FirstCarolinaCare
Spinal Surgery Prior-authorization Guidelines

Subject LUMBAR FUSION (arthrodesis)

Next Review 06/2014

General Requirements for Lumbar Spinal Fusion:

1. Prior-authorization is required for elective procedures and physicians should submit requests to FirstCarolinaCare’s Medical Management Department at least two weeks prior to the anticipated date of an elective surgery.
2. The minimal documents necessary to accurately and expeditiously complete pre-authorization requests for spinal fusion are:
   a. Specific procedures requested with CPT/ICD-9 codes and disc levels indicated
   b. Office notes, including a current history and physical exam
   c. Detailed documentation of extent and response to conservative therapy, including outcomes of any procedural interventions, medication use and physical therapy/physiatry notes
   d. Most recent radiology reports for MRI’s, CT’s, etc. Imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede.
   e. Flexion-extension films for spinal fusion requests based upon instability
   f. Oswestry Disability Index or results of SF-36. Forms must be signed and dated by the member. Psychiatric evaluation may be required based on the results of these tests.
   g. Medical clearance reports (as indicated)
   h. Documentation of nicotine-free status – see Tobacco Cessation requirement below.
3. The patient must have an appropriate indication for Lumbar Spinal Fusion as defined in the Indications for Lumbar Spinal Fusion section below
4. The patient must have significant symptoms that correlate with physical exam findings AND radiologist-interpreted imaging reports including:
   a. Significant functional impairment or loss of function resulting in inability or significantly decreased ability to perform normal, daily activities of work, school, or at-home duties.
   b. Persistent, debilitating pain is defined as: Significant level of pain on a daily basis defined on a Visual Analog Scale (VAS) as greater than 4. Pain on a daily basis that has a documented negative impact on activities of daily living despite optimal conservative therapy as described below.

The following guidelines may not apply to patients with traumatic spinal fractures or dislocations, primary infections, neoplasms of the spine or those with “red-flag” symptoms such as severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome.

5. The requesting surgeon should have personally evaluated the patient on at least two occasions prior to requesting surgery.
6. **Patient has participated in optimal conservative care** for the indication-specific duration as specified in the **Indications for Lumbar Spinal** Fusion section below. Lumbar fusion surgery is considered **not medically necessary** when the patient demonstrates substantial improvement on clinical re-evaluation as a result of these measures. Conservative care **must include the following**:
   a. The use of prescription oral analgesic medications, preferably anti-inflammatories **AND**
   b. Documented participation in a formal, active physical therapy program or through an FCC-approved vendor. **AND**
   c. Evaluation and appropriate management of associated behavioral, cognitive, and addiction issues if present (See requirement #7 below for additional information).
   d. Other conservative measures which may **not** be substituted for those above but which may be used adjunctively can include:
      § A home exercise program
      § Activity modification, as appropriate
      § Facet or epidural injections
      § Other measures
   e. **The purpose of performing conservative measures is not to simply fulfill surgical prerequisites or add complexity to the pre-authorization process.** According to best-practice guidelines and evidence-based medicine, initial and preferred long-term treatments for back pain are conservative in nature. It is recognized that some individuals with back pain will require surgery. Many patients will obtain lasting benefit from conservative treatments and thus avoid more invasive procedures. **One of the primary goals of this policy is to help identify and most appropriately manage these patients.**

7. **Patient has completed and signed a functional assessment**
   a. SF-36 and/or **Oswestry Disability Index**
   b. If the mental health component of the SF-36 score is less than 36 or the ODI is greater than 40%, psychological evaluation is required.
   c. The purpose of psychological evaluation assessment is to help the surgeon identify specific psychological barriers to successful treatment, including those that may be undiagnosed (e.g. chronic pain syndrome, depression, secondary gain, etc.). In certain circumstances, these issues may require treatment prior to and/or following surgery (22). The primary purpose of this evaluation is **not** to determine mental stability to undergo surgery. This evaluation must be performed by either a clinical psychologist (PhD) or psychiatrist (MD/DO).
   d. If psychological risk factors are identified, a treatment plan to address these issues must be submitted. This can include both pre and post-surgical recommendations.

8. All members should be screened for **medical co-morbidities** and undergo thorough medical clearance as indicated.

9. **Tobacco Cessation**
   a. Because of the high risk of pseudoarthrosis, a patient anticipating a spinal fusion will adhere to a **tobacco-cessation program** that results in abstinence from tobacco for at least six weeks prior to elective surgery. (11)(18)(19)(20)(21)
   b. **Documentation of nicotine-free status by lab result (cotinine level)** in patients who have been documented tobacco-users is required. Labs are to be performed after 6 weeks
tobacco cessation and ample time should be afforded to submit this confirmation and complete the prior authorization process.

Indications for Lumbar Spinal Fusion

The following indications for lumbar fusion are considered Medically Necessary:

1. **Unstable traumatic spine fracture or dislocation**
2. **Primary or metastatic tumor causing pathologic fracture, cord compression, or instability**
3. **Spinal infectious disease**

The following indications for lumbar fusion may be considered Medically Necessary when all other reasonable causes of pain have been ruled-out and all other requirements have been met (as described in the General Requirements for Lumbar Spinal Fusion portion of this document):

1. **Spinal stenosis**
   a. In the presence of documented central/lateral recess/or foraminal stenosis, on MRI or other imaging, associated with spondylolisthesis. This must be demonstrated on plain x-rays which show 5 mm or more of translation or Grade 2 on the Meyerding grading system and one of the following:
      § Neurogenic claudication or radicular pain that has resulted in significant functional impairment despite at least 12 weeks of coordinated conservative including:
      o Interventional procedures such as ESI
      o Optimized pharmacologic therapies
      o Physical therapies
      § “Red flag” symptoms such as severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome.

2. **Severe, progressive, idiopathic scoliosis** (lumbar or thoracolumbar)
   a. Cobb angle >40 degrees.

3. **Severe degenerative scoliosis** with any one of the following:
   a. Documented progression of deformity with persistent axial pain and impairment or loss of function, unresponsive to at least 12 weeks of coordinated conservative care (as described above in #6 under General Requirements for Lumbar Spinal Fusion), or
   b. Persistent and significant neurogenic symptoms (radicular pain or claudication) with impairment or loss of function unresponsive to at least 12 weeks of coordinated conservative care.

4. **Isthmic spondylolisthesis** with
   a. Congenital or acquired pars defect, documented by x-ray AND
   b. Persistent back pain (with or without neurogenic symptoms) AND
   c. Impairment and loss of function, unresponsive to at least 6 months of coordinated conservative care (as described above in #6 under General Requirements for Lumbar Spinal Fusion).

5. **Recurrent disc herniation**
   a. For same-level disk herniation after two prior disectomies at that level.
   b. Neurological structure compression must again be demonstrated by most-recent imaging.

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c. Patient must have experienced significant initial relief of symptoms following prior disectomies.
d. There must be at least a 6 months’ time span since the most recent disk surgery.
e. For the current episode, the patient must have recurrent neurogenic symptoms and impairment or loss of function that has not responded to a minimum of 12 weeks of coordinated conservative care as described above (as described above in #6 under General Requirements for Lumbar Spinal Fusion).

6. **Adjacent segment degeneration** with
   a. Neural structure compression demonstrated by appropriate imaging
   b. Patient must have experienced significant initial relief of symptoms following prior fusion(s)
   c. There must be at least a 6 months’ time span since the previous fusion.
   d. For the current episode, the patient must have recurrent neurogenic symptoms and impairment or loss of function that has not responded to a minimum of 12 weeks of coordinated conservative care (as described above in #6 under General Requirements for Lumbar Spinal Fusion).

7. **Pseudoarthrosis**
   a. Patient must have persistent axial back pain
   b. Patient must have experienced significant initial relief of symptoms following prior fusion(s)
   c. Pseudoarthrosis is confirmed on imaging
   d. There must be at least a 6 months’ time span since the previous fusion

8. **Iatrogenic or degenerative flat back syndrome** with significant sagittal imbalance

9. **Patients who have had previous decompressive surgery** resulting in 75% unilateral facet loss or 50% bilateral facet loss and require additional surgery that would result in instability.

The following indications for lumbar spine fusion are considered investigational

1. **Sacroiliac Joint Fusion**
   Sacroiliac Joint Fusion including minimally invasive and percutaneous sacroiliac joint fusion for the treatment of sacroiliac joint and mechanical low back pain. Reported clinical outcomes are mixed and therefore no strong conclusions can be made regarding safety and efficacy when performed for the treatment of mechanical back pain. (15)

2. **Degenerative Disc Disease**
   Degenerative disc disease (DDD) is considered a normal part of the aging process. Clinical symptoms are typically consistent with mechanical back pain, which is aggravated by activity and relieved by rest. In contrast to conditions resulting in instability, DDD is described as axial spine pain with no or minimal abnormalities of spinal alignment or disc contour. Treatments are conservative and involve patient education regarding the disease process, activity modification, physical therapy focusing on muscle strengthening and analgesics (e.g., non-steroidal anti-inflammatory, local injection). Lumbar fusion is associated with more risks than conservative treatment, and when compared to structured rehabilitation and behavioral therapy programs there is no meaningful difference in clinical outcomes (e.g., pain relief, functional improvement) (13). Discography is not encouraged in the assessment of these patients due to questionable clinical relevance and potential adverse effects. Discography results will not be considered as an indication for surgery.
3. **Facet syndrome**
   Management of facet syndrome should be conservative and may include physical therapy, anti-inflammatory medications, and facet injections. According to the International Society for the Advancement of Spine Surgery (ISASS 2011), lumbar fusion for facet syndrome is no longer generally accepted and should only be performed in the context of a clinical trial.

The following sole indications for lumbar fusion are considered **Not Medically Necessary**:

1. **Initial discectomy/laminectomy** for neural structure decompression.
   The North American Spine Society (NASS) published evidence-based guidelines for the diagnosis and treatment of degenerative lumbar spinal stenosis in 2007. According to the guidelines regarding the results of medical/interventional management of spinal stenosis:
   a. Of patients with mild to moderate lumbar spinal stenosis initially receiving medical/interventional treatment and followed for two to 10 years, approximately 20-40% will ultimately require surgical intervention. Of the patients who do not require surgical intervention, 50-70% will have improvement in their pain.
   b. In patients with severe symptoms of lumbar spinal stenosis, decompressive surgery alone is effective approximately 80% of the time.
   c. In patients with lumbar spinal stenosis and spondylolisthesis, decompression with fusion results in better outcomes than decompression alone.
   d. Of patients with lumbar spinal stenosis without spondylolisthesis or instability, there is no evidence to support the addition of a fusion.

2. **Spinal stenosis without spondylolisthesis**
   Fusion is indicated only if there is radiographic evidence of instability (e.g., spondylolisthesis). Spinal instability associated with stenosis may arise intraoperatively; cases of severe stenosis require more extensive decompression (i.e., complete facetectomy or resection of pars interarticularis creating a pars defect), which may destabilize the spine. According to a policy statement published by ISASS (2011) on lumbar fusion surgery, fusion is indicated when an adequate decompression for the treatment of spinal stenosis requires creation of a pars defect or removal of either 75% of one facet joint or >50% of both facet joints.

3. **Back pain without imaging to support the need for fusion as specified above**

4. **In patients who are using tobacco and do not have “red-flag” symptoms:**
   Such as severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome.

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**Regarding Medicare Advantage Patients:**

Medicare Advantage follows the medical policies of the Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) for the Medicare contractors in the state of North Carolina.

If no NCD or NC LCD policy exists on the topic, it defaults to the FCC commercial policy for medical necessity determination.

North American Spine Society (www.spine.org) accessed 1/13
NASS Clinical Guidelines - Degenerative Spinal Stenosis

Medical/interventional treatment may be considered to provide long-term (2-10 years) improvement in patients with degenerative lumbar spinal stenosis and has been shown to improve outcomes in a large percentage of patients.

Grade of Recommendation: C

Decompressive surgery is suggested to improve outcomes in patients with moderate to severe symptoms of lumbar spinal stenosis.

Grade of Recommendation: B

NASS Clinical Guidelines – Degenerative Lumbar Spondylolisthesis

Surgery is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: B

Direct surgical decompression is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: I (Insufficient Evidence)

Indirect surgical decompression is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: I (Insufficient Evidence)

Surgical decompression with fusion is recommended for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone.

Grade of Recommendation: B

The addition of instrumentation is recommended to improve fusion rates in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

The addition of instrumentation is not recommended to improve clinical outcomes for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

Decompression and fusion is recommended as a means to provide satisfactory long-term results for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.
Grade of Recommendation: C

References:

2. Cigna Medical Coverage Policy – Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions including Sacroiliac Fusion
3. Aetna – Clinical Policy Bulletin; Spinal Surgery: Laminectomy and Fusion


