Medical Coverage Policy | Image-Guided Minimally Invasive Lumbar Decompression IG-MLD for Spinal Stenosis

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 07|21|2015

OVERVIEW
Image-guided minimally invasive lumbar decompression (IG-MLD) describes a novel percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis (LSS). In this procedure, a specialized cannula and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

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 for members enrolled in a Medicare approved clinical trial 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 CMS (Centers for Medicare and Medicaid Services) criteria. Clinical trials may be found at http://www.clinicaltrials.gov/

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS, such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

Commercial Products
Image-guided minimally invasive lumbar decompression is considered not medically necessary as there is insufficient peer reviewed literature that demonstrates that the procedure is effective.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
In LSS, the space around the spinal cord narrows, compressing the spinal cord and the nerve roots. The most common symptom of LSS is back pain with neurogenic claudication, i.e., pain, numbness, or weakness in the legs that worsens with standing or walking and is alleviated with 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 one of the most common reasons for back surgery and the most common reason for lumbar spine surgery in adults older than 65 years of age. The goal of surgical treatment is to "decompress" the spinal cord and/or nerve roots. For patients

with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life. Less invasive surgical procedures have been developed, such as open laminotomy and microendoscopic laminotomy. Limited evidence on the comparative efficacy of these procedures suggests that less invasive procedures may achieve a roughly similar benefit with less adverse effects. The present policy addresses posterior decompression of central LSS with a percutaneous treatment that is performed under fluoroscopic guidance. Percutaneous IG-MLD using a specially designed tool kit (mild®) has been proposed as an ultraminimally invasive treatment of central LSS. In this procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a 6-gauge cannula that is 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 additional 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 to be used near the lateral neural elements and are contraindicated for disc procedures.

Alternative posterior decompressive surgical procedures include:

- Decompressive laminectomy, the classic treatment for LSS, which 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 muscles 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 the resultant instability. Laminectomy may 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. In contrast to 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 (MEDL) is similar to laminotomy but uses endoscopic visualization. The position of the tubular working channel is confirmed by fluoroscopic guidance, and serial dilators (METRx™ lumbar endoscopic system; Medtronic) 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.

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 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.

Posterior decompression for lumbar spinal stenosis (LSS) has been evolving toward increasingly minimally invasive procedures in an attempt to minimize postoperative morbidity and spinal instability. In general, the literature comparing surgical procedures is limited. The evidence available suggests that less invasive surgical decompression may reduce perioperative morbidity without impairing long-term outcomes when performed in appropriately selected patients.

In contrast to conventional surgical decompression, the mild® procedure is a percutaneous decompressive procedure 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 it be required. One small controlled trial with short-term follow-up and small case series of patients treated with image-guided minimally invasive lumbar decompression report improvements in pain and functioning, but controlled trials are lacking, and the efficacy of this procedure compared with alternatives cannot be determined at this time. Due to the unknown impact on health outcomes, randomized controlled trials in appropriate patients are needed to compare this novel procedure with the established alternatives. Therefore, this procedure is considered not medically necessary as there is insufficient peer-reviewed literature that demonstrates that the procedure is effective.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are covered for BlueCHiP for Medicare when filed with the Q0 modifier. These codes are considered not medically necessary for Commercial products.

0275T
G0276

Modifier Q0 Investigational clinical service provided in a clinical research study that is in an approved research study

Note: Medicare claims filed without the Q0 modifier will deny as not medically necessary.

RELATED POLICIES

CPT Category III Codes

PUBLISHED

Provider Update, August 2015

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