Medical Policy Manual Surgery, Policy No. 176

Image-Guided Minimally Invasive Decompression (IG-MSD) for Spinal Stenosis

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

This minimally invasive spinal procedure uses a specialized catheter and instruments to sculpt bone and tissue near the spinal canal to treat back pain.

MEDICAL POLICY CRITERIA

Image-guided minimally invasive cervical, thoracic, or lumbar decompression is considered **investigational.**

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation, Surgery, Policy No. 118
2. Artificial Intervertebral Disc, Surgery, Policy No. 127
3. Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Energy (Nucleoplasty), Surgery, Policy No. 131
4. Dynamic Stabilization of the Spine, Surgery, Policy No. 143
5. Automated Percutaneous and Endoscopic Discectomy, Surgery, Policy No. 145
6. Interspinous and Interlaminar Stabilization and Distraction Devices (Spacers), Surgery, Policy No. 155

7. Percutaneous Axial Anterior Lumbar Fusion, Surgery, Policy No. 157
8. Total Facet Arthroplasty, Surgery, Policy No. 171
9. Interspinous Fixation (Fusion) Devices, Surgery, Policy No. 172
10. Lumbar Spinal Fusion, Surgery, Policy No. 187

BACKGROUND

Image-guided minimally invasive spinal decompression (IG-MSD) describes a novel percutaneous procedure for decompression of the spinal canal in patients with spinal stenosis using image-guided navigation systems for the purpose of improving orientation to the unexposed anatomy. Common imaging techniques include fluoroscopy, computed tomography and X-ray. In this procedure, a specialized cannula and surgical tools are used under image-guidance for bone and tissue sculpting near the spinal canal.

In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and the nerve roots. Lumbar spinal stenosis is the most common and most frequent symptom of 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 with symptom onset usually beginning at 40-50 years and older. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots. Although treatment of disc herniation or surgical fusion of vertebrae may be required as a component of decompression, the present policy addresses decompression of spinal stenosis with a percutaneous treatment that is performed under image-guidance.

Most (IG-MSD) procedures are performed on the lumbar spine. Percutaneous image-guided minimally invasive lumbar decompression (IG-MLD) using a specially designed tool kit has been proposed as an ultra-minimally invasive treatment of central spinal stenosis. In percutaneous IG-MLD, the epidural space is filled with contrast medium under image-guidance. Using a 6-gauge cannula that is 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 image-guidance, with additional 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 to be used near the lateral neural elements and are contraindicated for disc procedures.

Alternative decompressive surgical procedures include:

> Decompressive laminectomy, the classic treatment for spinal stenosis, which unroofs the spinal canal by extensive resection of posterior or anterior 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. In cases of lumbar decompression, the extensive resection and injury to the posterior spine and supporting muscles 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 the resultant instability. In thoracic decompression cases, neurological

complications rates in up to 14.5% of cases have been reported.[1] Laminectomy may be used for extensive multi-level 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. 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 of the lumbar spine. 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.

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. FDA product code: HRX.

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.

The Totalis™ Direct Decompression System received 510(k) market clearance from the FDA in November 2012, with the intended use as an interspinous access platform to perform percutaneous lumbar decompressive procedures for a variety of conditions. The Totalis™ system uses a small cannula, or tube, which is placed through a small incision where a specialized instrument is inserted in order to remove bone or tissue. X-ray images are used to help guide the Totalis instrument during the procedure.

There are no FDA approved guidance tool kits for image-guided cervical or thoracic spinal decompression.

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.

EVIDENCE SUMMARY

Evaluating the safety and effectiveness of image-guided minimally invasive spinal

decompression (IG-MSD) requires randomized comparisons with conventional techniques for decompression of spinal stenosis. These comparisons are necessary to determine whether the benefits of IG-MSD outweigh any risks and whether they offer advantages over the conventional surgical techniques described above with respect to symptom control, durability of treatment effects, adverse effects, and the need for further surgical treatment.

The primary outcomes for treatment of spinal stenosis are pain reduction and improvement in functional levels. Both of these outcomes can be influenced by variables other than the spinal surgery under investigation such as nonspecific effects, placebo response, the natural history of the disease, and/or regression to the mean. Therefore, they need to be evaluated in well-designed randomized, controlled trials that include large study populations and long-term follow-up.

SYSTEMATIC REVIEWS

Members of the Standards Division of the International Spine Intervention Society (ISIS) published a systematic review (SR) of the IG-MLD literature in 2014.[2] Overall, the body of evidence addressing the IG-MLD procedure was rated as low quality. Included in the review were one randomized controlled trial[3] and 13 nonrandomized cohort studies/series[4-16]. Pain measurements using a visual analog score (VAS) or Zurich Claudication Questionnaire (ZCQ) showed a weighted mean improvement of 41% in the short-term (four to six weeks), 46% at three months, 42% at six months, and 49% at one year. However, mean VAS remained greater than three at all times after treatment. Categorical data was not provided so the proportions of patients who experienced minimal clinically meaningful outcome could not be determined. Ten studies assessed function using the Oswestry Disability Index (ODI) or Roland-Morris Disability Questionnaire (RMDQ). With a baseline ODI score of 47.0, the ODI improved by a weighted mean of 16.5 at six weeks, 16.2 at 12 weeks, 15.4 at six months, and 14.0 at one year. One study that reported two year outcomes was considered to be of questionable validity and the data were not accepted. The mean final ODI was greater than 30 in the majority of studies, which would not meet one author's definition of a minimally acceptable outcome. No direct procedure-related complications were identified in the included studies, although the possibility of damage to dura and nerve roots while performing this procedure was noted. The authors concluded that further study is needed in high-quality studies "that are independent of industry funding and that provide categorical data."

One systematic review of percutaneous lumbar decompression for symptomatic lumbar spinal stenosis (LSS) was published in 2012.[17] The review found no reports of major device- or procedure-related adverse events or deaths in 373 patients. One-year efficacy data was reported to show statistically significant improvement in pain and mobility. However, this review precludes conclusions because it included all IRB-approved study patients as well as a retrospective safety survey, apparently without regard to the design quality of each study.

A 2009 systematic review was commissioned by the American Pain Society (APS) and conducted at the Oregon Health Sciences University Evidence-Based Practice Center.[18] The review included randomized controlled trials and systematic reviews of surgery for various causes of low back pain including symptomatic spinal stenosis. However, studies were limited to laminectomy; evidence related to more recent decompressive surgical procedures was not reviewed.

RANDOMIZED CLINICAL TRIALS

In 2023, Deer published results from a prospective randomized controlled study, the MOTION study [19]. Participants were randomly assigned to one of two groups: the mild procedure (minimally invasive decompression) + conventional medical management (CMM) or CMM-only. Primary study outcomes included a Walking Tolerance Test, subsequent lumbar spine interventions, and adverse events. A total of 155 patients completed the study, with 77 patients allocated to the mild + CMM and 78 patients allocated to CMM-only. At 2-year follow-up, 64 patients from the mild + CMM and 67 patients from CMM-only were included for analyses. At 2-years, 77.6% of CMM-only patients had undergone subsequent lumbar spine interventions compared to 10.6% of mild + CMM patients ($p<0.0001$). For the Walking Tolerance Test, mild + CMM group improved on average 197% compared to baseline ($p=0.0002$), while CMM-only improved by 22%, which was not statistically significant. No adverse events related to the device or procedure were reported from baseline to 2 years. Further research is needed with larger sample sizes and longer duration to further investigate the effects of minimally invasive decompression on patient health outcomes.

In 2016, Staats and Benyamin published six-month and one-year outcomes for the ongoing, manufacturer-sponsored MiDAS ENCORE study, comparing IG-MSD using the mild® Device Kit with epidural steroid injection (ESI).[20, 21] This nonblinded study included 302 Medicare beneficiaries, 65 years or older who had neurogenic claudication symptoms for at least three months, and had failed physical therapy, home exercise programs, and oral analgesics. The study also required radiologic evidence of lumbar spinal stenosis (LSS) with ligamentum flavum greater than 2.5 mm confirmed by preoperative magnetic resonance imaging or computed tomography. Comorbidities know to affect spinal stenosis were allowed providing they were not considered to be severe by the treating physician. More patients in the ESI group withdrew prior to study treatment (22 vs 6), due primarily to a decision to have surgery or other nonstudy therapy (n=8) or dissatisfaction with randomization results (n=6). This unequal dropout rate raises the possibility of bias due to patient expectations and nonblinding of patients and assessors. At baseline, the IG-MILD group scored 53.0 on the 100-point ODI, 7.7 out of 10 points on the numeric rating scale for pain (NRS-P), and 2.9 to 3.8 on the subscales of the Zurich Claudication Questionnaire (ZCQ). Baseline scores in the control group were similar, at 51.7, 7.8, and 2.8 to 3.8, respectively.

Six-month and one-year results were published in 2016. Patients in the ESI group received a mean of 1.7 injections over the first six months of the study. Patients who withdrew from the study after treatment but before the six-month follow-up (10 IG-MLD, 20 ESI) were considered treatment failures. The primary end point, the proportion of responders achieving the minimally important difference (MID) of 10 on the ODI, was significantly higher in the IG-MLD group than the ESI group (62.2% vs 35.7% at six months, $p<0.001$; 58.0% vs 27.1% at one year, $p<0.001$). Secondary efficacy end points were the proportion of responders for the MID on the NRS-P (2 of 10 points) and the ZCQ (0.5 change). For the NRS-P score, at six months, 55.9% of IG-MLD patients were responders compared with 33.3% of controls ($p<0.001$) and at one year, 57.3% of IG-MLD patients were responders compared with 27.1% of controls. At six months, mean improvement in NRS-P score was 2.9 for the IG-MLD group and 0.9 for the controls. The percentage of responders on the ZCQ was greater for the IG-MLD group than in the ESI group in all subdomains. Adverse events were low (1.3% for both groups), and there were no serious device or procedure-related adverse events in either group.

Two-year follow-up data for patients treated with IG-MLD in the MiDAS ENCORE trial was published in 2018.[22] Follow-up data was available for 69% of study participants. At two years, percent response and mean improvement (n=98 to 99) for IG-MLD patients were 71.7% and

3.6 (95% CI 3.1 to 4.2) for pain, 72.4% and 22.7 (95% CI 18.5 to 26.9) for disability (ODI), 83.5% and 1.0 (0.8 to 1.2) for symptom severity subscale of the ZCQ, 59.6% and 0.8 (95% CI 0.6 to 0.9) for the physical function subscale of the ZCQ, and 76.8% and 2.0 (95% CI 1.8 to 2.2) for the patient satisfaction subscale of the ZCQ. Comparative data for the ESI cohort was not reported.

Limitations of this study include different delivery intensity between the control and intervention group, the inclusion of a significantly high proportion of patients with comorbidities that the intervention was not designed to address, and lack of a comparator at the two-year follow-up. In addition, the allocation concealment was unclear, there was a high loss to follow-up, and power calculations were not clearly reported.

NONRANDOMIZED CLINICAL STUDIES

Mekhail (2021) published a retrospective longitudinal observational cohort study to evaluate the long-term durability of the Minimally invasive lumbar decompression (mild®) procedure.[23] Outcomes included the incidence of open lumbar decompression surgery, change in pain levels and opioid use. Of patients (n=75) who received the mild® procedure from 2010-2015 nine (12%) required surgery (2.4% per year). The authors report a significant difference in NRS pain scores between baseline and all 3 follow-up time points, including 3, 6, and 12-months post- mild® treatment ($p < 0.0001$ for each time point). They also report a decrease in opioid medications utilization between baseline and 3, 6, and 12-months after mild® treatment ($p = 0.0048$, $p = 0.0015$, and $p = 0.0067$, respectively). Eighteen subjects were treated with opioid medications prior to the mild® intervention. Limitations include confounding factors affecting the incidence of subsequent open surgery were not identified, reported pain scores, reliability of opioid consumption reporting and missing follow-up data.

Nerland (2015) published results from a multicenter study that compared laminectomy versus minimally invasive decompression surgery for spinal stenosis to better understand patient's level disability and quality of life post-surgery.[24] Findings showed no differences between the two groups on level of disability and quality of life, report favorable outcomes in both groups at on year post treatment.

Although these studies, and the others included in the SRs above, suggest that IG-MSD may result in short-term improvements, it is difficult to determine the durability of any treatment effects due to the short-term follow-up and small sample sizes. Other methodological limitations that make these studies unreliable include the lack of randomized comparison of IG-MSD with standard surgical treatments. In addition, the small study populations limit the ability to rule out the role of chance as an explanation of study findings. Therefore, this evidence is insufficient to determine whether IG-MSD offers any advantages over standard surgical procedures.

PRACTICE GUIDELINE SUMMARY

A number of United States-based clinical practice guidelines were identified for interventional and minimally invasive spinal decompression procedures for treatment of spinal stenosis. However, none of the following addressed image-guided spinal decompression:

- American Pain Society (APS)[25]
- American Society of Anesthesiologists/American Society of Regional Anesthesia and Pain Medicine[26]

- American Society of Interventional Pain Physicians[27]
- North American Spine Society (NASS)[28]
- Department of Veterans Affairs / Department of Defense[29]

LUMBAR SPINAL STENOSIS CONSENSUS GROUP MIST GUIDELINES

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.[30] 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."

AMERICAN SOCIETY OF PAIN AND NEUROSCIENCE CONSENSUS GUIDANCE

In 2022 the American Society of Pain and Neuroscience (ASPN) created a consensus guidance for best practice for minimally invasive surgical treatment of symptomatic spinal stenosis.[31] The authors indicate that Percutaneous image-guided lumbar decompression (PILD) should be considered for the treatment of mild-to-moderate LSS in the presence of NC, 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. (Grade A; Level of certainty high; Level of evidence 1-A.) An expert panel performed systematic literature searches that served as the evidence basis for the recommendations and consensus points. Level of certainty grades were based on the quality of the published studies used in the review. A high level of certainty was based on at least one well designed, controlled and randomized clinical trial (level of evidence 1-A).

SUMMARY

There is not enough research to show that image-guided minimally invasive spinal decompression (IG-MSD) improves health outcomes, including pain reduction and improvement in functional levels, for people with symptomatic spinal stenosis. Therefore, IG-MSD for cervical, thoracic or lumbar decompression is considered investigational.

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CODES

Codes	Number	Description
CPT	0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
	0275T	;lumbar
HCPCS	None	

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