Clinical Policy Title: Spinal surgeries

Clinical Policy Number: 03.03.03

Effective Date: March 1, 2016
Initial Review Date: November 20, 2013
Most Recent Review Date: March 6, 2018
Next Review Date: March 2019

CP# 03.03.01 Spinal cord stimulators for chronic pain
CP# 03.02.02 Radiofrequency ablation treatment for spine pain
CP# 03.02.07 Spine pain — facet joint injections
CP# 03.03.04 Spine pain — epidural injections
CP# 03.03.08 Intravenous lidocaine infusion for neuropathic pain
CP# 03.03.06 Biofeedback for chronic pain
CP# 03.03.05 Spine pain — trigger point injections

Coverage policy

Select Health of South Carolina considers the use of spinal surgeries for cervical, lumbar, or thoracic laminectomy; lumbar spinal fusion; percutaneous polymethylmethacrylate vertebroplasty; vertebroplasty; kyphoplasty; sacroplasty; coccygectomy; and lumbar decompression with or without discectomy to be clinically proven and, therefore, medically necessary when the following criteria are met (Lu 2017, Hayes 2016, Parkin 2015):

1. Cervical, lumbar, and thoracic laminectomy are considered medically necessary for any of the following:
   - Spinal fracture, dislocation (associated with mechanical instability), locked facets, or displaced fracture fragment confirmed by imaging studies, such as computed tomography (CT) or magnetic resonance imaging (MRI).
   - Spinal infection confirmed by imaging studies (e.g., CT or MRI).
• Spinal tumor confirmed by imaging studies (e.g., CT or MRI).
• Epidural hematomas confirmed by imaging studies (e.g., CT or MRI).
• Synovial cysts, or arachnoid cysts causing spinal cord or nerve root compression with unremitting pain, confirmed by imaging studies (e.g., CT or MRI) and with corresponding neurologic deficit, where symptoms have failed to respond to six weeks of conservative therapy (unless there is evidence of cord compression, or progressive neurologic deficit, which requires urgent intervention).
• Severe spinal stenosis (recess, foraminal, central stenosis) with unremitting pain, with stenosis confirmed by imaging studies (e.g., CT or MRI) at the level corresponding to neurologic findings, where symptoms have failed to respond to six weeks of conservative therapy (unless there is evidence of cord compression, or progressive neurologic deficit, which requires urgent intervention).
• Other mass lesions confirmed by imaging studies (e.g., CT or MRI), on individual case review.

2. Lumbar spinal fusion is considered medically necessary when clear documentation is recorded, including patient acknowledgement of alternative options for any of the following indications:
• Adult scoliosis, kyphosis, or pseudoarthrosis (non-union of prior fusion), which is associated with radiological (e.g., CT or MRI) evidence of mechanical instability or deformity of the lumbar spine that has failed three months of conservative management.
• Spinal fracture, dislocation (associated with mechanical instability), locked facets, or displaced fracture fragment confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy.
• Spinal infection confirmed by imaging studies (e.g., CT or MRI) and/or other studies (e.g., biopsy), which may be combined with a laminectomy.
• Spinal tumor confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy.
• Spondylolisthesis with segmental instability confirmed by imaging studies (e.g., CT or MRI), when both of the following criteria are met:
  - Significant spondylolisthesis, grade III, IV, or V.
  - Rapidly progressive neurologic compromise (i.e., cauda equina syndrome [loss of bowel or bladder control]).
• Severe spinal stenosis with unremitting pain confirmed by imaging studies (e.g., CT or MRI) that has failed three months of conservative management when any of the following are present:
  - Decompression is performed in an area of segmental instability as manifested by gross movement on flexion-extension radiographs.
  - Decompression coincides with an area of significant degenerative instability (e.g., scoliosis or any degree of spondylolisthesis, grade I, II, III, IV, or V).
  - Decompression creates an iatrogenic instability by the disruption of the posterior elements where facet joint excision exceeds 50 percent bilaterally.
or complete excision of one facet is performed.

- Spinal tuberculosis.
- Spinal debridement for infection (e.g., osteomyelitis).

3. Pedicle screws for spinal fixation are considered medically necessary for the following indications:
   - Fusion adjacent to prior lumbar fusion.
   - Fusion after decompression.
   - Pseudoarthrosis repair.
   - Existing painful spinal instability documented on imaging post-laminectomy spondylolisthesis.
   - Scoliosis and kyphosis requiring spinal instrumentation.
   - Segmental defects or loss of posterior elements following tumor resection.
   - Spinal trauma of all types, including fractures and dislocations.
   - Isthmic spondylolisthesis — grades III to IV (it usually is not considered until a patient has failed to find pain relief with at least six months focused on a range of nonsurgical treatments).
   - Thoracic fractures.

4. Percutaneous polymethylmethacrylate vertebroplasty is considered medically necessary for persons with persistent, debilitating pain in the cervical, thoracic, or lumbar vertebral bodies resulting from any of the following:
   - Multiple myeloma.
   - Painful and/or aggressive hemangiomas.
   - Painful vertebral eosinophilic granuloma.
   - Painful, debilitating osteoporotic collapse or compression fractures (e.g., Kummell’s disease).
   - Primary malignant neoplasm of bone or bone marrow.
   - Secondary osteolytic metastasis, excluding sacrum and coccyx.
   - Steroid-induced fractures.
   - When the following criteria have all been met:
     - Other causes of pain, such as herniated intervertebral disk, have been ruled out by CT or MRI.
     - Severe debilitating pain or loss of mobility that cannot be relieved by optimal medical therapy (e.g., acetaminophen, non-steroid anti-inflammatory drugs, narcotic analgesics, braces, or physical therapy).
     - The affected vertebra has not been extensively destroyed and is at least one-third of its original height.

5. Vertebroplasty, kyphoplasty, and sacroplasty is considered a covered service only in the following circumstances:
• Documented vertebral body collapse from osteoporotic fracture documented on imaging study and with severe pain in the same region and who has failed conservative therapy for at least two to six weeks.
• Severe debilitating pain associated with vertebral body destruction from osteolytic metastasis, multiple myeloma, aggressive vertebral hemangioma, or eosinophilic granuloma of the vertebra.
• Congenital malformations or acquired with musculoskeletal degenerative diseases.

6. Coccygectomy is considered medically necessary for individuals with coccygodynia who have tried and failed to respond to six months of conservative management.

7. Lumbar decompression with or without discectomy is considered medically necessary for rapid progression of neurologic impairment (e.g., foot drop, extremity weakness, numbness or decreased sensation, saddle anesthesia, or bladder or bowel dysfunction) confirmed by imaging studies (e.g., CT or MRI).

8. Spinal surgery in persons with prior spinal surgery is considered medically necessary when any of the above criteria (1 – 4) is met.

Select Health of South Carolina considers the use of lumbar spinal fusion experimental and investigational for degenerative disc disease and all other indications not listed above because of insufficient evidence of its effectiveness for these indications.

Select Health of South Carolina considers the use of lumbar artificial disc replacement to be investigational because the effectiveness of its use has not been established in peer-reviewed professional literature. Cervical spine artificial disc replacement will be considered case by case as a program exception.

Limitations:

Pedicle screw fixation is considered experimental and investigational and, therefore, medically not necessary for the following and potentially other indications:
• Decompressive laminectomy for spinal stenosis without evidence of instability.
• Degenerative disc disease.
• Failed lumbar surgery without documentation of instability pattern or pseudarthrosis.
• First-time intervertebral disc herniation.
• Isolated low-back pain without spinal instability or neurologic deficits.
• Single-level discectomy.
Vertebroplasty, kyphoplasty, sacroiliac fusion, and sacroplasty are considered experimental and investigational and, therefore, medically not necessary for the following and potentially other indications:

- Vertebroplasty, kyphoplasty, and sacroplasty may not be covered for prophylaxis of osteoporosis because there is no evidence that such therapy can prevent a fracture.
- Treatment of chronic or old compression fractures.
- Vertebroplasty, kyphoplasty, and sacroplasty are contraindicated if there is osteomyelitis, tuberculosis of the spine, spinal stenosis, and allergy to the cement, coagulopathy, or anticoagulation.

This policy is limited to surgical approaches to spine disease. All other uses of spinal surgeries are not medically necessary. Please see other policies for medical and chiropractic approaches to spine pain.

**Alternative covered services:**

- Facet joint injection.
- Chiropractic manipulation in the first four weeks if there is no radiculopathy.
- Heat or cold modalities for home use.
- Low-impact exercise (e.g., stationary bike, swimming, or walking).
- Pharmacotherapy (e.g., non-narcotic analgesics, non-steroidal anti-inflammatory drugs, or muscle relaxants).
- Trigger point injections.
- Epidural spinal injections.
- Cognitive-behavioral therapy.
- Interdisciplinary rehabilitation.

Generally, conservative therapy is not recommended in the presence of progressive neurologic deficits, when spinal fracture or dislocation is unstable or for progressive spinal deformity. When conservative management is attempted and fails, surgery may be required for conditions with underlying pathology as determined by radiological findings.

**Background**

Many clinical practice guidelines are currently available regarding appropriate indications for lumbar spine surgery. The most common pathological occurrences of lumbar spine are herniated lumbar discs, lumbar stenosis, and lumbar spondylolisthesis. These conditions are commonly treated surgically if conservative treatments do not give sufficient pain relief of the patient, particularly for refractory leg pain from radicular compression, which can be very severe. Even with spondylolisthesis, the most common symptom is leg pain, from secondary radicular compression arising from foramina, lateral recess, or central spinal stenosis; most lumbar fusions are an adjunct to nerve decompression procedure. An early study of lumbar fusion in spondylolisthesis, for example, showed that recurrence of
leg pain was predictable if a prophylactic fusion was not performed at the time of the nerve decompression procedure.

Low-back pain affects approximately 60 percent – 90 percent of the U.S. population at some point in their lives and may be caused by a wide variety of conditions, although in some cases no specific etiology is identified.

The initial evaluation of patients with low-back pain involves ruling out potentially serious conditions such as infection, malignancy, spinal fracture, or a rapidly progressing neurologic deficit suggestive of the cauda equina syndrome, bowel or bladder dysfunction, or weakness, which suggest the need for early diagnostic testing. Patients without these conditions are initially managed with conservative therapy.

Advances in spine surgery can benefit a number of patients because of the ways that the surgery can off-load the impact of anatomical pathology. The patient may improve or have re-exacerbations as a result. This policy addresses several different spinal surgical technologies with the finding that some have greater evidence and greater acceptance than others. The use of laminectomy and spinal fusion have wide acceptance, whereas the use of artificial disks and pedicle screws still do not have standard acceptance.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 11, 2018. Search terms were: "back pain (MeSH)," "low back pain (MeSH)," and "spinal surgery."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**
For adults < 50 years of age with no signs or symptoms of systemic disease, symptomatic therapy without imaging is appropriate. For patients 50 years of age and older, or those whose findings suggest systemic disease, plain radiography and simple laboratory tests can almost completely rule out underlying systemic diseases. Advanced imaging (e.g., CT or MRI) should be reserved for patients who are considering surgery or those in whom systemic disease is strongly suspected.

Conservative care without immediate imaging is also considered appropriate for patients with radiculopathy, as long as symptoms are not bilateral or associated with urinary retention. Except when red flag (see Appendix A) signs are present, MRI should not be performed in patients whose neurologic signs and symptoms are of a duration less than four to six weeks. Ninety percent of acute attacks of sciatica will resolve with conservative management (see the section on alternative covered services) within four to six weeks.

Spinal fusion surgery is intended to reduce spinal pain by fusing adjacent vertebra, which eliminates motion and removes pressure from spinal nerves. The surgery has been performed for decades, but has wide regional variation in its indications. There have been few rigorous studies on the effectiveness of spinal fusion.

Spinal fusion is generally performed in the cervical or lumbar vertebral segments where there is the greatest motion. It is frequently performed for stabilization after discectomy or other spinal surgeries. There are a number of surgical procedures amenable to achieve fusion of the cervical or lumbar regions but no one technique has evidence of superiority. For cervical spine fusion, the fusion is typically performed with the use of transplanted bone, usually from the iliac crest.

Controlled studies on indications for cervical spine fusion are few. There is general consensus among surgeons that the indications for which there are the greatest levels of evidence include:

- Failure of conservative management of patients with cervical radicular symptoms.
- After cervical discectomy, especially when spondylosis or osteophyte compression is present.
- Post-trauma with cervical vertebral fractures and instability.

The primary indications for lumbar fusion are for kyphosis, scoliosis, trauma with nerve root compression, spondylolisthesis, and vertebral instability from infection or tumor. Surgery for spinal fusion may be endoscopic or open. The following are the more common approaches to lumbar spinal fusion surgery:

- Posterolateral fusion.
- Posterior lumbar interbody fusion.
- Transforaminal lumbar interbody fusion.
- Endoscopic or minimally invasive transforaminal lumbar interbody fusion.
- Anterior lumbar interbody fusion.
• Laparoscopic anterior lumbar interbody fusion.
• Circumferential fusion.
• Axial interbody fusion (Axial Lumbar Interbody Fusion System manufactured by TranS1 Inc.).

Comparison of the outcome of these different procedures for the various indications has not been done systematically. Consensus among the various meta-analyses is that the spinal fusion is effective except in cases of acute spinal instability caused by trauma, infection, or neoplastic process. Patients need to be fully informed as to the acute and long-term risks of surgery. In most cases, patients will have failed aggressive rehabilitation before considering surgery.

The Spine Patient Outcomes Research Trial (SPORT) was designed to compare the effectiveness of surgical and nonsurgical treatment among participants with confirmed diagnoses of intervertebral disk herniation, spinal stenosis, and degenerative spondylolisthesis. The performance of lumbar fusion in the case of spondylolisthesis is now considered routine, with minimal disagreement among the guidelines (although this is being tested as one arm of the randomized SPORT study).

Reviews by the American College of Physicians (ACP), and American Academy of Orthopedic Surgeons (AAOS) have all suggested that there may be some potential greater benefit of fusion over conservative therapies, but that the studies were not designed to make conclusions on specific benefits.

The North American Spine Society (NASS) indicates that there is grade B evidence that patients achieve more rapid relief of pain from cervical radiculopathy with surgical management compared to medical management, but no differences were found at 12 months post-operatively. The approach to the cervical spine may be by either an anterior or a posterior route to accomplish vertebral fusion. The use of interbody graft is associated with improved outcomes for cervical fusion. The NASS study further indicates that most cases of cervical radiculopathy occur at a single level, and are less commonly found at two levels. In general there is a paucity of multi-level disease. Finally, the majority of reoperations are the result of further degeneration caused by forces on the vertebral bodies above or below the fused vertebrae.

Pedicle screws help stabilize vertebral structures with implants and improve the outcomes of spinal surgery. Spinal fusion is accomplished with rods and plates that may extend to multiple spine segments, and are often attached to the spine with pedicle screws. Pedicle screw fixation systems consist of steel or titanium plates that are longitudinally interconnected and anchored to adjacent vertebrae using bolts, hooks, or screws. Pedicle screw fixation in the spine is used to produce a rigid connection between two or more adjacent vertebrae. The maneuver is intended to correct deformity and to stabilize the spine, thereby reducing pain and alleviating neurologic deficits. It is most often used in the lumbosacral spine from L1 to S1, and may also be used in the thoracic spine.

After discectomy, interbody spacers are inserted into the intervertebral space with or without additional pedicle screws and plate/rod fixation (Hodges 2012. Thakkar 2012). Optimally, the screws should
transverse the central aspect of the pedicle and align parallel to the superior end plate in a neutral position. A misaligned pedicle screw can compromise the biomechanics of the structural repair, causing symptom recurrence, new symptoms, or neurovascular injury.

Accurate placement of pedicle screws is paramount to the success of spinal surgery. Even when an experienced surgeon uses standard fluoroscopic guidance, screws can be misaligned medially in approximately 5 percent of cases, and inferolaterally in approximately 15 percent of cases. A recent systematic review of studies, including a total of 1,105 patients in which 6,617 screws were inserted during lumbar or thoracic surgery, showed that in the studies using the free-hand technique, the percentage of screws fully contained in the pedicle ranged from 69 percent – 94 percent with the aid of fluoroscopy; from 28 percent – 85 percent using CT navigation; from 89 percent – 100 percent; and using fluoroscopy-based navigation from 81 percent – 92 percent (Gelalis, 2012). Screws positioned with the free-hand technique more often perforated the cortex medially, whereas screws placed with CT guidance perforated more often laterally (Gelalis, 2012). Newer alternatives to these methods for guidance of pedicle screw placement involve intraoperative 3D navigation (Ughwanogho et al., 2010).

A breach of the pedicle wall and cortical perforation can have serious consequences if the screw encroaches on a nerve root or blood vessel. A significant breach of the medial wall into the spinal cord can lead to paralysis while an inferiorly placed screw can cause radiculopathy. When guided by the imaging methods described earlier, pedicle screws can be accurately placed using anatomical landmarks (free-hand technique). Concurrent monitoring of somatosensory- and dermatomal somatosensory-evoked potentials to detect nerve-root irritation and electromyography are useful ancillary technologies that may be employed in this regard (Silberman, 2011, Purushothamdas, 2011, Gelalis, 2012, Patil 2012, Thakkar 2012).

The current medical literature suggests that rigid fixation of the lumbar spine with pedicle screws improves the chances of successful fusion as compared with patients with lumbar spine fusion not supplemented with internal fixation. Internal fusion and fixation are major operative procedures with significant risks reserved for patients with spinal instability associated with neurologic deficits, major spinal deformities, spinal fracture, spinal dislocation, or complications from tumor. Spinal fusion and pedicle screw fixation have not been shown effective for the treatment of isolated chronic low back pain, and surgery is not advocated to treat this diagnosis in the absence of instability or neurologic deficits.

Excision of tissues compressing the spinal cord (posterior decompression) is a common treatment for patients with herniated or subluxed vertebrae (spondylolisthesis), degenerative intervertebral discs, certain types of vertebral fractures, or spinal tumors. Spinal instability following decompression may be sufficiently severe to require stabilization by bony fusion (arthrodesis) of affected and adjacent vertebrae using implanted autologous bone grafts. Following placement of the graft, further mechanical stability may be provided by combinations of various surgically implanted hooks, rods, or wires. Severe instability may require surgical implantation of plates or rods anchored to vertebral pedicles using
pedicle screw fixation systems to provide rigid three-column fixation or minimize the risk of incomplete fusion (pseudoarthrosis or pseudarthrosis) or the loss of alignment during fusion.

Percutaneous vertebroplasty and percutaneous kyphoplasty are similar therapeutic procedures to reduce the pain of vertebral compression fractures that are the result of osteoporosis, osteolytic vertebral metastases or myeloma, or vertebral hemangioma. Bone cement is injected into the fracture site under fluoroscopic control or CT guidance. Balloon-assisted vertebroplasty or kyphoplasty are modifications in which an inflatable balloon expands the vertebral height prior to the injection of the cement. Percutaneous sacroplasty uses a similar technique for reduction of pain from sacral fractures.

The U.S. Food and Drug Administration (FDA) has identified serious complications related to the use of acrylic bone cements (i.e., polymethylmethacrylate). Leakage of cement can cause soft tissue injury and nerve root pain. Rare complications such as pulmonary embolism and cardiorespiratory failure have also been reported.

The AAOS (2010) performed a review of the treatment of osteoporotic spinal compression fractures. The strength of evidence was weak for the use of kyphoplasty or vertebroplasty with osteoporotic fractures in symptomatic patients who are neurologically intact. The authors could not distinguish outcome differences between patients managed with bracing, physical therapy, exercise, or kyphoplasty. The American College of Radiology (ACR) also reviewed the literature and concluded that vertebroplasty or kyphoplasty should not be considered a primary treatment of osteoporotic fractures. These techniques are recommended only for individuals who have failed conservative therapy.

Artificial disc replacement and intervertebral disc prostheses for both cervical and lumbar disease have emerged as treatments for the loss of mobility inherent with spinal fusion. Indication is limited to degenerative disc disease in skeletally mature adults. The FDA has advised that intervertebral discs should be limited to individuals who have degenerative disc disease at a single level in the lumbar spine (from L4 to S1) or for a single level of the cervical spine (from C3 to C7) that has no more than 3 mm of spondylolisthesis at the involved level. Additionally, intervertebral discs should only be used in individuals who have no relief from pain after at least six months of nonsurgical treatment.

Prostheses approved by the FDA include the Charité and ProDisc-L devices, the Prestige Cervical Disc, the ProDisc-C, and the BRYAN Cervical Disc. Contraindications include active systemic infection or infection localized to the site of implantation, osteoporosis or osteopenia, bony lumbar stenosis, allergy or sensitivity to implant materials, and isolated radicular compression syndromes, especially in cases related to disc herniation or a pars defect.

Limitations for cervical disc replacement include moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of greater than 50 percent of its normal height. Also, marked cervical instability (i.e., subluxation ≥ 3.5 mm, angulation, or more than 11 degrees greater than adjacent segments), significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis,
rheumatoid arthritis, or compromise due to current or past trauma), and significant kyphotic deformity or significant reversal of lordosis.

Studies have demonstrated non-inferiority of artificial disc replacement to discectomy and fusion in both cervical and lumbar regions but follow-up is limited to two years. There are no studies showing the long-term effectiveness of artificial discs. Early models did have propensity to migrate from the original implanted position. Long-term impacts are not known and alternatives such as physical therapy, exercise, medication, and durable medical equipment are available.

Policy updates:

Hayes (2016) studied the comparative effectiveness of vertebroplasty versus sham, conservative treatment, or kyphoplasty for osteoporotic vertebral compression fractures after several recent randomized controlled studies suggested that percutaneous vertebroplasty may have superior efficacy relative to sham in some patient populations. There was no change in the risk of additional vertebral compression fractures following vertebroplasty versus other comparator groups, including sham, conservative treatment, facet block, and kyphoplasty. Vertebroplasty and kyphoplasty also offered comparable benefit for treatment of vertebral compression fractures due to osteoporosis on measures of pain, disability, or quality of life. However, some data suggest that vertebroplasty procedures may be associated with higher rates of morbidity and mortality than kyphoplasty. The authors concluded that, in the absence of further evidence of efficacy, kyphoplasty may be the safer alternative for patients when both options are available.

Parkin (2015) in a comprehensive narrative review of nonmalignant spinal pain, particularly persistent pain, found that management that addresses both the physical and psychosocial components are necessary to address the multidimensional nature of spinal pain. The authors noted that care services that tailor care to the individual person with pain tend to achieve better outcomes and greater satisfaction with care, while most likely containing costs. They also opine that further research will be necessary to offer insight into clinical outcomes of complex interventions to inform health care policy and practice.

During the past twelve months there has been further information published regarding spinal surgeries.

A systematic review and meta-analysis (Lu 2017) compared the efficacy and safety of the Mobi-C cervical artificial disc versus anterior cervical discectomy and fusion in patients with symptomatic degenerative disc disease. Compared with anterior cervical discectomy and fusion surgery for symptomatic degenerative disc disease, Mobi-C was associated with a significantly improved symptom scores (Std. mean difference = \(0.32; 95\% \text{ CI} = 0.10-0.53; P = .004\)), patient satisfaction (odds risk [OR] = 2.75; 95\% confidence interval [CI] = 1.43-5.27; \(P = .002\)), and reduced subsequent surgical intervention (OR = 0.20; 95\% CI = 0.11-0.37; \(P < .001\)). Mobi-C was found to produce comparable neurological deterioration (OR = 0.77; 95\% CI = 0.35-1.72; \(P = .53\)), radiographic success (OR = 1.18; 95\% CI = 0.39-3.59; \(P = .77\)), and overall success (OR = 2.13; 95\% CI = 0.80-5.70; \(P = .13\)).
Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Hayes (2016)</td>
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<td><strong>Key points:</strong></td>
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<td>• Recent RCTs have suggested that VP may have superior efficacy relative to sham in some patient populations, possibly patients with acute VP symptoms lasting &lt; two weeks.</td>
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<td>• There are no consistent differences in the risk of additional VCFs following VP versus other comparator groups, including sham, conservative treatment, facet block, and kyphoplasty.</td>
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<td>• VP and kyphoplasty offer comparable benefit for treatment of VCFs due to osteoporosis on measures of pain, disability, or quality of life in well-designed RCTs.</td>
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<td>• Real-world data from very large database studies suggest that VP may be associated with higher rates of morbidity and mortality than kyphoplasty.</td>
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<td>• Due to the observational nature of these studies, it is unclear what factors are driving this finding.</td>
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<td>• Until additional studies are conducted to determine the variables underlying the higher mortality and morbidity rates with VP, kyphoplasty may be the safer alternative for patients when both options are available.</td>
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<tr>
<td>Parkin (2015)</td>
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<td><strong>Key points:</strong></td>
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<td>• Narrative review of nonmalignant spinal pain found that management that addresses both the physical and psychosocial components is necessary to address the multidimensional nature of spinal pain.</td>
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<td>• Tailored care tends to achieve better outcomes and greater satisfaction with care.</td>
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<td>• Further research will be necessary to inform health care policy and practice.</td>
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</tbody>
</table>

References

Professional society guidelines/other:


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

L34291 Surgery: Injections of the Spinal Canal. Cahaba Government Benefit Administrators®, LLC. Website: [https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=L36879&KeyWordLookUp>Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAAA=&&](https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=L36879&KeyWordLookUp>Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAAA=&& Accessed January 18, 2018.

L36879 Surgery: Spinal Cord Stimulators for Chronic Pain. Website: [https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=L36879&KeyWordLookUp>Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAAA=&&](https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=L36879&KeyWordLookUp>Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAAA=&& Accessed January 18, 2018.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill in accordance with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>22533</td>
<td>Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
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<tr>
<td>22534</td>
<td>Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22558</td>
<td>Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
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<tr>
<td>22585</td>
<td>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)</td>
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<tr>
<td>22612</td>
<td>Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)</td>
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<tr>
<td>22614</td>
<td>Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure)</td>
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<tr>
<td>CPT Code</td>
<td>Description</td>
<td>Comments</td>
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<tr>
<td>22630</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar</td>
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<tr>
<td>22632</td>
<td>Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22633</td>
<td>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</td>
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</tr>
<tr>
<td>22634</td>
<td>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 (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22800</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments</td>
<td></td>
</tr>
<tr>
<td>22802</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments</td>
<td></td>
</tr>
<tr>
<td>22804</td>
<td>Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments</td>
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</tr>
<tr>
<td>22808</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments</td>
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<tr>
<td>22810</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments</td>
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<tr>
<td>22812</td>
<td>Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments</td>
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<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical</td>
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<tr>
<td>22840</td>
<td>Posterior non-segmental instrumentation (e.g., harrington rod technique, pedicle fixation across one interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at c1, facet screw fixation) (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22841</td>
<td>Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22842</td>
<td>Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22843</td>
<td>Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22844</td>
<td>Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)</td>
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<tr>
<td>22861</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical</td>
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<tr>
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<tr>
<td>M43.00</td>
<td>Spondylolysis, site unspecified</td>
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<td>M43.02</td>
<td>Spondylolysis of cervical region</td>
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<tr>
<td>M43.03</td>
<td>Spondylolysis of cervicothoracic region</td>
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<td>M43.04</td>
<td>Spondylolysis of thoracic region</td>
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<tr>
<td>M43.05</td>
<td>Spondylolysis of thoracolumbar region</td>
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<td>M43.06</td>
<td>Spondylolysis of lumbar region</td>
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<td>M43.07</td>
<td>Spondylolysis lumbosacral region</td>
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<td>M43.08</td>
<td>Spondylolysis of sacral and sacrococcygeal</td>
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<tr>
<td>M43.09</td>
<td>Spondylolysis of multiple sites in spine</td>
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<tr>
<td>M51.24</td>
<td>Other intervertebral disc displacement, thoracic region</td>
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<tr>
<td>M51.25</td>
<td>Other intervertebral disc displacement, thoracolumbar region</td>
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<tr>
<td>S12.24XA</td>
<td>Type III traumatic spondylolisthesis of third cervical vertebra, initial encounter for closed fracture</td>
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<tr>
<td>S12.44XA</td>
<td>Type III traumatic spondylolisthesis of fifth cervical vertebra, initial encounter for closed fracture</td>
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<tr>
<td>S12.54XA</td>
<td>Type III traumatic spondylolisthesis of sixth cervical vertebra, initial encounter for closed fracture</td>
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</table>

**Appendix A**

Red-flag symptoms may indicate more serious neurologic conditions from spinal instability. These may be categorized as the following:

- Suspected unstable fractures of the spine, which may be evidenced by a history of a recent fall or injury, and major motor weakness of a limb, progressive neurological deficits, or bladder or bowel dysfunction.
- History of cancer with suspicion of metastatic spread, which may be evidenced by major motor weakness of a limb, pain that increases at night or at rest, progressive neurological deficits, bladder or bowel dysfunction, or unexplained weight loss of more than 10 pounds in six weeks.
- Infection with suspicion of an epidural abscess/diskitis, which may be evidenced by progressive neurological deficits, or fever of 100.4° F for more than 48 hours, and C-reactive protein > 10 mg/L, or recent (within two weeks) interventional spine procedures, or ESR > 20 mm/hour, or immunocompromised (either immunodeficiency from any cause or IV drug abuse).
- Cauda equina syndrome, which may be evidenced by bladder or bowel dysfunction, saddle anesthesia, or progressive neurological deficits.