

## Medical Policy



### Title: Lumbar Spinal Fusion

#### **Professional**

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### **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. A number of these indications are controversial, for example when lumbar spinal fusion is performed in combination with discectomy for either herniated discs or degenerative disc disease, or in combination with decompression of the spinal canal for spinal stenosis when there is no suggestion of instability.

### **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 described previously described are not present. For example, fusion is frequently performed in combination with discectomy or laminectomy when these procedures do not result in instability of the spine. 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. As 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 that is not responsive to nonsurgical measures (eg, nonsteroidal anti-inflammatory drugs, analgesics, physical therapy), when definite indications for fusion are not present. Across the U.S., 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.

**Regulatory Status**

Lumbar spinal fusion is a surgical procedure and does not require approval by the U.S. Food and Drug Administration (FDA). A variety of instrumentation used in lumbar spinal fusion is cleared for marketing by FDA. Infuse (rhBMP-2) and OP-1 (rhBMP-7) are approved by FDA 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) Severe 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, 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, or lateral listhesis on imaging  
**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 smoking for at least 3 months 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. Smoking
  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
- 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. Smoking within the previous 3 months 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. Key studies are described next.

#### Spinal Stenosis with Spondylolisthesis

A 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.

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.

Weinstein et al reported findings from the multicenter controlled trial (Spine Patient Outcomes Research Trial [SPORT]) that compared surgical and nonsurgical treatment for lumbar degenerative spondylolisthesis.(3,4) 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 timepoint, 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.

A 1991 study by Herkowitz et al evaluated decompression, with or without fusion, in 50 patients with spondylolisthesis and spinal stenosis.(5) All patients had failed a trial of nonoperative treatment. This quasirandomized prospective study used alternating assignment to the 2 treatment groups. At a mean follow-up of 3 years (range, 2.4-4.0), the patients who had posterolateral lumbar fusion together with decompression had significantly improved outcomes, as measured by overall outcomes and numeric rating scales, compared with the group of patients who underwent decompression alone.

### Section Summary

Findings from the SPORT trial, in which 95% of patients in the surgical group underwent decompression with fusion and the smaller study by Herkowitz et al that specifically assessed the addition of fusion to decompression, support that the use of lumbar spinal fusion improves outcomes in patients with spinal stenosis associated with spondylolisthesis.

### 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), severity of the condition (degrees of 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 to be 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 U.S., surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.(6)

In 2001, Danielsson and Nachemson reported 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.(7) 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. An average of 9.5 vertebrae were fused. Clinical and radiologic follow-up was obtained in 89% of patients at a mean of 22 years (range, 20-28). Curve progression was 3.5° for surgically-treated curves and 7.9° for brace-treated curves. Five patients (4%) treated surgically and 39 (36%) treated with bracing had an increase in the Cobb angle of more than 10°.



## Section Summary

Long-term follow-up of a large case series supports guidelines from the Scoliosis Research Society that fusion can reduce curve progression in patients with curves greater than 40°. This is likely to result in reduced morbidity for treated patients.

### Adult Symptomatic Lumbar Scoliosis

In 2009, Bridwell et al reported a prospective multicenter cohort study that compared operative versus nonoperative treatment of adult symptomatic lumbar scoliosis (defined as a minimum Cobb angle of 30°) in 160 consecutively enrolled patients.(8) Operative versus 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, the patients were matched using propensity scores that included baseline Cobb angle, Oswestry Disability Index (ODI), Scoliosis Research Society subscore, and a numerical rating scale for back and leg pain. The percentage of patients who returned for follow-up at 2 years was higher for operative than nonoperative patients (95% vs 45%), though the baseline measures for patients who were lost to follow-up was similar to those who were followed for 2 years. At the 2-year follow-up, nonoperative treatment had not improved quality of life or any other outcome measures, while the operative group showed significant improvement in all outcomes.

## Section Summary

No randomized controlled trials (RCTs) were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. A cohort study, which may be subject to selection bias from the patient choice of treatment, reported superior outcomes in patients treated with fusion compared with nonoperative controls.

### Isthmic Spondylolisthesis

In 2000, Moller and Hedlund reported a study of 111 patients with adult isthmic spondylolisthesis who were randomly assigned to posterolateral fusion (with or without instrumentation, n=77) or to an exercise program (n=34).(9) Inclusion criteria for the study were lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and a severely restricted functional ability. The mean age of patients was 39 years, with a mean age at onset of symptoms of 26 years. At 1- and 2-year follow-up, functional outcome (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 better in the surgically treated group compared with the exercise group.

## Section Summary

One RCT was identified that compared fusion versus an exercise program for patients with symptomatic isthmic spondylolisthesis. Results of this trial support that the use of fusion for this condition improves functional status compared with conservative treatment.

### Spinal Fracture

A 2006 qualitative systematic review compared operative and nonoperative treatment for thoracolumbar burst fractures in patients without neurologic deficit.(10) Two RCTs were identified, one by Wood et al in 2003 (described next) and a second small study by Alany et al with 20 patients.

The study by Wood et al 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.(11) At an average follow-up of 44 months (24 month minimum) the patients completed assessments of pain and function. At follow-up, the 2 groups were similar in the average fracture kyphosis, canal compromise, and return to work. Patients treated nonoperatively reported less disability on the ODI and Short Form-36 physical function, lower pain scores, and had fewer complications.

### **Section Summary**

Results of this small randomized trial indicate that spinal fusion may be associated with worse outcomes compared with conservative care in patients with spinal fracture without instability or neural compression.

### Lumbar Disc Herniation With Radiculopathy

Weinstein et al also reported on randomized (n=501) and observational (n=743) cohorts of patients from the SPORT trial with lumbar disc herniation and radiculopathy who received either discectomy or nonoperative care.(12,13) There was no mention of any patient undergoing fusion following discectomy. Specific inclusion criteria at enrollment were radicular pain (below the knee for lower lumbar herniations, into the anterior thigh for upper lumbar herniations) and evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise—positive between 30° and 70° or positive femoral tension sign) or a corresponding neurologic deficit (asymmetrical depressed reflex, decreased sensation in a dermatomal distribution, weakness in a myotomal distribution). Additionally, all participants were surgical candidates who had undergone advanced vertebral imaging (97% magnetic resonance imaging (MRI), 3% computed tomography (CT)) showing disk herniation (protrusion, extrusion, sequestered fragment) at a level and side corresponding to the clinical symptoms. Patients with multiple herniations were included if only 1 of the herniations was considered symptomatic (ie, if only 1 was planned to be operated on). Exclusion criteria included prior lumbar surgery, cauda equina syndrome, scoliosis greater than 15°, segmental instability (>10° angular motion or >4-mm translation), vertebral fractures, spine infection or tumor, inflammatory spondyloarthropathy, pregnancy, comorbid conditions contraindicating surgery, inability/unwillingness to have surgery within 6 months. In the randomized cohort, 50% of patients assigned to discectomy and 30% of patients assigned to nonoperative treatment received surgery in the first 3 months. Intention-to-treat analysis for the randomized cohort found a small advantage for patients assigned to discectomy with no significant differences between the 2 groups for the primary outcome measures. Analysis by treatment received found significant advantages for discectomy. In the observational cohort, the 528 patients who chose surgery had greater improvement in the primary outcome measures of bodily pain, physical function, and ODI compared with the 191 patients who received usual nonoperative care. All groups improved over time.

### **Section Summary**

Current evidence, which includes a large RCT, supports that surgical treatment with discectomy improves outcomes for lumbar disc herniation with radiculopathy. However, there is no evidence to support that the addition of spinal fusion to discectomy improves outcomes in patients with the sole indication of lumbar disc herniation without instability.

### Chronic Low Back Pain Without Radiculopathy

Nonspecific chronic low back pain (CLBP) is persistent low back pain that is not attributable to a recognizable, known specific pathology such as infection, tumor, osteoporosis, fracture, structural deformity (eg, spondylolisthesis, scoliosis), inflammatory disorder, radiculitis, or cauda equine syndrome. Surgical interventions, including fusion and disc arthroplasty, have been applied with the belief that abnormal intersegmental movement or degenerative pathology may be the cause of CLBP.(14)

A systematic review from 2013 assessed the number of studies that had been published up until that time on surgical fusion for CLBP.(15) As of September 2012, 4 RCTs with a total of 981 patients had been published comparing surgical versus nonsurgical approaches to CLBP. In contrast, 33 RCTs with a total of 3790 patients had compared variations of surgical techniques.

Another systematic review from 2013 compared lumbar fusion versus conservative treatment in patients with CLBP.(16) Meta-analysis of 4 trials (described next) with a total of 666 patients reported a reduction in the ODI that was -2.91 in favor of lumbar fusion. However, this did not attain statistical significance or the minimal clinically significant difference in ODI of 10 points. There was evidence of publication bias that favored placebo. The review concluded that there is strong evidence that lumbar fusion does not lead to a clinically significant reduction in perceived disability compared with conservative treatment in patients with CLBP and degenerative spinal disease. The review also concluded that it is unlikely that further research on the subject would alter this conclusion.

In 2012, the Agency for Healthcare Research and Quality posted for public comment a draft of an updated technology assessment on spinal fusion for treating painful lumbar degenerated discs or joints.(17) The draft, which reviewed 4 of the studies described next, concluded that the evidence was minimally sufficient to conclude that fusion was associated with improved back pain and function at 2 years compared with physical therapy, but that the clinical significance of these findings was uncertain. This technology assessment is being finalized for publication.

One of the studies that compared surgical versus nonsurgical treatment for CLBP was a 2001 multicenter trial by the Swedish Lumbar Spine Study Group.(18) In this study, 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. With intention-to-treat analysis, the surgical group showed a greater reduction in back pain (33% vs 7%), disability according to ODI (25% vs 6% reduction), Million visual analog score (VAS, 28% vs 8%), and General Function Score (GFS, 31% vs 4%). Significantly more surgical patients were back to work (36% vs 13%), and more reported their outcome as better or much better (63% vs 29%).

A 2005 trial from the English Spine Stabilisation Trial Group was a pragmatic multicenter randomized trial that compared spinal fusion with an intensive (approximately 75 hours) physical and cognitive-behavioral rehabilitation program.(19) Patients (n=349) who had back pain for at least 1 year and were considered candidates for surgical stabilization of the spine by the treating physician were randomized if the clinician and patient were uncertain which of the

study treatment strategies were best. Radiologic findings were not part of the inclusion criteria. By the 2-year follow-up, 48 (28%) of patients who were randomized to rehabilitation had undergone surgery. Results for 1 of the 2 primary outcome measures (ODI) showed a modest but significantly greater improvement (4.1 points) in the surgery group. There were no significant differences between the groups for the walking test or for any of the secondary outcome measures.

In 2010, Brox et al reported 4-year follow-up from 2 randomized trials that compared surgery versus cognitive intervention and exercises in 124 patients with disc degeneration.(20) One of the studies enrolled patients with CLBP and radiographic evidence of disc degeneration; the other enrolled patients with chronic back pain after previous surgery for disc herniation. The criteria for symptomatic degenerative disc disease were based on imaging without other diagnostic tests to identify the source of the CLBP. The combined 4-year follow-up rate was 92% in the surgical group and 86% in the nonsurgical group. In the nonsurgical group, 24% had undergone surgery by 4 years. In the surgical group, 15 (25%) had reoperation for persistent complaints or deterioration of the condition. In the intention-to-treat analysis, there was no significant difference between the groups in the ODI or in the percentage of patients who were on disability at 4 years. For the secondary outcomes, the only treatment effect identified was a reduction of fear-avoidance beliefs favoring cognitive intervention and exercises. Interpretation of this study is limited by the high percentage of crossovers from nonsurgical to surgical treatment.

A smaller trial that is frequently cited is a 2011 study by Ohtori et al.(21) In this study, patients with discogenic low back pain for at least 2 years (without radiculopathy) were selected following demonstration of disc degeneration at 1 level based on MRI, pain provocation on discography, and pain relief following intradiscal injection of anesthetic. Forty-six patients did not agree to undergo discography or intradiscal anesthetic injection, and 11 patients were excluded because of negative results. Most of the patients (70%) were categorized with a bulging disc and the remaining had evidence of disc degeneration on MRI. The 41 patients included in the study were divided into a walking and stretching group (over a period of 2 years, n=20), or discectomy and fusion (n=21). The approach was anterior lumbar interbody fusion (ALIF, n=15) or alternatively posterolateral fusion (PLF, n=6) if the anterior approach was technically difficult due to blood vessel anatomy. At 2 years of follow-up, there was improvement for all groups on the VAS, Japanese Orthopedic Association Score, and ODI. The 2 surgical groups scored significantly better compared with the minimal treatment group on all measures, with some advantage of ALIF over PLF. For example, VAS improved from 7.7 to 4.7 in the minimal treatment group, from 7.4 to 1.3 in the ALIF group, and from 6.5 to 3.5 in the PLF group. A limitation of this study is the minimal treatment provided to the control group.

### Section Summary

The results of trials comparing fusion with nonsurgical management in this population are mixed. A meta-analysis of results from 4 RCTs found no clinically significant advantage of lumbar fusion over conservative therapy in patients with CLBP that is not attributable to a recognizable, known specific pathology such as, infection, tumor, osteoporosis, fracture, structural deformity (eg, spondylolisthesis, scoliosis), inflammatory disorder, radiculitis, or cauda equine syndrome. The strongest benefits of surgery were reported in a study of patients who had been on sick leave or disability for more than 1 year, while no advantage of surgery was found when the 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 percentage of patients who cross over to surgery, variances in the type of spinal fusion (eg, posterolateral vs interbody), and uncertainty in establishing whether the source of CLBP is from degenerative disc disease.

### **Clinical Input Received Through 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 NASS and American Association of Neurological Surgeons/Congress of Neurological Surgeons, with 3 additional reviewers identified through a third physician specialty society and 2 academic medical centers. The input addressed specific criteria to determine the medical necessity of lumbar spinal fusion.

### **Summary**

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, or allogeneic donor bone. The literature was examined on the use of fusion for the following indications:

- *Spinal Stenosis with spinal instability.* Findings from the SPORT trial, in which 95% of patients in the surgical group underwent decompression with fusion, and a smaller study that specifically assessed the addition of fusion to decompression, support that fusion in patients with spinal stenosis associated with spondylolisthesis improves outcomes and therefore may be considered medically necessary for this indication.
- *Idiopathic Scoliosis.* Long-term follow-up of a large case series and guidelines from the Scoliosis Research Society provide support that fusion can reduce curve progression in patients with curves greater than 40°. Therefore, lumbar spinal fusion may be considered medically necessary for this population.
- *Degenerative Scoliosis.* No randomized controlled trials were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. A cohort study found superior outcomes in patients treated with fusion compared with nonoperative controls. Based on this evidence, clinical input, and the strong rationale for its efficacy, spinal fusion may be considered medically necessary for adults with degenerative scoliosis.
- *Isthmic Spondylolisthesis.* One RCT was identified that compared fusion versus an exercise program in patients with symptomatic isthmic spondylolisthesis. Results of this trial support that fusion may be considered medically necessary for this condition.
- *Spinal Fracture.* Results of 1 small randomized trial indicate that spinal fusion for patients with spinal fracture without instability or neural compression may result in worse outcomes than nonsurgical management, and therefore spinal fusion is considered not medically necessary for this indication.
- *Herniated Discs.* Current evidence, which includes the large randomized controlled SPORT trial, supports surgical treatment with discectomy for lumbar disc herniation. Evidence is insufficient to conclude that the addition of fusion to discectomy improves outcomes in patients with lumbar disc herniation without instability. As a result, lumbar spinal fusion is considered investigational for this indication.

- *Nonspecific Chronic Low Back Pain.* Meta-analysis of results from 4 RCTs found no clinically significant advantage of lumbar fusion over conservative therapy in patients with nonspecific chronic low back pain that is unresponsive to conservative management. While some trials have reported a benefit, others have not. Due to the uncertainty as to whether outcomes are improved, spinal fusion is considered investigational for this population.

### Practice Guidelines and Position Statements

In 2014, the North American Spine Society (NASS) published coverage policy recommendations for lumbar fusion.(22) 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 describes situations where lumbar fusion would not be indicated as disc herniation in the absence of instability or spondylolisthesis; stenosis in the absence of instability, foraminal stenosis or spondylolisthesis; and discogenic low back pain that does not meet the recommended criteria.

2008 Guidelines from NASS addressed the diagnosis and treatment of *degenerative lumbar spondylolisthesis*.(2,23)

- NASS gave a grade B recommendation for 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, and a grade C recommendation for 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.

2011 Guidelines from NASS the addressed multidisciplinary spine care for adults with a chief complaint of *degenerative lumbar spinal stenosis*.(1,24)

- The guidelines indicate that the nature of the pain and associated patient characteristics should be more typical of a diagnosis of spinal stenosis than herniated disc. The evidence review addressed whether the addition of lumbar fusion to surgical decompression improves surgical outcomes in the treatment of spinal stenosis compared with treatment by decompression alone. NASS gave a grade B recommendation (fair evidence) for decompression alone for patients with leg predominant symptoms without instability

2012 Guidelines from NASS addressed multidisciplinary spine care for the diagnosis and treatment of *lumbar disc herniation with radiculopathy*.(25,26)

- The guidelines indicate 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. The best evidence available suggests that outcomes are equivalent in patients with radiculopathy due to lumbar disc herniation whether or not a fusion is performed. Grade of Recommendation: I (Insufficient Evidence)

A series of 2005 guidelines from the American Association of Neurological Surgeons (AANS) addressed fusion procedures for the lumbar spine.

- *One- or two-level degenerative disease without stenosis or spondylolisthesis:* Lumbar fusion is recommended as a standard treatment for carefully selected patients.(27)
- *Disc herniation and radiculopathy:* There was insufficient evidence to recommend a treatment standard. As an option 1) Lumbar spinal fusion is not recommended as routine treatment following primary disc excision in patients with a herniated lumbar disc causing

radiculopathy. 2) Lumbar spinal fusion is recommended as a potential surgical adjunct in patients with a herniated disc in whom there is evidence of preoperative lumbar spinal deformity or instability. 3) Lumbar spinal fusion is recommended as a potential surgical adjunct in patients with significant chronic axial low-back pain associated with radiculopathy due to a herniated lumbar disc. 4) Reoperative discectomy is recommended as a treatment option in patients with a recurrent lumbar disc herniation. 5) Reoperative discectomy combined with fusion is recommended as a treatment option in patients with a recurrent disc herniation associated with lumbar instability, deformity, or chronic axial low-back pain.(28)

- *Stenosis and spondylolisthesis*: There was insufficient evidence to recommend a treatment standard or guideline. As an option, the performance of a lumbar posterolateral fusion (PLF) is recommended for patients with lumbar stenosis and associated degenerative spondylolisthesis who require decompression.(29)
- *Stenosis without spondylolisthesis*: There was insufficient evidence to recommend a treatment standard or guideline. As an option, 1) In situ posterolateral lumbar fusion is not recommended as a treatment option in patients with lumbar stenosis in whom there is no evidence of preexisting spinal instability or likely iatrogenic instability due to facetectomy. 2) In situ lumbar PLF is recommended as a treatment option in addition to decompression in patients with lumbar stenosis without deformity in whom there is evidence of spinal instability.(30)

A 2009 clinical practice guideline from the American Pain Society (APS) describes the following recommendations (31):

- In patients with *nonradicular low back pain* who do not respond to usual, noninterdisciplinary interventions, it is recommended that clinicians consider intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis" (strong recommendation, high-quality evidence)
- In patients with nonradicular low back pain, common *degenerative spinal changes*, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option" (weak recommendation, moderate-quality evidence)
- It is recommended that shared decision making regarding surgery for *nonspecific low back pain* include a specific discussion about intensive interdisciplinary rehabilitation as a similarly effective option, the small to moderate average benefit from surgery versus noninterdisciplinary nonsurgical therapy, and the fact that the majority of such patients who undergo surgery do not experience an optimal outcome. This recommendation is based on evidence that fusion surgery is superior to nonsurgical therapy without interdisciplinary rehabilitation, but no more effective than intensive interdisciplinary rehabilitation.
- There is insufficient evidence to determine if laminectomy with fusion is more effective than laminectomy without fusion.

In 2009, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) provided clinical guidelines on early management of persistent nonspecific low back pain.(32)

- NICE recommends that practitioners consider referral for spinal fusion for people who have completed an optimal package of care that includes a combined physical and psychological treatment program and still have severe nonspecific low back pain for which they would consider surgery.

**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)                                     |
| 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
- 22851 Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)

ICD-9 Diagnoses

170.2	Malignant neoplasm of vertebral column, excluding sacrum and coccyx
192.3	Malignant neoplasm of spinal meninges
198.3	Secondary malignant neoplasm of brain and spinal cord
198.4	Secondary malignant neoplasm of other parts of nervous system
198.5	Secondary malignant neoplasm of bone and bone marrow
225.3	Benign neoplasm of spinal cord
225.4	Benign neoplasm of spinal meninges
237.5	Neoplasm of uncertain behavior of brain and spinal cord
237.6	Neoplasm of uncertain behavior of meninges
238.0	Neoplasm of uncertain behavior of bone and articular cartilage
324.1	Intraspinal abscess
722.73	Intervertebral disc disorder with myelopathy; lumbar region
722.83	Postlaminectomy syndrome; lumbar region
724.02	Spinal stenosis, lumbar region
724.03	Spinal stenosis, other than cervical; lumbar region, with neurogenic claudication
724.6	Other and unspecified disorders of back; disorders of sacrum - Instability - lumbosacral
730.08	Acute osteomyelitis, other specified sites [spinal]
730.18	Chronic osteomyelitis, other specified sites [spinal]
730.28	Unspecified osteomyelitis, other specified sites [spinal]
730.78	Osteopathy resulting from poliomyelitis, other specified sites [spinal]
730.88	Other infections involving bone in disease classified elsewhere, other specified sites [spinal]
730.98	Unspecified infection of bone of other specified sites [spinal]
733.13	Pathologic fracture of vertebrae
733.82	Nonunion of fracture
737.30-737.39	Kyphoscoliosis and scoliosis
737.42	Lordosis, curvature of spine associated with other conditions
738.4	Acquired spondylolisthesis
756.12	Spondylolisthesis
805.4-805.5	Fracture of vertebral column without mention of spinal cord injury, lumbar
806.4-806.5	Fracture of vertebral column with spinal cord injury, lumbar
839.20	Dislocation of lumbar vertebra, closed
839.30	Dislocation of lumbar vertebra, open
V45.4	Arthrodesis status

ICD-10 Diagnoses (Effective October 1, 2015)

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
M48.06	Spinal stenosis, lumbar region
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"> <li>▪ Updated to current language from previous language of:</li> </ul> <p>"A. Lumbar spine fusion surgery is considered medically necessary for any one of the following conditions:</p> <ol style="list-style-type: none"> <li>1. Spinal fracture with instability or neural compression</li> <li>2. Tumor or infection (including abscess, osteomyelitis, or discitis) when debridement or resection is necessary to the extent that the spine becomes unstable</li> <li>3. Spinal stenosis with ALL of the following: <ol style="list-style-type: none"> <li>a. Associated spondylolisthesis demonstrated on imaging and</li> <li>b. Any one of the following: <ol style="list-style-type: none"> <li>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</li> <li>2) Detailed history and exam documenting signs and symptoms of Severe or rapidly progressive motor loss, neurogenic claudication or cauda equina syndrome</li> </ol> </li> </ol> </li> <li>4. Severe, progressive idiopathic scoliosis (i.e., lumbar or thoracolumbar) with Cobb angle &gt; 40 degrees</li> <li>5. Severe degenerative scoliosis with any one of the following: <ol style="list-style-type: none"> <li>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</li> </ol> </li> </ol>

	<p>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.</p> <p>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</p> <p>7. Recurrent disc herniation, i.e. 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> <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"> <li>▪ Disc herniation</li> <li>▪ Degenerative disc disease</li> <li>▪ Initial discectomy/laminectomy for neural structure decompression</li> <li>▪ Facet syndrome</li> </ul> <p><u>Policy Guidelines</u></p> <p>1. Conservative nonsurgical therapy must include the following:</p> <ul style="list-style-type: none"> <li>a. Use of prescription strength analgesics (including anti-inflammatory medications if not contraindicated), and</li> <li>b. Participation in physical therapy (including active exercise), and</li> <li>c. Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present.</li> </ul> <p>2. Significant functional impairment may include documentation of the following:</p> <ul style="list-style-type: none"> <li>▪ Inability or significantly decreased ability to perform normal daily activities of work, school or at-home duties.</li> </ul> <p>3. Persistent debilitating pain is defined as:</p> <ul style="list-style-type: none"> <li>a. Significant level of pain on a daily basis defined on a Visual Analog Scale (VAS) as greater than 4; and</li> <li>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."</li> </ul>
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	In Coding section:
	<ul style="list-style-type: none"> <li>▪ Added CPT Codes: 22586, 22818, 22819, 22841</li> <li>▪ Added ICD-9 Codes: 722.73, 722.83, 724.03, 724.6</li> <li>▪ Added ICD-10 Codes</li> </ul>
	Rationale section updated
	References updated

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