that compared surgical with nonsurgical treatment for CLBP was a 2001 multicenter trial by the Swedish Lumbar Spine Study Group.²⁵ In this trial, 294 patients with CLBP for at least 2 years, sick leave or disability for at least 1 year (mean, 3 years), and radiologic evidence of disc degeneration were randomized into 1 of 3 types of spinal fusion or to physical therapy supplemented by other nonsurgical treatment. Patients were excluded if they had specific radiologic findings such as spondylolisthesis, new or old fractures, infection, inflammatory process, or neoplasm. By intention-to-treat analysis, the surgical group showed greater reductions than the nonsurgical group in back pain (33% vs 7%), disability according to ODI score (25% reduction vs 6% reduction), visual analog scale pain score (28% vs 8%), and General Function Score (31% vs 4%). Significantly more surgical patients were also back to work (36% vs 13%) and more reported their outcomes as better or much better (63% vs 29%).

A 2005 pragmatic multicenter randomized trial from the Spine Stabilization Trial Group compared spinal fusion with an intensive (\approx 75 hours) physical and cognitive-behavioral rehabilitation program.²⁶ Patients (N=349) who had back pain for at least 1 year and were considered candidates for surgical stabilization by the treating physician were randomized if the clinician and patient were uncertain which study treatment strategies would be best. Radiologic findings were not part of the inclusion criteria. By the 2-year follow-up, 48 (28%) of patients randomized to rehabilitation had undergone surgery. Results for 1 of the 2 primary outcome measures (ODI score) showed a modest but significantly greater improvement (4.1 points) in the surgery group. There were no significant differences between groups for the walking test or any of the secondary outcome measures.

Section Summary: Chronic Low Back Pain Without Radiculopathy

The results of trials comparing fusion with nonsurgical management in a CLBP population are mixed. A meta-analysis assessing 4 RCTs found no clinically significant advantage for lumbar fusion over conservative therapy in patients with CLBP not attributable to a known specific pathology (eg, infection, tumor, osteoporosis, fracture, structural deformity, an inflammatory disorder, radiculitis, cauda equine syndrome). The strongest benefits of surgery were reported in a trial of patients who had been on sick leave or disability for more than 1 year, but no advantage of surgery was found when patients or surgeon were unsure of whether surgery or conservative therapy would be the best treatment strategy. Interpretation of these studies is limited by the high percentages of patients who crossed over to surgery, variances in the type of spinal fusion used (eg, posterolateral vs interbody), and uncertainty in establishing whether the source of CLBP was degenerative disc disease.

SUMMARY OF EVIDENCE

For individuals who have spinal stenosis undergoing decompression surgery who receive lumbar spinal fusion, the evidence includes RCTs with mixed results. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Two RCTs published in 2016 compared decompression surgery plus fusion with decompression surgery alone. These trials reached different conclusions 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 SSSS found no benefit of surgery related to clinical outcomes, while the SLIP trial reported a small benefit in clinical outcomes and a reduction in the number of subsequent surgeries when fusion was added to decompression. In the earlier SPORT, decompression surgery plus fusion

was compared with conservative, nonsurgical treatment. Ninety-five percent of patients in the surgical group underwent decompression with fusion and had better outcomes than patients receiving nonoperative therapy. This trial, however, did not isolate the impact of fusion from that of decompression surgery. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have adult degenerative scoliosis who receive lumbar spinal fusion, the evidence includes a nonrandomized comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. No RCTs were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. Evidence includes a prospective comparative cohort study, which evaluated outcomes in adults with symptomatic scoliosis who were treated with spinal fusion surgery or nonoperatively. Although the surgically treated group had better outcomes than the conservatively managed group, there was potential bias in this study due to the self-selection of treatment and high loss to follow-up in the conservatively managed group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have isthmic spondylolisthesis who receive lumbar spinal fusion, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. One RCT identified compared fusion with an exercise program for patients 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 the effects of the technology on health outcomes.

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

For individuals who have lumbar disc herniation with radiculopathy who are undergoing discectomy who receive lumbar spinal fusion, the evidence includes an RCT and a nonrandomized comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Current evidence, which includes the large SPORT RCT, supports surgical treatment with discectomy for lumbar disc herniation. The

evidence does not support a conclusion that the addition of fusion to discectomy improves outcomes in patients with lumbar disc herniation without instability. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have CLBP without radiculopathy who receive lumbar spinal fusion, the evidence includes RCTs and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Meta-analysis of results from 4 RCTs found no clinically significant advantage of lumbar fusion over conservative therapy in patients with nonspecific CLBP unresponsive to conservative management. While some trials have reported a benefit, others have not. The evidence is insufficient to determine the effects of the technology on health outcomes.

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

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

In response to requests, input was received from the North American Spine Society, American Association of Neurological Surgeons, and Congress of Neurological Surgeons, with 3 additional reviewers identified through a third physician specialty society, as well as 2 academic medical centers when this policy was created in 2014. The input addressed specific criteria to determine the medical necessity of lumbar spinal fusion.

PRACTICE GUIDELINES AND POSITION STATEMENTS

North American Spine Society

In 2014, North American Spine Society (NASS) published coverage policy recommendations for lumbar fusion.²⁷ Specific criteria were described for infection, tumor, traumatic injuries, deformity (eg, scoliosis), stenosis, disc herniations, synovial facet cysts, discogenic low back pain, and pseudoarthrosis. NASS isolated situations where lumbar fusion would not be indicated: disc herniation in the absence of instability or spondylolisthesis; stenosis in the absence of instability; foraminal stenosis or spondylolisthesis; and discogenic low back pain.

Other 2014 guidelines from NASS addressed the diagnosis and treatment of *degenerative lumbar spondylolisthesis*.²⁸ NASS gave a grade B recommendation to surgical decompression with fusion for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone. A grade C recommendation was given to decompression and fusion as a means to provide satisfactory long-term results for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

The 2011 NASS guidelines (updated in 2013) addressed multidisciplinary spine care for adults with a chief complaint of *degenerative lumbar spinal stenosis*.^{1,29} The guidelines indicated that the nature of the pain and associated patient characteristics should be more typical of a diagnosis of spinal stenosis than herniated disc. NASS addressed whether the addition of lumbar fusion to surgical decompression improved surgical outcomes in the treatment of spinal stenosis compared with treatment by decompression alone. NASS gave a grade B recommendation (fair

evidence) to decompression alone for patients with leg predominant symptoms without instability.

The 2012 NASS guidelines (updated in 2014) addressed multidisciplinary spine care for the diagnosis and treatment of *lumbar disc herniation with radiculopathy*.^{30,31} The guidelines indicated that “there is insufficient evidence to make a recommendation for or against fusion for specific patient populations with lumbar disc herniation with radiculopathy whose symptoms warrant surgery. Recommendation: I (Insufficient Evidence).”

American Association of Neurological Surgeons and Congress of Neurological Surgeons

The 2014 guidelines from American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) addressed fusion procedures for the lumbar spine.³² These guidelines indicated that there was no evidence that conflicted with the recommendations formulated in the 2005 guidelines for fusion procedures for the lumbar spine (see Table 1).

Table 1. AANS and CNS 2014 Guidelines on Fusion Procedures for the Lumbar Spine

Recommendation	Grade	LOE
One- or 2-level degenerative disease without stenosis or spondylolisthesis (part 7)³³		
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)³⁴		
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)³⁵		
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)³⁶		
Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with degenerative spondylolisthesis in patients who desire surgical treatment.	B	II
There was insufficient evidence to recommend a standard fusion technique.		Insufficient
Stenosis without spondylolisthesis (part 10)³⁷		
Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who undergo surgical intervention.	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

AANS: American Association of Neurological Surgeons; CNS: Congress of Neurological Surgeons; DDD: degenerative disc disease; LOE: level of evidence.

AANS and CNS has also provided recommendations on³²:

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

American Academy of Orthopaedic Surgeons

Information updated in 2015 from the American Academy of Orthopaedic Surgeons has indicated that the type of treatment required for idiopathic scoliosis in children and adolescents depends on the kind and degree of the curve, child's age, and number of remaining growth years until the child reaches skeletal maturity.³⁸

- Observation is appropriate when the curve is mild (<25°) or if the child is near skeletal maturity.
- The goal of bracing is to prevent scoliotic curves from worsening. Bracing can be effective if the child is still growing and has a spinal curvature between 25° and 45°. There are several types of braces, most being the underarm type.
- Surgery may be recommended if the curve is greater than 45° and the child is still growing. If the patient has reached skeletal maturity, surgery may still be recommended for scoliotic curves that exceed 50° to 55°. An implant made up of rods, hooks, screws, and/or wires is used to straighten the spine. Bone graft from the bone bank, or from the patient's hip region, is also used to help the operated portion of the spine heal solid.
- At present, the main research focus in idiopathic scoliosis is investigation into genetic factors as a cause of scoliosis.

National Institute for Health and Care Excellence

In 2017, the U.K.'s National Institute for Health and Care Excellence (NICE) provided clinical guidelines on lateral interbody fusion for lumbar spine low back pain.⁴² NICE states that lumbar fusion may be appropriate for "people with severe, life-limiting, chronic low back pain that does not respond to conservative treatments." The evidence on lateral interbody fusion was considered "adequate in quality and quantity." Also in 2017, NICE reexamined lumbar disc replacement and reported higher complication rates were found in patients who underwent fusion.⁴⁰ The conclusion was that disc replacement was not warranted and spinal fusion for nonspecific low back pain should only be performed as part of a randomized controlled trial.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

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

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
- 20931 Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
- 20936 Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)
- 20937 Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
- 20938 Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
- 20939 Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure)
- 22533 Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
- 22534 Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
- 22558 Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
- 22585 Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
- 22586 Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
- 22612 Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
- 22614 Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)
- 22630 Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
- 22632 Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)

- 22633 Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
- 22634 Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; each additional interspace and segment (List separately in addition to code for primary procedure)
- 22800 Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
- 22802 Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
- 22804 Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
- 22808 Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
- 22810 Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
- 22812 Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
- 22818 Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
- 22819 Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
- 22840 Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
- 22841 Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
- 22842 Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
- 22843 Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
- 22844 Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)
- 22845 Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
- 22846 Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
- 22847 Anterior instrumentation; 8 or more vertebral segments (List separately in addition to code for primary procedure)

- 22848 Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
- 22849 Reinsertion of spinal fixation device
- 22853 Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
- 22854 Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
- 22859 Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
- 0195T Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace
- 0196T Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L4-L5 interspace (List separately in addition to code for primary procedure)

ICD-10 Diagnoses

- M41.06 Infantile idiopathic scoliosis, lumbar region
- M41.07 Infantile idiopathic scoliosis, lumbosacral region
- M41.116 Juvenile idiopathic scoliosis, lumbar region
- M41.117 Juvenile idiopathic scoliosis, lumbosacral region
- M41.126 Adolescent idiopathic scoliosis, lumbar region
- M41.127 Adolescent idiopathic scoliosis, lumbosacral region
- M41.26 Other idiopathic scoliosis, lumbar region
- M41.27 Other idiopathic scoliosis, lumbosacral region
- M41.46 Neuromuscular scoliosis, lumbar region
- M41.47 Neuromuscular scoliosis, lumbosacral region
- M41.56 Other secondary scoliosis, lumbar region
- M41.57 Other secondary scoliosis, lumbosacral region
- M41.86 Other forms of scoliosis, lumbar region
- M41.87 Other forms of scoliosis, lumbosacral region
- M41.9 Scoliosis, unspecified
- M43.13 Spondylolisthesis, cervicothoracic region
- M43.14 Spondylolisthesis, thoracic region
- M43.15 Spondylolisthesis, thoracolumbar region
- M48.05 Spinal stenosis, thoracolumbar region
- M48.061 Spinal stenosis, lumbar region without neurogenic claudication
- M48.062 Spinal stenosis, lumbar region with neurogenic claudication
- M48.07 Spinal stenosis, lumbosacral region

M53.2X5	Spinal instabilities, thoracolumbar region
M53.2X6	Spinal instabilities, lumbar region
M53.2X7	Spinal instabilities, lumbosacral region

REVISIONS

07-08-2013	Policy added to the bcbsks.com web site on 06-07-2013. Effective on 07-08-2013, 30 days after posting.
10-31-2014	Policy added to the bcbsks.com web site on 10-01-2014. Effective on 10-31-2014, 30 days after posting.
	Description section updated
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Updated to current language from previous language of: <p>"A. Lumbar spine fusion surgery is considered medically necessary for any one of the following conditions:</p> <ol style="list-style-type: none"> 1. Spinal fracture with instability or neural compression 2. Tumor or infection (including abscess, osteomyelitis, or discitis) when debridement or resection is necessary to the extent that the spine becomes unstable 3. Spinal stenosis with ALL of the following: <ol style="list-style-type: none"> a. Associated spondylolisthesis demonstrated on imaging and b. Any one of the following: <ol style="list-style-type: none"> 1) Documented detailed history of neurogenic claudication or radicular pain that results in significant functional impairment with documented exam and corroborating documentation of central / lateral recess / or foraminal stenosis on imaging with documentation of failure of at least 3 months of conservative care or 2) Detailed history and exam documenting signs and symptoms of Severe or rapidly progressive motor loss, neurogenic claudication or cauda equina syndrome 4. Severe, progressive idiopathic scoliosis (ie, lumbar or thoracolumbar) with Cobb angle > 40 degrees 5. Severe degenerative scoliosis with any one of the following: <ol style="list-style-type: none"> a. Documented progression of deformity with persistent axial (non-radiating) 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, documented by detailed history and exam, unresponsive to at least 3 months of conservative care. 6. Isthmic spondylolisthesis, either congenital or acquired pars defect, documented on imaging, and with persistent back pain (with or without neurogenic symptoms), and with impairment of function unresponsive to no less than 6 months of conservative nonsurgical care 7. Recurrent disc herniation, ie at same level and same side, no less than 6 months after previous disc surgery; with documented detailed history of radicular pain or claudication, documented exam and impairment of function unresponsive to at least 3 months of conservative care and with neural compression documented with appropriate imaging in a patient who had experienced significant interval relief of prior symptoms <p><i>(Original policy was mis-numbered with no #8)</i></p>

	<p>9. Pseudarthrosis, documented radiographically, no less than 6 months after initial fusion, with persistent axial back pain, with or without neurogenic symptoms, with impairment of function, in a patient who has experienced significant interval relief of prior symptoms</p> <p>10. Documented clinically symptomatic iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy</p> <p>B. Lumbar spine fusion surgery is considered not medically necessary unless one of the above conditions is met.</p> <p>C. Lumbar spinal fusion is also considered not medically necessary if the sole indication is any one or more of the following conditions:</p> <ul style="list-style-type: none"> ▪ Disc herniation ▪ Degenerative disc disease ▪ Initial discectomy/laminectomy for neural structure decompression ▪ Facet syndrome <p><u>Policy Guidelines</u></p> <p>1. Conservative nonsurgical therapy must include the following:</p> <ul style="list-style-type: none"> a. Use of prescription strength analgesics (including anti-inflammatory medications if not contraindicated), and b. Participation in physical therapy (including active exercise), and c. Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present. <p>2. Significant functional impairment may include documentation of the following:</p> <ul style="list-style-type: none"> ▪ Inability or significantly decreased ability to perform normal daily activities of work, school or at-home duties. <p>3. Persistent debilitating pain is defined as:</p> <ul style="list-style-type: none"> a. Significant level of pain on a daily basis defined on a Visual Analog Scale (VAS) as greater than 4; and b. Pain on a daily basis that has a documented impact on activities of daily living in spite of optimal conservative non-surgical therapy as outlined above and appropriate for the patient."
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added CPT Codes: 22586, 22818, 22819, 22841 ▪ Added ICD-9 Codes: 722.73, 722.83, 724.03, 724.6 ▪ Added ICD-10 Codes.
	<p>Rationale section updated</p>
	<p>References updated</p>
<p>02-05-2015</p>	<p>In Title section:</p> <ul style="list-style-type: none"> ▪ Added "See Also: Interspinous Fixation (Fusion) Devices" and link to website.
<p>07-07-2016</p>	<p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In Item A 1 b 2, added "ly restricted functional ability" to read "Severely restricted functional ability or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equine syndrome" ▪ In Item A 6, added "(by the presence of hardware failure after solid fusion)" to read "Pseudoarthrosis, documented radiologically (by the presence of hardware failure after solid fusion), when <u>all</u> of the following are present:" ▪ In Item A 9 b, removed "or" and added ", or severe stenosis at that level requiring decompression" to read "Eccentric disc space collapse, spondylolisthesis, acute single level scoliosis, lateral listhesis on imaging, or severe stenosis at that level requiring decompression"

	<ul style="list-style-type: none"> ▪ In Item 10 d, removed "smoking" and "at least 3 months" and added "tobacco use or nicotine replacement products" and "6 weeks" to read "Absence of tobacco use or nicotine replacement products for 6 weeks prior to surgery date" ▪ In Item B 3 d, removed "Smoking" and added "Tobacco use or nicotine replacement products" ▪ In Policy Guidelines, Item 1, removed "Smoking" and "3 months" and added "Tobacco use or nicotine replacement products" and "6 weeks" to read "Tobacco use or nicotine replacement products within the previous 6 weeks is a contraindication for lumbar spinal fusion."
	Updated Rationale section.
	Updated References section.
10-12-2016	Corrections made to Rationale section.
01-01-2017	In Coding section: <ul style="list-style-type: none"> ▪ Added CPT codes: 22853, 22854, 22859 (<i>New codes, effective January 1, 2017</i>). ▪ Removed CPT code: 22851 (<i>Termed code, effective December 31, 2016</i>).
05-24-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
10-01-2017	In Coding section: <ul style="list-style-type: none"> ▪ Added ICD-10 codes: M48.061, M48.062. ▪ Removed ICD-10 code: M48.06.
01-01-2018	In Coding section: <ul style="list-style-type: none"> ▪ Added CPT code: 20939. ▪ Removed ICD-9 codes.
08-15-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: <ul style="list-style-type: none"> ▪ Added CPT codes: 0195T, 0196T.
	Updated References section.
	Added Appendix section.

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APPENDIX

Procedures for Lumbar Interbody Fusion

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

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

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

MI: minimally invasive.

Anterior Lumbar Interbody Fusion

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

Posterior Lumbar Interbody Fusion

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

canal pathology (eg, spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum) as well as stabilization of the spine through interbody fusion.

Transforaminal Lumbar Interbody Fusion

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

Lateral Lumbar Interbody Fusion

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

Oblique Lateral Interbody Fusion

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

Circumferential Fusion

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

Posterolateral Fusion

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