BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.126 Image-Guided Minimally Invasive Decompression for Spinal Stenosis

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2012

Related Policies:

7.01.107 - Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Image-Guided Minimally Invasive Decompression for Spinal Stenosis

Description

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Image-guided minimally invasive 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.

OBJECTIVE

The objective of this evidence review is to determine whether image-guided minimally invasive lumbar decompression improves the net health outcome in patients with spinal stenosis.

POLICY STATEMENT

Image-guided minimally invasive spinal decompression is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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. Food and Drug Administration 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

Summary of Evidence

For individuals who have lumbar spinal stenosis who receive image-guided minimally invasive lumbar decompression (MILD), the evidence includes a large, randomized controlled trial (RCT) (N=302), a second RCT (N=138) comparing MILD to non-surgical conventional medical management (CMM), a systematic review that included a small RCT (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 RCT (MIDAS Encore) compared image-guided MILD with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Results suggested reductions in pain and improvements in function scores in the image-guided minimally invasive lumbar decompression group versus 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 MOTION RCT compared MILD as first-line therapy in combination with nonsurgical CMM to CMM alone in 138 individuals with lumbar spinal stenosis. At 1-year follow-up, patients in the MILD + CMM group experienced a 16.1-point composite Oswestry Disability Index (ODI) mean improvement (the primary outcome), compared with a 2.0-point mean improvement for participants in the CMM-alone arm ($p<.001$). A major limitation of this trial was the wide variation in CMM interventions received by individuals in both the intervention and control groups; for example, 38.7% of individuals in the CMM alone group received no interventional therapy. Lack of blinding and follow-up for only 12 months were additional limitations. The available evidence is insufficient to determine the efficacy of MILD compared with placebo, open decompression, or conservative treatment. Well-designed and conducted trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical or thoracic spinal stenosis who receive image-guided minimally invasive spinal decompression, no evidence was identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Lumbar Spinal Stenosis Consensus Group

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 (MIST Guidelines).[13,] 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."

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.[14,] Treatment recommendations included:

- Interlaminar epidural steroid injection for short-term (6 weeks to 6 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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 (NCD 150.13).[15,] 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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2013	Replace policy	Policy updated with literature review, references added, reordered and renumbered. No change in policy statement.
September 2014	Replace policy	Policy updated with literature review; references 5-6 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statement changed from medically necessary for central stenosis without nerve root compression or disc herniation to investigational for all conditions.
June 2019	Replace policy	Policy updated with literature review through February 19, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 30, 2020; references added. Policy statement unchanged.
Junel 2021	Replace policy	Policy updated with literature review through March 7, 2021; no references added. Rationale section revised to add clinical context. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through March 4, 2022; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through March 6, 2023; reference added. Policy statements unchanged.
June 2024	Replace policy	Policy updated with literature review through March 11, 2024; reference added. Policy statement unchanged.