MEDICAL POLICY

POLICY TITLE	**IMAGE-GUIDED MINIMALLY INVASIVE LUMBAR DECOMPRESSION (IG-MLD) FOR SPINAL STENOSIS AND DISCOGRAPHY**
POLICY NUMBER	**MP-1.021**

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**5/1/2018**
Effective Date:	**1/1/2019** **RETIRED –** See policy history*

I. POLICY

Provocative discography

Lumbar provocative discography
Lumbar provocative discography may be considered **medically necessary** for evaluation for disc pathology in persons with persistent, severe low back pain (LBP) and abnormal interspaces on magnetic resonance imaging (MRI), where other diagnostic tests have failed to reveal clear confirmation of a suspected disc as the source of pain, and surgical intervention is being considered.
Lumbar provocative discography is considered **investigatio**nal for all other indications as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure

Cervical and thoracic provocative discography
Cervical and thoracic provocative discography are considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure

Functional anesthetic discography

Functional anesthetic discography is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure

Image-guided minimally invasive lumbar decompression
Image-guided minimally invasive lumbar decompression is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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Cross-references:

MP-1.124 Percutaneous Intradiscal Electrothermal IDET and Radiofrequency Annuloplasty

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: 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

III. DESCRIPTION/BACKGROUND

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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 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.

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.

Treatment

Conventional Posterior Decompression Surgery

For patients with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life.

For patients with cervical or thoracic stenosis, surgical treatment includes discectomy or foraminal decompression.

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A systematic review by Chou et al (2009) assessed surgery for back pain; it was commissioned by the American Pain Society and conducted by and evidence-based center.[1,2] 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 that evaluated laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis).[3,4] 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 and Oswestry Disability Index). 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. Spine Patient Outcomes Research Trial 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.

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.

Microendoscopic decompressive laminotomy, 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 microendoscopic decompressive laminotomy, 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.

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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

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.

Food and Drug Administration product code: HRX.

Functional anesthetic discography (FAD)

Functional anesthetic discography is a diagnostic procedure that involves injecting an anesthetic agent directly into a spinal disc. Proponents suggest FAD can be used to confirm the presence of injured discs as the source of the patient's low back pain symptoms. According to the manufacturer, FAD is designed to diagnose and potentially treat low back pain caused by degenerative disc disease. During this procedure, under light sedation and x-ray guidance, a small catheter is inserted into the suspected disc and anchored in place with a small balloon. After recovering from light sedation, the patient is asked to engage in physical activity to reproduce pain. Local anesthetic is then injected in the disc believed to be causing the patient's pain. Reduction in pain is considered diagnostic. If the injection into a specific disc relieves the patient's back pain, the disc can be further evaluated for potential treatment. If the test does not relieve the patient's pain, the physician can investigate other possible causes of pain.

Provocative Discography

Lumbar discography (also known as lumbar provocative discography and provocative lumbar discography) is a test that is used to ascertain if a disc is painful on injection. It is an invasive procedure that entails the injection of radiopaque contrasting materials (1 to 3 ml) into the intervertebral disc followed by computed tomography (CT) to examine disc abnormality. Discography can provide radiographical evaluation of the integrity of the nucleus pulposus and annular rings to determine tears or other lesions that could be the cause of LBP. It can measure disc nociception -- a normal disc should not cause pain when injected; however, a disc that is physiologically compromised can mimic the pain experienced by the patient. Discography is usually carried out when other diagnostic tests have failed to identify the cause of LBP. However, its use is still controversial.

IV. RATIONALE

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SUMMARY OF EVIDENCE

Image-Guided Minimally Invasive Lumbar Decompression
For individuals who have lumbar spinal stenosis or cervical or thoracic spinal stenosis who receive IG-MLD, the evidence includes a large, ongoing RCT (N=302), a systematic review of a 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 with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the IG-MLD group vs the control group. The trial was unblinded and there is evidence of differing expectations and follow-up in the 2 groups, suggesting a high risk of bias. The available evidence is insufficient to determine the efficacy of mild® compared with placebo or to determine the efficacy of IG-MLD compared with 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.

Provocative Discography

Lumbar discography
The clinical value of lumbar discography is more widely debated than cervical or thoracic. The diagnosis of discogenic pain due to disc degeneration, internal disc disruption or annular tears, for example, is considered difficult and controversial by many authors.

Cervical Discography

Cervical discography is utilized less frequently than lumbar discography as a diagnostic tool and has not been as widely studied.

Professional Society/Organizations:
The American Society of Interventional Pain Physicians' updated evidence-based guidelines for interventional techniques in chronic spinal pain (Manchikanti et al, 2013) stated that "The evidence for diagnostic accuracy for lumbar provocation discography is fair and the evidence for lumbar functional anesthetic discography is limited …. The evidence for the diagnostic accuracy of cervical discography is limited …. The evidence for thoracic discography is limited".

Furthermore, the American College of Radiology Expert Panel on Musculoskeletal Imaging's "Appropriateness Criteria® chronic neck pain" (Newman et al, 2013) stated that "X-ray discography was considered but not recommended".

An updated practice guideline on "Chronic pain management" by the American Society of Anesthesiologists Task Force and the American Society of Regional Anesthesia and Pain Medicine (2010) stated that "Provocative discography may be considered for the evaluation of selected patients with suspected discogenic pain. Provocative discography should not be used for the routine evaluation of the patient with chronic non-specific back pain".

The New York State Workers' Compensation Board's guidelines on "Mid and low back injury medical treatment" (2013) stated that "Discography, whether performed as a solitary test or when paired with imaging (e.g., MRI), is not recommended for acute, subacute, chronic back pain or radicular pain syndromes. Improvement in surgical outcomes has not been shown to follow the use of discography, and there is evidence that performing discography on normal discs is associated with an enhanced risk of degenerative changes in those discs in later years".

An UpToDate review on "Acute lumbosacral radiculopathy: Pathophysiology, clinical features, and diagnosis' (states that "Discography is a controversial technique of uncertain utility that involves the injection of contrast under fluoroscopy into the nucleus of a disc thought to be the cause of a patient's low back pain. The test is considered positive if it demonstrates an annular disruption and reproduces the patient's usual low back pain symptoms. It is not helpful in the evaluation of lumbosacral radiculopathy".

Furthermore, an UpToDate review on "Subacute and chronic low back pain: Nonsurgical interventional treatment" states that "Discography is a diagnostic test in which contrast is injected under fluoroscopy into the nucleus of a disc thought to be the cause of a patient's low back pain, with a positive test based on the reproduction to the patient's pain. Its reliability is controversial because of the absence of a clearly defined gold-standard reference test and false positive results in patients without low back pain. In our opinion, provocative discography remains unproven as a diagnostic test. Nonetheless, trials of interventional procedures targeting

degenerated intervertebral discs have typically selected patients for inclusion based on results of provocative discography. Elimination of pain following injection of a local anesthetic into a degenerated disc (discoblock) has been proposed as an alternative to provocative discography".

V. DEFINITIONS TOP

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
- LTIF – lateral transpsoas interbody fusion
- MEDL – microendoscopic decompressive laminotomy
- MILD – microscopic muscle-preserving interlaminar decompression involves a small skin incision at the interspinous level and partial drilling of the spinous process.
- PELA – percutaneous endoscopic laser annuloplasty.
- PLD – percutaneous lumbar discectomy
- PIRFT – percutaneous intradiscal radiofrequency thermocoagulation
- PLIF – posterior lumbar interbody fusion
- TLIF – transforaminal interbody fusion
- XLIF –Extreme lateral interbody fusion

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THERMOCOAGULATION IS the use of high-frequency currents to produce coagulation to destroy tissue.

STENOSIS is a constriction or narrowing of a passage or orifice**.**

VI. BENEFIT VARIATIONS

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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 BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross'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 BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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.

Cervical and thoracic provocative discography are considered investigational; therefore, not covered:

CPT Codes ®							
62291	72285						

Image-guided minimally invasive lumbar decompression (IG-MLD) is considered investigational; therefore, not covered:

CPT Codes ®							
64999							

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HCPCS Code	Description
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

Lumbar provocative discography may be considered medically necessary:

**Functional anesthetic discography (FAD) is investigational*

CPT Codes ®							
62290	72295						

ICD-10-CM Diagnosis Code	Description
M43.06	Spondylolysis, lumbar region
M43.07	Spondylolysis, lumbosacral region
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M46.46	Discitis, unspecified, lumbar region
M46.47	Discitis, unspecified, lumbosacral region
M47.16	Other spondylosis with myelopathy, lumbar region
M47.26	Other spondylosis with radiculopathy, lumbar region
M47.27	Other spondylosis with radiculopathy, lumbosacral region
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.896	Other spondylosis, lumbar region
M47.897	Other spondylosis, lumbosacral region
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M48.07	Spinal stenosis, lumbosacral region
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M51.26	Other intervertebral disc displacement, lumbar region
M51.27	Other intervertebral disc displacement, lumbosacral region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region
M51.46	Schmorl's nodes, lumbar region
M51.47	Schmorl's nodes, lumbosacral region
M51.86	Other intervertebral disc disorders, lumbar region
M51.87	Other intervertebral disc disorders, lumbosacral region
M54.16	Radiculopathy, lumbar region

M54.17	Radiculopathy, lumbosacral region
M54.30	Sciatica, unspecified side
M54.31	Sciatica, right side
M54.32	Sciatica, left side
M54.40	Lumbago with sciatica, unspecified side
M54.41	Lumbago with sciatica, right side
M54.42	Lumbago with sciatica, left side
M54.5	Low back pain
M96.1	Post-laminectomy syndrome, not elsewhere classified
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region

IX. REFERENCES

TOP

Image-guided minimally invasive lumbar decompression

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13. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.126, Image-Guided Minimally Invasive Decompression for Spinal Stenosis. April 2018.*

Functional Anesthetic Discography

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Provocative Discography

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X. POLICY HISTORY

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MP 1.021	**CAC 7/27/04**
	CAC 9/27/05
	CAC 1/31/06
	CAC 1/30/07
	CAC 1/29/08 Consensus
	CAC 11/25/08
	CAC 11/24/09 Policy statement revised to include axial lumbar interbody fusion and functional anesthetic discography considered investigational.
	CAC 7/27/10 Policy statement revised to include Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) as an investigational procedure.
	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 Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty, MP 1.125

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	Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) and MP 1.126 Minimally Invasive Lumbar Interbody Fusion. The statement indicating functional anesthetic 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
	CAC 11/26/13 Consensus review. References updated; no changes to the policy statements.
	CAC 11/25/14 Consensus review. No changes to the policy statements. Background and references updated. Rationale added**.**
	CAC 1/27/15 Minor revision. Policy title revised to "Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis and Discography". Policy now addresses provocative lumbar, cervical, and thoracic discography. Lumbar provocative discography considered medically necessary for specific indications of low back pain when surgical intervention is being considered. All other indications of lumbar provocative discography are considered investigational. Cervical and thoracic provocative discography also added as investigational. Background, rationale, and reference update.
	CAC 1/26/16 Consensus. No change to policy statements. References and rationale updated. Added Medicare variation to reference NCD 150.13. Coding reviewed/updated.
	7/1/16 Coding updated.
	Admin update 1/1/17: Product variation section updated.
	CAC 7/25/17 Consensus. No change to policy statements. References and rationale updated. Coding Reviewed
	Admin update 10/1/17: Added new ICD 10 codes effective from 10/1/17 and deleted old codes.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	5/1/18 Consensus. Background and references updated. Rationale condensed.
	9/20/18 Retired. Please refer to TurningPoint Healthcare for management of these services effective 1/1/2019.*

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