Lumbar Spinal Fusion

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

1. **Spinal stenosis** with both of the following sub-criteria:
   a. Either one of the following:
      1. Associated spondylolisthesis is verified on plain x-rays and spinal instability is present with a 4 mm shift in the sagittal plane measured on functional flexion/extension films; OR
      2. Spinal instability is anticipated due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis (the posterior part of the vertebra that connects the upper and lower joints); imaging studies must document encroachment on the nerve root channel (neural foramen); **AND**
   b. Either one of the following:
      1. Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 month 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 one of the following:
   a. Cobb angle greater than 40 degrees 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 month of conservative care

3. **Severe degenerative scoliosis** (i.e., lumbar or thoracolumbar) with a minimum Cobb angle of 30 degrees, or significant sagittal imbalance (e.g., sagittal vertical axis > 5 cm), and with one of the following:
   a. Documented progression of deformity with persistent axial (non-radiating) pain and impairment or loss of function unresponsive to at least 1 year of conservative therapy 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 one of the following:
      1. Condition is unresponsive to at least 3 months of conservative nonsurgical care OR
      2. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome are present
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 or 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 (radicular pain or neurogenic claudication) 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

Lumbar spinal fusion is considered investigational if the sole indication is any one of the following conditions:
- Chronic nonspecific low back pain without radiculopathy
- Degenerative disc disease
- Disc herniation
- Facet syndrome
- Initial discectomy/laminectomy for neural structure decompression

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

Multiple level lumbar spinal fusions are considered not medically necessary when the criteria listed above are not met for all levels that will be surgically fused.

NOTE: Smoking during the 6-weeks just prior to scheduled surgery is a contraindication for lumbar spinal fusion. (See Policy Guidelines for Definition of Terms and Documentation requirements related to smoking cessation)

This policy does not address the pre-operative cessation of smokeless/chewing/dipping/snuff tobacco or nicotine replacements such as electronic cigarettes (e-cigs), nicotine gum, nicotine lozenges and nicotine patches because there was no literature or studies found, to date, that report the effect of these products on orthopedic surgical outcomes. (See Policy Guidelines for Definition of Terms and Documentation requirements related to smoking cessation)

See Policy Guidelines for Documentation that must be submitted for review.

Related Policies

7.01.85 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

7.01.87 Artificial Intervertebral Disc: Lumbar Spine
## Definition of Terms

**Cauda equina syndrome (CES)** – Cauda equina are the nerve roots (resembling a horse’s tail) that continue from where the spinal cord ends, and branches down to the lower part of the body. (Cauda equina is Latin for horse’s tail).

- Cauda Equina Syndrome (CES) - is considered a surgical emergency with a rapid progression of neurologic symptoms that may include but are not limited to:
  - severe sharp/stabbing debilitating low back pain that starts in the buttocks and travels down one or both legs, with severe muscle weakness,
  - inability to start/stop urine flow,
  - inability to start/stop bowel movement,
  - loss of sensation below the waist and
  - absence of lower extremity reflexes.

CES is caused by compression of the cauda equina nerves of the lower spine by a herniated disk, infection, cancer, trauma, or spinal stenosis.

**Neurogenic claudication** (also known as pseudoclaudication) – A common indicator of lumbar spinal stenosis. The problem is caused by an inflamed nerve coming from the spinal column. The sensation of pain or weakness in the legs that is relieved with a change in position or leaning forward are some of the symptoms.

**Conservative nonsurgical therapy** - For the duration specified should include the following:
- Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
- Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants (if not contraindicated) AND
- Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present
- Documentation of patient compliance with preceding criteria.

**Persistent debilitating pain** - Defined as:
- Significant level of pain on a daily basis defined on a visual analog scale (VAS) as greater than 4; AND
- Pain on a daily basis that has a documented impact on activities of daily living in spite of optimal conservative nonsurgical therapy as outlined above and appropriate for the patient.

**Radicular pain** – Pain that radiates along a dermatome of a nerve due to inflammation/irritation/compression of the nerve root that connects to the spinal column. Also known as radiculitis, a common form is sciatica

**Restricted functional ability** – Severely restricted functional ability generally includes loss of function and/or documentation of inability or significantly decreased ability to perform normal daily activities of work, school or at-home duties.

**Smoking cessation** – Smoking cessation for the 6-weeks prior to scheduled (non-emergent) surgery applies to smoking cigarettes, cigars and pipe smoking of tobacco.
Documentation
The following information must be submitted to ensure an accurate, expeditious and complete review for lumbar spinal fusion surgery:

- Specific procedures requested with related procedure/diagnosis codes and identification of the disc levels for surgery
- Office notes that include a current history and physical exam
- Clinical notes that document the requesting surgeon personally evaluated the individual at least twice before submitting a request for surgery (except in cases of malignancy, trauma, infection or rapidly progressive neurologic symptoms)
- Detailed documentation of the extent and response to conservative therapy, including outcomes of any procedural interventions, medication use and physical therapy/physiatrist notes
- Documentation of current smoking status, and a written statement that the patient was non-smoking for the 6-weeks prior to scheduled (non-emergent) surgery. (Not applicable to emergent surgery). (See Definition of Terms for smoking cessation)
- Copy of the radiologist's report for diagnostic imaging (MRI, CT, etc.) done within the past 12 months prior to surgery. Imaging must be performed and read by an independent radiologist. If there are discrepancies in the interpretation of the imaging, the radiologist's report will supersede
- Copy of most recent x-ray report of flexion-extension films that show the presence of lumbar spine instability

Description

Background
Fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction (see Appendix). Anterior (ALIF) or posterior lumbar interbody fusion (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 [LTIF], extreme lateral interbody fusion [XLIF], direct lateral lumbar interbody fusion [DLIF]), 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 (DDD). DDD 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 non-specific low back pain that is not responsive to nonsurgical measures (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], analgesics, and physical therapy), when definite indications for fusion are not present. Across the United States, there is wide
variation in the rates of lumbar spinal fusion, and many experts consider lumbar fusion to be overused, indicating a need for better standardization and uniformity in the application of this procedure.

**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 the FDA. Infuse (rhBMP-2) and OP-1 (rhBMP-7) are approved by the FDA for specified indications.

**Scope**
Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Benefit Application**
N/A

**Rationale**
This policy was created in March 2011 with a regular literature search of the MEDLINE database. The most recent literature review was performed through August, 2015. Below is a summary of key studies to date.

**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.

The NASS defines lumbar degenerative spondylolisthesis as an acquired anterior displacement of one 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 time point, 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 non-operative treatment. This quasi-randomized prospective study used alternating assignment to the 2 treatment groups. At a mean follow-up of 3 years (range, 2.4 to 4.0), the patients who had posterolateral lumbar fusion (PLF) together with decompression had significantly improved outcomes, as measured by overall outcomes and numeric rating scales, compared to 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, or secondary), the 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 United States 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 non-operative 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, non-operative 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 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 to non-operative 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 to the exercise group.

Section Summary
One RCT was identified that compared fusion vs. 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 to conservative treatment.

Spinal Fracture
A 2006 qualitative systematic review compared operative and nonoperative treatment for thoracolumbar burst fractures in patients without neurological deficit. (10) Two RCTs were identified, one by Wood et al. in 2003 (described below) 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 neurological deficit or loss of structural integrity to fusion with instrumentation or to non-operative 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 SF-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 to 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, or weakness in a myotomal distribution). Additionally, all participants were surgical candidates who had undergone advanced vertebral imaging (97% magnetic resonance imaging, 3% computed tomography) showing disk herniation (protrusion, extrusion, or sequestered fragment) at a level and side corresponding to the clinical symptoms. Patients with multiple herniations were included if only one of the herniations was considered symptomatic (i.e., if only one 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, or inability/unwillingness to have surgery within 6 months. In the randomized cohort, 50% of patients assigned to discectomy and 30% of patients assigned to non-operative treatment received surgery in the first 3 months. Intent-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 to the 191 patients who received usual non-operative 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.

Tobacco Use and Spinal Fusion
Tobacco use has been recognized as a contributor to poor healing and is associated with an increased risk of non-union by several researchers. Deyo, et al., found an increased risk of major complications in their 2010 study of adults who underwent lumbar fusion for spinal stenosis. (14) As early as 1986, (Brown et al.) noted a higher rate of pseudoarthrosis in individuals who used tobacco and underwent spinal fusion. (15) Anderson, et al (2001) found that fusion mass was decreased in smokers, and that smokers had a lower bone density over all. (16) They also found that smoking cessation increases fusion rates to close to those of non-smokers. Tobacco use has also been associated with less pain relief, poorer functional improvement in rehabilitation, and poorer rates of satisfaction (17) Others have reported that smoking cessation correlates with outcomes that are similar to those seen in non-smokers (18).

The American Academy of Orthopedic Surgeons (AAOS) strongly recommends avoiding use and exposure to tobacco products because of the negative impact on the musculoskeletal system including the bones, muscle, tendons and ligaments (19, 20). Lumbar fusion is usually an elective surgery; and ideally individuals should be in the best physical condition prior to undergoing surgery. The guidelines recommend smoking cessation for 4-8 weeks prior to surgery. The International Society of Advancement for Spine Surgery also recommends that while undergoing conservative care prior to surgery smokers should be encouraged to stop smoking as smoking aggravates low back pain, is a risk factor for multiple systemic health problems, and increases the risk from poor outcomes of spine surgery (21).

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 (e.g., 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. (22)

A systematic review from 2013 assessed the number of studies that had been published up until that time on surgical fusion for CLBP. (23) 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 3,790 patients had compared variations of surgical techniques.

Another systematic review from 2013 compared lumbar fusion vs. conservative treatment in patients with CLBP. (24) 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 to 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 (AHRQ) posted for public comment a draft of an updated technology assessment on spinal fusion for treating painful lumbar degenerated discs or joints. (25) As of September, 2014, AHRQ lists the report as in the final production phase. (26) The draft, which reviewed 4 of the studies described below, 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 multi-center trial by the Swedish Lumbar Spine Study Group. (27) 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 intent-to-treat analysis, the surgical group showed a greater reduction in back pain (33% vs. 7%), disability according to the 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 multi-center randomized trial that compared spinal fusion with an intensive (approximately 75 hours) physical and cognitive-behavioral rehabilitation program. (28) 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. Radiological 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 and colleagues reported 4-year follow-up from 2 randomized trials that compared surgery versus cognitive intervention and exercises in 124 patients with disc degeneration. (29) 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 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 non-surgical group. In the non-surgical group, 24% had undergone surgery by 4 years. In the surgical group, 15 (25%) had re-operation 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 cross-overs from non-surgical to surgical treatment.

A smaller trial that is frequently cited is a 2011 study by Ohtori et al. (30) 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. A majority 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 visual analog score (VAS), Japanese Orthopedic Association Score (JOAS), and the ODI. The 2 surgical groups scored significantly better compared to 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 to non-surgical 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 (e.g. spondylolisthesis, scoliosis), inflammatory disorder, radiculitis, or cauda equina 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 (e.g., posterolateral versus interbody), and uncertainty in establishing whether the source of CLBP is from DDD.

**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 the North American Spine Society and American Association of Neurological Surgeons, and the 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. This input has been incorporated into the policy.

Summary of Evidence
Lumbar spinal fusion (arthrodesis) is a surgical technique that involves fusion of two 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 degrees. Therefore, lumbar spinal fusion may be considered medically necessary for this population.

- **Degenerative Scoliosis.** 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 to non-operative 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 RCT 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 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. As a result, lumbar spinal fusion is considered investigational for this indication.

- **Non-specific 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 non-specific 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

**North American Spine Society (NASS)**
In 2014, NASS published policy recommendations for lumbar fusion. (31) 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 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.

The 2008 guidelines from NASS addressed the diagnosis and treatment of degenerative lumbar spondylolisthesis. (2, 32)

- 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.

The 2011 guidelines from NASS addressed multidisciplinary spine care for adults with a chief complaint of degenerative lumbar spinal stenosis. (1, 33)

- 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 to treatment by decompression alone. The NASS gave a grade B recommendation (fair evidence) for decompression alone for patients with leg predominant symptoms without instability.

The 2012 guidelines from NASS addressed multidisciplinary spine care for the diagnosis and treatment of lumbar disc herniation with radiculopathy. (34, 35)

- 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)

American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS)
The 2014 guidelines from the AANS and CNS addressed fusion procedures for the lumbar spine. (36) The 2014 guidelines state that there is no evidence that conflicts with the recommendations formulated in the 2004 guidelines for fusion procedures for the lumbar spine.

- One-level or two-level degenerative disease without stenosis or spondylolisthesis (part 7): AANS/CNS recommends 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 degenerative disc disease without stenosis or spondylolisthesis (grade B, based on multiple Level II studies). (37) 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). (38)

- 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 disc (grade C, level IV evidence). 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 (grade C, level III evidence). (39)

- 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. (40)

- Stenosis without spondylolisthesis (part 10): Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention (grade B, level II/III evidence). In the absence of deformity or instability, lumbar fusion is not recommended as it has not been shown to improve outcomes in patients with isolated stenosis (grade C, level IV evidence) (41)

- AANS/CNS also provided recommendations on (36):
  - Assessment of functional outcome following lumbar fusion (part 2),
  - Assessment of economic outcome (part 3),
  - Radiographic assessment of fusion status (part 4),
  - Correlation between radiographic outcome and function (part 5),
  - Interbody techniques for lumbar fusion (part 11),
  - Pedicle screw fixation as an adjunct to posterolateral fusion (part 12),
  - Injection therapies (part 13),
  - Brace therapy (part 14),
Electrophysiological monitoring (part 15), Bone growth extenders and substitutes (part 16), and Bone growth stimulators (part 17).

American College of Occupational and Environmental Medicine (ACOEM)
A 2011 ACOEM update of their guidelines on low back disorders state that for third lumbar discectomy on the save disc, spinal fusion at the time of discectomy as an option has a recommendation of inconclusive/insufficient evidence (I). (42)

American Pain Society (APS)
A 2009 clinical practice guideline from the (APS describes the following recommendations: (43)
- 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 non-interdisciplinary 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.

National Institute for Health and Clinical Excellence (NICE)
In 2009, the United Kingdom’s NICE provided clinical guidelines on early management of persistent non-specific low back pain. (44)
- 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 non-specific low back pain for which they would consider surgery.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (USPSTF) has not addressed lumbar fusion.

Medicare National Coverage
In 2006, the Medicare Evidence Development and Coverage Advisory Committee was convened to provide recommendations on the quality and strength of evidence for the benefits and risks of spinal fusion surgery for chronic low back pain from lumbar degenerative disc disease. (45) Included in the meeting materials was a technology assessment that was commissioned by Agency for Healthcare Research and Quality to evaluate spinal fusion for treatment of degenerative disease affecting the lumbar spine.

References
3. Weinstein JN, Lurie JD, Tosteson TD et al. Surgical versus nonsurgical treatment for lumbar degenerative


45. Centers for Medicare and Medicaid Services. Spinal Fusion for the Treatment of Low Back Pain Secondary to Lumbar Degenerative Disc Disease. 2006. Available online at: http://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?TAId=41&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CCN CD%7CMEDCA%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Both&s=all&CntGrpType=1&KeyWord=health&KeyWordLookUp=Title&KeyWordSearchType=Exact&ICD=525.65&CptHcpcCode=222222&DateTag=C&bc=AAAAAAAAAAAAAAAA%3D%3D. Accessed September, 2015.

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0309T</td>
<td>Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft, when performed, lumbar, L4-L5 interspace (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td></td>
<td>22533</td>
<td>Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
</tr>
<tr>
<td></td>
<td>22534</td>
<td>Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression; thoracic or lumbar, each additional vertebral segment</td>
</tr>
<tr>
<td></td>
<td>22558</td>
<td>Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
</tr>
<tr>
<td></td>
<td>22585</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td>22586</td>
<td>Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace</td>
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<tr>
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<td>22612</td>
<td>Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)</td>
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<tr>
<td></td>
<td>22614</td>
<td>Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td></td>
<td>22630</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar</td>
</tr>
<tr>
<td></td>
<td>22632</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td>22633</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>22634</td>
<td>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)</td>
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<td>22800</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments</td>
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<tr>
<td></td>
<td>22802</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments</td>
</tr>
<tr>
<td></td>
<td>22804</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments</td>
</tr>
<tr>
<td></td>
<td>22808</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments</td>
</tr>
<tr>
<td></td>
<td>22810</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments</td>
</tr>
<tr>
<td></td>
<td>22812</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments</td>
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<td></td>
<td>62290</td>
<td>Injection procedure for discography, each level; lumbar</td>
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<td>63030</td>
<td>Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, lumbar</td>
</tr>
</tbody>
</table>
Procedures used for lumbar interbody fusion differ primarily in the direction of approach to the spine, i.e., from the front (anterior), from the back (posterior or transforaminal) or from the side (lateral). An alternative approach to interbody fusion is arthrodesis of the transverse processes alone (posterolateral) which does not fuse the adjoining vertebral bodies. Circumferential fusion fuses both the adjacent vertebral bodies and the transverse processes, typically using both an anterior and posterior approach to the spine.

Open and Minimally Invasive Approaches to Lumbar Interbody Fusion (LIF)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Access</th>
<th>Approach</th>
<th>Visualization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior (ALIF)</td>
<td>Open, MI, or laparoscopic</td>
<td>Transperitoneal or retroperitoneal</td>
<td>Direct, endoscopic or laparoscopic with fluoroscopic guidance</td>
</tr>
<tr>
<td>Posterior (PLIF)</td>
<td>Open or MI</td>
<td>Incision centered over spine with laminectomy/laminotomy and retraction of nerve</td>
<td>Direct, endoscopic or microscopic, with fluoroscopic guidance</td>
</tr>
<tr>
<td>Transforaminal (TLIF)</td>
<td>Open or MI</td>
<td>Offset from spine, through the intervertebral foramen via unilateral facetectomy</td>
<td>Direct, endoscopic or microscopic, with fluoroscopic guidance</td>
</tr>
<tr>
<td>Lateral Extreme lateral (XLIF) Direct lateral (DLIF)</td>
<td>MI</td>
<td>Retroperitoneal through transpsoas</td>
<td>Direct, with neurologic monitoring and fluoroscopic guidance</td>
</tr>
</tbody>
</table>

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

Posterior Lumbar Interbody Fusion (PLIF)
PLIF can be performed through either a traditional open procedure with a midline incision or with a minimally invasive approach using bilateral paramedian incisions. In the open procedure, the midline muscle attachments are divided along the central incision to facilitate wide muscle retraction and laminectomy. In minimally invasive PLIF, tubular retractors may be used to open smaller central bilateral working channels to access the pedicles and foramen. Minimally invasive PLIF typically involves partial laminotomies and facetectomies. The decompression allows treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum), as well as stabilization of the spine through interbody fusion.

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

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

**Circumferential Fusion**

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

**Posterolateral Fusion (PLF)**

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/08/11</td>
<td>Add to Surgery Section - New Policy held for provider notification. The effective and publication date will be 9/1/2011.</td>
</tr>
<tr>
<td>05/18/11</td>
<td>Policy Published - The policy was published on the internal and external sites with an effective date of September 1, 2011.</td>
</tr>
<tr>
<td>12/2/11</td>
<td>Related Policies updated; 7.01.115 removed.</td>
</tr>
<tr>
<td>01/11/12</td>
<td>Codes 22633 and 22634 added.</td>
</tr>
<tr>
<td>09/11/12</td>
<td>Replace policy - Policy statements extensively revised for clarification. Instability clarified by adding 4 mm of translational instability. Spinal stenosis criteria clarified. Pseudoarthrosis criteria clarified by adding lucency around the hardware per x-ray or CT scan. Failure of 6 months of nonsurgical care removed from all policy statements. Added reference 16.</td>
</tr>
<tr>
<td>10/09/12</td>
<td>Replace policy - Added definitions for truncal imbalance. Added clarity to spondylolisthesis statement – It is measured in the sagittal plane on functional flexion and extension views on upright x-ray. MRI and CT removed from bullet. Added references 17 and 18.</td>
</tr>
<tr>
<td>12/19/12</td>
<td>Update Related Policies – Add 7.01.85.</td>
</tr>
<tr>
<td>01/10/13</td>
<td>Coding update. CPT codes 22586 and 0309T, effective 1/1/13, added to policy.</td>
</tr>
<tr>
<td>04/08/13</td>
<td>Clarification only. “Acute” added to describe spinal fracture within the Policy section. Literature reviewed.</td>
</tr>
<tr>
<td>12/06/13</td>
<td>Update Related Policies. Add 7.01.138.</td>
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<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
</tr>
<tr>
<td>07/14/14</td>
<td>Annual review. Policy updated with literature review through October 23, 2013; considered medically necessary under specified conditions. Policy rewritten and reorganized.</td>
</tr>
<tr>
<td>01/13/15</td>
<td>Annual Review. Policy updated with literature review through September 2014; no change in policy statements. References 18 and 28-34 added. The following codes were removed from the policy as they do not facilitate adjudication: ICD-9 &amp; ICD-10 diagnosis; CPT 20930-20938, 22840-22847 &amp; 22851.</td>
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<tr>
<td>02/03/15</td>
<td>Update Related Policies. Add 7.01.130.</td>
</tr>
<tr>
<td>04/14/15</td>
<td>Interim Update. Policy updated within the Policy Guidelines section to state that smoking within the previous 6 weeks (previously stated 3 months) is a contraindication for lumbar spinal fusion; supportive Rationale added within said section and references 14-21 added (others renumbered). An additional bullet has been added within the same section within the minimal documentation requirement to document proof of smoking cessation for 6 weeks prior to surgery.</td>
</tr>
<tr>
<td>10/13/15</td>
<td>Interim Update. Clarified medically necessary policy criteria to state that presence of both spondylolisthesis and instability must be met for spinal stenosis (previously stated or instability). Added Definition of Terms subheading with definition of smoking cessation. Added Documentation requirement that medical record include a written statement that patient was non-smoking the 6-weeks prior to scheduled surgery (previously stated “proof/evidence” without specificity). Added statement about documentation that must be submitted for review including copy of radiologist’s MRI/CT report. Policy statements revised as noted.</td>
</tr>
</tbody>
</table>
Interim Update. Added clarification to Documentation requirement that the diagnostic imaging (CT, MRI) must be done within 12 months prior to the surgery. Clarified the Definition of Terms for neurogenic claudication. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

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