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Image-Guided Minimally Invasive Decompression for Spinal Stenosis

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Related Policies (if applicable)
None

Disclaimer

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Coverage

Image-guided minimally invasive spinal decompression for spinal stenosis **is considered experimental, investigational and/or unproven.**

Policy Guidelines

NOTE: This policy does not address surgical, directly visualized decompression of the spine (i.e., discectomy, foraminotomy, or laminotomy).

Description

Image-guided minimally invasive 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. Image-

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

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.

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 lumbar spinal stenosis, 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 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 (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 non instrumented fusion) in patients with or without degenerative spondylolisthesis. The 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 lumbar spinal stenosis, 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.

Image-Guided Minimally Invasive Spinal Decompression
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.

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 (FDA) 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.

FDA product code: HRX.

Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, 2 domains are examined: the relevance, and 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

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 policy.

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 (ODI) to assess functional limitations. Most studies also use a broader functional status index such as the 36-Item Short-Form Health Survey (SF-36) or 12-Item Short-Form Health Survey (SF-12), 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:

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

Review of Evidence

This medical policy addresses posterior decompression of lumbar spinal stenosis with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided minimally invasive lumbar decompression includes 3 RCTs in a total of 478 individuals and a number of prospective and retrospective cohort studies and case series.

Randomized Controlled Trials

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 & Medicaid Services under coverage with evidence development. This nonblinded study, conducted at 26 interventional pain management centers in the U.S., randomized patients in a 1:1 ratio to image-guided minimally invasive lumbar decompression or epidural steroid injections. (5) This trial included Medicare beneficiaries 65 years or 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 lumbar spinal stenosis 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 image-guided minimally invasive lumbar decompression technique.

Baseline scores were similar in both groups (see Table 1). However, more patients in the epidural steroid injection 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 would suggest risk 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 image-guided minimally invasive lumbar decompression, 32 epidural steroid injections) were considered treatment failures.

Six-month and 1-year results were published in 2016 (see Table 1). (5, 6) Patients in the epidural steroid injection group were allowed up to 4 epidural steroid injection treatments and received a mean of 2 injections over 1 year. The primary endpoint, the proportion of responders achieving the minimally important difference of at least a 10-point improvement on the ODI score, was significantly higher in the image-guided minimally invasive lumbar decompression group than in the epidural steroid injection group at both 6 months and 1 year. Secondary efficacy endpoints were the proportion of responders achieving the minimally important difference on the numeric rating scale for pain and the Zurich Claudication Questionnaire. 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. Although 2-year results have been published, there was no comparative analysis because crossover was permitted after 1 year, and the majority of participants in the CMM arm elected to undergo the MILD procedure. (9)

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

Table 1. MiDAS ENCORE* Results

Outcomes	Baseline Score, Mean (SD)	Percent Response at 6 Months, %	Percent Response at 1 Year, %	Percent Response (%) and Mean Improvement at 2 Years (95% CI)
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-MLD)
IG-MLD	7.7 (1.4)	55.9**	57.3**	71.7 / 3.6 (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**	72.4 / 22.7 (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*	73.5 / 1.0 (0.8 to 1.2)
ESI	Pain: 3.8 (0.5) Neuroischemic: 3.2 (0.8)	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**	59.6 / 0.8 (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	NA	64.8**	61.5**	76.8 / 2.0 (1.8 to 2.2)
ESI	NA	30.2	33.3	NR

* MiDAS ENCORE: Evidence based Neurogenic Claudication Outcomes Research trial. (6, 7)
CI: confidence interval; ESI: epidural steroid injection; IG-MLD: image guided minimally invasive lumbar decompression; MIC: minimally important change; NA: not applicable; NR: not reported; NRS: Numeric

Rating Scale; ODI: Oswestry Disability Index; SD: standard deviation; 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 ≥2point 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 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 literature review; this is not a comprehensive gaps 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. Clinically significant difference not prespecified; 6. Clinically 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 literature review; this is not a comprehensive gaps 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.

Deer et al. (2024) reported on two-years results from the MOTION study. (9) Two-year follow-up included 64 *mild* + CMM and 67 CMM-Alone patients. All outcome measures showed significant improvement from baseline for *mild* + CMM, whereas the majority of CMM-Alone patients had elected to receive *mild* treatment or other lumbar spine interventions by 2 years, precluding valid 2-year between-group comparisons. Neither group reported any device- or procedure-related adverse events. The design of the MOTION study was intended to reflect the real-world environment in the clinic setting, including the patient population and the variety of CMM treatment options available to the investigator to employ at their discretion. As a result, the variability in type and number of CMM treatments may be viewed as a limitation. And while the use of CMM in both groups in this study simulates real-world practice, the type and frequency of CMM needed for each of the two groups could result in confounding, as patients in the CMM-Alone group may have received systematically more CMM. Another limitation is the loss of patient performance evaluations in the treatment groups due to crossover to *mild* or other disallowed procedures, especially in the CMM-Alone group, which resulted in unusable 2-year results for continuous outcomes in that group and precluded between-group comparisons for those outcomes.

Systematic Reviews

Prior to publication of MiDAS ENCORE trial results, the International Spine Intervention Society published a systematic review of the image-guided minimally invasive lumbar decompression literature. (10) Included were an RCT with 38 patients (11) and 12 cohort studies or series. Pain measurements, using a visual analog score or the Zurich Claudication Questionnaire, showed a weighted mean improvement of 41% in the short term (4 to 6 weeks), 46% at 3 months, 42% at 6 months, and 49% at 1 year. However, mean visual analog score scores exceeded 3 at all times posttreatment. Ten studies assessed function, 9 using the Oswestry Disability Index and 1 using the Roland-Morris Disability Questionnaire. Oswestry Disability Index 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. (12) 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 image-guided minimally invasive lumbar decompression procedure was of low quality.

Observational Study

Mekhail et al. (2021) examined the long-term durability of the *mild* procedure through 5-year follow-up. Pain relief and opioid medications utilization during 12-month follow-up were also assessed. (13) All patients diagnosed with lumbar spinal stenosis secondary to ligamentum flavum hypertrophy who underwent mild from 2010 through 2015 at the Cleveland Clinic

Department of Pain Management were included in this retrospective longitudinal observational cohort study. The primary outcome measure was the incidence of open lumbar decompression surgery at the same level(s) as the mild intervention during 5-year follow-up. Secondary outcome measures were the change in pain levels using the Numeric Rating Scale and opioid medications utilization using Morphine Milligram Equivalent dose per day from baseline to 3, 6, and 12 months post-mild procedure. Postprocedural complications (minor or major) were also collected. Seventy-five patients received mild during the protocol-defined time period and were included in the study. Only 9 out of 75 patients required lumbar surgical decompression during the 5-year follow-up period. Subjects experienced statistically significant pain relief and reduction of opioid medications utilization at 3, 6, and 12 months compared to baseline. The study bears all limitations of retrospective data analysis. Possible other confounding factors affecting the incidence of subsequent open surgery, reported pain scores, and opioid consumption may not have been measured. Missing follow-up data for a few patients may pose a limitation as well.

Section Summary: Image-Guided Minimally Invasive Lumbar Decompression

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 versus 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 was an additional limitation. Two-year results showed significant improvement from baseline for *mild* + CMM, however the loss of patient performance evaluations in the treatment groups due to crossover to *mild* or other disallowed procedures, especially in the CMM-Alone group, resulted in unusable 2-year results for continuous outcomes in that group and precluded between-group comparisons for those outcomes. Five-year results from a single-center retrospective observational study found that only 9 of 75 patients previously treated with *mild* required lumbar surgical decompression. However, conclusions are limited by the retrospective nature of the study, along with a several other confounding factors. 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

Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this policy.

Populations
The population of interest is individuals with cervical or thoracic 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 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.

Interventions
The therapy being considered is image-guided minimally invasive cervical or thoracic decompression.

Image-guided minimally invasive spinal 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 practice is currently being used to treat cervical or thoracic spinal stenosis: conservative therapy and open decompression.

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

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 ODI 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 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 an 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:

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

Review of Evidence

No evidence assessing use of image-guided minimally invasive cervical or thoracic decompression for treatment of patients 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 spinal 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 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 (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 versus 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 Oswestry Disability Index (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 was an additional limitation. Two-year results showed significant improvement from baseline for *mild* + CMM, however the loss of patient performance evaluations in the treatment groups due to crossover to *mild* or other disallowed procedures, especially in the CMM-Alone group, resulted in unusable 2-year results for continuous outcomes in that group and precluded between-group comparisons for those outcomes. Five-year results from a single-center retrospective observational study found that only 9 of 75 patients previously treated with *mild* required lumbar surgical decompression. However, conclusions are limited by the retrospective nature of the study, along with a several other confounding factors. 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 outcomes.

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.

Practice Guidelines and Position Statements

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 (MIST Guidelines). (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)."

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. (15) Treatment recommendations included:

- Interlaminar epidural steroid injection for short-term (six 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.

American Society of Pain and Neuroscience

Consensus guidance from the American Society of Pain and Neuroscience (2022) (16) stated: "PILD [posterior image-guided lumbar decompression] should be considered for the treatment of mild-to-moderate LSS [lumbar spinal stenosis] in the presence of NC [neural compression], with less than or equal to a grade 2 spondylolisthesis, and with a contribution of spinal narrowing with at least 2.5 mm of LFH [ligamentum flavum hypertrophy]." Grade A; Level of certainty high; Level of evidence 1-A.

Medicare National Coverage

The Centers for Medicare & Medicaid Services determined that percutaneous image-guided lumbar decompression would be covered by Medicare when provided in a clinical study through coverage with evidence development for beneficiaries with lumbar spinal stenosis enrolled in an approved clinical study meeting criteria in the decision memo (NCD 150.13). (17) According to the national coverage decision, percutaneous image-guided lumbar decompression is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This procedure is proposed as a treatment for symptomatic lumbar spinal stenosis unresponsive to conservative therapy. This procedure is generally described as a noninvasive 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, computed tomography) with contrast media to identify and monitor the compressed area via epidurogram.

Ongoing and Unpublished Clinical Trials

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

Table 4. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03072927[a]	MILD® Percutaneous Image-Guided Lumbar Decompression: A Medicare Claims Study	4000	Dec 2026
NCT04594980	An Open-Label Randomized Controlled Study of the Efficacy of Surgical Treatment in Patients With Single Level Lumbar Spinal Stenosis Using Minimally Invasive Decompression and Fusion and Traditional Open	96	Feb 2025

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0274T, 0275T
HCPCS Codes	G0276

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2024	Document updated with literature review. Coverage unchanged. No new references added.
02/01/2024	Document updated with literature review. Coverage unchanged. References 8, 9, 13 and 16 added.
10/15/2022	Document updated with literature review. Coverage unchanged. No new references added, some references updated.

09/01/2021	Reviewed. No changes.
09/01/2020	Document updated with literature review. Coverage unchanged. NOTE clarified to: “NOTE: This policy does not address surgical, directly visualized decompression of the spine (i.e., discectomy, foraminotomy, or laminotomy).” References 7, 13, and 14 added.
08/01/2019	Document updated with literature review. Coverage unchanged. No new references added.
06/15/2018	Reviewed. No changes.
02/15/2018	Document updated with literature review. Coverage has changed from lumbar to spinal to include cervical/thoracic decompression. Title changed from: Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis.
10/15/2016	Document updated with literature review. Coverage unchanged.
07/01/2015	Reviewed. No changes.
02/15/2014	Document updated with literature review. Coverage unchanged.
07/01/2011	New medical document. Image-guided minimally invasive lumbar decompression (IG-MLD) for spinal stenosis is considered experimental, investigational and unproven.