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Medical Policy Manual

Topic: Lumbar Spinal Fusion

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Section: Surgery

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NOTE: This policy has been revised. The revised policy will be effective January 1, 2015. To view the revised policy, click here.

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Low back pain is a common affliction that can be caused by a variety of conditions including degenerative disc disease, muscle strain, skeletal trauma, infection, and tumor. It may be associated with radiculopathy or neurogenic claudication. Radiculopathy is caused by lumbar nerve root compression that may be due to disc protrusion, and/or osteophytes. Radicular pain is in the buttock, thigh, or calf areas. In addition to pain, this nerve root compression may be associated with sensory impairment, weakness, or diminished deep tendon reflexes. Neurogenic claudication is associated with spinal stenosis, with symptoms of leg pain, occasionally with weakness, brought on by walking or standing. Most cases of low back pain improve with conservative therapy including physical therapy, exercise, and/or analgesics. If the spine becomes unstable due to spondylolisthesis, trauma, infection or tumor, and for certain other identified causes of chronic, unremitting back pain, a fusion procedure is often recommended to provide stability or pain relief to the affected portion of the spine.

Lumbar arthrodesis (fusion) is a surgical procedure that joins two or more lumbar vertebrae together into one solid bony structure. This procedure may be used to treat spine instability, cord compression due to severe degenerative disc disease, fractures in the lumbar spine, or destruction of the vertebrae by infection or tumor. There are several methods or approaches to this surgery:

- The posterior approach from the back is the most common approach.
- The anterior/anterolateral approach through the abdomen.
- The anterior/posterior approach through the abdomen and from the back.

- The lateral extracavitary approach from the side or laterally.

After the vertebrae are exposed, pressure on the nerve roots and/or spinal cord is removed ("decompressed"). This usually includes removing part or all of the lamina bone, facet joints, any free disc fragments, filing down any nearby bone spurs, and/or foraminotomy. Bone grafts using the patient's own bone or cadaver bone are placed across the spaces between the vertebral bodies. Instrumentation (i.e., metal screws, rods, and/or plates) may be used to prevent movement of the vertebrae during the bone healing process.

MEDICAL POLICY CRITERIA

I. Lumbar spinal fusion may be considered **medically necessary** in skeletally mature patients with any of the following conditions:

A. Spinal fracture with instability or neural compression

B. Spinal repair surgery for dislocation, tumor, or infection (including abscess, osteomyelitis, discitis, or fungal infection) when debridement is necessary and the extent of the debridement to help eradicate the infection creates or could create an unstable spine.

C. Spinal stenosis with all of the following:

1. Associated spondylolisthesis demonstrated on plain x-rays

2. At least one of the following criteria are met:

a. Neurogenic claudication or radicular pain when all of the following criteria are met:

i. There is clinical documentation of significant functional impairment or loss of function, defined as inability or significantly decreased ability to perform normal daily activities of work, school, or at-home duties.

ii. There is clinical documentation that a minimum of 3 months of conservative nonoperative therapy (see II.A-C) failed to adequately treat the patient's symptoms

iii. Documented central, lateral recess, or foraminal stenosis on MRI or other imaging consistent with the patient's symptoms

b. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication, or cauda equina syndrome.

D. Severe, progressive idiopathic scoliosis (i.e., lumbar or thoracolumbar) with Cobb angle > 40 degrees.

E. Severe degenerative scoliosis when at least one of the following criteria are met:

1. Documented progression of deformity with persistent (daily) axial (non-radiating) pain and impairment or loss of function unresponsive to at least 3 months of conservative care (see II.A-C)

2. Persistent (daily) and significant neurogenic claudication or radicular pain with impairment or loss of function, unresponsive to at least 3 months of conservative care (see II.A-C).

F. Isthmic spondylolisthesis when all of the following criteria are met:

1. Either congenital (Wiltse type I) or acquired pars defect (Wiltse II), documented on x-ray

2. Persistent (daily) back pain, with or without neurogenic claudication or radicular pain, with significant impairment or loss of function, defined as inability or significantly decreased ability to perform normal daily activities of work, school, or at-home duties.

3. Symptoms have been unresponsive to at least 3 months of conservative nonsurgical care (see II.A-C)

G. Recurrent, same level, disk herniation when all of the following criteria are met:

1. Previous disk surgery was performed at least 6 months ago and resulted in significant interval relief of prior symptoms

2. Recurrent neurogenic claudication or radicular pain that has been unresponsive to at least 3 months of conservative nonsurgical care (see II.A-C)

3. There is clinical documentation of significant functional impairment or loss of function, defined as inability or significantly decreased ability to perform normal daily activities of work, school, or at-home duties.

4. Neural structure compression documented by recent imaging consistent with signs and symptoms

H. Adjacent segment degeneration when all of the following criteria are met:

1. Previous fusion was performed at least 12 months ago and resulted in significant interval relief of prior symptoms

2. Comprehensive evaluation by specialists other than the surgeon performing the procedure, documenting all of the following:

a. Recurrent neurogenic claudication or radicular pain

b. Significant functional impairment or loss of function defined as inability or significantly decreased ability to perform normal daily activities of work, school, or at-home duties.

c. Psychiatric/behavioral evaluation documenting appropriate management of associated cognitive, behavioral or addiction issues when present.

3. Symptoms have been unresponsive to at least 3 months of conservative nonsurgical care (see II.A-C)

4. Neural structure compression documented by recent imaging consistent with signs and symptoms

I. Radiologically documented pseudarthrosis (nonunion of prior fusion) when all of the following criteria are met:

1. Previous fusion was performed at least 6 months ago and resulted in significant interval relief of prior symptoms

2. Persistent (daily) axial back pain with or without neurogenic claudication or radicular pain

3. Significant functional impairment or loss of function defined as inability or significantly decreased ability to perform normal daily activities of work, school, or at-home duties.

J. Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy.

II. Conservative nonsurgical care for the duration specified in the criteria above must include all of the following:

A. Use of prescription strength analgesics (including anti-inflammatory medications if not contraindicated)

B. Documented participation in physical therapy that must include active strengthening and stretching exercises

C. Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present.

III. Lumbar spine arthrodesis (fusion) surgery is considered **not medically necessary** in the following circumstances:

A. When the above criteria are not met

B. If the sole indication is any one or more of the following conditions:

1. Disk Herniation

2. Degenerative Disk Disease

3. Initial diskectomy/laminectomy for neural structure decompression

4. Facet Syndrome

5. Low back pain that does not meet the criteria above

6. Non-instrumented fusion

SCIENTIFIC EVIDENCE

There are numerous factors that may affect outcomes in patients with low back pain such as the duration of the back pain, co-morbidities, treatment history, psychosocial influences, smoking status, and physician expertise. Although there is an extensive volume of published literature on the conservative, interventional, and surgical treatment of low back pain, clinical practice guidelines from U.S. professional associations vary in their recommendations related to patient selection criteria for lumbar spinal fusion. The following is a summary of the available recommendations for patients with chronic low back pain who may be candidates for lumbar spinal fusion.

American Association of Neurological Surgeons/Congress of Neurological Surgeons (ASSNS/CNS)[1]

This 2005 guideline was the most comprehensive guideline identified. The recommendations in these guidelines were divided into three categories as follows:

1. *Practice standards*: High degree of clinical certainty based on Class I evidence (one or more well-designed, randomized, controlled clinical trials (RCTs)
2. *Guidelines:* Moderate degree of clinical certainty based on Class II evidence (one or more well-designed comparative studies such as nonrandomized cohort studies, case-control studies, and other comparable studies including less well-designed RCTs
3. *Practice options:* Unclear clinical certainty from Class III evidence including observational studies such as case series, expert opinion, flawed RCTs.

Intractable low back pain (LBP) without stenosis or spondylolisthesis[2]

- Lumbar fusion recommended for carefully selected patients with chronic disabling LBP due to one- or two-level degenerative disease without stenosis or spondylolisthesis. (Standard; Class I evidence)
- Intensive physical therapy (PT) and cognitive therapy recommended for chronic disabling LBP when conventional medical management has failed. (Option; Class III evidence)

Degenerative disease with stenosis without spondylolisthesis[3]

- There was insufficient Class I or II evidence to recommend a treatment standard or guideline for fusion following decompression for this indication
- Treatment options (Class III evidence) included the following:
    - Posterolateral lumbar fusion (PLF) is not recommended for lumbar stenosis in the absence of spinal instability (preexisting or iatrogenic due to facetectomy)
    - Lumbar PLF was recommended as a treatment option with decompression surgery when there is evidence of instability

Lumbar stenosis with associated degenerative spondylolisthesis[4]

- There was insufficient Class I or II evidence to recommend a treatment standard or guideline for fusion following decompression for stenosis with spondylolisthesis; however, PLF was listed as a

treatment option (Class III evidence) for this indication.

Disc herniation and radiculopathy[5]

- There was insufficient Class I or II evidence to recommend a treatment standard or guideline
- Lumbar spinal fusion is not recommended as routine treatment following primary disc excision for herniated disc causing radiculopathy (Class III evidence)
- Lumbar spinal fusion is considered a potential surgical adjunct in the following circumstances:
    - Herniated disc with evidence of preoperative spinal deformity or instability
    - Significant chronic axial LBP associated with radiculopathy due to herniated disc
    - Reoperative discectomy without fusion for recurrent lumbar disc herniation
    - Reoperative discectomy with fusion for recurrent disc herniation associated with lumbar instability, deformity, or chronic axial LBP

Instrumentation[6]

- There was insufficient Class I or II evidence to recommend a treatment standard or guideline
- Pedicle screw (PS) fixation is recommended as option for patients with LBP treated with PLF who are at high risk for fusion failure as PS fixation improves fusion success rates. (Class III evidence)
- PS fixation is not recommended as a routine adjunct to PLF in patients with chronic LBP secondary to degenerative disc disease because evidence is conflicting regarding the beneficial effect on functional outcome, and there is consistent evidence that the use of PS fixation is associated with higher costs and complications. (Class III evidence)

North American Spine Society (NASS)[7,8]

Note: These guidelines do not apply to functional neurological deficits (motor weakness or EMG findings of radiculopathy).

"The majority of patients with symptomatic degenerative lumbar spondylolisthesis and an absence of neurologic deficits will do well with conservative care. Patients who present with sensory changes, muscle weakness or cauda equina syndrome, are more likely to develop progressive functional decline without surgery."[7]

- In the absence of reliable evidence, the workgroup's experience-based opinion for conservative treatment of degenerative lumbar stenosis suggested that PT and exercise may be effective in improving outcomes as part of a comprehensive treatment strategy (Grade of recommendation I: insufficient or conflicting evidence not allowing a recommendation for or against intervention) [8]
- Decompression alone is suggested for patients with leg predominant symptoms without instability (Grade of recommendations B: Fair evidence from Level II or III studies, lesser quality RCTs, case series, retrospective reviews with consistent findings)
- Decompression with fusion was recommended for symptomatic stenosis and degenerative spondylolisthesis **(**Grade of recommendations B)[7]
- Surgery (unspecified) was recommended for symptoms recalcitrant to trial of medical/interventional treatment of unspecified duration **(**Grade of recommendations B**)**

The addition of instrumentation to fusion was recommended to improve fusions rates, but not to improve clinical outcomes in treatment of spinal stenosis and degenerative lumbar spondylolisthesis **(**Grade of

recommendations B)[7]

American Pain Society (APS)[9]

- For nonradicular LBP with common degenerative spinal changes and persistent and disabling symptoms, the APS made a weak recommendation based on moderate-quality evidence that surgery may provide improved outcomes compared with non-interdisciplinary rehabilitation, but not for intensive interdisciplinary rehabilitation. The APS further recommended that clinicians discuss with patients the risks and benefits of surgery versus intensive interdisciplinary nonsurgical therapy since the majority of these patients do not experience an optimal outcome with surgery.
- Instrumented fusion is associated with enhanced fusion rates but insufficient evidence exists to determine whether it improves clinical outcomes, and additional costs are substantial. In addition, there is insufficient evidence to recommend a specific fusion method, though more technically difficult procedures may be associated with higher complication rates.
- The benefits of fusion versus nonsurgical therapy have only been demonstrated in a relatively narrow group of patients with at least moderately severe pain or disability unresponsive to nonsurgical therapies for at least one year and without serious psychiatric or medical comorbidities or other risk factors for poor surgical outcomes.
- The evidence is insufficient to determine whether concurrent fusion improves outcomes when laminectomy is performed for spinal stenosis with persistent disabling leg pain.

American College of Physicians/American Pain Society (ACP/APS)[10]

- For chronic or subacute LBP not improved with self-care, the guidelines listed the following therapy options: intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence)
- MRI or CT imaging is recommended for patients with "persistent back and leg pain who are potential candidates for invasive interventions as plain radiography cannot visualize discs or accurately evaluate the degree of spinal stenosis. However, clinicians should be aware that findings on MRI or CT (such as bulging disc without nerve root impingement) are often nonspecific."
- Surgery (unspecified) is considered a treatment option for persistent symptoms associated with spinal stenosis.

American Physical Therapy Association[11]

The following therapies were recommended for subacute and chronic LBP:

- With spinal instability and/or impaired movement coordination: Trunk coordination, strengthening, and endurance exercises (Grade of recommendation A: Strong evidence; recommendation supported by preponderance of level I high quality prospective studies or RCTs [at least one required], and/or level II lesser quality studies)
- With mobility deficits: Repeated exercises in a specific direction determined by treatment response (Grade of recommendation A)
- With radiating pain: Lower-quarter nerve mobilization procedures (Grade of recommendation C: Weak evidence; single level II study or preponderance of Level III [case-controlled or retrospective studies] or IV [case series] studies, including consensus statements)

The following therapies were recommended for chronic LBP:

- Without generalized pain: Moderate- to high-intensity exercise (Grade of recommendation A)
- With generalized pain: Progressive low-intensity, submaximal fitness and endurance activities for chronic LBP (Grade of recommendation A)
- With lower extremity pain: Thrust manipulative and nonthrust mobilization procedures (Grade of recommendation A)
- In older patients with chronic LBP with radiating pain: Flexion exercises combined with other interventions such as manual therapy, strengthening exercises, nerve mobilization, and progressive walking (Grade of recommendation C)

Other recommendations:

- There is conflicting evidence for lumbar traction for the treatment of LBP. There is preliminary evidence that a specific subgroup of patients with signs of nerve root compression along with peripheralization of symptoms or a positive crossed straight leg raise will benefit from intermittent lumbar traction in the prone position. However, there is moderate evidence that intermittent or static lumbar traction should *not* be used in the treatment of chronic LBP or acute or subacute nonradicular LBP. (Grade of recommendation D: Conflicting evidence; conclusions from higher-quality studies disagree)

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2. Resnick, DK, Choudhri, TF, Dailey, AT, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: intractable low-back pain without stenosis or spondylolisthesis. *J Neurosurg Spine*. 2005 Jun;2(6):670-2. PMID: 16028735
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10. Chou, R, Qaseem, A, Snow, V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*. 2007 Oct 2;147(7):478-91. PMID: 17909209
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CROSS REFERENCES

Electrical Bone Growth Stimulators (Osteogenic Stimulation), Durable Medical Equipment, Policy No. 83.11

Artificial Intervertebral Disc, Surgery, Policy No. 127

Dynamic Stabilization of the Spine, Surgery, Policy No. 143

Percutaneous Axial Anterior Lumbar Fusion, Surgery, Policy No. 157

Interspinous Fixation (Fusion) Devices, Surgery, Policy No. 172

CODES	NUMBER	DESCRIPTION
CPT	20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
	20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
	20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)
	20937	; morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
	20938	; structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
	22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
	22534	; thoracic or lumbar, each additional vertebral segment (List separately

CODES	NUMBER	DESCRIPTION
		in addition to code for primary procedure)
	22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
	22585	Anterior approach for Lumbar Fusion (Anterior Retroperitoneal Exposure); each additional interspace (List separately in addition to code for primary procedure)
	22612	Arthrodesis, posterior technique, craniocervical (occiput-C2); lumbar (with lateral transverse technique, when performed)
	22614	; each additional vertebral segment (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	; 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 and segment; lumbar
	22634	; each additional interspace and segment (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	; 7 to 12 vertebral segments
	22804	; 13 or more vertebral segments
	22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
	22810	; 4 to 7 vertebral segments
	22812	; 8 or more vertebral segments
	22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)

CODES	NUMBER	DESCRIPTION
	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	; 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
	22844	; 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	; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
	22847	; 8 of 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
	22851	Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)
HCPCS	None	