

Protocol

Image-Guided Minimally Invasive Decompression for Spinal Stenosis

(701126)

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| Medical Benefit | | Effective Date: 10/01/18 | Next Review Date: 07/19 |
| Preauthorization | No | Review Dates: 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18 | |

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

| Populations | Interventions | Comparators | Outcomes |
|--|--|--|--|
| Individuals: <ul style="list-style-type: none">• With lumbar spinal stenosis | Interventions of interest are: <ul style="list-style-type: none">• Image-guided minimally invasive lumbar decompression | Comparators of interest are: <ul style="list-style-type: none">• Conservative therapy• Open decompression | Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Functional outcomes• Health status measures• Treatment-related morbidity |
| Individuals: <ul style="list-style-type: none">• With cervical or thoracic spinal stenosis | Interventions of interest are: <ul style="list-style-type: none">• Image-guided minimally invasive lumbar cervical or thoracic decompression | Comparators of interest are: <ul style="list-style-type: none">• Conservative therapy• Open decompression | Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Functional outcomes• Health status measures• Treatment-related morbidity |

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.

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 RCT (N=302), a systematic review of 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 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 decom-

pression. 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.

POLICY

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

MEDICARE ADVANTAGE

For Medicare Advantage percutaneous image-guided lumbar decompression (PILD) may have potential for coverage when provided through Coverage with Evidence Development (CED) for members with lumbar spinal stenosis who meet the criteria of and are enrolled in an approved clinical study.

Effective for services performed on or after December 7, 2016, there may be potential for coverage through a prospective, longitudinal study of PILD procedures using an FDA-approved/cleared device that completed a CMS-approved randomized control trial (RCT), that met the criteria listed for an approved clinical study.

MEDICARE ADVANTAGE POLICY GUIDELINES

Registries must be reviewed and approved by CMS. All approved registries will be posted on the CED website located at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>.

BACKGROUND

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 (LSS) are back pain with neurogenic claudication (i.e., 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. LSS 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 LSS, 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.^{1,2} 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).^{3,4} All four studies found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (e.g., average eight 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 (i.e., 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 LSS, 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 LSS 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 (e.g., 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.

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 LSS. In this procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a six 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.

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.

RELATED PROTOCOL

Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers)

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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12. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for percutaneous image-guided lumbar decompression for lumbar spinal stenosis (150.13). 2014; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=358&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&Keyword=decompression&KeywordLookup=Title&KeywordSearchType=And&bc=gAAAABAAAAAAA>. Accessed March 8, 2018.