

Lumbar Fusion and Intervertebral Fusion Devices

Last Review Date: April 12, 2024

Number: MG.MM.SU.55c

Medical Guideline Disclaimer

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Related Medical Guidelines

<u>Artificial Intervertebral Discs</u> Interspinous Distraction Devices

Definitions

Spinal fusion surgery is designed to stop motion at a painful vertebral segment, which in turn should decrease pain generated from the joint.

There are many approaches to lumbar spinal fusion surgery; all involve the following:

- Addition of bone graft to a spinal segment
- Setting up biological response to create artificial induction of bone ossification that enables bone graft to grow between two vertebral elements resulting in bone fusion (aka arthrodesis)
- Arresting joint-segment motion achieved through boney fusion creation of one fixed bone that replaces a mobile joint

Spinal access may be achieved through anterior, posterior and lateral approaches utilizing open surgical (large incision) or minimally invasive/minimal access techniques. (Tables $\underline{1}$ and $\underline{2}$)

The two main types of fusion (which may be used in conjunction with each other) are:

- Posterolateral fusion places bone graft between transverse processes in back of the spine; vertebrae 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 bone graft between vertebrae in area usually occupied by the intervertebral disc; fusion then occurs between endplates of the vertebrae

Types of fusion instrumentation for rigid stabilization consists of pedicle screws, cages/dynamic stabilization devices.

Table 1: Covered Open/Minimally Invasive/Minimal Access Fusion Procedures when clinical criteria are met.

Procedure	Access	Approach	Visualization
Anterior lumbar interbody fusion (ALIF)	Open, MI or laparoscopic	Transperitoneal or retroperitoneal	Direct, endoscopic or laparoscopic with fluoroscopic guidance
Direct lateral interbody fusion (DLIF)	МІ	Retroperitoneal through transpsoas	Direct, with neurologic monitoring and fluoroscopic guidance
Lateral interbody fusion (e.g., extreme lateral interbody fusion [XLIF®])	МІ	Retroperitoneal through transpsoas	Direct, with neurologic monitoring and fluoroscopic guidance
Posterior lumbar interbody fusion (PLIF)	Open or MI	Incision centered over spine with laminectomy/laminotomy and retraction of nerve	Direct, endoscopic or microscopic, with fluoroscopic guidance
Transforaminal lumbar interbody fusion (TLIF)	Open or MI	Offset from spine, through the intervertebral foramen via unilateral facetectomy	Direct, endoscopic or microscopic, with fluoroscopic guidance

Table 2: Non-covered Minimally Invasive/Minimal Access Fusion Procedures (Limitations/Exclusions)

Procedure	Access	Approach	Visualization
Axial lumbar interbody fusion (AxiaLIF®)	MI	Pre-sacral space	Direct, endoscopic or laparoscopic with fluoroscopic guidance
Laparoscopic anterior lumbar interbody fusion (LALIF) (AKA anterior para-axial, trans-sacral or paracoccygeal interbody fusion)	Laparoscopic	Transperitoneal or retroperitoneal	Direct, endoscopic or laparoscopic with fluoroscopic guidance

Guideline

Coverage Position Statements

- I. EmblemHealth considers the fusion procedures listed in <u>Table 1</u> to be clinically appropriate when fusion <u>criteria</u> are met.
- II. EmblemHealth considers cadaveric allograft and demineralized bone matrix (e.g., Accell, AlloFuse, Allogor DBM, Allomatrix, DBX, DynaGraft, DynaGraft, Exactech Resorbable Bone Paste, Grafton DBM, Intergro DBM, Magnifuse, Optefil, Opteform, Origen DBM, OrthoBlast, Ostefil, OsteoSelect, OsteoSponge, and Progenix) to be medically necessary for spinal fusions.
- III. EmblemHealth considers recombinant human bone morphogenetic protein-2 (rhBMP-2), including, but not limited to the InFUSE[®] bone graft, to be medically necessary as an adjunct to instrumented ALIF or posterolateral lumbar intertransverse fusion. (See <u>Limitations/Exclusions</u> for posterior lumbar interbody fusion [PLIF] and TLIF)

Criteria

Lumbar fusion is considered medically necessary when any of the following criteria (1–10) are met.

- **1.** Spinal stenosis; **both**:
 - A. Any
 - a. Spondylolisthesis (degenerative or isthmic) demonstrated on imaging
 - b. Spinal instability demonstrated on imaging
 - c. Spinal instability anticipated secondary to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis
 - B. Either
 - a. Neurogenic claudication or radicular pain resulting in significant functional impairment in member who has failed ≥ 3 months of conservative care with documentation of central/lateral recess/or foraminal stenosis on imaging
 - b. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling radicular pain or cauda equina syndrome
- 2. Severe progressive idiopathic scoliosis; either:
 - A. Cobb angle > 40°
 - B. Spinal cord compression with neurogenic claudication or radicular pain that results in significant functional impairment in a member who has failed ≥ 3 months of conservative care
- **3.** Severe degenerative scoliosis (lumbar or thoracolumbar) with Cobb angle \leq 30° or significant sagittal imbalance (e.g., sagittal vertical axis \geq 5 cm); and any:
 - A. Documented progression of deformity with persistent axial (nongraduating) pain and impairment or loss of function unresponsive to ≥ 1 year of nonoperative treatment
 - **B.** Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to ≥ 1 year of conservative nonsurgical care
 - **C.** Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling radicular pain or cauda equina syndrome
- Congenital scoliosis and congenital kyphosis in members with functional and/or neurological impairment
- 5. Isthmic spondylolisthesis; all:
 - A. Congenital (Wiltse type I) or acquired pars defect (Wiltse II) documented on x-ray
 - **B.** Persistent back pain (with or without neurogenic symptoms) with impairment or loss of function
 - C. Either unresponsive to ≥ 6 months of conservative nonsurgical care or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling radicular pain or cauda equina syndrome
- Recurrent same level disc herniation (post 2 discectomies) occurring at ≥ 3 months post previous surgery; all:
 - A. Recurrent neurogenic symptoms (radicular pain or claudication) or evidence of nerve-root irritation, as demonstrated by a positive nerve-root tension sign, positive femoral tension sign or a corresponding neurologic deficit
 - B. Impairment or loss of function

- C. Unresponsive to ≥ 3 months of medical management with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling radicular pain, or cauda equina syndrome
- **D.** Neural structure compression/instability documented by imaging at a level and side corresponding to the clinical symptoms
- 7. Pseudoarthrosis documented on imaging; all:
 - A. \geq 6 months post initial fusion
 - **B.** Refractory to medical management with persistent axial back pain (with or without neurogenic symptoms) or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication, disabling radicular pain or cauda equina syndrome
 - **C.** Member achieved significant symptom-relief prior to current onset of impairment/ functional loss
- 8. Spinal instability secondary to fracture/pseudoarthrosis, dislocation, infection (including tuberculosis), abscess/cyst or tumor when an extensive surgery is required that could be destabilizing
- **9.** Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance (≥ 5cm) causing functional limitations (e.g., significant pain, decreased ability to ambulate/perform ADLs, etc.)
- 10. Adjacent level disease; all:
 - A. Persistent back pain (with or without neurogenic symptoms) with impairment or loss of function that is unresponsive to \geq 3 months of conservative therapy
 - **B.** Eccentric disc space collapse, spondylolisthesis, acute single level scoliosis or lateral listhesis on imaging
 - **C.** Symptoms and functional measures correlate with imaging findings
 - **D.** Significant relief achieved for ≥ 6 months after prior fusion

Limitations/Exclusions

- 1. The use of instrumentation and bone formation/grafting materials must be used strictly in accordance with FDA-approved labeling. (Note: Osteogenic protein-1 [aka OP-1 implant or bone morphogenic protein-7/rhBMP-7 has been removed from the U.S. market]
- Repeat lumbar fusion operations will be reviewed on a case-by-case basis upon submission of medical records and imaging studies that demonstrate remediable pathology. The below must also be documented and available for review of repeat fusion requests:
 - **A.** Rationale as to why surgery is preferred over other non-invasive or less invasive treatment procedures.
 - **B.** Signed documentation that the member has participated in the decision-making process and understands the high rate of failure/complications
- 3. Lumbar fusion is not considered medically necessary if the sole condition is any:
 - C. Chronic nonspecific low back pain without radiculopathy
 - D. Degenerative disc disease without stenosis/spondylolisthesis
 - E. Disc herniation
 - F. Facet syndrome
 - G. Initial discectomy/laminectomy for neural structure decompression

- **4.** The following fusion procedures are not considered medically necessary due to insufficient evidence of therapeutic value:
 - A. Axial lumbar interbody fusion (AxiaLIF[®])
 - B. Laparoscopic anterior lumbar interbody fusion (LALIF)
- 5. Multi-level fusion is not considered medically necessary if clinical criteria are not met for all levels.
- 6. The use of rhBMP-2 is considered investigational and not medically necessary as an adjunct to PLIF or TLIF.
- 7. Use of an autograft is not considered medically necessary due to lack of feasibility or secondary to contraindications as follows; **any**:
 - A. Tissue no longer available, as member received a previous autograft
 - B. Insufficient autogenous tissue available for procedure
 - C. Member is deemed an unacceptable candidate for autograft; **any**:
 - a. > 65 years of age
 - b. Excessive risk of anatomic disruption (e.g., fracture) secondary to harvesting of autograft from donor site
 - c. Increased risk of autograft secondary to concurrent medical conditions/comorbidities
 - d. Poor quality bone (e.g., osteoporosis)
 - e. Obesity
 - f. Presence of morbidity (infection, or fracture) preventing harvesting at autograft donor site
- 8. Documented compliance of non-smoking three months prior to surgical intervention

Revision History

Apr. 12, 2024	Added congenital scoliosis and congenital kyphosis as covered indications
Apr. 8, 2022	Added documented requirement pertaining to smoking
Mar. 10, 2027	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar

Applicable Procedure Codes

22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment
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
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment

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); each additional interspace
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 and segment; 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 and segment; each additional interspace and segment
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, methylmethacrylate) 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

Applicable ICD-10 Diagnosis Codes

A18.01	Tuberculosis of spine
C41.2	Malignant neoplasm of vertebral column
D16.6	Benign neoplasm of vertebral column
D33.4	Benign neoplasm of spinal cord
G06.1	Intraspinal abscess and granuloma
G83.4	Cauda equina syndrome
G95.20	Unspecified cord compression
G95.29	Other cord compression
G95.9	Disease of spinal cord, unspecified
M41.04	Infantile idiopathic scoliosis, thoracic region
M41.05	Infantile idiopathic scoliosis, thoracolumbar region
M41.06	Infantile idiopathic scoliosis, lumbar region
M41.07	Infantile idiopathic scoliosis, lumbosacral region
M41.114	Juvenile idiopathic scoliosis, thoracic region
M41.115	Juvenile idiopathic scoliosis, thoracolumbar region
M41.116	Juvenile idiopathic scoliosis, lumbar region
M41.117	Juvenile idiopathic scoliosis, lumbosacral region
M41.124	Adolescent idiopathic scoliosis, thoracic region
M41.125	Adolescent idiopathic scoliosis, thoracolumbar region
M41.126	Adolescent idiopathic scoliosis, lumbar region
M41.127	Adolescent idiopathic scoliosis, lumbosacral region
M41.24	Other idiopathic scoliosis, thoracic region
M41.25	Other idiopathic scoliosis, thoracolumbar region

M41.26	Other idiopathic scoliosis, lumbar region
M41.27	Other idiopathic scoliosis, lumbosacral region
M41.84	Other forms of scoliosis, thoracic region
M41.85	Other forms of scoliosis, thoracolumbar region
M41.86	Other forms of scoliosis, lumbar region
M41.87	Other forms of scoliosis, lumbosacral region
M41.9	Scoliosis, unspecified
M43.05	Spondylolysis, thoracolumbar region
M43.06	Spondylolysis, lumbar region
M43.07	Spondylolysis, lumbosacral region
M43.15	Spondylolisthesis, thoracolumbar region
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M46.24	Osteomyelitis of vertebra, thoracic region
M46.25	Osteomyelitis of vertebra, thoracolumbar region
M46.26	Osteomyelitis of vertebra, lumbar region
M46.27	Osteomyelitis of vertebra, lumbosacral region
M46.34	Infection of intervertebral disc (pyogenic), thoracic region
M46.35	Infection of intervertebral disc (pyogenic), thoracolumbar region
M46.36	Infection of intervertebral disc (pyogenic), lumbar region
M46.37	Infection of intervertebral disc (pyogenic), lumbosacral region
M46.46	Discitis, unspecified, lumbar region
M46.47	Discitis, unspecified, lumbosacral region
M46.95	Unspecified inflammatory spondylopathy, thoracolumbar region
M46.96	Unspecified inflammatory spondylopathy, lumbar region
M46.97	Unspecified inflammatory spondylopathy, lumbosacral region
M47.16	Other spondylosis with myelopathy, lumbar region
M47.26	Other spondylosis with radiculopathy, lumbar region
M47.27	Other spondylosis with radiculopathy, lumbosacral region
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.896	Other spondylosis, lumbar region
M47.897	Other spondylosis, lumbosacral region
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M48.07	Spinal stenosis, lumbosacral region
M48.35	Traumatic spondylopathy, thoracolumbar region
M48.36	Traumatic spondylopathy, lumbar region
M48.37	Traumatic spondylopathy, lumbosacral region
M48.45XA	Fatigue fracture of vertebra, thoracolumbar region, initial encounter for fracture
M48.46XA	Fatigue fracture of vertebra, lumbar region, initial encounter for fracture
M48.47XA	Fatigue fracture of vertebra, lumbosacral region, initial encounter for fracture
M48.55XA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture
M48.56XA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
M48.57XA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
M48.8X5	Other specified spondylopathies, thoracolumbar region
M48.8X6	Other specified spondylopathies, lumbar region
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M48.8X7	Other specified spendule withing lumbassers region
	Other specified spondylopathies, lumbosacral region
M51.05	Intervertebral disc disorders with myelopathy, thoracolumbar region
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M51.26	Other intervertebral disc displacement, lumbar region
M51.27	Other intervertebral disc displacement, lumbosacral region
M51.35	Other intervertebral disc degeneration, thoracolumbar region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region
M51.86	Other intervertebral disc disorders, lumbar region
M51.87	Other intervertebral disc disorders, lumbosacral region
M51.9	Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M80.08XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.08XK	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.80XP	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with
	malunion
M84.58XA	Pathological fracture in neoplastic disease, other specified site, initial encounter for fracture (Vertebrae)
M96.1	Postlaminectomy syndrome, not elsewhere classified
M99.13	Subluxation complex (vertebral) of lumbar region
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region
M99.83	Other biomechanical lesions of lumbar region
Q76.2	Congenital spondylolisthesis
Q76.3	Congenital scoliosis due to congenital bony malformation
Q76.415	Congenital kyphosis, thoracolumbar region
S32.000A	Wedge compression fracture of unspecified lumbar vertebra, initial encounter for closed fracture
S32.000B	Wedge compression fracture of unspecified lumbar vertebra, initial encounter for open fracture
S32.001A	Stable burst fracture of unspecified lumbar vertebra, initial encounter for closed fracture
S32.001B	Stable burst fracture of unspecified lumbar vertebra, initial encounter for open fracture
S32.002A	Unstable burst fracture of unspecified lumbar vertebra, initial encounter for closed fracture
S32.002B	Unstable burst fracture of unspecified lumbar vertebra, initial encounter for open fracture
S32.008A	Other fracture of unspecified lumbar vertebra, initial encounter for closed fracture
S32.008B	Other fracture of unspecified lumbar vertebra, initial encounter for open fracture
S32.009A	Unspecified fracture of unspecified lumbar vertebra, initial encounter for closed fracture
S32.009B	Unspecified fracture of unspecified lumbar vertebra, initial encounter for open fracture
S32.010A	Wedge compression fracture of first lumbar vertebra, initial encounter for closed fracture
S32.010B	
	Wedge compression fracture of first lumbar vertebra, initial encounter for open fracture
S32.011A	Wedge compression fracture of first lumbar vertebra, initial encounter for open fracture Stable burst fracture of first lumbar vertebra, initial encounter for closed fracture

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S32.059B Unspecified fracture of fifth lumbar vertebra, initial encounter for open fracture		
S32.9xxK Fracture of unspecified parts of lumbosacral spine and pelvis, subsequent encounter for fracture with nonunion		
	S32.9xxK	Fracture of unspecified parts of lumbosacral spine and pelvis, subsequent encounter for fracture with nonunion

S33.0xxA	Traumatic rupture of lumbar intervertebral disc, initial encounter
S33.100A	Subluxation of unspecified lumbar vertebra, initial encounter
S33.101A	Dislocation of unspecified lumbar vertebra, initial encounter
S33.110A	Subluxation of L1/L2 lumbar vertebra, initial encounter
S33.111A	Dislocation of L1/L2 lumbar vertebra, initial encounter
S33.120A	Subluxation of L2/L3 lumbar vertebra, initial encounter
S33.121A	Dislocation of L2/L3 lumbar vertebra, initial encounter
S33.130A	Subluxation of L3/L4 lumbar vertebra, initial encounter
S33.131A	Dislocation of L3/L4 lumbar vertebra, initial encounter
S33.140A	Subluxation of L4/L5 lumbar vertebra, initial encounter
S33.141A	Dislocation of L4/L5 lumbar vertebra, initial encounter

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