BlueCross BlueShield Federal Employee Program.

FEP 7.01.126 Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis

Effective Date: July 15, 2018

Related Policies:
7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis

Description

Image-guided minimally invasive lumbar decompression (IG-MLD) 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. IG-MLD is proposed as an alternative to existing posterior decompression procedures.

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.

U.S. Food and Drug Administration product code: HRX.

POLICY STATEMENT

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

BENEFIT APPLICATION

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

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RATIONALE

Summary of Evidence

For individuals who have lumbar spinal stenosis or cervical or thoracic spinal stenosis who receive IG-MLD, 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 IG-MLD 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 IG-MLD group vs the control group. The trial was unblinded and there is evidence of differing expectations and follow-up in the two 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 IG-MLD 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

No guidelines or statements were identified.

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.[12]

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.

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POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
June 2013	Update Policy	Policy updated with literature review, references added, reordered and renumbered. No change in policy statement.
September 2014	Update Policy	Policy updated with literature review; references 5-6 added. Policy statement unchanged.
June 2018	Update 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.