07.01.89 Image-Guided Minimally Invasive Decompression for Spinal Stenosis

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Related Policies:

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Summary

Description

Image-guided minimally invasive decompression describes a percutaneous procedure for decompression of the central spinal canal in individuals 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.

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.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether image-guided minimally invasive lumbar decompression improves the net health outcome in individuals with spinal stenosis.

PRIOR APPROVAL

Not applicable.

POLICY

Image-guided minimally invasive spinal decompression is considered **investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

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 individuals with lumbar spinal stenosis, surgical laminectomy has established benefits in reducing pain and improving quality of life.

For individuals 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. 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). 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. 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 are conducted entirely under fluoroscopic guidance, with contrast media added throughout the procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central canal. The devices are not intended for use near the lateral neural elements and are contraindicated for disc procedures.

Regulatory Status

In 2006, the X-Sten MILD® Tool Kit (now the mild® device kit, X-Sten Corp. renamed Vertos Medical) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for treatment of various spinal conditions. This set of specialized surgical instruments is used to perform percutaneous lumbar decompressive procedures.

Vertos's mild® instructions state that the device is not intended for disc procedures but rather for tissue resection at the perilaminar space, within the interlaminar space, and at the ventral aspect of the lamina. The device is not intended for use near the lateral neural elements and remains dorsal to the dura using image guidance and anatomic landmarks.

Food and Drug Administration product code: HRX.

RATIONALE

This evidence review was created in January 2010 with searches of the PubMed database. The most recent literature update was performed through July 2025.

Evidence reviews 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 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 individuals 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:

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

This evidence review 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. 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). 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. 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. 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.

Study relevance, design, and conduct limitations are summarized in Table 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-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)

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)
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**	59.60.8 (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	NA	64.8**	61.5**	76.82.0 (1.8 to 2.2)
ESI	NA	30.2	33.3	NR

* MiDAS ENCORE: Evidence-based Neurogenic Claudication Outcomes Research trial.
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 ≥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 (ZCQ). 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<.001
* p=.001

Table 2. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
MiDAS ENCORE (2016, 2018),	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 2 years not reported for comparator.
Deer et al (2022) 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 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. 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)	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 2 year follow-up.
Deer et al (2022) 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 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.

Systematic Review

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. Included were an RCT with 38 patients 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., 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.

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 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

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 review.

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 individuals 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 individuals 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 a 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

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.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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). 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.[13,] Treatment recommendations included:

- Interlaminar epidural steroid injection for short-term (6 weeks to 6 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral;, cervical or thoracic
	62330	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; one interspace, lumbar
	62331	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure)
HCPCS		
	G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial
Type of Service	Surgery	
Place of Service	Inpatient	

POLICY HISTORY

Date	Action	Action
July 2025	Annual Review	Policy Renewed
July 2024	Annual Review	Policy Renewed
July 2023	Annual Review	Policy Revised – content moved from retired policy “Miscellaneous Surgical Treatments of Back Pain”
January 2022	Interim Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
October 2019	Interim Review	Policy Revised
July 2019	Annual Review	Policy Revised

Date	Action	Action
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
August 2015	Annual Review	Policy Revised
September 2014	Annual Review	Policy Revised
October 2013	Annual Review	Policy Revised
November 2012	Annual Review	Policy Renewed
November 2011	Annual Review	Policy Renewed
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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