POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, lumbar spinal fusion has been medically proven to be effective and is considered medically appropriate for the following indications:

A. Spinal stenosis with any one of the following:
   1. Spinal instability, demonstrated on imaging; OR
   2. Spondylolisthesis; OR
   3. Spinal instability is anticipated due to need for bilateral or wide decompression with a physiological significant resection of the facet; OR
   4. Recurrent stenosis at a previously decompressed motion segment;

   AND either of the following:
   1. Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed a reasonable effort and intensity of medical management within the last 6 months, unless deemed to be contraindicated (as defined in Guidelines section I) and has documentation of significant central/lateral recess/or foraminal stenosis on MRI or other imaging, OR
   2. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling pain in a specific radicular distribution, or cauda equina syndrome.

B. Severe degenerative scoliosis (lumbar or thoracolumbar) with a minimum Cobb angle of 30° or significant coronal or sagittal imbalance (eg, sagittal vertical axis greater than 5 cm), AND with any one of the following:
   1. Documented progression of deformity with persistent axial (nonradiating) pain and impairment or loss of function unresponsive to at least 1 year of conservative therapy; OR
   2. 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
   3. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling pain in a specific radicular distribution, or cauda equina syndrome.

C. Isthmic spondylolisthesis when ALL the following are present:
   1. Congenital or acquired pars defect, documented on imaging; AND
   2. Persistent back pain (with or without neurogenic symptoms), with impairment or loss of function; AND
   3. Either unresponsive to a reasonable effort and intensity of medical management within the last 6 months, unless deemed to be contraindicated (as defined in Guidelines section I) or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling pain in a specific radicular distribution, or cauda equina syndrome.

D. Recurrent, same level disc herniation after at least two previous discectomies and , at least 3 months after last disc surgery, when all of the following are present:
   1. Recurrent neurogenic symptoms (radicular pain or claudication) or clinical evidence of nerve-root irritation; AND
   2. Impairment or loss of function; AND
   3. Unresponsive to a reasonable effort and intensity of medical management within the last 6 months, unless deemed to be contraindicated (as defined in Guidelines section I) or with severe or rapidly progressive
symptoms of motor loss, neurogenic claudication, disabling pain in a specific radicular distribution, or cauda equina syndrome; AND
4. Neural structure compression and/or instability documented by imaging at a level and side corresponding to the clinical symptoms.

E. Radiologically documented pseudoarthrosis, with or without instrumentation/hardware failure, when ALL of the following are present:
   1. No less than 6 months after initial fusion; AND
   2. Conservative treatment has been exhausted; AND
   3. Persistent axial back pain, with or without neurogenic symptoms, or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling pain in a specific radicular distribution, or cauda equina syndrome; AND
   4. Patient had experienced significant interval relief of prior symptoms.

F. Spinal instability due to fracture, dislocation, infection, abscess, or tumor or when extensive surgery is required that could create an unstable spine.

G. Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance (greater than or equal to 5cm) that causes functional limitations such as decreased abilities in performing ADLs and ambulating and significant pain.

H. Adjacent level disease (above or below the previous fusion) when ALL of the following are present:
   1. Persistent back pain (with or without neurogenic symptoms) with impairment or loss of function that is unresponsive to a reasonable effort and intensity of medical management within the last 6 months, unless deemed to be contraindicated (as defined in Guidelines section I); AND
   2. Eccentric disc space collapse, spondylolisthesis, acute single level scoliosis, stenosis requiring decompression, or lateral listhesis on imaging; AND
   3. Symptoms and functional measures correlate with imaging finding; AND
   4. At least 6 months since the previous fusion.

I. Discogenic low back pain secondary to a degenerated disc when ALL the following have been met:
   1. Advanced single level disease as evidenced on imaging with severe degeneration of the disc and extensive modic changes (at least modic type 2) as compared to other normal or mildly degenerative levels; AND
   2. Presence of symptoms for at least one year and patient has not been responsive to a reasonable effort and intensity of medical management within the last 6 months, unless deemed to be contraindicated; AND
   3. Absence of active psychiatric disorders (those disorders that are untreated), or active substance abuse (refer to Guidelines section V); AND
   4. Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain.

II. Based upon our criteria and assessment of peer-reviewed literature, lumbar spinal fusion has not been medically proven effective and is therefore considered investigational for the following indications:
   A. Chronic non-specific low back pain without radiculopathy;
   B. Disc herniation;
   C. In conjunction with initial discectomy/laminectomy for neural structure decompression; or
   D. Facet syndrome.

III. Based upon our criteria and assessment of peer-reviewed literature, multi-level lumbar spinal fusion requests are considered medically appropriate when each level meets the criteria for the specific indication as outlined in policy statement I.

Refer to Corporate Medical Policy #7.01.83 Minimally Invasive/Minimal Access Techniques for Lumbar Interbody Fusion.
POLICY GUIDELINES:

I. Intensive medical management must include, but is not limited to, the following interventions:
   A. Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response. Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants; AND
   B. Participation in at least 3 months of physical therapy (including active exercise) or chiropractic care or documentation of why the patient could not tolerate physical therapy/chiropractic care; AND
   C. Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues.
   D. Documentation must include evidence of patient compliance with the preceding criteria.

II. Evidence shows that tobacco use is considered a risk factor for poor healing and is associated with non-union. Tobacco use (e.g., cigarettes, cigars, pipes, smokeless tobacco in the form of chew or snuff or e-cigarettes) within the previous 4 weeks is a contraindication for lumbar spinal fusion. The Health Plan requires a statement and evidence of nicotine-free status by a laboratory result (cotinine level) that the member (who is a current user) has been a nonuser for the period of 4 weeks prior to the scheduled surgery, unless the fusion is being performed for an emergent medical condition.

III. Documentation requirements include recent physical therapy or chiropractic records (must include PT discharge notes) and Oswestry Disability Index (ODI) or results of the short form (SF)-36.

IV. The most recent radiology reports (e.g., MRIs CTs) must be performed and read by an independent radiologist. If discrepancies in the interpretation of the imaging occur between the surgeon and radiologist, a discussion must occur between the surgeon and radiologist to reach a concordant finding. An additional independent review of the images and radiology reports may be required if needed.

V. Patients with discogenic pain must be screened by their physician for major psychopathology. All patients who have current symptoms which concern the physician, or who have had a psychiatric hospitalization must have a psychiatric evaluation. A psychiatrist or clinical psychologist who is providing ongoing care for the patient may provide this evaluation. Psychological testing as screening tool or as part of the psychological evaluation prior to surgery is considered not medically necessary.

VI. It is highly recommended that obese/morbidly obese patients undergo weight loss (at least 10% excess weight loss/EWL) prior to an elective fusion surgery as obesity can be associated with increased complications and potentially worse outcomes.

VII. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Low back pain affects approximately 90% of the U.S. population at some point in their lives and may be caused by a wide variety of conditions. Conservative management typically consists of rest, exercise, analgesics, local injections, lumbar bracing, physical therapy and chiropractic care. Generally, conservative therapy is not recommended in the presence of progressive neurological deficits, when spinal fracture or dislocation is unstable or for progressive spinal deformity. When conservative management is attempted and fails, surgery may be required for conditions with underlying pathology as determined by radiological findings.

Spinal fusion/arthrodesis, also known as spondylodesis or spondylosyndesis, is a well-established surgical technique for infectious conditions of the spine (e.g., spinal tuberculosis). It has also been considered the standard treatment for progressive spinal deformities (e.g., scoliosis) and traumatic injuries. Additionally, lumbar fusion is performed for clearly defined spinal instability. Fusing of the spine is used primarily to eliminate the pain caused by abnormal motion of the vertebrae by immobilizing the faulty vertebrae themselves. Supplementary bone tissue, either from the patient (autograft) or a donor (allograft), is used in conjunction with the body's natural bone growth (osteoblastic) processes to fuse the vertebrae. There are two main types of lumbar spinal fusion, which may be used in conjunction with each other. Posterolateral fusion places the bone graft between the transverse processes in the back of the spine. These vertebrae are
then fixed in place with screws and/or wire through the pedicles of each vertebra attaching to a metal rod on each side of the vertebrae. Interbody fusion places the bone graft between the vertebrae in the area usually occupied by the intervertebral disc. The fusion then occurs between the endplates of the vertebrae. Using both types of fusion is known as 360-degree fusion. Three types of interbody fusion include anterior lumbar interbody fusion (ALIF); posterior lumbar interbody fusion (PLIF); and transforaminal lumbar interbody fusion (TLIF). 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 following surgery to improve fusion success rates. External factors such as smoking, osteoporosis, certain medications, and heavy activity can prolong or even prevent the fusion process.

**RATIONALE:**

Lumbar spinal fusion is a surgical procedure and does not require approval by the U.S. Food and Drug Administration (FDA). A variety of instrumentation used in lumbar spinal fusion is cleared for marketing by FDA.

**Smoking**

Tobacco use is considered a risk factor for poor healing and is associated with nonunion. It is well-established that smoking is a preventable cause of morbidity and mortality. The American Academy of Orthopedic Surgeons (AAOS) strongly recommends avoiding use and exposure to tobacco products due to the severe and negative impact on the musculoskeletal system including the bones, muscle, tendons and ligaments (AAOS, 2010). Lumbar fusion is in most situations an elective surgery; it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery. A policy statement published by the International Society of Advancement for Spine Surgery (ISASS, 2011) indicates 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 (ISASS, 2011). The North American Spine Society (NASS) lists the absence of smoking for at least 3 months prior to the surgery date in their coverage policy recommendations for lumbar fusion for the diagnosis discogenic low back pain. Anderson et al. (2010) reported that smoking negatively affects fusion mass and furthermore; smoking results in lower bone mineral density, particularly in the spine. Deyo et al. (2010) evaluated trends and complications in adults who underwent lumbar fusion for spinal stenosis and noted that not only did major complications increase with increased comorbidity, but that there was a substantially greater risk among those with chronic lung disease compared to those without. Particularly with spinal fusion, tobacco use has been associated with increased risk of pseudoarthrosis. In addition, tobacco use has been associated with poorer clinical outcomes such as less pain relief, poorer functional rehabilitation and less overall patient satisfaction (Vogt, et al., 2002).

Cotinine, the primary metabolite of nicotine, is currently regarded as the best biomarker of tobacco smoke exposure. Measuring cotinine is preferable to measuring nicotine because cotinine persists longer in the body with a plasma half-life of about 16 hours. Non-smokers exposed to typical levels of second hand smoke have serum cotinine levels less than 1 ng/ml, with heavy exposure to second hand smoke producing levels in the 1-10 ng/ml range. Active smokers almost always have levels higher than 10 ng/ml and sometimes higher than 500 ng/ml. Therefore, non-smoking is defined as a serum cotinine level of less than or equal to 10 ng/ml (National Biomonitoring Program, Centers for Disease Control and Prevention Dec 2013).

**Disc herniation/degenerative disc disease (DDD)**

Current evidence, which includes a large randomized controlled trial (RCT) by Weinstein and colleagues (SPORT), 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 (e.g., Takeshima, et al. 2000, Otani, et al. 2014 ).

WC Jacobs and colleagues (2011) conducted a systematic review to assess the effects of surgery versus conservative therapy (including epidural injections) for patients with sciatica due to lumbar disc herniation. Randomized controlled trials of adults with lumbar radicular pain, which evaluated at least one clinically relevant outcome measure (pain, functional status, perceived recovery, lost days of work) were included. In total, five studies were identified, two of which with a low risk of bias. One study compared early surgery with prolonged conservative care followed by surgery if needed; three studies compared surgery with usual conservative care, and one study compared surgery with epidural injections. Data were not pooled because of clinical heterogeneity and poor reporting of data. One large low-risk-of-bias
Evidence supporting lumbar fusion, as a method of treatment for DDD is limited, and few well-designed clinical studies have supported arthrodesis as superior to nonoperative therapy for improving clinical outcomes (e.g., Resnick, et al., 2005). In 2012, the Agency for Healthcare Research and Quality posted for public comment a draft of an updated technology assessment on spinal fusion for treating painful lumbar degenerated discs or joints. The draft, which reviewed 4 studies, 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. When comparing intense rehabilitation and cognitive therapy to lumbar fusion, the reported clinical outcomes demonstrate lumbar fusion is no more effective than intense rehabilitation combined with cognitive therapy (e.g., Brox, et al., 2010; Mirza, et al., 2007; Brox, et al., 2006; Fairbank, et al., 2005). However, there is a small subset of patients with advanced single level disease and extensive modic changes who can find pain relief with spinal fusion when strict radiologic and clinical inclusion criteria are followed.

The North American Spine Society (NASS) states that lumbar fusion is not indicated for disc herniation as an adjunct to primary excision of a central or posterolateral disc herniation at any level in the absence of instability or spondylolisthesis.

Chronic low back pain (CLBP)
A systematic review from 2013 by Saltychev, et al. compared lumbar fusion versus conservative treatment in patients with CLBP. The Meta-analysis of 4 trials 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. The review concluded that there is strong evidence that lumbar fusion does not lead to a clinically significant reduction in perceived disability compared with conservative treatment in patients with CLBP and degenerative spinal disease. The review also concluded that it is unlikely that further research on the subject would alter this conclusion.

T Ibrahim and colleagues performed a meta-analysis of randomized controlled trials to investigate the effectiveness of surgical fusion for the treatment of chronic low back pain compared to non-surgical intervention. The meta-analysis comparison was based on the mean difference in Oswesty Disability Index (ODI) change from baseline to the specified follow-up of patients undergoing surgical versus non-surgical treatment. Of the 58 articles identified, three studies were eligible for primary analysis and one study for sensitivity analysis, with a total of 634 patients. The authors found that surgical fusion for chronic low back pain favored a marginal improvement in the ODI compared to non-surgical intervention. This difference in ODI was not statistically significant and was of minimal clinical importance. Surgery was found to be associated with a significant risk of complications. Therefore, the cumulative evidence at the present time does not support routine surgical fusion for the treatment of chronic low back pain.

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

Chronic low back pain
It has been demonstrated that early surgery in patients with 6-12 weeks of radicular pain leads to faster pain relief when compared with prolonged conservative treatment, but there were no differences after 1 and 2 years. Another large low-risk-of-bias trial between surgery and usual conservative care found no statistically significant differences on any of the primary outcome measures after 1 and 2 years. Future studies should evaluate who benefits more from surgery and who from conservative care.
Adolescent Idiopathic Scoliosis
Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), severity of the condition (degrees of curve), and the remaining growth expected for the patient at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high risk of curve progression. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, in the U.S., surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.(Richards, et al, 2005). Long-term follow-up of a large case series by Danielson and Nachemson 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
No randomized controlled trials (RCTs) were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. A cohort study in 2009 by 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. Operative versus nonoperative treatment was decided by the patient and medical team. Nonoperative treatment included observation (21%), medications (26%), medications plus physical therapy and/or injections (40%), and other treatment without medications (13%). For analysis, the patients were matched using propensity scores that included baseline Cobb angle, Oswestry Disability Index (ODI), Scoliosis Research Society subscore, and a numerical rating scale for back and leg pain. The percentage of patients who returned for follow-up at 2 years was higher for operative than nonoperative patients (95% vs 45%), though the baseline measures for patients who were lost to follow-up was similar to those who were followed for 2 years. At the 2-year follow-up, nonoperative treatment had not improved quality of life or any other outcome measures, while the operative group showed significant improvement in all outcomes.

Isthmic Spondylolisthesis
A RCT 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. 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). Inclusion criteria for the study were lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and a severely restricted functional ability. The mean age of patients was 39 years, with a mean age at onset of symptoms of 26 years. At 1- and 2-year follow-up, functional outcome (assessed by the Disability Rating Index) had improved in the surgery group but not in the exercise group. Pain scores improved in both groups, but were significantly better in the surgically treated group compared with the exercise group.

CODES:

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CPT:

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<tr>
<th>Code</th>
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<td>Allografts and autografts used in spine surgery (code range)</td>
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<td>Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
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<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 (List separately in addition to code for primary procedure)</td>
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<td>Spinal instrumentation (code range)</td>
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**ICD9:**

- 722.73  Intervertebral disc disorder with myelopathy, lumbar region
- 722.83  Postlaminectomy syndrome, lumbar
- 724.02-724.03 Spinal stenosis, lumbar (code range)
- 724.6  Instability, lumbosacral
- 733.82  Pseudoarthrosis
- 737.19  Acquired kyphosis (Flatback syndrome)
- 737.30, 737.32 Scoliosis
- 738.4  Acquired spondylolisthesis
- 756.12  Spondylolisthesis anomaly of spine

**ICD10:**

- M40.35-M40.37 Flatback syndrome thoracolumbar, lumbar or lumbosacral region (code range)
- M41.05-M41.9 Scoliosis (code range)
- M43.00-M43.07 Spondylolysis, thoracolumbar, lumbar or lumbosacral region (code range)
- M43.10-M43.17 Spondylolisthesis, thoracolumbar, lumbar or lumbosacral region (code range)
- M43.27  Fusion of spine, lumbosacral region

*Proprietary Information of Excellus Health Plan, Inc.*
REFERENCES:


Proprietary Information of Excellus Health Plan, Inc.


Sorensen LT. Wound healing and infection in surgery. The clinical impact of smoking and smoking cessation: a systematic review and meta-analysis. *Arch Surg* 2012 Apr;147(4):373-83.


* key article

**KEY WORDS:**

Degenerative disc disease, Disc herniation, Lumbar arthrodesis, Lumbar fusion, Scoliosis, Spinal stenosis, spondylodesis, spondylosyndes, Spondylolisthesis

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based upon our review, lumbar fusion is not addressed in National or regional CMS coverage determinations or policies.