
Medical Policy



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***Current Policy Effective Date: 3/1/24**

Title: Spinal Surgery-Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD, MELD, Percutaneous IG-MLD or PILD) for Spinal Stenosis

Description/Background

In lumbar spinal stenosis (LSS), 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 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 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.

A systematic review by Chou et al (2009) assessed surgery for back pain; it was commissioned by the American Pain Society and conducted by an evidence-based center.^{1,2} Four higher quality randomized trials were reviewed; they compared surgery with nonsurgical therapy for spinal

stenosis, including two 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 (e.g., 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 (i.e., 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, is an open procedure that 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, open procedures sometimes termed lamino-foraminotomies, 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.

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 (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 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 sculptor, 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

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. FDA product code: HRX

Medical Policy Statement

Image-guided minimally invasive lumbar decompression (IG-MLD, MELD, Percutaneous IG-MLD/ PILD) for Spinal Stenosis is experimental/investigational.* It has not been scientifically demonstrated to improve patient clinical outcomes.

****Note: 0275T is considered experimental/investigational for commercial members. For Medicare Advantage members, use G0276 for dates of service 1/1/15 and later; see Government Regulations section for full guidelines.***

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

G0276*

*For Medicare contracts only

Other codes (investigational, not medically necessary, etc.):

0275T

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD)

Clinical Context and Therapy Purpose

The purpose of image-guided minimally invasive lumbar decompression is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with lumbar spinal stenosis.

The following **PICO** was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with lumbar 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 are back pain with neurogenic claudication (i.e., 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. Lumbar spinal stenosis 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.

Interventions

The therapy being considered is image-guided minimally invasive lumbar decompression. Image-guided minimally invasive lumbar decompression describes a percutaneous procedure for decompression of the central spinal canal in patients with spinal stenosis and hypertrophy of the ligamentum flavum. In this procedure, a specialized cannula and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

Comparators

The following practices are currently being used to treat lumbar spinal stenosis: Conservative therapy and open decompression.

Image-guided minimally invasive lumbar decompression is proposed as an alternative to existing posterior decompression procedures.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, health status measures, and treatment-related morbidity.

Outcome measures for spinal surgery are relatively well-established. Most studies used back and leg visual analog scores or the Zurich Claudication Questionnaire to assess pain and the Oswestry Disability Index to assess functional limitations. Most studies also use a broader functional status index such as the SF-12 or SF-36, particularly the physical function subscale of SF-36. Determining the minimal clinically important differences (MCID) for these measures is complex. The MCID for a given measure can depend on the baseline score or severity of illness, the method used to calculate MCID, and the times at which the scores are measured. For these reasons, some investigators prefer to calculate a minimum detectable difference (MDD).

Both short-term and long-term outcomes are important in evaluating spinal treatments. Net benefit should take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36, Zurich Claudication Questionnaire, or visual analog scale measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

The present evidence review addresses posterior decompression of lumbar spinal stenosis (LSS) with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided minimally invasive lumbar decompression (IG-MLD) includes 3 RCTs in a total of 478 individuals, and a number of prospective and retrospective cohort studies and case series.

Randomized Controlled Trials (RCTs)

The largest RCT (N = 302) was the MiDAS ENCORE (Evidence-based Neurogenic Claudication Outcomes Research) trial (NCT02093520). The protocol for the trial was approved by the Centers for Medicare and Medicaid Services under coverage with evidence development. This nonblinded study, conducted at 26 interventional pain management centers in the United States, randomized 302 patients in a 1:1 ratio to IG-MLD or epidural steroid injections (ESIs).⁵ This trial included Medicare beneficiaries 65 years of older who had neurogenic claudication symptoms for at least 3 months and had failed standard therapies, including: physical therapy, home exercise programs, and oral analgesics.

Selection criteria required radiologic evidence of LSS with ligamentum flavum greater than 2.5 mm confirmed by preoperative magnetic resonance imaging or computed tomography. Patients had a number of spinal stenosis cofactors in addition to ligamentum flavum hypertrophy, including bulging disc (91%), foraminal narrowing (88%), facet hypertrophy (84%), facet arthropathy (82%), and degenerative disc disease (71%), that could not be addressed by the IG-MLD technique.

Baseline scores were similar in the 2 groups (see Table 1). However, more patients in the ESI group withdrew prior to trial treatment (22 patients vs. 6 patients) due to dissatisfaction with randomization results and decisions to have surgery or other nonstudy therapy. This unequal dropout rate raises the possibility of bias due to nonblinding of patients and assessors and patient expectations. Patients who withdrew from the trial after treatment but before the 1-year follow-up (22 IG-MLD, 32 ESI) were considered treatment failures.

Six-month and 1-year results were published in 2016 (see Table 1).^{5,6} Patients in the ESI group were allowed up to 4 ESI treatments and received a mean of 2 injections over 1 year. The primary end point—the proportion of responders achieving the minimally important difference (MID) of at least a 10-point improvement on the Oswestry Disability Index (ODI) score—was significantly higher in the IG-MLD group than in the ESI group at both 6 months and 1 year. Secondary efficacy end points were the proportion of responders achieving the MID on the numeric rating scale for pain and the Zurich Claudication Questionnaire (ZCQ). Adverse events were low (1.3% for both groups). Responder rates in patients with spinal comorbidities were reported to be similar to overall responder rates. However, it may be difficult to separate out the effect of comorbidities, because over 80% of patients had 1 or more spinal stenosis comorbidities.

Two-year follow-up data for patients treated with image-guided minimally invasive lumbar decompression in the MiDAS ENCORE trial was published in 2018.⁷ Follow-up data was available for 69% of study participants and is summarized in Table 1. Comparative data for the epidural steroid injection cohort was not reported.

The MOTION RCT (NCT03610737) compared minimally invasive lumbar decompression as first-line therapy in combination with nonsurgical conventional medical management (CMM) to CMM alone.⁸ At 1-year follow-up, patients in the MILD + CMM group experienced a 16.1-point composite ODI mean improvement (the primary outcome), compared with a 2.0-point mean improvement for participants in the CMM-alone arm ($p < .001$). A major limitation of this trial was the wide variation in CMM interventions received by both individuals in the intervention and control groups. For example, 38.7% of individuals in the CMM alone group received no interventional therapy. Although this was intended by design to reflect real-world practice, it

precludes drawing conclusions about the comparative effectiveness of the procedure versus standard care. Lack of blinding and follow-up for only 12 months were additional limitations.

Study relevance, design, and conduct limitations are summarized in Table 2 and 3.

Table 1. MiDAS ENCORE Results

Outcomes	Baseline Score	% Responders at 6 Mo.	% Responders at 1 Year	% Responders at 2 Years
Pain (NRS) ¹	N=143 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=99 (IG-MD)
IG-MLD	7.7 (1.4)	55.9**	57.3**	71.73.6 (3.1 to 4.2)
ESI	7.8 (1.3)	33.3	27.1	NR
Disability (ODI) ²	N=143 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=98 (IG-MLD)
IG-MLD	53.0 (12.9)	62.2**	58.0**	72.422.7 (18.5 to 26.9)
ESI	51.7 (12.0)	35.7	27.1	NR
ZCQ: Symptom Severity ³	N=142 (IG-MLD)N=129 (ESI)	N=142 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=98 (IG-MLD)
IG-MLD	Pain: 3.8 (0.5) Neuroischemic: 3.2 (0.9)	52.8**	51.7**	73.51.0 (0.8 to 1.2)
ESI	Pain: 3.8 (0.5) Neuroischemic: 3.2 (0.9)	28.7	31.8	NR
ZCQ: Physical Function ³	N=143 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=98 (IG-MLD)
IG-MLD	2.9 (0.5)	52.4**	44.1**	59.60.8 (0.6 to 0.9)
ESI	2.8 (0.4)	14.0	17.8	NR
ZCQ: Patient Satisfaction ³	N=142 (IG-MLD)N=129 (ESI)	N=142 (IG-MLD)N=129 (ESI)	N=143 (IG-MLD)N=129 (ESI)	N=98 (IG-MLD)
IG-MLD	N/A	64.8**	61.5**	76.82.0 (1.8 to 2.2)
ESI	N/A	30.2	33.3	NR

* MiDAS ENCORE: Evidence-based Neurogenic Claudication Outcomes Research trial.^{6,7}

ESI: epidural steroid injection; IG-MLD: image-guided minimally invasive lumbar decompression; NRS: numeric rating scale; ODI: Oswestry Disability Index; ZCQ: Zurich Claudication Questionnaire.

¹ Pain score as determined with the Numerical Rating Scale, with 0 reflecting no pain and 10 reflecting worst possible pain. A positive response was defined by a ≥2-point improvement in score.

² Disability score as determined with the Oswestry Disability Index (0-100), with a score of 0-20 reflecting minimal disability, a score of 21-40 reflecting moderate disability, and a score of 41-60 reflecting severe disability.

A positive response was defined with an improvement (decrease) of 10 or more points as determined by the Minimally Important Change (MIC).

³ Pain symptom severity, physical function, and patient satisfaction with the procedure was assessed with relevant subdomains of the Zurich Claudication Questionnaire. Lower scores indicate better health status or higher patient satisfaction with treatment.

A ≥0.5-point improvement in ZCQ subdomain scores denotes a MIC and defines a positive response. Patient satisfaction scores are only assessed post-treatment.

** p<0.001

* p=0.001

Table 2. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
MIDAS ENCORE (2016, 2018) ^{6,7}	4. Study population had a significantly high proportion of patients with comorbidities that the intervention was not designed to address.		3. Delivery not similar intensity as intervention.		1-2. Follow-up data at two years not reported for comparator.
Deer et al (2022) ⁸ , MOTION			2, 3. Conventional medical management interventions varied (by design); chosen at investigator's discretion.		1. Follow-up was 12 months; 24 months is preferred.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 3. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
MIDAS ENCORE (2016, 2018) ^{6,7}	3. Allocation concealment unclear.	1. Not blinded to treatment assignment.		1. High loss to follow-up or missing data.	1. Power calculations not clearly reported. 2. Power not calculated for primary outcome. 3. Not clear if power calculations were based on clinically important difference(s).	3. Confidence intervals and/or p values not reported for all outcome measures. 4. Comparative treatment effects not reported for two year follow-up.
Deer et al (2022) ⁸ , MOTION		1. Not blinded to treatment assignment.				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. No intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Systematic Reviews

Prior to publication of MiDAS ENCORE trial results, the International Spine Intervention Society published a systematic review of the IG-MLD literature.⁹ Included were 1 RCT with 38 patients and 12 cohort studies or series.¹⁰ Pain measurements, using a visual analog score (VAS) or the ZCQ, showed a weighted mean improvement of 41% in the short term (4-6 weeks), 46% at 3 months, 42% at 6 months, and 49% at 1 year. However, mean VAS scores exceeded 3 at all times post treatment. Ten studies assessed function, 9 using the ODI or 1 using the Roland-Morris Disability Questionnaire. ODI scores improved by a weighted mean of 16.5 at 6 weeks, 16.2 at 12 weeks, 15.4 at 6 months, and 14.0 at 1 year, a weighted cumulative decline to 33 from 47 at baseline. The study by Chopko (2013), reporting 2-year outcomes, was of questionable validity, and data were not included.¹¹ Mean final ODI scores exceeded 30 for most studies, which would not be considered in the normal range. No direct procedure-related complications were identified in the selected studies, although the possibility of damage to dura and nerve roots with this procedure was noted. Overall, the body of evidence addressing the IG-MLD procedure was of low quality.

Section Summary: IG-MLD

The largest RCT (MIDAS Encore) compared image-guided MILD with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Results suggested reductions in pain and improvements in function scores in the image-guided minimally invasive lumbar decompression 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 MOTION RCT compared MILD as first-line therapy in combination with nonsurgical conventional medical management (CMM) to CMM alone in 138 individuals with lumbar spinal stenosis. At 1-year follow-up, patients in the MILD + CMM group experienced a 16.1-point composite ODI mean improvement (the primary outcome), compared with a 2.0-point mean improvement for participants in the CMM-alone arm ($p < .001$). A major limitation of this trial was the wide variation in CMM interventions received by individuals in both the intervention and control groups; for example, 38.7% of individuals in the CMM alone group received no interventional therapy. Lack of blinding and follow-up for only 12 months were additional limitations. The available evidence is insufficient to determine the efficacy of MILD compared with placebo, open decompression, or conservative treatment. Well-designed and conducted trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure.

IMAGE-GUIDED MINIMALLY INVASIVE CERVICAL OR THORACIC DECOMPRESSION

Review of Evidence

No evidence assessing use of image-guided minimally invasive cervical or thoracic decompression for treatment of individuals with cervical or thoracic spinal stenosis was found.

Section Summary: Image-Guided Minimally Invasive Cervical or Thoracic Decompression

There is no evidence to inform conclusions about use of image-guided minimally invasive cervical or thoracic decompression to treat cervical or thoracic spinal stenosis.

SUMMARY OF EVIDENCE

For individuals who have lumbar spinal stenosis who receive image-guided minimally invasive lumbar decompression (MILD), the evidence includes a large, randomized controlled trial (RCT) (N=302), a second RCT (N=138) comparing MILD to non-surgical conventional medical

management (CMM), a systematic review that included 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 (MIDAS Encore) compared image-guided MILD with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Results suggested reductions in pain and improvements in function scores in the image-guided minimally invasive lumbar decompression 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 MOTION RCT compared MILD as first-line therapy in combination with nonsurgical CMM to CMM alone in 138 individuals with lumbar spinal stenosis. At 1-year follow-up, patients in the MILD + CMM group experienced a 16.1-point composite ODI mean improvement (the primary outcome), compared with a 2.0-point mean improvement for participants in the CMM-alone arm ($p < .001$). A major limitation of this trial was the wide variation in CMM interventions received by individuals in both the intervention and control groups; for example, 38.7% of individuals in the CMM alone group received no interventional therapy. Lack of blinding and follow-up for only 12 months were additional limitations. The available evidence is insufficient to determine the efficacy of MILD compared with placebo, open decompression, or conservative treatment. Well-designed and conducted trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical or thoracic spinal stenosis who receive image-guided minimally invasive spinal decompression, no evidence was identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

North American Spine Society

In 2011, the North American Spine Society revised clinical practice guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis.¹³ Treatment recommendations included:

- Interlaminar epidural steroid injection for short-term (two weeks to six months) symptom relief in patients with neurogenic claudication or radiculopathy; however, there is conflicting evidence regarding long-term efficacy. (Grade of Recommendation: B)
- A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injection for medium-term relief of pain. (Grade of Recommendation: C)
- Decompressive surgery to improve outcomes in patients with moderate to severe symptoms of lumbar spinal stenosis. (Grade of Recommendation: B)

No specific recommendations on percutaneous image-guided lumbar decompression were provided.

Lumbar Spinal Stenosis Consensus Group

In 2018, the Lumbar Spinal Stenosis Consensus Group, composed of a panel of nationally recognized spine experts, convened to evaluate the available literature and develop guidelines for minimally invasive spine treatment.¹⁴ Based on a systematic review of the available literature on percutaneous image-guided lumbar decompression, the consensus committee determined there is sufficient support to warrant Level I evidence (Grade A, Level I, Consensus strong).

Grade A evidence is defined as "extremely recommendable (good evidence that the measure is effective and that benefits outweigh the harms.)"

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03072927 ^a	MILD® Percutaneous Image-Guided Lumbar Decompression: A Medicare Claims Study	4000	Dec 2024
NCT04594980	An open-label randomized controlled study of the efficacy of surgical treatment in patients with single level lumbar stenosis using minimally invasive decompression and fusion and traditional open	96	Feb 2025

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Government Regulations

National:

National Coverage Determination (NCD) for Percutaneous image-guided lumbar decompression for lumbar spinal stenosis (PILD) (150.13). Effective Date of this Version: 1/9/14; Implementation Date: 6/27/17.¹⁵

II. Effective for services performed on or after December 7, 2016, CMS will cover through a prospective, longitudinal study PILD procedures using an FDA-approved/cleared device that completed a CMS-approved randomized control trial (RCT) that met the criteria listed in section I above.

The CMS-approved prospective, longitudinal study must answer at least one of the following questions:

- i. Does PILD provide a clinically meaningful improvement of function (e.g., reduced acute and post-acute hospitalizations, nursing home care or inpatient rehabilitation services) and/or quality of life in Medicare beneficiaries with LSS compared to other treatments?
- ii. Does PILD provide a clinically meaningful reduction in pain (e.g., as measured by class, dose, duration of prescription pain medication use) in Medicare beneficiaries with LSS compared to other treatments?
- iii. Does PILD affect the overall clinical management of LSS and decision making, including use of other medical treatments or services (e.g., repeat PILD procedures, other interventions and surgical treatments), compared to other treatments?

The prospective, longitudinal study must also meet the following criteria:

1. The protocol must specify a statistical analysis and a minimum length of patient follow-up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of the benefit.
2. The eligibility requirements, both inclusion and exclusion criteria that were specified in the CMS-approved RCT protocol, must be maintained in the new prospective, longitudinal study.
3. All study sites and study results must be listed in the ClinicalTrials.gov database.

All CMS-approved clinical research studies must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
- b. The rationale for the study is well supported by available scientific and medical evidence.
- c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
- d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
- e. The study is sponsored by an organization or individual capable of completing it successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the CFR at 45 CFR Part 46. If a study is regulated by the FDA, it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
- g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
- h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
- i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
- j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the AHRQ Registry of Patient Registries (RoPR).
- k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
- l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, tAHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Local:

WPS LCD (L35490) for Category III codes, last effective revision date: For services performed on or after 04/27/2023.

“0275T-This is a procedure proposed as a treatment for symptomatic Lumbar Spinal Stenosis (LSS) unresponsive to conservative therapy. This procedure is generally described as a non-invasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epidurogram. Effective for claims with dates of service on or after January 9, 2014, PILD is covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) through Coverage with Evidence Development (CED) for beneficiaries with LSS who are enrolled in an approved clinical study and meets the criteria listed in NCD-150.13. Transmittal 167. Effective for claims with dates of service on or after December 7, 2016, Medicare will cover PILD under CED for beneficiaries with LSS who are enrolled in a CMS-approved prospective longitudinal study PILD procedure using and FDA-approved/cleared device that completed a CMS-approved RCT (randomized controlled trial) that met the criteria listed in the January 2014 NCD (see CR 8757, transmittal #2959, dated May 16, 2014). This is an expansion of coverage for PILD under CED, therefore the current coding and editing instructions remain unchanged.”

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Interspinous /Interlaminar Stabilization/Distractor Devices (Spacers)
- Spinal Surgery-Automated Percutaneous and Endoscopic Discectomy
- Spinal Surgery-Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/12	10/11/11	10/31/11	Joint policy established
9/1/13	6/18/13	6/26/13	Routine maintenance, references added. Updated Medicare section to indicate change in Medicare coverage. No change in position statement for other lines of business.
11/1/14	8/21/14	8/25/14	Routine maintenance, references added. Updated Medicare section to indicate change in Medicare coverage: For claims with dates of service on or after January 9, 2014, PILD, procedure code 0275T, is a covered service only when billed as part of a clinical trial approved by CMS per NCD-167, No change in position statement for other lines of business.
7/1/15	4/24/15	5/8/15	Added HCPCS code G0276 to the policy for Medicare Advantage members only. No change in policy status for commercial members. Policy title updated to include all acronyms for the procedure.
7/1/16	4/19/16	4/19/16	Routine policy maintenance. Policy status unchanged.
7/1/17	4/18/17	4/18/17	Updated rationale, added reference #5. No change in policy status.
7/1/18	4/17/18	4/17/18	Updated background, rationale and government sections. Added reference #6 and deleted reference # 12-16. No change in policy status.
7/1/19	4/16/19		Routine policy maintenance. No change in policy status.
7/1/20	4/14/20		Routine policy maintenance. No change in policy status.
3/1/21	12/15/20		Routine policy maintenance. No change in policy status. Reviewed materials sent in by Vertos Medical.
3/1/22	12/14/21		Routine policy maintenance, no change in policy status.
3/1/23	12/20/22		Routine policy maintenance, no change in policy status.
3/1/24	12/19/23		Updated rationale, added reference #8. No change in policy status. Vendor managed: N/A (ds)

Next Review Date: 4th Qtr. 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SPINAL SURGERY-IMAGE-GUIDED MINIMALLY INVASIVE LUMBAR
DECOMPRESSION (IG-MLD, MELD, PERCUTANEOUS IG-MLD OR PILD) FOR SPINAL
STENOSIS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.