Cohere Medicare Advantage Policy - Thoracolumbar Spinal Fusion with or without Pelvic Fixation

Clinical Policy for Medical Necessity Review

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Important Notices

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GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

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Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Cohere Medicare Advantage Policy - Thoracolumbar Spinal Fusion with or without Pelvic Fixation
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Thoracolumbar Spinal Fusion with or without Pelvic Fixation

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1,2]

- Local Coverage Determination (LCD). Lumbar Spinal Fusion (L37848)
  - Billing and Coding: Lumbar Spinal Fusion (A56396)

Description

Lumbar or thoracic spinal fusion (arthrodesis) is performed via an anterior, posterior, and/or posterolateral approach. An incision is made to access the affected region of the back, whether the lower (lumbar) spine or middle (thoracic) spine. Metal rods, screws, or plates are installed to facilitate fusion of two or more portions of the spine by physically holding the spine in a certain fixed position. As part of the surgery, the lamina bone may be partially or completely removed, and any degenerative changes or abnormal disc material may also be excised. Fusion cages or grafts may be used. Spinal fusion provides more rapid relief than non-surgical treatment options, which can prevent further spinal cord dysfunction and neurological deficits, particularly in moderate or severe cases. Similarly, during pelvic fixation, portions of the pelvis are stabilized with screws or rods.[3] In all fusion procedures, the bones are "encouraged" to grow together - to fuse - by installing instrumentation, bone-like material, or bone grafts.[4,5]

Medical Necessity Criteria

Indications

Thoracolumbar spinal fusion with or without pelvic fixation is considered appropriate if **ALL** of the following are **TRUE**[1]:

- **ANY** of the following:
  - Current nicotine user with no product use for 6 weeks; and **ANY** of the following[6-8]:

        - Negative urine (cotinine) lab test within 30 days; **OR**
        - Surgery is urgently required due to documented reason; **OR**
    - No history of nicotine product use within the last 12 months; **OR**
    - No lifetime history of nicotine product use; **AND**
- **ANY** of the following indications for lumbar fusion. Note: if more than one level is fused under this indication, the record must reflect that each fused level is affected by one of the below conditions[1]:
    - Radiographic or clinical evidence of instability due to **ANY** of the following[1]:
        - Congenital deformities; **OR**
        - Trauma; **OR**
        - Fractures; **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**
    - **ALL** of the following[1]:
        - **ANY of the following:**
            - Symptomatic spinal deformity (in the absence of instability or neural compression); **OR**
            - Chronic degenerative conditions; **AND**
        - Failure of conservative management for greater than 12 months, including **ALL** of the following:
            - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; **AND**
            - Physical therapy, including a physician-directed home exercise program; **AND**
            - **ANY** of the following:
                - Corticosteroid injection if medically appropriate; **OR**
                - Documentation that corticosteroid injection is contraindicated; **AND**
        - The patient has a functional limitation in daily activities due to back pain or discomfort; **AND**
        - Spinal deformity with **ANY** of the following:

        - Pelvic incidence - lumbar lordosis (PI-LL) mismatch greater than 10 degrees; **OR**
        - 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**
    - Hardware failure (broken screw, rod fracture, loose screw, halo signs on pedicle screws, fracture through screw, etc.) necessitating revision surgery[9,10]; **OR**
    - Revision surgery for pseudarthrosis following initial thoracic or lumbar spinal fusion surgery when **ALL** of the following are met[1]:
        - 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 for greater than 12 months, including **ALL** of the following:
            - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; **AND**
            - Physical therapy, including a physician-directed home exercise program; **AND**
            - **ANY** of the following:
                - Corticosteroid injection if medically appropriate; **OR**
                - Documentation that corticosteroid injection is contraindicated; **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[1]; **OR**
    - The procedure is **lumbar fusion with decompression** and **ALL** of the following is **TRUE**[4,5,11]:
        - Patient meets medical necessity for lumbar fusion as outlined above; **AND**
        - **ANY** of the following:
            - Imaging findings of symptomatic neural compression; **OR**

        - Radiographic findings of moderate or greater foraminal stenosis or multilevel central stenosis supports the need for a decompression that would reasonably be expected to cause iatrogenic instability; **OR**
- A **thoracic spinal fusion** is considered appropriate with **ANY** of the following[12,13,14]:
    - Trauma/injury/fracture[15,16,17]; **OR**
    - Tumor[18,19]; **OR**
    - Thoracic spinal stenosis[20,21]; **OR**
    - The procedure is thoracic fusion with or without decompression with **ALL** of the following:
        - Radiographic evidence of **ANY** of the following:
            - Lumbar curve greater than 40 degrees requiring extension into the thoracic spine; **OR**
            - Positive sagittal balance or sagittal vertebral axis (SVA) greater than 5 cm; **AND**
        - Failure of conservative management for greater than 6 weeks, including **ALL** of the following:
            - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated; **AND**
            - Physical therapy, including a physician-directed home exercise program; **AND**
            - **ANY** of the following:
                - Corticosteroid injection if medically appropriate; **OR**
                - Documentation that corticosteroid injection is contraindicated; **OR**
    - Junctional fusion for adjacent segment disease (e.g., stenosis, kyphosis, listhesis) is appropriate when **ANY** of the following is **TRUE**:
        - Adjacent cervical fusion is medically appropriate and approvable; **OR**
        - Adjacent lumbar fusion is medically appropriate and approvable; **OR**
        - Adjacent thoracic fusion is medically appropriate and approvable; **OR**
- **Pelvic fixation** (e.g., attachment of caudal end of instrumentation to pelvic bony structures other than sacrum) for **ANY** of the following[3,22-24]:

- A long arthrodesis involving five or more vertebral levels or four or more vertebral levels; **OR**
- Three-column osteotomies in the lower thoracic or lumbar spine; **OR**
- Sacral fractures with spinopelvic dissociation; **OR**
- Lumbosacral arthrodesis in the setting of osteoporosis; **OR**
- High-grade spondylolisthesis (grade three or higher according to the Meyerding classification system); **OR**
- Correction of lumbar deformity or pelvic obliquity; **OR**
- A tumor that requires bone removal from the lumbar vertebrae or sacrum.

Non-Indications

Thoracolumbar spinal fusion with or without pelvic fixation may not be considered appropriate if **ANY** of the following is **TRUE**:

- In lumbar stenosis when greater than 50% bilateral facet resection is not required to achieve neurologic decompression[25]; **OR**
- Isolated facet fusion[26]; **OR**
- Interspinous fusion (including interspinous fusion devices, such as the Minuteman device).[27,28]

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 extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); 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

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established," Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for **thoracolumbar spinal fusion with or without pelvic fixation** may include:

- Adverse effects from delayed or denied treatment in order to comply with the **requirement for current smokers to abstain from nicotine** for at least 6 weeks and provide a urine sample that is negative for cotinine (unless surgery is urgently required for documented reasons). Social determinants of health (SDOH) remain an important area of ongoing orthopaedic surgery research, with recent literature raising questions regarding the healthcare disparities that may be potentiated by care limitations based on smoking status/nicotine dependence. These disparities include inequitable access to effective cessation resources, as well as systemic sociodemographic, racial, and ethnic differences that contribute to an individual's ability to achieve and sustain smoking cessation. The American Academy of Orthopaedic Surgeons (AAOS) has issued Information Statement 1047, published in 2016, which states that patients who are active smokers are at increased risk for complications, and that patients may reduce serious surgical risk (including risk of death) through cessation of smoking prior to elective orthopaedic surgery; the AAOS also notes the special role orthopaedic surgeons play in counseling patients on the benefits of reduced or eliminated tobacco use prior to surgery. Importantly, unconfirmed cessation is not endorsed as a hard stop to elective orthopaedic surgery; rather, the surgeon's unique role as an advocate for preoperative smoking cessation is emphasized.[6-8]
- Adverse effects from delayed (i.e., in order to complete 3 months of conservative treatment) or denied treatment for **lumbar spinal fusion for the treatment of chronic degenerative conditions**, such as persistent

chronic pain and functional disability, potentially resulting in decreased ability to work, exercise, or perform the activities of daily living, as well as risk for opioid dependence.[29-34]

- Adverse effects from delayed or denied treatment for **thoracic spinal fusion**, such as progressive spinal deformity leading to chronic back pain, shortness of breath, impaired pulmonary function, reduced exercise tolerance, and nerve compression. These problems may compound or persist if the patient is skeletally immature, potentially resulting in permanent growth asymmetry and lifelong physical and functional differences if not surgically corrected.[35-38]
- Adverse effects from delayed or denied treatment for **pelvic fixation**, such as worsening spinopelvic dissociation in the setting of acute trauma, inadequate fixation among patients with multilevel spinal disease, or incomplete treatment of pelvic obliquity. Patients who are inappropriately denied pelvic fixation and receive spinal fixation alone may go on to suffer pseudarthroses, implant fracture, and screw loosening secondary to osteoporosis.[39-41]
- Adverse effects from delayed or denied treatment for **lumbar fusion with decompression**, such as worsening neurogenic claudication, chronic back pain, and functional disability, potentially resulting in decreased ability to work, exercise, or perform the activities of daily living, as well as risk for opioid dependence.[42,43]

The potential clinical benefits of using these criteria for **thoracolumbar spinal fusion with or without pelvic fixation** may include:

- Improved patient selection, resulting in better long-term outcomes. Ideal surgical candidates are **lifetime nonsmokers, have not smoked for a period of 12 months, or are current smokers who have abstained** from nicotine use for at least 6 weeks prior to surgery and can provide a negative urine test for cotinine (unless surgery is urgently required for documented reasons). According to the American Academy of Orthopaedic Surgeons (AAOS), there are increased patient safety risks conferred by tobacco use, including pneumonia, impeded healing, surgical site infection, postoperative cardiopulmonary events, and death. Among spinal fusion patients, smoking has been associated with an increased overall perioperative complication rate, increased risk of nonunion, and increased postoperative pain and disability. Smoking cessation, conversely, may mitigate these risks. In addition, among spinal

fusion patients, preoperative smoking cessation is associated with lower postoperative pain scores, reduced opioid intake, reduced risk of chronic pain, improved quality of life, and improved patient satisfaction. Smoking status is a profoundly powerful modifiable risk factor for short-term and long-term health.[44,45]

- Earlier resolution or improvement of symptoms after conservative care (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) as a prerequisite to **lumbar spinal fusion for the treatment of chronic degenerative conditions**, resulting in reduced healthcare costs, eliminated need for surgical management and the accompanying surgical risks, and reduced patient burden. Nonsurgical management is generally easier to access for patients relative to surgery or other invasive treatments.[29-34]
- Improved patient selection for **thoracic fusion**, resulting in better long-term outcomes. Ideal surgical candidates have failed conservative treatment for a period of at least 6 weeks and have severe scoliotic disease such that there is a risk for long-term disfigurement or pulmonary sequelae if the spinal curvature is not surgically corrected.[35-38]
- Improved patient selection for **pelvic fixation**, resulting in better long-term outcomes. Ideal surgical candidates have significant disease of the pelvis, including sacral fractures with spinopelvic dissociation, or are undergoing extensive spinal fixation; if the pelvis is inappropriately fixed for a patient with less severe disease that may have been resolved through other less invasive means, the patient may experience lifelong mobility limitations, creating difficulty with certain activities, movements, or exercises.[3,39-41]
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with lumbar stenosis who require less than 50% bilateral facet resection to achieve neurologic decompression are not optimal surgical candidates because their disease may be better treated through noninvasive, nonsurgical means. Patients who undergo inappropriate **lumbar spinal fusion** are at risk for surgical site infection, nerve damage, excessive bleeding or clotting, and failed fusion necessitating further surgery. Other complications of inappropriate surgery may include chronic pain, mobility limitations, and nerve pain.[42,43]
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Evaniew et al. (2022) performed a retrospective observational study to evaluate the effects of lumbar fusion surgery in patients with various back conditions. A total of 84 patients were evaluated at 11 centers from 2015 to 2019. In this study, the primary outcome was the level of improvement in back pain at the 12 month follow up mark. Secondary outcomes measured included satisfaction, disability, health-related quality of life, and rates of adverse events. The authors of this study observed a statistically significant improvement of back pain at 12 months with 81% of patients reporting satisfaction with their surgery. Patients also experienced significant improvements of disability and health-related quality of life.[46]

Jain et al. (2015) published an overview of the indications for adult and pediatric pelvic fixation. The authors described the role pelvic fixation plays in the definitive correction of congenital anomalies of the lumbar spine, lumbosacral fractures, and severe spondylolisthesis with the aim of facilitating long-term functional improvements and overall quality of life.[3]

Anand et al. (2023) conducted a retrospective literature review to evaluate the clinical impact of selective fusion of the thoracolumbar spine on adults with significant "double curve" deformities (i.e., presence of both a lumbar and thoracic curve). This review was performed on 438 patients who underwent minimally invasive fusion between 2007 and 2020. Although both curves were not definitively corrected - as is the traditional dogma - clinical improvements were found alongside significant correction of the unfixed thoracic spine. The authors observed significant improvements in pain scores and disability metrics, and recorded no instances of hardware failure such as rod breakage or screw loosening. They concluded the clinical benefit of selective fusion of "double curve" patients, contradicting the previous thought pattern that both curves must be definitively fused.[47]

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Clinical Guideline Revision History/Information

Original Date: May 22, 2024		
Review History		
Version 2	6/10/2024	422.101 Disclaimer added
Version 2.1	3/20/2025	Updated policy per CMS revisions for 9/12/2024 ● Updated Effective date ● Updated Links and Bookmarks
Version 3	5/29/2025	Annual policy review & restructuring. Updated literature, medical evidence (including references) Thoracic spinal fusion criteria added - previously missing Added nicotine abstention requirement across policy Policy title changed from 'Lumbar Spinal Fusion' to 'Thoracolumbar Spinal Fusion with or without Pelvic Fixation' Added conservative care requirement for chronic degenerative conditions Removed redundant indication for revision/repeat surgery Added non-indications for interspinous fusion, facet fusion. Added thoracic fusion indications: trauma, fracture, tumor, spinal stenosis, injury.

		Added indication for revision surgery due to hardware failure (broken screw, rod fracture, loose screw, halo signs on pedicle screws, fracture through screw, etc.)