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POLICY LAST UPDATED: 05|02|2017

OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis is covered only as part of a Center for Medicare and Medicaid (CMS) approved clinical trial. Refer to the Related Policy section. All other indications (cervical and thoracic) are not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Image-guided minimally invasive spinal decompression (cervical, thoracic, and lumbar) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

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 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. The most common symptoms of lumbar spinal stenosis (LSS) 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. 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.

Treatment

Conventional Posterior Decompressive Surgery

For patients with cervical or thoracic stenosis, surgical treatment includes discectomy or foraminal decompression. For patients with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life. A 2009 systematic review of surgery for back pain, commissioned by the American Pain Society, was conducted by the Oregon Health Sciences University Evidence-based Practice Center. Four higher quality randomized trials were reviewed; they compared surgery with nonsurgical therapy for spinal stenosis, including 2 studies from the multicenter Spine Patient Outcomes Research Trial (SPORT) 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 [SF-36] and Oswestry Disability Index [ODI]). 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. SPORT 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 (MEDL).

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.

MEDL, 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 MEDL, 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 (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.

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 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.

Regulatory Status

The mild® tool kit (Vertos Medical) initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the U.S. Food and Drug Administration (FDA) in 2006, with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions. Vertos' mild® instructions for use state that the devices are 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. These devices are not intended for use near the lateral neural elements and remain dorsal to the dura using image guidance and anatomical landmarks.

Note: The abbreviation MILD has also been used for microscopic muscle-preserving interlaminar decompression, which involves a small skin incision at the interspinous level and partial drilling of the spinous process, with decompression performed under microscopic visualization.

For individuals who have central lumbar spinal stenosis who receive IG-MLD, the evidence includes a large, ongoing randomized controlled trial (RCT; N=302) and a systematic review of 1 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 to epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and had failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the IG-MLD group versus the control group. The trial was unblinded and there was evidence of differing expectations and follow-up in the 2 groups, resulting in a high risk of bias. The available evidence is insufficient to determine the efficacy of mild® compared to placebo or to determine the efficacy of IG-MLD compared to 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. Therefore, this procedure is considered not medically necessary.

BlueCHiP for Medicare

Effective for services performed on or after January 09, 2014, the Centers for Medicare & Medicaid Services (CMS) has determined that percutaneous image guided lumbar decompression (PILD) will be covered by Medicare when provided in a clinical study under section 1862(a) (1) (E) through Coverage with Evidence Development (CED) for beneficiaries with LSS who are enrolled in an approved clinical study that meets the CMS criteria.

CODING

BlueCHiP for Medicare

The following codes may be allowed for BlueCHiP for Medicare members as part of a CMS approved clinical study:

0275TQ0 Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

G0276Q0 Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

Note: If you are treating a BlueCHiP for Medicare member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy Clinical Trials BlueCHiP for Medicare.

Modifier Q0 – Investigational clinical service provided in a clinical research study that is in an approved research study (Medicare claims filed without the Q0 modifier will deny as not medically necessary)

The following code is not medically necessary:

0274T Percutaneous laminotomy/laminectomy (intradiscal approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic

Commercial Products

The following codes are not medically necessary:

0274T Percutaneous laminotomy/laminectomy (intradiscal approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic

0275T Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

G0276 Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

RELATED POLICIES

Clinical Trials BlueCHiP for Medicare
CPT Category III Codes

PUBLISHED

Provider Update, July 2017
Provider Update, June 2016
Provider Update, August 2015

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