**MEDICAL COVERAGE GUIDELINES**
**SECTION: SURGERY**

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# IMAGE-GUIDED MINIMALLY INVASIVE SPINAL DECOMPRESSION

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Medical Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



## Description:

Image-guided minimally invasive lumbar decompression (IG-MLD) is a percutaneous procedure performed under fluoroscopic guidance using a specialized cannula and surgical tools for bone and tissue sculpting near the spinal canal. IG-MLD has been investigated as a minimally invasive alternative for decompression of the central spinal canal for individuals with lumbar stenosis.

Image-guided decompression of the cervical or thoracic spine has also been investigated as an alternative to open decompression.

The X-Sten MILD Tool Kit or Vertos Medical mild® Device Kit is a set of specialized surgical instruments intended to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions. These tools 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.

## IMAGE-GUIDED MINIMALLY INVASIVE SPINAL DECOMPRESSION (cont.)

**Criteria:**

- Image-guided minimally invasive lumbar decompression(IG-MLD) is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

- Image-guided decompression of the cervical or thoracic spine is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

**Resources:**

1. 7.01.126 BCBS Association Medical Policy Reference Manual. Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis. Re-issue date 04/10/2014; issue date 03/11/2010.

FDA 510K Summary for X-Sten MILD Tool Kit, Vertos Medical mild® Device Kit:

- FDA-approved indication: Intended to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions.