Clinical Policy Title: Spinal surgeries

Clinical Policy Number: 03.03.03

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Next Review Date: January 2017

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

About this Policy: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage Policy

AmeriHealth Caritas Pennsylvania considers the use of spinal surgeries for cervical, lumbar or thoracic laminectomy, lumbar spinal fusion, percutaneous polymethylmethacrylate vertebroplasty (PPV), vertebroplasty, kyphoplasty, sacroplasty, coccyectomy, and lumbar decompression with or without discectomy to be clinically proven and therefore, medically necessary when the following criteria are met:

1. Cervical, lumbar, or thoracic laminectomy is 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); OR
- Spinal tumor confirmed by imaging studies (e.g., CT or MRI); OR
- Epidural hematomas confirmed by imaging studies (e.g., CT or MRI); OR
- 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); OR
- 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); OR
- Other mass lesions confirmed by imaging studies (e.g., CT or MRI), upon 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; OR
   - 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; OR
   - 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; OR
   - Spinal tumor confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy; OR
   - Spondylolisthesis with segmental instability confirmed by imaging studies (e.g., CT or MRI), when both of the following criteria are met:
     - Significant spondylolisthesis, grades III, IV, or V.
     - Rapidly progressive neurologic compromise (i.e., cauda equina syndrome [loss of bowel/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; OR
     - Decompression coincides with an area of significant degenerative instability
(e.g., scoliosis or any degree of spondylolisthesis (grades I, II, III, IV or V); OR
- 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 non-surgical treatments).
- Thoracic fractures.

4. Percutaneous polymethylmethacrylate vertebroplasty (PPV) 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; OR
- Painful and/or aggressive hemangiomas; OR
- Painful vertebral eosinophilic granuloma; OR
- Painful, debilitating osteoporotic collapse/compression fractures (e.g., Kummell’s disease); OR
- Primary malignant neoplasm of bone or bone marrow; OR
- Secondary osteolytic metastasis, excluding sacrum and coccyx; OR
- Steroid-induced fractures; AND
- The following criteria have been met:

  - Other causes of pain such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging; AND
  - Severe debilitating pain or loss of mobility that cannot be relieved by optimal medical therapy (e.g., acetaminophen, non-steroid anti-inflammatory drugs
(NSAIDS), narcotic analgesics, braces, physical therapy, etc.) ; AND
- 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 6 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, bladder dysfunction 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.

AmeriHealth Caritas Pennsylvania considers the use of lumbar spinal fusion experimental and investigational for degenerative disc disease (DDD) and all other indications not listed above because of insufficient evidence of its effectiveness for these indications.

AmeriHealth Caritas Pennsylvania considers the use of lumbar artificial disc replacement to be investigational as the effectiveness of its use has not been established in peer reviewed professional literature. Cervical spine artificial disc replacement will be considered on a case by case basis as a program exception.

Limitations:

Pedicle screw fixation is considered experimental and investigational, and therefore medically not necessary for, but not limited to, the following 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, and sacroplasty are considered experimental and investigational, and therefore medically not necessary for, but not limited to, the following indications:
• Vertebroplasty, kyphoplasty, and sacroplasty may not be covered for prophylaxis of osteoporosis as 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/cold modalities for home use.
• Low impact exercise (e.g., stationary bike, swimming, walking)
• Pharmacotherapy (e.g., non-narcotic analgesics, NSAIDs, or muscle relaxants).
• Trigger point injections.
• Epidural spinal injections (ESI).
• 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 foraminal, lateral
recess or central spinal stenosis; most lumbar fusion 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 (LBP) affects approximately 60 — 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. Age-related intervertebral disc degeneration, typically resulting in degeneration of the discs themselves, facet joint arthrosis and segmental instability, is a leading causative factor (Kwon et al., 2003). According to the National Center for Health Statistics (Patel, 2007), each year, 14.3 percent of new patient visits to primary care physicians are for LBP, and nearly 13 million physician visits are related to complaints of chronic LBP. The causes of LBP are numerous. For individuals with acute LBP, the precise etiology can be identified in only about 15 percent of cases (Lehrich et al., 2007).

The initial evaluation of patients with LBP 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. The most common pathological causes of LBP are attributed to herniated lumbar discs (lumbar disc prolapse, slipped disc), lumbar stenosis and lumbar spondylolisthesis (Lehrich et al., 2007).

Advances in spine surgery can be beneficial in 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 a wide range of acceptance whereas e use of artificial disks and pedicle screws still are in search of standard acceptance.

**Searches**

AmeriHealth Caritas Pennsylvania 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 December 23, 2015. Searched 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**

Guidelines for the approach to the initial evaluation of spinal pain (i.e., LBP) were issued by the Agency for Healthcare Research and Quality (AHRQ) during the last decade of the twentieth century, and reiterated in subsequent systematic reviews (Jarvik, 2002; Chou et al., 2007; NICE, 2009). 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 Alternative covered services) within four to six weeks. Only five percent of sciatica patients remain disabled longer than three months (Gibson et al., 2007; Lehrich et al., 2007; AHCPR, 1994).

In the American Pain Society/American College of Physicians Clinical Practice Guideline on Nonpharmacologic Therapies for Acute and Chronic Low Back Pain, Chou (2007) reached the following conclusions:

- "Therapies with good evidence of moderate efficacy for chronic or subacute low back pain are cognitive-behavioral therapy, exercise, spinal manipulation, and interdisciplinary rehabilitation.
- For acute low back pain, the only therapy with good evidence of efficacy is superficial heat."

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. Cochrane (2007) suggests that transplanted bone may be minimally more effective but that the use of cages results in lower complications.

Controlled studies on indications for cervical spine fusion are few in number. 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 (PLF).
- Posterior lumbar interbody fusion (PLIF).
- Transforaminal lumbar interbody fusion (TLIF).
- Endoscopic or minimally invasive transforaminal lumbar interbody fusion (MITLIF).
- Anterior lumbar interbody fusion (ALIF).
- Laparoscopic anterior lumbar interbody fusion (LALIF).
- 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 risks and long term risks of surgery. In most cases will have failed aggressive rehabilitation prior to consideration of surgery.

The Spine Patient Outcomes Research Trial (SPORT) was designed to compare the effectiveness of surgical and non-surgical 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 Agency for Healthcare Research and Quality (AHRQ), 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 aid in the stabilization of vertebral structures with implants and improve the outcomes of
spinal surgery. Spinal fusion is accomplished with rods and plates which 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 inter-connected 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 et al., 2012; Thakkar et al., 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 1105 patients in which 6617 screws were inserted
during lumbar or thoracic surgery showed that in the studies using the fee-hand technique, the
percentage of screws fully contained in the pedicle ranged from 69 — 94 percent with the aid of
fluoroscopy from 28 — 85 percent using CT navigation; from 89 — 100 percent and using fluoroscopy-
based navigation from 81 — 92 percent (Gelalis et al., 2012). Screws positioned with the fee-hand
technique more often perforated the cortex medially, whereas screws placed with CT guidance
perforated more often laterally (Gelalis et al., 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 upon 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 (EMG) are useful ancillary technologies that may be employed in this regard (Silberman et al., 2011; Purushothamdas et al., 2011; Gelalis et al., 2012; Patil et al., 2012, Thakkar et al., 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 has 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 in order to provide rigid three-column fixation, minimize the risk of incomplete fusion (pseudoarthrosis or pseudarthrosis), or 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 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 with regard to the use of kyphoplasty/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 (DDD) in skeletally mature adults. The FDA has advised that intervertebral discs should be limited to individuals who have DDD 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 have no more than 3mm 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 non-surgical treatment.

Prostheses that have been approved by the FDA include the Charite 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, or 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 or angulation or >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 alternatives.

Policy updates:
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.

Summary of Clinical Evidence

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Parkin (2015)</td>
<td>Key points:</td>
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<td></td>
<td>• Narrative review of nonmalignant spinal pain</td>
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<td>Hayes (2013)</td>
<td>Key points:</td>
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| • Found that management that addresses both the physical and psychosocial components are necessary to address the multidimensional nature of spinal pain.  
• Tailored care tends to achieve better outcomes and greater satisfaction with care.  
• Further research will be necessary to inform health care policy and practice. |

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<th>NICE (2009)</th>
<th>Key points:</th>
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| • There is adequate evidence to support the use of artificial lumbar discs provided that normal arrangements are in place for consent, audit, and clinical governance.  
• Artificial lumbar disc is indicated for symptomatic degenerative disc disease in lumbar spine that is refractory to conservative treatment. |

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<th>Dettori (2008)</th>
<th>Key points:</th>
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| • Systematic review of four randomized controlled trials comparing lumbar fusion to nonsurgical treatments.  
• Found 15% (58/399) of patients receiving lumbar fusion experienced complications (i.e., re-operation with rates ranging up to 46%, infection, device-related complications, thrombosis, bleeding/vascular complications, and dural injury.  
• A 12% two-year incidence rate of major complications following lumbar spinal fusion was reported, with a re-operation rate of 14.6% for that population. |

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<th>Cochrane (2007)</th>
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<td>• Systematic review Identified 40 randomized controlled trials and two quasi-randomized trials on the surgical management of lumbar disc prolapse.</td>
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<td><strong>Mirza (2007)</strong></td>
<td><strong>Key points:</strong></td>
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<td>The authors found these studies contain major design weaknesses, particularly with sample size, randomization, blinding, and duration of follow-up.</td>
<td>Systematic review of four RCTs comparing lumbar fusion surgery to non-surgical treatment of chronic back pain associated with lumbar disc degeneration.</td>
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<td>Outcome measures in clinical studies of LBP have not been standardized making it difficult to compare the results of clinical studies of similar treatment.</td>
<td>One study suggested greater improvement in back-specific disability for fusion compared to unstructured nonoperative care at two years, but the trial did not report data according to intent-to-treat principles.</td>
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<td>Three trials suggested no substantial difference in disability scores at one-year and two-years when fusion was compared to a three-week cognitive-behavior treatment addressing fears about back injury, while others had high rates of cross-over (greater than 20 % for each treatment) and loss of follow-up (20 %).</td>
<td>The authors concluded that surgery may not be more efficacious than structured cognitive-behavior therapy; however, methodological limitations of the randomized trials prevent firm conclusions.</td>
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<th><strong>ECRI (2007)</strong></th>
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<td>Studied lumbar fusion and discography in chronic uncomplicated DDD associated with chronic LBP.</td>
<td>Sufficient evidence that lumbar fusion surgery is more effective than non-surgical treatments in patients without prior back surgery, but the strength of evidence was described as weak.</td>
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<td>Found insufficient evidence that lumbar fusion surgery is more effective than non-surgical treatments in patients without prior back surgery, but the strength of evidence was described as weak.</td>
<td>The evidence was insufficient to determine whether lumbar fusion provides a greater improvement in back pain than intensive exercise/rehabilitation plus CBT in patients without prior back surgery.</td>
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<td>The evidence was insufficient to determine the relative benefits of lumbar fusion compared to conventional physical therapy in patients with or without prior back surgery.</td>
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<th><strong>SPORT (2006)</strong></th>
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<td>SPORT included 13 multi-disciplinary spine centers across the United States examining the efficacy of open diskectomy versus non-operative treatment for lumbar intervertebral disk herniation and persistent signs and symptoms of radiculopathy lasting at least 6 weeks.</td>
<td>Intent-to-treat analyses demonstrated substantial improvements for all primary and secondary outcomes in both treatment groups.</td>
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<td>Between-group differences in improvements were consistently in favor of surgery for all periods, but not statistically significant.</td>
<td>The authors reported that both surgical and non-operative treatment groups improved substantially over a two-year period.</td>
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<th><strong>Carragee (2003).</strong></th>
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<td>If radiculopathy or strong evidence of dysfunction of a specific nerve root is confirmed more invasive treatment, including spine surgery, may be proposed as a treatment option.</td>
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<td>The primary rationale of any form of surgery for disc prolapse is to provide decompression of the affected nerve root to relieve the individual's symptoms.</td>
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</table>
The addition of fusion with or without instrumentation is considered when there are concerns about instability. Open discectomy and a number of other less invasive surgical approaches are appropriate. The surgical treatment of sciatica with discectomy is ineffective in a sizable percentage of patients, and re-herniation occurs after 5 — 15% of such procedures.

**Glossary**

**Arthrodesis (spinal fusion)** — Spinal surgery that joins (fuses) two or more vertebrae together. Different methods of performing spinal fusion may include using bone that is harvested from elsewhere in the body or is obtained from a bone bank to bond adjoining vertebrae. Securing metal implants to the vertebrae to hold them together until new bone grows between the vertebrae is another method of achieving the same bond.

**Bone Tamp** — A device used in orthopedic surgery to reduce fractures and manage bone grafts. This instrument can be used inside a bone to elevate depressed areas after a fracture, assisting with the stabilization process. It can also be used to pack bone into place at a graft site.

**Coccygectomy** — A surgical procedure during which the coccyx is removed. It can be performed for many reasons for instance in patients with coccyx pain (tailbone pain), but is typically reserved for patients with malignant cancer or for patients whose tailbone has failed to respond to nonsurgical treatment (usually irradiation). Coccygectomy is treatment of last resort for coccydynia, but is considered a required treatment for sacrococcygeal teratoma and other germ cell tumors arising from the coccyx.

**Discectomy** — Surgical removal of herniated disc material that presses on a nerve root or the spinal cord.

**Facetectomy** — Surgical procedure which involves decompression of a spinal nerve root.

**Kyphoplasty** — Variation of a vertebroplasty (which attempts to restore the height and angle of kyphosis of a fractured vertebra). The procedure typically includes the use of a small balloon that is inflated in the vertebral body to create a void prior to cement delivery within the cancellous bone. Once the void is created, the procedure continues in a similar manner as a vertebroplasty, but the bone cement is typically delivered directly into the newly created void.

**Laminectomy** — Surgical procedure that removes a portion of the vertebral bone called the lamina. At its most minimally invasive, the procedure requires only a small skin incision.

**Laminotomy** — An orthopedic/neurosurgical procedure that removes part of a lamina of the vertebral arch in order to decompress the corresponding spinal cord and/or spinal nerve root. Laminotomy is
also often accompanied by facetectomy.

**Laminoplasty** — An orthopedic surgical procedure for treating spinal stenosis by relieving pressure on the spinal cord. The procedure involves cutting the lamina on both sides of the affected vertebrae (cutting through on one side and merely cutting a groove on the other) and then swinging the freed flap of bone open thus relieving the pressure on the spinal cord (much like an unlatched door on hinges).

**Mechanical Instability** — Of the spine, the inability of the spine to maintain its normal configuration under physiologic mechanical load. This may be the result of congenital anomalies, degeneration, neoplasia, rupture of ligaments or of a disc causing impingement of the nerves resulting in pain and/or disability.

**Percutaneous vertebroplasty and kyphoplasty** — Medial spinal procedures in which bone cement is injected through a small hole in the skin (percutaneously) into a fractured vertebra with the goal of relieving back pain caused by vertebral compression fractures. Kyphoplasty, in which an inflatable bone tamp, is used to elevate the fracture prior to cement injection.

**Scoliosis** — A condition in which the spine curves abnormally from side to side (S-shaped or C-shaped) rather than being straight. The spine may also be twisted, or rotated. Severe cases of scoliosis may require bracing or surgery. Bracing is usually successful in stopping the curve from getting worse, but it does not correct or straighten the spine.

**Spondylosis** — A defect or fracture of the pars interarticularis of the vertebral arch — the most common cause of spondylolisthesis.

**Spondylolisthesis** — Anterior or posterior displacement of a vertebral body, or the vertebral column, in relation to the vertebrae below. This most commonly occurs at the lumbosacral junction with L5 slipping over S1, but it can occur at higher levels as well.

**Spondylosis** — Denotes degenerative osteoarthritis of the joints between the spinal vertebrae and/or neural foramina.

**Radiculopathy** — One or more nerves affected by cause sufficient to interfere with its normal function (radicular neuropathy). This can result in pain (radicular pain), weakness, numbness, or difficulty controlling specific muscles.

**References**

**Professional society guidelines/other:**


Peer-reviewed references


**Clinical Trials:**

Searched clinicaltrials.gov on January 6, 2016 using terms “spine surgery” | Open Studies. 54 studies found, 2 relevant.


https://clinicaltrials.gov/ct2/show/NCT01609374?term=artificial+disk&rank=16  

CMS National Coverage Determination (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

L35942  Fusion for Degenerative Joint Disease of the Lumbar Spine  
Vertebroplasty: Noridian Administrative Services, LLC.  
"Local Coverage Determination (LCD) for Vertebroplasty, Vertebral Augmentation; Percutaneous (L24383)". Accessed Jan 6, 2016.

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.

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<td>ARTHRODESIS, LATERAL EXTRACAVITARY TECHNIQUE, INCLUDING MINIMAL DISCECTOMY TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION); LUMBAR</td>
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Appendix A.

Red flag symptoms may be indicative of 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, or 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, or pain which increases at night or at rest, or progressive neurological deficits, or bladder or bowel dysfunction, or unexplained weight loss of more than ten 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/hr., or immunocompromised (either immunodeficiency from any cause or IV drug abuse).
- Cauda equina syndrome which may be evidenced by bladder or bowel dysfunction, or saddle anesthesia, or progressive neurological deficits.