I. POLICY

Image-guided minimally invasive lumbar decompression is considered investigational. Functional Anaesthetic discography is considered investigational.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Cross-reference

MP-1.093 Artificial Intervertebral Disc (Lumbar and Cervical)
MP-1.123 Automated Percutaneous Discectomy
MP-1.125 Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)
MP-1.124 Percutaneous IDET Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[Y] SeniorBlue HMO**
[Y] SeniorBlue PPO**

[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

[Note: Final page is signature page and is kept on file, but not issued with Policy.]
Refer to FEP Medical Policy Manual MP- 7.01.126 Image-Guided Minimally Invasive Lumbar Decompression (IG_MLD) for Spinal Stenosis. The FEP Medical Policy manual can be found at: www.fepblue.org

** Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 150.13. Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS).

### III. DESCRIPTION/BACKGROUND

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. In this procedure, a specialized cannula and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

**Background**

In lumbar spinal stenosis (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 over 65 years of age. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots. Although treatment of disc herniation may be required as a component of lumbar decompression, 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 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 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 post-operatively 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 multi-level 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 utilizes 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 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.

Functional Anaesthetic Discography is a procedure used for delivering radiopaque contrast, local anesthetics, and or saline into the intradiscal space and for diagnosing discogenic pain.

IV. DEFINITIONS

**Collagen** is a strong, fibrous insoluble protein found in connective tissue, including the dermis, tendons, ligaments, deep fascia, bone and cartilage.

**Intervertebral Disc** is the fibrocartilaginous tissue between the vertebral bodies. The outer portion is the annulus fibrosus; the inner portion is the nucleus pulposus. The disc is the shock absorber, or cushion, and permits movement.

**Minimally Invasive Procedures** also called minimal access procedures used to perform spinal surgeries. These may include the following: (Note; this is not an all inclusive list.)

- ALIF – anterior lumbar interbody fusion
- AxiaLIF – axial approach to interbody fusion which is performed perpendicular to the long axis of the spine with access through the sacrum. Also called anterior para-axial, trans-sacral or paracoccygeal interbody fusion performed with the AxiaLIF® and AxiaLIF 2 Level systems.
- DLIF - Direct lateral interbody fusion
- IDET – intradiscal electrothermal annuloplasty
- IG-MLD – image-guided minimally invasive lumbar decompression.
- LASE – annuloplasty using a laser-assisted spinal endoscopy
V. Benefit Variations

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VI. Disclaimer

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.
VII. REFERENCES

Image-guided minimally invasive lumbar decompression


Lingreen R, Grider JS. Retrospective review of patient self-reported improvement and post-procedure findings for mild (minimally invasive lumbar decompression). Pain Physician 2010; 13(6):555-60

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<th>POLICY TITLE</th>
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**Functional Anaesthetic Discography**


**Other sources**


[Note: Final page is signature page and is kept on file, but not issued with Policy.]
VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, and therefore not covered, when used to report minimally invasive disc procedures as outlined in the Policy section:

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Investigational, and therefore not covered:

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IX. POLICY HISTORY

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<td>CAC 7/27/10 Policy statement revised to include Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) as an investigational procedure.</td>
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<td><strong>Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis (Formerly Minimally Invasive Disc Procedures)</strong></td>
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CAC 7/26/11 Adopt BCBSA for IG-MLD. Title changed. No change to policy statement regarding this procedure remains investigational. Other minimally invasive procedures extracted from this policy and separated into individual policies. See MP 1.123 Automated Percutaneous Discectomy, MP 1.124 Percutaneous Intradiscal Electrothermaol (IDET) Annuloplasty and Percutaneous intradiscal Radiofrequency Annuloplasty, MP 1.125 Decompression of the Intervertebral Disc Using Laser Energy (Laser Discetomy) or Radiofrequency Coblation (Nucleoplasty) and MP 1.126 Minimally Invasive Lumbar Interbody Fusion. The statement indicating functional anaesthetic discography is considered investigational remains in this policy with no changes.

CAC 10/30/12 Consensus. No change to policy statements. FEP variation changed to reference MP- 7.01.126 Image-Guided Minimally Invasive Lumbar Decompression (IG_MLD) for Spinal Stenosis.

Codes reviewed 10/18/12 klr

CAC 11/26/13 Consensus review. References updated; no changes to the policy statements.

6/2/14 Administrative change. Added Medicare variation to reference NCD 150.13.

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