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.

REFERENCES

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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6. Benyamin RM, Staats PS, MiDASEI. MILD(R) is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE randomized controlled trial. *Pain Physician.* May 2016;19(4):229-242. PMID 27228511

**POLICY HISTORY**

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review, references added, reordered and renumbered. No change in policy statement.</td>
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<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 5-6 added. Policy statement unchanged.</td>
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<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>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.</td>
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