

## Draft Policies - Surgery

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Lumbar Spinal Fusion

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### Coverage:

**NOTE #1:** Conservative non-surgical therapy must include, but is not limited to:

- a. Use of prescription strength analgesics (including anti-inflammatory medications, if not contraindicated); and
- b. Participation in physical therapy that includes a program of active exercise;and
- c. Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present.

**NOTE #2:** Significant functional impairment may include documentation of inability, or significantly decreased ability, to perform normal daily activities of work, school, or at-home duties.

**NOTE #3:** Persistent debilitating pain is defined as:

- a. Significant level of pain on a daily basis defined on a Visual Analog Scale (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.

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

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

1. Spinal fracture with instability or neural compression;**or**
2. Spinal repair surgery for dislocation, tumor, or infection (including, but not limited to, abscess, osteomyelitis, discitis, or fungal infection) when extensive surgery is required that could create an unstable spine; **or**
3. Spinal stenosis, with:
  - a) Associated spondylolisthesis demonstrated on plain x-rays, **and**
  - b) Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative non-surgical therapy, and has documentation of central, lateral recess, or foraminal stenosis on MRI or other appropriate

imaging; **or**

4. Recurrent, same level, disc herniation at least 3 months after previous disc surgery in a patient who had experienced significant interval of relief of prior symptoms, and who has:

a) Recurrent neurogenic symptoms (radicular pain or claudication), **and**

b) Significant functional impairment, unresponsive to at least 3 months of conservative non-surgical therapy, **and**

c) Neural structure compression documented by MRI or other appropriate imaging; **or**

5. Adjacent segment degeneration, at least 3 months after previous fusion in a patient who had experienced significant interval of relief of prior symptoms, and who has

a) Recurrent neurogenic symptoms (radicular pain or claudication), **and**

b) Significant functional impairment, unresponsive to at least 3 months of conservative non-surgical therapy, **and**

c) Neural structure compression documented by MRI or other appropriate imaging; **or**

6. Isthmic spondylolisthesis, either congenital (Wiltse type I) or acquired pars defect (Wiltse II), that has been documented on x-ray, with persistent back pain (with or without neurogenic symptoms) and significant functional impairment in a patient who has failed at least 3 months of conservative non-surgical therapy; **or**

7. Severe progressive idiopathic scoliosis (i.e., lumbar or thoracolumbar) with Cobb angle greater than 40 degrees; **or**

8. Severe degenerative scoliosis with any one of the following:

a) Persistent axial (non-radiating) pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative non-surgical therapy, and has documentation of progression of deformity; **or**

b) Persistent and significant neurogenic symptoms (claudication or radicular pain) that results in significant functional impairment in a patient who has failed at least 3 months of conservative non-surgical therapy; **or**

9. Pseudoarthrosis, documented radiographically, no less than 3 months after initial fusion in a patient who had experienced significant interval of relief of prior symptoms, and who has:

a) Persistent axial back pain, with or without neurogenic symptoms; **and**

b) Significant functional impairment, **or**

10. Iatrogenic or degenerative flat back syndrome with significant sagittal imbalance, when fusion is performed with spinal osteotomy; **or**

11. Spinal tuberculosis.

Unless one of the above conditions is met, lumbar spinal fusion surgical procedures **are considered not medically necessary**.

Lumbar spinal fusion surgical procedures **are considered not medically necessary** if the sole indication is any one or more of the following:

1. Disc herniation,
2. Chronic nonspecific low back pain without radiculopathy,
3. Degenerative disc disease (DDD),
4. Initial discectomy/laminectomy for neural structure decompression,
5. Facet syndrome.

**NOTE:** For additional information on physical therapy please refer to medical policy THE803.010 Physical Therapy (PT) and Occupational Therapy (OT) Services.

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

### **Description:**

Lumbar spinal fusion (arthrodesis) is a surgical technique that involves 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 transpsoas interbody fusion/lateral interbody fusion (e.g., lateral transpsoas interbody fusion, extreme lateral interbody fusion, direct lateral lumbar interbody fusion), and transforaminal interbody fusion (TLIF). Posterolateral fusion (PLF) fuses the transverse processes alone and should be differentiated from the interbody procedures (e.g., 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. 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 (e.g., 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, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). Various instruments used in lumbar spinal fusion have been cleared for marketing by the FDA (e.g., INFUSE [rhBMP-2], OP-1 [rhBMP-7]) for specified indications.

## **Rationale:**

### **Spinal Stenosis**

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

There are 2 published RCTs that assessed the benefit of adding fusion to laminectomy, i.e. decompressive surgery alone compared to decompressive surgery plus fusion, both of these were published in 2016. These trials reported somewhat different results concerning benefit for the combined procedure. (3, 4)

In the Swedish Spinal Stenosis Study (SSS), 247 patients between 50 and 80 years of age who had lumbar spinal stenosis at 1 or 2 levels were randomized to undergo decompression plus fusion surgery or decompression surgery alone. (3) 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 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, did not differ significantly between groups at the 2- or 5-year follow-ups. 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%).

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 I, 3-14 mm) and symptomatic lumbar spinal stenosis. (4) Decompression was performed by laminectomy with partial removal of the medial facet joint. The fusion group, which underwent posterolateral instrumented fusion (PLF), had more blood loss and longer hospital stays. The primary outcome measure, change in 36-Item Short-Form Health

Survey (SF-36) 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 (MID) for 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 MID for ODI score was prespecified as a 10-point improvement, but the percentages of patients who achieved the MID 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 are questions about risk of surgeon bias in the recommendation for additional fusion surgery in patients who had undergone decompression alone.

A 1991 quasi-randomized 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 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 lumbar fusion (PLF) 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.

In 2007 and 2009, Weinstein et al. reported findings from the widely cited multicenter controlled trial (Spine Patient Outcomes Research Trial [SPORT]). The primary comparison in this study was decompressive surgery plus fusion compared to nonsurgical treatment for patients with lumbar spinal stenosis and degenerative spondylolisthesis. (6, 7) 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 I spondylolisthesis reached different conclusions. Both trials reported more frequent operative and perioperative adverse outcomes with the addition of fusion. The SSS trial found no benefit of surgery on clinical outcomes measured by ODI score, while the SLIP trial reported a small benefit measured by 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 the SPORT trial, 95% of patients in the surgical group underwent decompression with fusion and had improved outcomes compared to nonoperative therapy. Although this is an important trial of surgical therapy in patients with spinal stenosis, it evaluates whether the combination of decompressive surgery plus fusion is superior to nonsurgical therapy. It does not isolate the effect of fusion, therefore it is not possible to determine whether the benefit of surgery derived from decompression, fusion, or both. An earlier quasi-randomized study (Herkowitz et al.) 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, the lack of information on the surgical procedures in the SSS

trial, and the variation in outcome measures used. The current evidence base does not permit conclusions whether the addition of fusion to decompressive 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), 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 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. (8)

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. (9) 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 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 case series is consistent with 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 Degenerative 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. (10) 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, patients were matched using propensity scores that included baseline Cobb angle, 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 (95%) than nonoperative patients (45%), 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 had not improved quality of life or any other outcome measures, while the operative group showed significant improvement in all outcomes.

#### Section Summary: Adult Degenerative Scoliosis

No randomized controlled trials (RCTs) were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. A cohort study, which may have been subject to selection bias from patient choice of treatment, reported superior outcomes in patients treated with fusion compared to 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). (11) 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 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.

### Section Summary: Isthmic Spondylolisthesis

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 identified 2 RCTs that compared operative and nonoperative treatment for thoracolumbar burst fractures in patients without neurologic deficit. (12) The larger study, by Wood et al. in 2003, is described next. The other study identified in the systematic review had only 20 patients.

The trial 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. (13) At an average follow-up of 44 months (24-month minimum), patients completed assessments of pain and function. At follow-up, the 2 groups were similar in average fracture kyphosis, canal compromise, and return to work. Patients treated nonoperatively reported less disability on the ODI and 36-Item Short-Form Health Survey physical function, lower pain scores, and had fewer complications.

### Section Summary: Spinal Fracture

Results of a small RCT indicate that, compared to 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 herniated disc. Therefore, the most relevant comparison is discectomy plus fusion compared to discectomy alone. No RCTs were identified with that specific comparison.

The largest trial on surgery for herniated disc is the SPORT discectomy trial, which reported on randomized (n=501) and observational (n=743) cohorts of patients with lumbar disc herniation and radiculopathy who received either discectomy or nonoperative care. (14, 15) There was no mention of any patient undergoing fusion following discectomy. 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 found significant advantages for discectomy on the primary outcome measures.

### Section Summary: Lumbar Disc Herniation With Radiculopathy

Current evidence is lacking on whether the addition of fusion to discectomy improves outcomes compared to discectomy alone. One large RCT, indicates that surgical treatment with discectomy improves outcomes for lumbar disc herniation with radiculopathy compared to

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 persistent low back pain not attributable to a known specific pathology such as infection, tumor, osteoporosis, fracture, structural deformity (e.g., spondylolisthesis, scoliosis), 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. (16)

A 2013 systematic review assessed studies on surgical fusion for CLBP. (17) As of September 2012, 4 RCTs (total N=981 patients) had compared surgical and nonsurgical approaches for CLBP. In contrast, 33 RCTs (total N=3790 patients) had compared variations of surgical techniques. A 2015 systematic review identified many of the same RCTs that evaluated fusion for CLBP attributed to degenerative disc disease (DDD); a number of the included studies compared fusion with total disc replacement for presumed DDD. (18)

A 2014 meta-analysis compared lumbar fusion to conservative treatment in patients with CLBP. (19) Meta-analysis of 4 trials (total N=666 patients) reported a reduction in the ODI score that was -2.91 in favor of lumbar fusion. However, this improvement was not statistically significant nor reached the minimal clinically significant 10-point difference in ODI score. There was evidence of publication bias that favored placebo. The meta-analysis 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 meta-analysis also noted it is unlikely that further research on the subject would alter this conclusion.

One of the studies that compared surgical and nonsurgical treatment for CLBP was a 2001 multicenter trial by the Swedish Lumbar Spine Study Group. (20) 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. With 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), Million visual analog scale (VAS) 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 outcome 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 (approximately 75 hours) physical and cognitive-behavioral rehabilitation program. (21) 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 were 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.

In 2010, Brox et al. reported 4-year follow-up from 2 randomized trials that compared surgery to cognitive intervention and exercises in 124 patients with disc degeneration. (22) One of the trials 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 DDD 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 were no significant differences between groups in ODI scores or in percentages of patients on disability at 4 years. For the secondary outcomes, the only treatment effect identified was a reduction of fear-avoidance beliefs favoring cognitive-behavioral therapy (CBT) and exercises. Results of this study are confounded by the high percentage of crossovers from nonsurgical to surgical treatment.

In 2013, Mannion et al. (23) reported 11-year follow-up (range, 8-15 years) on 3 RCTs, including the 2 RCTs by Brox and Fairbanks described above. Of 473 patients originally enrolled in the trials, 261 (55%) agreed to participate in long-term follow-up and completed the outcome questionnaires. When controlling for baseline factors, both intent-to-treat and as-treated analysis showed no significant advantage for fusion over multidisciplinary CBT and exercise rehabilitation for patient-reported outcomes. However, only 40% had ODI scores in the normal range (ODI score  $\leq$  22/100) for either group. In addition, 40% of patients randomized to CBT and exercise rehabilitation had crossed over to fusion by the long-term follow-up.

Frequently cited, the smaller 2011 trial by Ohtori et al. assessed patients with discogenic low back pain for at least 2 years (without radiculopathy), who 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. (24) Forty-six patients did not agree to undergo discography or intradiscal anesthetic injection, and 11 patients were excluded (negative results). Most patients (70%) were categorized with a bulging disc; the remainder had evidence of disc degeneration on MRI. The 41 patients included in the trial were divided into a walking and stretching group (over 2 years, n=20) and a discectomy and fusion group (n=21). The surgical approach was anterior lumbar interbody fusion (ALIF; n=15) or posterolateral fusion (PLF; n=6) if the anterior approach was technically difficult due to blood vessel anatomy. At 2-year follow-up, there was improvement for all groups for VAS scores, Japanese Orthopedic Association Score, and ODI scores. The 2 surgical groups scored significantly better than the exercise group on all measures, with some advantage of ALIF over PLF. For example, VAS scores improved from 7.7 to 4.7 in the walking and stretching 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 trial is the nature of the treatment provided to the control group.

### Section Summary: Chronic Low Back Pain Without Radiculopathy

The results of trials comparing fusion to nonsurgical management in this population are mixed. A meta-analysis of 4 RCTs found no clinically significant advantage for lumbar fusion over conservative therapy in patients with CLBP not attributable to a known specific pathology (e.g., infection, tumor, osteoporosis, fracture, structural deformity, 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 (e.g., posterolateral vs interbody), and uncertainty in establishing whether the source of CLBP was DDD.

### **Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in April 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

## Summary of Evidence

For individuals who have spinal stenosis undergoing decompressive surgery who receive lumbar spinal fusion, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. There are 2 RCTs that compared decompressive surgery plus fusion to decompressive surgery alone. These trials reached different conclusions on the benefit of adding fusion to decompression in patients with low-grade (0%-25% slippage) spondylolisthesis. Both trials reported a larger number of operative and perioperative adverse outcomes with the addition of fusion. The SSS trial found no benefit of surgery on clinical outcomes, while the SLIP trial reported a small benefit in clinical outcomes and a reduction in number of subsequent surgeries when fusion was added to decompression. In the SPORT trial, decompressive surgery plus fusion was compared to 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 apart from that of decompressive 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 case series and society guidelines. Relevant outcomes are symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. Long-term follow-up of the large case series and guidelines from the Scoliosis Research Society provide support that fusion can reduce curve progression in patients with Cobb angles greater than 40°. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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. A cohort study found superior outcomes in patients treated with fusion compared with nonoperative controls. This evidence and the strong rationale indicates that lumbar spinal fusion improves outcomes in adults with degenerative scoliosis. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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. The RCT compared fusion to an exercise program in patients with symptomatic isthmic spondylolisthesis. Results support the conclusion that fusion improves functional status for this condition. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lumbar disc herniation with radiculopathy 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. Evidence is insufficient to conclude that the addition of fusion to discectomy improves outcomes in patients with lumbar disc herniation

without instability. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

## Practice Guidelines and Position Statements

### North American Spine Society

In 2014, North American Spine Society (NASS) published coverage policy recommendations for lumbar fusion. (25) Specific criteria were described for infection, tumor, traumatic injuries, deformity (e.g., scoliosis), stenosis, disc herniations, synovial facet cysts, discogenic low back pain, and pseudoarthrosis. NASS isolated situations where lumbar fusion would not be indicated: disc herniation in the absence of instability or spondylolisthesis; stenosis in the absence of instability; foraminal stenosis or spondylolisthesis; and discogenic low back pain not meeting the recommended criteria.

The 2007 guidelines from NASS addressed the diagnosis and treatment of *degenerative lumbar spondylolisthesis*. (2, 26) 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. A grade C recommendation was given 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.

The 2011 NASS guidelines (updated in 2013) addressed multidisciplinary spine care for adults with a chief complaint of *degenerative lumbar spinal stenosis*. (1, 27) 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 improved 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

The 2012 NASS guidelines (updated in 2014) addressed multidisciplinary spine care for the diagnosis and treatment of *lumbar disc herniation with radiculopathy*. (28, 29) The guidelines state 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. (30) These guidelines stated that there is no evidence that conflicts with the recommendations formulated in the 2005 guidelines for fusion procedures for the lumbar spine.

- *One- or two-level degenerative disease without stenosis or spondylolisthesis*(part 7): AANS and CNS recommend that lumbar fusion be performed for patients whose low back pain is

refractory to conservative treatment (physical therapy or other nonoperative measures) and is due to 1- or 2-level DDD without stenosis or spondylolisthesis (grade B, based on multiple level II studies). (31) A grade C recommendation was given that 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)” be considered as a diagnostic option during the evaluation of a patient presenting with chronic low back pain (single level II study), but that the potential for acceleration of the degenerative process be included in the discussion of potential risks (part 6). (32)

- *Disc herniation and radiculopathy* (part 8): Lumbar spinal fusion is not recommended as routine treatment following primary disc excision in patients with a herniated lumbar disc causing radiculopathy (grade C, level IV evidence). 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 (grade C, level IV evidence). 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 (grade C, level III evidence). (33)

- *Stenosis and spondylolisthesis* (part 9): Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with degenerative spondylolisthesis in patients who desire surgical treatment (grade B, level II evidence). There was insufficient evidence to recommend a standard fusion technique. (34)

- *Stenosis without spondylolisthesis* (part 10): Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who undergo surgical intervention (grade B, level II/III evidence). 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 (grade C, level IV evidence). (35)

- AANS and CNS also provided recommendations on (30):

- o Assessment of functional outcome following lumbar fusion (part 2),

- o Assessment of economic outcome (part 3),

- o Radiographic assessment of fusion status (part 4),

- o Correlation between radiographic outcome and function (part 5),

- o Interbody techniques for lumbar fusion (part 11),

- o Pedicle screw fixation as an adjunct to posterolateral fusion (part 12),

- o Injection therapies (part 13),

- o Brace therapy (part 14),

- o Electrophysiologic monitoring (part 15),

- o Bone growth extenders and substitutes (part 16), and

- o Bone growth stimulators (part 17).

A 2011 American College of Occupational and Environmental Medicine update of its guidelines on low back disorders stated that for third lumbar discectomy on the same disc, spinal fusion at the time of discectomy as a surgical option is not recommended (inconclusive/insufficient evidence). (36)

### American Pain Society

A 2009 clinical practice guideline from the American Pain Society offered the following recommendations (37):

- 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.

### Scoliosis Research Society

The Scoliosis Research Society states that the treatment of adolescent idiopathic scoliosis falls into 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression. (38)

“Observation is generally for patients whose curves are less than 25° who are still growing, or for curves less than 50° in patients who have completed their growth.”

“Bracing is for patients with curves that measure between 25° and 40° during their growth phase. The goal of the brace is to prevent the curve from getting bigger.”

“Surgical treatment is used for patients whose curves are greater than 45° while still growing or greater than 50° when growth has stopped. The goal of surgical treatment is two-fold: First, to prevent curve progression and secondly to obtain some curve correction.... Implants are used to correct the spine and hold it in the corrected position until the spine segments which have been operated on are fused as one bone.”

“Alternative treatments to prevent curve progression or prevent further curve progression such as chiropractic medicine, physical therapy, yoga, etc. have not demonstrated any scientific value in the treatment of scoliosis.”

In general, adolescent idiopathic scoliosis curves progress in 2 ways: 1) during the rapid growth period of the patient and 2) into adulthood if the curves are relatively large. Because scoliosis gets larger during rapid growth, the potential for growth is evaluated taking into consideration the patient's age, whether females have had their first menstrual period, as well as radiographic

parameters. The Risser grading system rates a child's skeletal maturity on a scale of 0 to 5. Patients who are Risser 0 and 1 are growing rapidly, while patients who are 4 and 5 have stopped growing.

### American Academy of Orthopaedic Surgeons

Information updated in 2010 from the American Academy of Orthopaedic Surgeons indicates 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. (39)

- Observation is appropriate when the curve is mild ( $<25^{\circ}$ ) 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  $25^{\circ}$  and  $45^{\circ}$ . There are several types of braces, most being the underarm type.
- Surgery may be recommended if the curve is greater than  $45^{\circ}$  and the child is still growing. If the patient has reached skeletal maturity, surgery may still be recommended for scoliotic curves that exceed  $50^{\circ}$  to  $55^{\circ}$ . 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 of Arthritis and Musculoskeletal and Skin Diseases

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in 2012 indicated that many children who are sent to a physician by a school scoliosis screening program "have very mild spinal curves that do not need treatment." (40) When treatment is needed, an orthopedic spine specialist will suggest the best treatment for each patient based on the "patient's age, how much more he or she is likely to grow, degree and pattern of the curve, and the type of scoliosis."

- Observation may be advised if the patient "is still growing (is skeletally immature) and the curve is mild."
- Doctors may advise patients "to wear a brace to stop a curve from getting any worse in patients who are still growing with moderate spinal curvature. As a child nears the end of growth, the indications for bracing will depend on how the curve affects the child's appearance, whether the curve is getting worse, and the size of the curve."
- Surgery may be advised "to correct a curve or stop it from worsening when the patient is still growing, has a curve that is severe [ $>45^{\circ}$ ], and has a curve that is worsening."

NIAMS also stated that studies of the following treatments have not demonstrated prevention of curve progression or worsening:

- Chiropractic manipulation
- Electrical stimulation

- Dietary supplements
- Exercise.

National Institute for Health and Clinical Excellence

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. (41) This guidance is currently in update. NICE recommended 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.

**Contract:**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

**Coding:**

**CODING:**

**Disclaimer for coding information on Medical Policies**

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

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

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

<b>CPT/HCPCS/ICD-9/ICD-10 Codes</b>
<b>The following codes may be applicable to this Medical policy and may not be all inclusive.</b>
<b>CPT Codes</b>
20930, 20931, 20936, 20937, 20938, 22533, 22534, 22558, 22585, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22848, 22851
<b>HCPCS Codes</b>
None
<b>ICD-9 Diagnosis Codes</b>
Refer to the ICD-9-CM manual
<b>ICD-9 Procedure Codes</b>

Refer to the ICD-9-CM manual
<b>ICD-10 Diagnosis Codes</b>
Refer to the ICD-10-CM manual
<b>ICD-10 Procedure Codes</b>
Refer to the ICD-10-CM manual

### Medicare Coverage:

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

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

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

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**Policy History:**

Date	Reason TBD Document updated with literature review. Chronic nonspecific low back pain without radiculopathy was added to the following coverage statement: Lumbar spinal fusion surgical procedures are considered not medically necessary if the sole indication is any one or more of the following: Chronic nonspecific low back pain without radiculopathy.
4/15/2015	Reviewed. No changes.
8/15/2014	Document updated with literature review. The following changes were made to Coverage: 1) Spinal repair surgery for dislocation, tumor, or infection may be considered medically necessary when extensive surgery is required that could create an unstable spine; 2) Any criteria that stated 6 months of conservative treatment or waiting period now states 3 months. In addition, the Description and Rationale were completely revised.
5/1/2013	New medical document. Lumbar spinal fusion may be considered medically necessary when stated criteria are met, and is considered not medically necessary when criteria are not met if the sole indication is any one or more of the following: a) Disc herniation; b) Degenerative disc disease (DDD); c) Initial discectomy/laminectomy for neural structure decompression; or d) Facet syndrome.

**Archived Document(s):**

Title:	Effective Date:	End Date:
Lumbar Spinal Fusion	08-15-2014	04-14-2015
Lumbar Spinal Fusion	05-01-2013	08-14-2014

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