Cohere Medicare Advantage Policy - Lumbar Spinal Fusion

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Lumbar Spinal Fusion

Date of last literature review: 6/10/2024
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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Lumbar Spinal Fusion

Benefit Category

Not applicable

Recommended Clinical Approach

Surgery provides more rapid relief than non-surgical treatment options. Surgery can also prevent further spinal cord dysfunction and neurological deficits, particularly in moderate or severe cases.[1] Advanced imaging is recommended prior to surgical intervention.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of lumbar spinal fusion. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inadequate management of spinal conditions, leading to complications like progression of degenerative joint disease, worsening lumbar condition resulting in cauda equina with potential permanent deficits, worsening low back pain, and reduced mobility. In addition, reduced mobility can result in medical comorbidities. Patients with chronic low back pain are at risk for opioid dependence. Low back conditions can be hard to diagnose. Dhillon reports that specific spinal pathology is seen in 1-2% of patients, radiculopathy from disc disease or stenosis

occurs in 5% of patients, and non-specific low back pain occurs in 85-95% of patients.[13] Therefore, diagnosis is crucial in order for good outcomes.

- Risks with inappropriate surgical procedures include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic risk and need for repeat or additional procedures due to adjacent segment disease, hardware failure, pseudoarthrosis or infected hardware requiring removal and revision, and in some cases hospital readmission. According to Evanview et al, lumbar fusion is associated with a 19% rate of adverse events or complications.[14] The most common complication is pseudoarthrosis which requires additional surgery. Ruffilli et al evaluated 392 patients who had a lumbar fusion and noted 7.9% of patients had a postoperative surgical site infection within 30 days of surgery.[15] 3.8% of patients had proximal junction disease requiring revision surgery. Understanding the risk factors for these known complications is important for patient selection, and illustrates the need for surgical guidelines. They identified osteopenia and sarcopenia as the biggest risk factors. Marchbacher et al evaluated age and outcomes from lumbar fusion.[16] They reviewed 707 surgical cases and found a lower complication rate in younger patients, 7% complications compared to 17.5% in the older population. Careful consideration of age-related conditions and risks is necessary.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes by ensuring timely and appropriate access to lumbar spinal fusion for managing various spinal conditions. Evanview et al noted that lumbar fusion for degenerative disc disease results in a clinically significant improvement of low back pain.[14] Marchbacher et al noted better outcomes from lumbar fusion in

younger patients.[16] Mancuso et al reviewed 422 patients and found that pain relief was varied, two years after surgery 11% had no improvement in pain, 28% reported little to moderate improvement, 44% reported a lot of improvement, and 17% had complete improvement in pain.[17] Setting patient's expectations for the expected surgical outcomes is important.

- Smoking is a known risk factor for increased surgical compilations. Nunna et al evaluated 17 studies for a combined cohort of 37,897 patients and identified smoking was associated with one or more major adverse events in 2-level fusions.[18] Berman et al identified that smoking significantly increases the risk of pseudoarthrosis for patients undergoing both lumbar and cervical fusions.[19] In addition to nonunion, the other perioperative complications such as infection, adjacent segment disease, and dysphagia are also increased. They recommend smoking cessation for 4 weeks prior to surgery, and consideration of additional support for fusion, such as BMPs.

- Reduction in complications and adverse effects from unnecessary procedures.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Lumbar spinal fusion** is considered appropriate if **ALL** of the following is **TRUE**[2]:
  - ◆ **ANY** of the following is **TRUE**:
    - The patient has not smoked in greater than or equal to the last 6 weeks[2]; **OR**
    - The patient is a smoker with an acute or traumatic lumbar spine condition; **AND**
  - ◆ **ANY** of the following:
    - When one or more levels are involved in a lumbar spinal fusion procedure, there must be medical record documentation of radiographic or clinical evidence of instability due to **ANY** of the following[3]:
      - Congenital deformities; **OR**
      - Trauma; **OR**
      - Fractures; **OR**
      - Chronic degenerative conditions; **OR**
      - Tumor; **OR**
      - Infection; **OR**
      - Erosive conditions; **OR**
      - Space-occupying lesions; **OR**
      - Iatrogenic causes, including expected instability as a consequence of another medically necessary spine procedure; **OR**

- The patient is experiencing symptomatic spinal deformity (in the absence of instability or neural compression) with **ALL** of the following:
    - The patient has a functional limitation in daily activities due to back pain or discomfort; **AND**
    - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 12 months. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **AND**
    - Spinal deformity with **ANY** of the following:
        - Sagittal or coronal imbalance by at least 5 cm as measured on radiographic imaging of the entire spine; **OR**
        - Progression of the deformity by at least 10 degrees; **OR**
        - Scoliotic curvature of greater than 30 degrees; **OR**
- Revision surgery for pseudarthrosis following an initial spine surgery when **ALL** of the following are met:
    - The patient experienced reduced pain initially following surgery; **AND**
    - One year has elapsed since the prior surgery; **AND**
    - There is clear radiographic evidence of pseudoarthrosis; **AND**
    - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 12 months. Documentation should

include detailed evidence of the measures taken, rather than solely a physician's statement; **AND**

- There is documentation in the patient's medical record that counseling has been provided that the procedure is being performed as a last resort treatment option, and that the patient agrees to undergo surgery following informed consent; **OR**

- Disc excision for decompression due to symptomatic compression of neural elements with medical record documentation of the neural elements for each level fused; **OR**
- The procedure is **lumbar fusion with/without decompression** with radiographic evidence of instability or iatrogenic instability caused by the decompression at all levels planned to be fused and **ANY** of the following is **TRUE**[4-5]:
  - The patient has signs or symptoms of a potential cauda equina syndrome and **ALL** of the following[6]:
    - MRI reveals compressive pathology; **AND**
    - **ANY** of the following symptoms:
      - Bowel, bladder, and erectile dysfunction; **OR**
      - Diffuse motor weakness; **OR**
      - Saddle-distribution anesthesia; **OR**
  - The patient has **lumbar stenosis** and **ALL** of the following are **TRUE:**
    - **ANY** of the following **lumbar stenosis symptoms**[5]:
      - Lower extremity pain, weakness, fatigue, paresthesias, and sensory changes; **OR**
      - Gluteal and low back pain (LBP); **OR**

- Bilateral or unilateral symptoms; **OR**
- Symptoms may present only with activity; **OR**
- Exacerbating factors include standing, walking, and other upright exercises; **OR**
- Pain may be relieved in a sitting or supine position or with forward flexion at the waist; **OR**
- Lower extremity pain that is made worse by walking; **AND**

◆ **ANY** of the following lumbar stenosis **physical examination** findings[7-8]:

- Focal motor weakness or sensory deficit; **OR**
- Decreased or absent lower extremity reflexes; **OR**
- Wide-based gait; **OR**
- Positive Romberg's test (poor standing balance with eyes closed); **OR**
- Positive straight leg raise (SLR; reproduction of lower extremity pain upon extension at the knee); **AND**

◆ MRI reveals compressive pathology and **ANY** of the following[9]:

- The patient fails to show significant improvement in pain or disability level due to symptoms, despite receiving conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than

6 weeks. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **OR**

- The patient has severe pain or disability affecting their quality of life and limiting their daily life (including working and being unable to provide self-care); **OR**
- The patient has progressive neurological motor deficits; **OR**

- The patient has **lumbar radiculopathy** and **ALL** of the following are **TRUE:**
  - **ANY** of the following **lumbar radiculopathy** symptoms:
    - Lower extremity pain, paresthesia, weakness, or numbness in a myotomal or dermatome distribution; **OR**
    - Increased pain with coughing, sneezing, or straining; **OR**
    - Low back pain; **AND**
  - **ANY** of the following lumbar radiculopathy **physical examination** findings[7-8]:
    - Sensory disturbance (i.e., loss of sensation or decreased sensory response) or weakness in a dermatomal/myotomal distribution; **OR**
    - Absent or decreased Achilles reflex; **OR**
    - Reduced spinal mobility; **AND**
  - **ANY** of the following positive specialty tests:
    - Straight leg raise; **OR**

        - Crossed Lasègue's (or crossed straight leg raise); **OR**
        - Femoral nerve stretch; **OR**
        - Slump; **AND**
    - MRI reveals compressive pathology and **ANY** of the following[9]:
        - The patient fails to show significant improvement in pain or disability level due to symptoms, despite receiving conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented for a period of greater than 6 weeks. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **OR**
        - The patient has severe pain or disability affecting their quality of life and limiting their daily life (including working and being unable to provide self-care); **OR**
        - The patient has progressive neurological motor deficits.

Non-Indications

- ➔ **Lumbar Spinal Fusion** may not be considered appropriate if **ANY** of the following is **TRUE**:
    - The patient has smoked within the last 6 weeks (exception for acute or traumatic lumbar spine conditions).[3]

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
20999	Unlisted procedure, musculoskeletal system, general
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
22533	Arthrodesis, lateral, lumbar
22534	Each additional, thoracic or lumbar, (add-on code)
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22610	Arthrodesis, posterior or posterolateral technique, single interspace; thoracic (with lateral transverse

	technique, when performed)
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)

22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22830	Exploration of spinal fusion
22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
22842	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
22843	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
22844	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and

	sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
22846	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
22847	Anterior instrumentation; 8 or more vertebral segments (List separately in addition to code for primary procedure)
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody

	arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methyl methacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22899	Unlisted procedure, spine

Medical Evidence

Kreiner et al. (2020) published a systematic review of guidelines for low back pain diagnosis and treatment. Insufficient evidence was found to recommend for or against a particular fusion technique for the treatment of low back pain. No literature evidence was found to adequately address differences in clinical outcomes or functional status for single-level vs. multilevel fusions. No studies were found to address the effectiveness of fusion over discectomy, discectomy with rhizotomy or decompression alone.[10]

The American College of Radiology (ACR) Expert Panel on Neurological Imaging has published appropriateness criteria related to myelopathic evaluation. Agarwal et al. (2021) updated the previous criteria for myelopathy with MRI recommended as initial imaging for acute onset myelopathy. MRI is also recommended for chronic or progressive myelopathy due to its superior resolution of soft tissue and ability to evaluate surrounding structures. CT may be appropriate, with CT myelography of possible use prior to surgical intervention.[12] Non-contrast MRI is usually appropriate for low back pain (LBP); radiography and CT may be appropriate for LBP with and without radiculopathy. This applies to surgical candidates with persistence or progression of symptoms having failed six weeks of medical management. MRI, CT, and CT myelography are recommended for suspected cauda equina syndrome. In cases of osteoporosis or chronic steroid use, radiography, non-contrast MRI, or CT is usually appropriate.[11]

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Clinical Guideline Revision History/Information

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