MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Lumbar Decompression**
Policy Number	**7.01.97**
Category	**Technology Assessment**
Original Effective Date	**06/21/18**
Committee Approval Date	**12/20/18, 07/18/19, 01/16/20, 02/18/21, 02/17/22, 02/16/23, 07/20/23**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, an initial primary lumbar decompression has been medically proven to be effective and, therefore, is considered **medically appropriate** for spinal stenosis/spondylolisthesis, when **ALL** criteria in **A or B** are met:

A. **NEUROGENIC CLAUDICATION**:

1. Subjective symptoms including at least **BOTH** of the following:
   a. Clinically significant function limiting pain and/or symptoms on a daily basis (e.g., inability to perform household chores, prolonged standing, or essential job functions); and
   b. Pain, cramping, weakness, or tingling in the lower back, buttock(s), and leg(s) brought about by walking or positions that cause thecal sac or nerve root compression (e.g., standing, extension) and **EITHER** of the following:
      i. Symptoms worsen with standing and/or walking; or
      ii. Symptoms are alleviated with sitting and/or forward flexion; and
2. Objective physical examination findings concordant with recent (within six (6) months) MRI/CT; and
3. The patient has not experienced clinically meaningful improvement with at least **TWO (2)** of the following, unless contraindicated:
   a. Prescription strength analgesics, steroids, and/or NSAIDS for six (6) weeks; and/or
   b. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for six (6) weeks; and/or
   c. Epidural steroid injection(s)/selective nerve root block(s); and
4. Recent (within six (6) months) MRI/CT identifies nerve root impingement and/or thecal sac impingement that is concordant with patient symptoms and physical examination findings and caused by **ONE (1) OR MORE** of the following:
   a. Herniated disc(s); and/or
   b. Synovial cyst or arachnoid cyst; and/or
   c. Central/lateral/foraminal stenosis; and/or

5. All of sources of pain have been excluded; and
6. Absence of unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary pain, opioid and alcohol use disorders);

OR

B. <u>RADICULOPATHY</u>

1. The patient has subjective symptoms, including at least **TWO (2)** of the following
   a. Significant level of pain on a daily basis, defined as either of the following:
      i. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to seven (7); or
      ii. Severe, disabling, crippling, or incapacitating pain; and/or
   b. Persistent, radiating pain into the buttock(s) and/or lower extremity(ies) on a daily basis that has a documented, negative impact on activities of daily living despite optimal conservative treatment as described below; and/or
2. Objective physical examination findings including **EITHER** of the following:
   a. Nerve root tension sign including **ANY** of the following:
      i. Positive straight leg raise; or
      ii. Crossed straight leg raise; or
      iii. Femoral stretch test
   b. Neurologic deficit including **ANY** of the following:
      i. Dermatomal sensory deficit; or
      ii. Functionally limiting motor weakness (e.g., foot drop, quadriceps weakness); or
      iii. Reflex changes
3. The patient has not experienced clinically meaningful improvement with at least **TWO (2)** of the following, unless contraindicated:
   a. Prescription strength analgesics, steroids, and/or NSAIDS for six (6) weeks; and/or
   b. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for six (6) weeks; and/or
   c. Epidural steroid injection(s)/selective nerve root block(s).
4. Recent (within six (6) months) imaging findings identifies nerve root impingement and/or thecal sac impingement that is concordant with patient symptoms and physical examination findings and is caused by **ONE (1) OR MORE** of the following:
   a. Herniated disc(s) and/or
   b. Synovial cyst or arachnoid cyst; and/or
   c. Central/lateral/foraminal stenosis; and/or
5. All of sources of pain have been excluded; and/or
6. Absence of unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary pain, opioid and alcohol use disorders).

II. Based upon our criteria and assessment of the peer-reviewed literature, a repeat lumbar decompression has been medically proven to be effective and, therefore, is considered **medically appropriate** when **ALL** of the criteria noted in Policy Statement I above, plus **ALL** of the following, are met:
   A. More than 12 weeks have elapsed since last decompression surgery; and
   B. Patient experienced initial relief of symptoms following previous decompression procedure at same level(s), unless post-operative imaging demonstrates persistent, significant neurologic compression at the surgical level.

III. Based upon our criteria and assessment of the peer-reviewed literature, lumbar decompression performed for **ANY** of the following sole indications is considered not medically necessary:
   A. Signs and symptoms with no correlation to advanced imaging studies; or
   B. Annular tears; or
   C. Disc bulge with no neural impingement or cord compression on advanced diagnostic imaging; or
   D. Concordant discography; or

E. MR spectroscopy results; or
F. Degenerative disc disease

IV. Based upon our criteria and assessment of the peer-reviewed literature, the following procedures have not been medically proven to be effective and, therefore, are considered **investigational**:
A. Percutaneous lumbar discectomy;
B. Percutaneous laser discectomy;
C. Laser-assisted/percutaneous laser disc decompression; and
D. Percutaneous nucleotomy
E. Vertos Medical mild® Surgical Procedure

Refer to Corporate Medical Policy #7.01.16 Automated Percutaneous Discectomy and Image-Guided, Minimally Invasive Decompression

Refer to Corporate Medical Policy #7.01.62 Intervertebral Disc Decompression: Laser (Laser Discectomy) and Radiofrequency Coblation (Disc Nucleoplasty) Techniques

Refer to Corporate Medical Policy #7.01.75 Interspinous and Interlaminar Stabilization/Distraction Implants (Spacers).

Refer to Corporate Medical Policy #7.01.83 Minimally Invasive/Minimal Access Techniques for Lumbar Interbody Fusion.

Refer to Corporate Medical Policy #7.01.90 Lumbar Fusion for Adults.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services.

POLICY GUIDELINES

I. Acceptable imaging modalities are CT scan, MRI, and myelogram. Imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, interpretations by the radiologist will supersede. Discography or magnetic resonance (MR) spectroscopy results will not be used as a determining factor of medical necessity for any requested procedures. Use is not endorsed.

II. Clinically meaningful improvement is defined as global assessment showing at least 50% improvement.

III. URGENT/EMERGENT CONDITIONS: All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of such indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies, such as a CT scan or MRI, are required. Provider-directed, non-surgical management (Statement I.C.) and absence of unmanaged significant behavioral health disorders (Statement I.F.) are **NOT** required. Urgent/emergent conditions for lumbar decompression include **ANY** of the following:
A. acute/unstable traumatic spinal fractures or dislocations, with or without neural compression; or
B. cauda equina syndrome (CES); or
C. epidural hematoma; or
D. documentation of progressive neurological deficit on two separate physical examinations; or
E. infection (e.g., discitis, epidural abscess, osteomyelitis); or
F. primary or metastatic neoplastic disease causing pathologic fracture, cord compression or instability; or
G. severe or rapidly progressive symptoms of motor loss, bowel incontinence or bladder incontinence/retention due to a neuro-compressive pathology; or
H. documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated.

DESCRIPTION

Narrowing/stenosis or spondylolisthesis that creates a narrowing of the spinal canal can cause chronic pain, numbness, and muscle weakness in an individual's arms or legs. Spinal decompression can be performed anywhere along the spine from the neck (cervical) to the lower back (lumbar). The procedure is performed through a surgical incision in the back (posterior). The lamina is the bone that forms the backside of the spinal canal and makes a roof over the spinal cord.

Removing the lamina and other soft tissues gives more room for the nerves, relieves pressure, and allows for removal of bone spurs. Depending on the extent of stenosis, one vertebra (single-level) or more (multi-level) may be involved. There are several types of decompression surgery:

I. Laminectomy is the removal of the entire bony lamina, a portion of the enlarged facet joints, and the thickened ligaments overlying the spinal cord and nerves.
II. Laminotomy is the removal of a small portion of the lamina and ligaments, usually on one side. Laminotomy leaves the natural support of the lamina in place, decreasing the chance of post-operative spinal instability. In some cases, an endoscope may be used, allowing for a smaller, less-invasive incision.
III. Foraminotomy is the removal of bone around the neural foramen, the space between vertebrae where the nerve root exits the spinal canal. This method is used when disc degeneration has caused the height of the foramen to collapse, resulting in a pinched nerve. It can be performed with a laminectomy or laminotomy.

Posterior decompression for spinal stenosis 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 spinal decompression using a specially designed tool kit (mild®) has been proposed as an ultra-minimally invasive treatment of central lumbar spinal stenosis. 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.

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.

RATIONALE

The Spine Patient Outcomes Research Trial (SPORT) was funded by the National Institutes of Health (NIH) to study the outcomes from surgical and non-surgical management of three conditions: intervertebral disc herniation, degenerative spondylolisthesis, and lumbar spinal stenosis. Both surgical and non-surgical care of intervertebral disc herniation resulted in significant improvement in symptoms of low back and leg pain. However, the treatment effect of surgery for intervertebral disc herniation was less than that seen in individuals with degenerative spondylolisthesis and lumbar spinal stenosis. The preliminary four-year outcomes data demonstrated more significant degrees of improvement in pain levels and function with surgical versus non-surgical treatment in the chronic conditions of lumbar spinal stenosis and lumbar spinal stenosis with spondylolisthesis (Asghar, 2012; Weinstein, 2006a; Weinstein, 2006b; Weinstein, 2007; Weinstein, 2009).

According to the American Pain Society (APS), decompressive laminectomy may be an acceptable option for individuals experiencing disabling and persistent leg pain due to spinal stenosis, either with or without degenerative spondylolisthesis. The APS reports that decompressive laminectomy is associated with moderate benefits, compared to non-surgical therapy, through one (1) to two (2) years, though the effects of the procedure appear to diminish with long-term follow-up. Although individuals, on average, do not worsen without surgery, improvements are less than those observed in individuals with radiculopathy due to herniated lumbar disc. The APS guidelines indicate that there is

insufficient evidence to determine whether laminectomy with fusion is more effective than laminectomy without fusion. The authors recommended that shared decision-making regarding surgery include a specific discussion about moderate/average benefits, which appear to decrease over time, in affected individuals who undergo surgery (Chou, 2009).

The MOTION study was a prospective, multicenter, randomized controlled trial that aimed to provide outcome data for patients with lumbar spinal stenosis (LSS) suffering from neurogenic claudication secondary to hypertrophic ligamentum flavum. 177 patients were randomized to either conventional medical management (CMM alone) or minimally invasive lumbar decompression in combination with CMM (mild +CMM). Baseline function was evaluated with the Oswestry Disability Index (ODI), Numerical Pain Rating Scale (NPRS), and Zurich Claudication Questionnaire (ZCQ) scores. Magnetic resonance images or computed tomographic images (when magnetic resonance imaging was not possible) of the spine were assessed. The primary efficacy endpoint was mean improvement in Owestry Disability Index (ODI) score at one-year follow-up compared with baseline. Secondary endpoints included ZCQ and NPRS patient-reported outcomes. Mean improvement from baseline to one-year follow-up for all outcome measures demonstrated statistical significance in favor of mild + CMM versus CMM alone. The authors concluded that the results of this study confirm the use of the mild Procedure as a safe and effective first-line treatment for the indicated LSS patient population. Although results of this study are promising, further research is warranted examining long term follow up of outcomes (Deer, 2022).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar

Code	Description
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional vertebral segment (List separately in addition to code for primary procedure)

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
C72.0	Malignant neoplasm of spinal cord
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
G06.1	Intraspinal abscess and granuloma
M43.15-M43.17	Spondylolisthesis, thoracolumbar, lumbar or lumbosacral region (code range)
M48.05-M48.07	Spinal stenosis, thoracolumbar, lumbar or lumbosacral region (code range)

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*Key Article

KEY WORDS

Lumbar foraminotomy, Lumbar decompression, Lumbar laminectomy, Spinal stenosis, Spondylolisthesis

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon review, lumbar decompression is not addressed in a National or Local Medicare coverage determination or policy.