Image-Guided Minimally Invasive Decompression for Spinal Stenosis

Policy # 00278
Original Effective Date: 11/16/2010
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Interspinous and Interlaminar StabilizationDistraction Devices (Spacers) is addressed separately in medical policy 00221.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers image-guided minimally invasive spinal decompression to be **investigational.***

Background/Overview

Spinal Stenosis

In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and its nerve roots. The goal of surgical treatment is to "decompress" the spinal cord and/or nerve roots.

The most common symptoms of lumbar spinal stenosis are back pain with neurogenic claudication (ie, pain, numbness, weakness) in the legs that worsens with standing or walking and is alleviated by sitting or leaning forward. Compression of neural elements generally occurs from a combination of degenerative changes, including ligamentum flavum hypertrophy, bulging of the intervertebral disc, and facet thickening with arthropathy. Spinal stenosis is often linked to age-related changes in disc height and arthritis of the facet joints. Lumbar spinal stenosis is among the most common reasons for back surgery and the most common reason for lumbar spine surgery in adults over the age of 65.

The most common symptoms of cervical/thoracic spinal stenosis are neck pain and radiculopathy of the shoulder and arm. The most common cause of cervical radiculopathy is degenerative changes, including disc herniation.

Treatment

Conventional Posterior Decompression Surgery
For patients with lumbar spinal stenosis, surgical laminectomy has established benefits in reducing pain and improving quality of life.

For patients with cervical or thoracic stenosis, surgical treatment includes discectomy or foraminal decompression.

A systematic review by Chou et al (2009) assessed surgery for back pain; it was commissioned by the American Pain Society and conducted by an evidence-based center. Four higher quality randomized trials were reviewed; they compared surgery with nonsurgical therapy for spinal stenosis, including two studies from the multicenter Spine Patient Outcomes Research Trial that evaluated laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis). All 4 studies found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (eg, average 8- to 18-point differences on the 36-Item Short-Form Health Survey and Oswestry Disability Index). However, there was insufficient evidence to determine the optimal adjunctive surgical methods for laminectomy (ie, with or without fusion, instrumented vs noninstrumented fusion) in patients with or without degenerative spondylolisthesis. Spine Patient Outcomes Research Trial continues to be referenced as the highest quality evidence published on decompressive surgery.

Less invasive surgical procedures include open laminotomy and microendoscopic laminotomy. In general, the literature comparing surgical procedures is limited. The literature has suggested that less invasive surgical decompression may reduce perioperative morbidity without impairing long-term outcomes when performed in appropriately selected patients. Posterior decompressive surgical procedures include: decompressive laminectomy, hemilaminotomy and laminotomy, and microendoscopic decompressive laminotomy.

Decompressive laminectomy, the classic treatment for lumbar spinal stenosis, unroofs the spinal canal by extensive resection of posterior spinal elements, including the lamina, spinous processes, portions of the facet joints, ligamentum flavum, and the interspinous ligaments. Wide muscular dissection and retraction is needed to achieve adequate surgical visualization. The extensive resection and injury to the posterior spine and supporting musculature can lead to instability with significant morbidity, both postoperatively and longer term. Spinal fusion, performed at the same time as laminectomy or after symptoms have developed, may be required to reduce resultant instability. Laminectomy may also be used for extensive multilevel decompression.

Hemilaminotomy and laminotomy, sometimes termed *laminoforaminotomy*, are less invasive than laminectomy. These procedures focus on the interlaminar space, where most of the pathologic changes are concentrated, minimizing resection of the stabilizing posterior spine. A laminotomy typically removes the inferior aspect of the cranial lamina, superior aspect of the subjacent lamina, ligamentum flavum, and the medial aspect of the facet joint. Unlike laminectomy, laminotomy does not disrupt the facet joints, supra- and interspinous ligaments, a major portion of the lamina, or the muscular attachments. Muscular dissection and retraction are required to achieve adequate surgical visualization.

Microendoscopic decompressive laminotomy, similar to laminotomy, uses endoscopic visualization. The position of the tubular working channel is confirmed by fluoroscopic guidance, and serial dilators are used to dilate the musculature and expand the fascia. For microendoscopic decompressive laminotomy, an endoscopic curette, rongeur, and drill are used for the laminotomy, facetectomy, and foraminotomy. The working channel may be repositioned from a single incision for multilevel and bilateral dissections.

Image-Guided Minimally Invasive Lumbar Decompression
Posterior decompression for lumbar spinal stenosis has been evolving toward increasingly minimally invasive procedures in an attempt to reduce postoperative morbidity and spinal instability. Unlike conventional surgical decompression, the percutaneous mild®‡ decompressive procedure is performed solely under fluoroscopic guidance (eg, without endoscopic or microscopic visualization of the work area). This procedure is indicated for central stenosis only, without the capability of addressing nerve root compression or disc herniation, should either be required.

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Percutaneous image-guided minimally invasive lumbar decompression using a specially designed tool kit (mild) has been proposed as an ultra-minimally invasive treatment of central lumbar spinal stenosis. In this procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a 6-gauge cannula clamped in place with a back plate, single-use tools (portal cannula, surgical guide, bone rongeur, tissue sculpter, trocar) are used to resect thickened ligamentum flavum and small pieces of lamina. The tissue and bone sculpting is conducted entirely under fluoroscopic guidance, with contrast media added throughout the procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central canal. The devices are not intended for use near the lateral neural elements and are contraindicated for disc procedures.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2006, the X-Sten MILD Tool Kit now the mild device kit (X-Sten Corp. renamed Vertos Medical) was cleared for marketing by the U.S. FDA through the 510(k) process for treatment of various spinal conditions. This set of specialized surgical instruments is used to perform percutaneous lumbar decompressive procedures.

Vertos's mild instructions state that the device is not intended for disc procedures but rather for tissue resection at the perilaminar space, within the interlaminar space, and at the ventral aspect of the lamina. The device is not intended for use near the lateral neural elements and remains dorsal to the dura using image guidance and anatomic landmarks.

Food and Drug Administration product code: HRX.

Rationale/Source

Image-guided minimally invasive lumbar decompression describes a percutaneous procedure for decompression of the central spinal canal in patients with spinal stenosis and hypertrophy of the ligamentum flavum. In this procedure, a specialized cannula and surgical tools (mild) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal. Image-guided minimally invasive lumbar decompression is proposed as an alternative to existing posterior decompression procedures.

For individuals who have lumbar spinal stenosis, or cervical or thoracic spinal stenosis who receive image-guided minimally invasive lumbar decompression, the evidence includes a large, ongoing randomized controlled trial (n=302), a systematic review of a small randomized controlled trial (n=38), and a number of prospective and retrospective cohort studies and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. The largest randomized controlled trial compared image-guided minimally invasive lumbar decompression with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the image-guided minimally invasive lumbar decompression group vs the control group. The trial was unblinded and there is evidence of differing expectations and follow-up in the 2 groups, suggesting a high-risk of bias. The available evidence is insufficient to determine the efficacy of mild compared with placebo or to determine the efficacy of image-guided minimally invasive lumbar decompression compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

North American Spine Society

In 2011, the North American Spine Society revised clinical practice guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis. Treatment recommendations included:

- Interlaminar epidural steroid injection for short-term (two weeks to six months) symptom relief in patients with neurogenic claudication or radiculopathy; however, there is conflicting evidence regarding long-term efficacy. (Grade of Recommendation: B)
- A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injection for medium-term relief of pain. (Grade of Recommendation: C)
- Decompressive surgery to improve outcomes in patients with moderate to severe symptoms of lumbar spinal stenosis. (Grade of Recommendation: B)

No specific recommendations on percutaneous image-guided lumbar decompression were provided.

Lumbar Spinal Stenosis Consensus Group MIST Guidelines
In 2018, the Lumbar Spinal Stenosis Consensus Group, composed of a panel of nationally recognized spine experts, convened to evaluate the available literature and develop guidelines for minimally invasive spine treatment. Based on a systematic review of the available literature on percutaneous image-guided lumbar decompression, the consensus committee determined there is sufficient support to warrant Level I evidence (Grade A, Level I, Consensus strong). Grade A evidence is defined as "extremely recommendable (good evidence that the measure is effective and that benefits outweigh the harms."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Effective for services performed on or after January 9, 2014, the Centers for Medicare & Medicaid Services has determined that percutaneous image-guided lumbar decompression for lumbar spinal stenosis is not reasonable and necessary.

The Centers for Medicare & Medicaid Services determined that percutaneous image-guided lumbar decompression would be covered by Medicare when provided in a clinical study through coverage with evidence development for beneficiaries with lumbar spinal stenosis enrolled in an approved clinical study meeting criteria in the decision memo.

According to the national coverage decision, percutaneous image-guided lumbar decompression is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This procedure is proposed as a treatment for symptomatic lumbar spinal stenosis unresponsive to conservative therapy. This procedure is generally described as a noninvasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (eg, fluoroscopic, computed tomography) with contrast media to identify and monitor the compressed area via epidurogram.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03072927[a]	MILD®‡ Percutaneous Image-Guided Lumbar Decompression: A Medicare Claims Study	4000	Dec 2020 (recruiting)
NCT03610737[a]	A Multi-center, Randomized Controlled Study of the VertosMILD Procedure With Conventional Medical Management Versus Conventional Medical Management Alone in the Treatment of Lumbar Spinal Stenosis (MOTION)	150	Feb 2022 (ongoing)
Unpublished			
NCT01129921[a]	Comparative Study of Sham Versus Mild®‡ (Minimally Invasive Lumbar Decompression) Procedure in Patients Diagnosed With Symptomatic Moderate to Severe Lumbar Central Canal Stenosis	40	Oct 2011 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

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11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. New policy.
11/03/2011	Medical Policy Committee review.
11/16/2011	Medical Policy Implementation Committee.
12/06/2011	Posted as Archived policy.
03/05/2012	Re-posted as active policy.
11/01/2012	Medical Policy Committee review.
11/28/2012	Medical Policy Implementation Committee. No change to coverage.
11/07/2013	Medical Policy Committee review.
11/20/2013	Medical Policy Implementation Committee. No change to coverage.
11/06/2014	Medical Policy Committee review.
11/21/2014	Medical Policy Implementation Committee. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review.
11/16/2015	Medical Policy Implementation Committee. No change to coverage.
11/03/2016	Medical Policy Committee review.
11/16/2016	Medical Policy Implementation Committee. No change to coverage.
11/02/2017	Medical Policy Committee review.
11/15/2017	Medical Policy Implementation Committee. Policy statement changed from "lumbar" to "spinal" to include cervical/thoracic decompression. "Lumbar" removed from title.
11/08/2018	Medical Policy Committee review.

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11/21/2018 Medical Policy Implementation Committee. No change to coverage.
11/07/2019 Medical Policy Committee review.
11/13/2019 Medical Policy Implementation Committee. No change to coverage.
11/05/2020 Medical Policy Committee review.
11/11/2020 Medical Policy Implementation Committee. No change to coverage.
Next Scheduled Review Date: 11/2021

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0274T, 0275T

HCPCS	G0276
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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