Minimally Invasive Spine Surgery Procedures (for Kansas Only)

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➲ Instructions for Use

Table of Contents **Page**

Application 1
Coverage Rationale 1
Definitions 1
Applicable Codes 3
Description of Services 4
Clinical Evidence 4
U.S. Food and Drug Administration 11
References 11
Policy History/Revision Information 12
Instructions for Use 12

Related Policies

- Discogenic Pain Treatment (for Kansas Only)
- Epidural Steroid Injections for Spinal Pain (for Kansas Only)
- Facet Joint and Medial Branch Block Injections for Spinal Pain (for Kansas Only)
- Spinal Fusion and Bone Healing Enhancement Products (for Kansas Only)
- Total Artificial Disc Replacement for the Spine (for Kansas Only)
- Vertebral Body Tethering for Scoliosis (for Kansas Only)

Application

This Medical Policy only applies to the state of Kansas.

Coverage Rationale

For medical necessity clinical coverage criteria for minimally invasive spine surgeries, refer to the InterQual® CP: Procedures:

- Decompression +/- Fusion, Lumbar
- Fusion, Lumbar Spine

Click here to view the InterQual® criteria.

The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy:

- Axial Lumbar Interbody Fusion (AxiaLIF®), a percutaneous Presacral access route to the L5-S1 vertebral bodies
- Percutaneous Image-Guided Lumbar Decompression (PILD)
- Percutaneous sacral augmentation (Sacroplasty) with or without a balloon or bone cement
- Minimally invasive lumbar decompression (mild®)
- Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)

Definitions

Automated Percutaneous Lumbar Discectomy (APLD): Is a minimally invasive surgical technique for treatment of herniated lumbar intervertebral discs. For this procedure, a thin, blunt-tipped suction and cutting probe is inserted through the skin, and the end of the probe is placed into the middle of the herniated disc under fluoroscopic guidance. This device is then used to remove some or all of the degenerated portion of the center of the disc. The goal of this procedure is to relieve pressure on nerve roots without damaging surrounding tissues, thereby minimizing postoperative complications and morbidity. APLD is intended as an alternative to chemonucleolysis, open discectomy, or other types of percutaneous

discectomy for individuals who have a relatively small degree of lumbar disc protrusion without fragmentation or complete extrusion of disc material and who have failed conservative therapy (Vertos Medical, 2018).

Axial Lumbar Interbody Fusion (AxiaLIF): Also called trans-sacral, transaxial, or para-coccygeal Interbody Fusion, is a minimally invasive technique used in L5-S1 (presacral) spinal fusions. The technique provides access to the spine along the long axis of the spine, as opposed to anterior, posterior, or lateral approaches. The surgeon enters the back through a very small incision next to the tailbone and the abnormal disc is taken out. Then a bone graft is placed where the abnormal disc was and is supplemented with a large metal screw. Sometimes, additional, smaller screws are placed through another small incision higher on the back for extra stability (Cragg, et al., 2004).

Endoscope: A thin, fiberoptic tube with a light and lens, used to examine the interior of the patient's body; provides minimally invasive access for diagnostic and surgical procedures (AANS, 2022).

Endoscopic Discectomy: Involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an Endoscope, and aspiration of disc material (Vertos Medical, 2018).

Fluoroscopy: Imaging technique to obtain real-time moving images of the internal structures of the body; this imaging uses an x-ray source and fluorescent screen; modern fluoroscopes couple the screen to an x-ray image intensifier and video camera allowing the images to be recorded and shown on a monitor (Vertos Medical, 2018).

Image-Guided Minimally Invasive Lumbar Decompression (mild®): A percutaneous procedure for decompression of the central spinal canal in individuals with lumbar spinal stenosis. In this procedure, a specialized cannula and surgical tools are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal (Vertos Medical, 2018).

Interlaminar Lumbar Instrumented Fusion (ILIF): During the ILIF procedure, the surgeon makes an incision in the lower back and an opening is created through the ligaments. This allows access to the spinous processes. The bone, ligament, or disc that is causing compression is removed to release pressure on the nerves. Allograft bone may be placed in the disc space. Bone, either autograft and/or allograft, is placed between the spinous processes and on the remaining lamina. An implant is inserted to stabilize the spine and secure the spinous processes until the fusion takes place (Veritas Health, 2022).

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF): Minimally invasive alternative to an open surgical approach to spinal fusion. The vertebrae are reached through an incision in the lower abdomen or side. This method employs a laparoscope to remove the diseased disc and insert an implant (i.e., rhBMP, autogenous bone, cages, or fixation devices) into the disc space intended to stabilize and promote fusion (Veritas Health, 2022).

Nucleoplasty: Also known as percutaneous disc decompression (PDD) or percutaneous plasma discectomy, uses x-ray images (Fluoroscopy) for guidance to insert a specialized catheter to reach the disc nucleus. Radiofrequency energy is used to ablate nuclear material and create small channels within the disc. This is thought to decompress the disc, reducing the pressure both inside the disc and on nerve roots.

Open Spine Surgery: Unlike the minimally invasive approach, traditional Open Spinal Surgery relies on longer skin incisions and more extensive tissue dissection to expose the surgical field.

Percutaneous or Endoscopic Lumbar Fusion: During a percutaneous endoscopic procedure the surgeon does not have direct visualization of the operative field, in contrast to an open approach. Visual guidance is obtained using either Fluoroscopy or a video monitor. Specialized instruments are typically used and advanced through a retractor, avoiding major soft tissue injury. The approach is associated with a steep learning curve, risk of radicular trauma with insertion of cages, and in some cases postoperative migration of the devices (Veritas Health, 2022).

Percutaneous Image-Guided Lumbar Decompression (PILD): A posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area (Veritas Health, 2022).

Posterior Lumbar Spine Surgery: Performed by approaching the spine through the individual's back by a traditional back midline incision or transforaminally through the opening between two spinal vertebrae (i.e., the foramen) where the nerves leave the spinal canal to enter the body [i.e., transforaminal lumbar Interbody Fusion (TLIF)] (Veritas Health, 2022).

Presacral: Anterior to the sacrum (Ortho Info, 2021).

Sacroplasty: A minimally invasive surgical treatment that attempts to repair sacral insufficiency fractures using bone cement. Sacral insufficiency fractures have traditionally been treated with conservative measures, including bed rest, analgesics, orthoses/corsets, and physical therapy. In some cases, pain persists and is refractory to these measures. For this procedure, two thin, hollow tubes are placed in the lower back, over the left half and right half of the sacrum, guided by images from x-rays or computed tomography scans. The surgeon then advances a needle through each tube to the site of the sacral fracture and injects 2 to 5 mL of bone cement (Hayes, 2018; updated January 2021).

Spinal Decompression: Spinal stenosis, which is a narrowing of the vertebral canal, is a common condition that can result in compression of the nerves. This can produce a variety of symptoms, including pain, numbness and muscle weakness. If surgery is recommended, it may be possible to remove the bone and soft tissues causing the nerve compression through an MIS approach using tubular dilators and a microscope or Endoscope. The more common decompressive procedures include laminectomy and foraminotomy (AANS, 2022).

Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems: The TESSYS® approach focuses on the endoscopic visualization of the foramen and a transforaminal approach in order to resect the herniated disc. The surgeon performs a foraminoplasty through which neural elements can be decompressed. Disc material is removed completely and directly through the foramen, which is gradually widened using specialized reamers and instruments. The iLESSYS® method uses endoscopic interlaminar access for the removal of herniated discs or the treatment of lumbar spinal stenosis. Generally, all lumbar levels can be treated with either approach.

Tubular Retractor: This technique involves progressive dilation of the soft tissues, as opposed to cutting directly through the muscles. By using tubes to keep the muscles out of the way, the surgeon works through the incision without having to expose the area widely. Sometimes, the surgeon will also utilize an Endoscope or microscope focused down the tube to assist with performing the surgery Once the procedure is complete, the Tubular Retractor can be removed, allowing the dilated tissues to come back together. Depending on the extent and type of surgery necessary, incisions can often be small (AANS, 2022).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed
0275T	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; lumbar
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22899	Unlisted procedure, spine
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar

CPT Code	Description
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar

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HCPCS Code	Description
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

Description of Services

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain and radiculopathy will resolve with conservative care, a surgical decompression is often considered when the pain is unimproved after several months and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of discectomy, in which the extruding disc material is excised. When performed with an operating microscope the procedure is known as microdiscectomy. Minimally invasive options have also been researched, in which some portion of the disc is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material.

In an attempt to alleviate many of the limitations of previous techniques, a Presacral approach to the lumbosacral junction has been investigated. Transaxial anterior lumbar Interbody Fusion is an emerging minimally invasive spinal fusion procedure used to treat patients with chronic lower back pain. This procedure is an alternative to traditional fusion techniques that utilize anterior or posterior approaches to directly expose the lumbosacral spine. In the case of transaxial anterior lumbar Interbody Fusion the spine is accessed percutaneously via the anterior surface of the sacrum (Ollendorf, et al., 2011).

Clinical Evidence

Axial Lumbar Interbody Fusion (AxiaLIF)

Although this method may be considered an emerging minimally invasive surgical approach, no randomized controlled trials evaluating axial LIF as a minimally invasive or percutaneous surgical procedure for the treatment of L5-S1 conditions were found in the peer-reviewed, published, scientific literature supporting safety and efficacy. Improvement in net health outcomes has not been clearly demonstrated when compared to standard surgical methods, and it remains unclear whether this surgical technique results in clinical benefits that are as good as or superior to standard surgical techniques. The evidence is insufficient to allow any conclusions regarding short- or long-term clinical benefits, possible complications, failure rates, relief of symptoms, improvement in functional levels, and the need for further surgery is as beneficial as other surgical approaches to lumbosacral interbody fusion.

An ECRI report for the AxiaLIF Plus System indicated that the evidence from case series in one systematic review and one additional case series (not in the systematic review) is at too high a risk of bias to support conclusions on safety and effectiveness of one-level lumbar interbody fusion or L5-S1 spondylolisthesis or spondylosis with AxiaLIF. Randomized controlled trials (RCTs) comparing patient-oriented outcomes (e.g., pain, functional status, reoperation rates) of AxiaLIF with other interbody fusion surgical approaches are needed to assess AxiaLIF's comparative effectiveness (ECRI, 2020).

Balsano et al. (2020) conducted a retrospective analysis to evaluate the radiographic and clinical results of patients treated with AxiaLIF® Technique (AxiaLIF®, AMSGroup, Italy) using a minimally invasive pre-sacral approach. From 2013 to 2018, a total of 52 patients have been treated (12 M, 40 F; mean age 46.3 years). Diagnosis included L5 isthmic spondylolisthesis low-grade dysplasia, primary and secondary degenerative disc disease. Forty-three patients have been followed for at least 2 years. Fusion assessment was based on plain radiographs and Brantigan fusion criteria at 1, 6, 12 and 24 months after surgery. All patients completed the VAS and ODI at baseline through last follow-up. Results: Clinical results showed good pain resolution. VAS back demonstrated an average reduction over baseline of 50%, 57%, 71%, 77% at 3, 6, 12 and 24 months, respectively ($p < 0.001$). ODI demonstrated an average reduction over baseline of 38%, 51%, 67%, and 72% at the same time points ($p < 0.001$). Complete fusion was demonstrated in 65% of cases, 30% partial fusion and 5% in the absence of bony bridges visible radiographically. We had two major complications, as 1 retroperitoneal hematoma and 1 spondylodiscitis, and one minor complication, as a superficial infection of the surgical wound. The authors concluded that the surgical treatment of degenerative disc disease at L5-S1 with minimally invasive technique AxiaLIF showed good radiographic and clinical outcomes with an acceptable rate of complications. Moreover,

shorter hospitalization and faster functional recovery are adding factors to the choice of this technique. This study is limited by its small sample size and retrospective observations. Although the results are promising, the small sample size and lack of a comparison group limit the generalizability of the findings.

Anand et al. (2018) conducted a single-center retrospective study to compare the fate of the lumbosacral junction in ALIF versus AxiaLIF patients in terms of clinical and radiographic outcomes. Adult spinal deformity patients, treated with CMIS techniques, with at least 2-year follow-up who underwent AxiaLIF or ALIF at the lumbosacral junction were included. Patients were separated into two groups: AxiaLIF (56 patients) and ALIF (38 patients). Outcome measures included segmental lordosis, sagittal vertical alignment, lumbar lordosis (LL), pelvic incidence-LL mismatch, and pseudarthrosis, major complication, and revision surgery rates. The ALIF group achieved greater postoperative and delta segmental lordosis, higher delta sagittal vertical alignment, higher delta LL, and lower postoperative pelvic incidence-LL mismatch. The pseudarthrosis, major complication, and revision surgery rates were higher in the AxiaLIF group. Five cases of pseudarthrosis at L5-S1 were seen, all in the AxiaLIF group. The authors concluded ALIF patients showed more favorable radiographic correction parameters and lower rates of pseudarthrosis, major complications, and revision surgeries. ALIF is the preferred strategy for L5-S1 arthrodesis at a bottom of a long construct. This study is limited by its small sample size and retrospective observations. In addition, the ALIF vs AxiaLIF surgeries were not randomized. Further research with randomized controlled trials is needed to validate these findings.

Schroeder et al. (2015) performed a systematic review of seventy-four articles discussing safety profile of axial interbody arthrodesis, but only 15 (13 case series and 2 retrospective cohort studies) met the study inclusion criteria. The authors concluded that review of the literature indicates that an axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%). However, these results are based mainly on retrospective case series by authors with a conflict of interest. The limited prospective data available indicate that the actual fusion rate may be lower, and the complication rate may be higher than currently reported.

Zeilstra et al (2013) reported their 6-year single-center experience with L5-S1 axial lumbar interbody fusion (AxiaLIF). A total of 131 patients with symptomatic degenerative disc disease refractory to non-surgical treatment were treated with AxiaLIF at L5-S1 and were followed for a minimum of 1 year. Main outcomes included back and leg pain severity, Oswestry Disability Index score, working status, analgesic medication use, patient satisfaction, and complications. Back and leg pain severity decreased by 51% and 42%, respectively, during the follow-up period. Back function scores improved 50% compared to baseline. The authors concluded that single-level AxiaLIF is a safe and effective means to achieve lumbosacral fusion in patients with symptomatic degenerative disc disease. Moreover, they noted that “Our study is limited by the retrospective nature of the analysis. Additionally, all patients underwent fusion at L5 to S1 and, therefore, no conclusions can be drawn regarding the effectiveness or safety of 2-level AxiaLIF from this report. Lastly, mean patient follow-up was 21 months. Although this represents one of the longest follow-up reports following AxiaLIF surgery, long-term clinical and radiographic outcomes are unknown”.

In a 5-year post-marketing surveillance study, Gundanna et al. (2011) reported complications associated with axial presacral lumbar interbody fusion in 9,152 patients. A single-level L5-S1 fusion was performed in 8,034 patients (88%), and a two-level L4-S1 fusion was performed in 1,118 patients (12%). Complications were reported in 1.3% of patients with the most commonly reported complications being bowel injury (0.6%) and transient intraoperative hypotension (0.2%). Other complications noted include superficial wound and systemic infections, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury and ureter injury. The overall complication rate was similar between single-level (1.3%) and two-level (1.6%) fusion procedures, with no significant differences noted for any single complication. The authors concluded that the overall complication rates compare favorably with those reported in trials of open and minimally invasive lumbar fusion surgery.

Clinical Practice Guidelines

American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)

AANS and CNS have jointly published a series of guidelines addressing fusion for degenerative disease of the lumbar spine (2014). Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention. In the absence of deformity or instability, lumbar fusion has not been shown to improve outcomes in patients with isolated stenosis, and therefore it is not recommended.

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Clinical Excellence (NICE) guidance stated that the evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized

complications. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into transaxial interbody lumbosacral fusion (NICE, 2018).

North American Spine Society (NASS)

NASS published guidelines on the treatment of degenerative spondylolisthesis in 2014. NASS has stated that there is insufficient evidence to make a recommendation for or against the cost-effectiveness of minimal access-based surgical treatments compared to traditional open surgical treatments for degenerative lumbar spondylolisthesis. This guideline did not specifically address axial lumbosacral interbody fusion (AxiaLIF).

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)

Evidence in the peer-reviewed scientific literature evaluating laparoscopic anterior lumbar interbody fusion is primarily in the form of prospective and retrospective case series, comparative trials, and nonrandomized trials. The average sample size of these studies varies but range on average from 40 to more than 200 patients. Many studies are outdated with average being over twenty years ago. Currently, the published, peer-reviewed scientific literature does not allow strong conclusions regarding the overall benefit and long-term efficacy of the laparoscopic approach compared to open spinal fusion.

Minimally Invasive Lumbar Decompression (MILD®)

Available studies have limitations that include: non-controlled trials, case series, non-blinded studies, and small number of participants. Well-designed studies that include: a larger number of participants at multi-centers, use of clear patient selection criteria, measures of outcome using standardized tools, comparison to conservative management, comparison with and without an anesthetic agent and longer-term outcomes are needed to validate the use/safety/effectiveness of this technology.

Hayes (2023) completed a Health Technology Assessment to evaluate the effectiveness and safety of the minimally invasive lumbar decompression (MILD) procedure, an approach that uses a proprietary surgical kit (mild®; Vertos Medical Inc.) to treat lumbar spinal stenosis (LSS) in adult (≥ 18 years old) patients. Patients had statistically significant and clinically significant improvements in pain, disability, and function after treatment with MILD compared with baseline that lasted for up to 1 to 2 years, but it is uncertain whether there is a longer durability of effect or whether MILD improved quality of life. The MILD procedure was associated with a reduction in use of pain medications in over half of patients, although some patients started their use de novo at some point during follow-up. A small number of patients required surgical reintervention within 1 to 5 years after MILD. A single study on the comparative efficacy of MILD with the Superion Indirect Decompression device only reported rates of surgical reintervention and provided no data on other outcomes, such as pain and disability. While finding that MILD led to a higher percentage of surgical reinterventions, the statistical significance of the difference between groups was not analyzed. The authors concluded Vertos mild® procedure may have the potential to provide greater improvement in pain and symptoms compared with epidural steroid injection and with conventional medical management, however, there are too few studies to draw definitive conclusions. Substantial uncertainty exists due to individual study limitations and the lack of long-term follow-up. Additional well-designed good-quality studies with follow-up durations > 2 years are needed to better establish the safety, effectiveness, and comparative effectiveness of this technology.

ECRI (2021) performed a literature review of the Vertos mild® device kit. Evidence from studies synthesized in systematic reviews shows the mild® procedure is safe and relieves LSS symptoms at up to one-year follow-up. Evidence from additional studies suggests the mild® procedure may be as effective but safer than laminectomy (three nonrandomized studies) and may be more effective than epidural steroid injections (one randomized controlled trial), but these findings need validation in additional RCTs to permit conclusions. Despite the large amount of available data, some evidence gaps remain. Additional RCTs are needed to verify findings and assess mild®'s effectiveness compared with other decompression procedures. Large, multicenter studies that assess the mild® procedure's long-term effectiveness (i.e., five years or longer) are also needed.

Mekhail and associates (2021) published the results of a retrospective observational cohort study evaluating mild® for treatment of lumbar spinal stenosis, with hypertrophic ligamentum flavum as a contributing factor (n = 75). The primary outcome measure was the incidence of open lumbar decompression surgery at the same level(s) as the MILD procedure during a five-year follow-up period. Secondary outcome measures included change in patient reported pain levels using the Numeric Rating Scale (NRS), and opioid medication use using the Morphine Milligram Equivalent dose per day from baseline to 3, 6, and 12 months post procedure. The mean patient age was 74.4 years, all had continued pain despite conservative management for an average of 6.8 years. Nineteen subjects had MILD performed at two levels, all others had single level surgery with the most frequent level treated being L4-L5. No major complications were reported, minor complications included post procedural soreness and ecchymosis, with one case of allergic dermatitis at the surgical site.

The authors reported a significant difference in the NRS pain scores from baseline and all three time points, 73.8%, 69.5% and 60.3% respectively for 3, 6 and 12 months post-procedure. Within five years nine subjects required open surgical decompression (2.4% annually), women had an odds ratio of 0.175 of having subsequent surgery compared with men. Only three had surgery at the exact same level as the MILD procedure, seven had surgery which involved more levels than the MILD. Only two subjects reported improvement in neurogenic claudication following the open procedure, three reported no improvement following open surgery, and three subjects did not have follow-up visits. In the author opinion MILD was durable over five years and may allow elderly patients the avoidance of open lumbar surgery. The study is limited by its retrospective design, lack of control group, and small sample population.

Merkow and colleagues (2020) published results of a systematic review evaluating outcomes of both mild® and Superion (intraspinous process device) separately, as treatment of lumbar spinal stenosis. Regarding mild® the authors review included eight studies; two RCTs, three prospective observational trials, and three retrospective observational trials. The authors concluded that mild® is modestly safe and effective for treatment of lumbar spinal stenosis, based primarily on the study by Staats, et al. 2018 showing two year outcomes.

Aldahshory et al. (2020) evaluated and compared the clinical outcomes of two different treatment modalities for degenerative lumbar canal stenosis (LCS): the classic laminectomy with posterolateral transpedicular screw fixation and mild®. This was a randomized study of 50 patients with degenerative LCS. The study compared two cohorts: Group A – 25 patients underwent classic lumbar laminectomy with posterolateral transpedicular fixation and Group B – 25 patients underwent mild®. There were no statistically significant differences between both treatment modalities in the Visual Analogue Score (VAS) for leg pain and back pain, the patient satisfaction index, and the Oswestry Disability Index after 1 year. The fusion operations were associated with higher estimates of blood loss and longer hospital stay. The authors concluded that mild® has the same satisfactory results as classic laminectomy with posterolateral fixation for the treatment of degenerative LCS with less bleeding loss and shorter hospitalization. The study limitations included a one-year follow-up that is not sufficient to assess the reoperation rate in case of adding fusion. Other limitations include small sample size and lack of information about the body mass index of each patient and the associated comorbidities.

In 2018, Deer and associates published consensus guidelines for minimally invasive spine treatment (MIST) for lumbar spinal stenosis. The United States Preventive Task Force (USPTF) criteria for evidence level and degree of recommendation was used along with strength of consensus for development of the guidelines. Within this guideline regarding percutaneous image guided lumbar decompression, the authors concluded the available evidence is level 1 and is supportive of PILD. In addition to retrospective and prospective studies reviewed by the consensus group, there were two comparative prospective trials that led to reimbursement approval by CMS, noted as being both Level 1 (Brown, et al., 2012; Staats, et al., 2016, detailed below), both compare PILD to lumbar ESI and not to open decompression. The recommendation by the authors is Grade A (good evidence the measure is effective and that benefits outweigh harms), Level 1 (at least 1 controlled and randomized trial, properly designed), Consensus strong (> 80% consensus).

Staats et al. (2018, included in ECRI above) reported results of a prospective, multicenter, randomized controlled clinical study. This study evaluated the long-term durability of the minimally invasive lumbar decompression (MILD) procedure in terms of functional improvement and pain reduction for patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophic ligamentum flavum. Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for MILD subjects only. Oswestry Disability Index, Numeric Pain Rating Scale, and Zurich Claudication Questionnaire were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related adverse events. The authors concluded that mild showed excellent long-term durability, and there was no evidence of spinal instability through 2-year follow-up. Given the minimally invasive nature of this procedure, its robust success rate, and durability of outcomes, mild® is an excellent choice for first-line therapy for select patients with central spinal stenosis suffering from neurogenic claudication symptoms with hypertrophic ligamentum flavum. Despite the above findings that study did have the following limitations, lack of a control group at 2-year follow-up. The randomized controlled portion of the study concluded at the primary end point of 1 year, and supplementary follow-up through 2 years was conducted for the mild patient group only. This study did not compare efficacy directly with open surgical approaches, including lumbar decompression, fusion, or spacers.

In another study, Chopko (2013) evaluated the long-term effectiveness and safety of mild® as a treatment of neurogenic claudication associated with lumbar spinal stenosis. The 2-year data are reported for 45 participants that were treated with mild® at 11 U.S. facilities. Outcome measurements included the VAS, ODI, and ZCQ. Interim data on the participants are included for 1 week, 6 months, and 1-year follow-up. The authors reported that at 2 years, the subjects demonstrated a statistically significant reduction of pain as measured by VAS, and significant improvement in physical function and mobility as measured by ZQC and ODI. The authors also reported major improvement occurred by 1-week follow-up and showed no difference between each subsequent follow-up, suggesting considerable stability and durability of the initial result over

time. There were no major adverse events or complications related to the procedure. Limitations of this study include its uncontrolled design and small size.

Brown et al. (2012) reported the results of a double-blind, randomized, prospective study of epidural steroid injections (ESI) and the mild® procedure at a single pain management center. A total of 38 individuals with symptomatic lumbar spinal stenosis (LSS) participated in the study and were randomized into two treatment groups: 21 participants in the mild® arm and 17 individuals in the ESI arm. Outcome measures were reported using the Visual Analog Scale (VAS), the Oswestry Disability Index (ODI) and Zurich Claudication Questionnaire (ZCQ) patient satisfaction score. The authors reported that at 6 weeks, the mild® participants improved from an average VAS baseline of 6.3 to a mean of 3.8. The ESI group had a mean VAS score of 6, at baseline compared with 6.3 at 6 weeks follow-up. Using the ODI, at 6 weeks follow-up, participants in the mild® group demonstrated a decrease from a baseline mean ODI from 38.8 to 27.4. In the ESI group, the initial ODI was 40.5 and at 6 weeks follow-up, the ODI was 34.8. In the mild® group, there was no significant change in the VAS and ODI scores from weeks 6 to 12. Participants in the ESI group were not measured at week 12. Participants were allowed to cross over from the ESI group to the mild® group before 12 weeks and eventually, all of the participants in the ESI group had the mild® procedure. A total of 14 of the 17 participants in the cross-over ESI group experienced an improvement in their VAS scores after the mild® procedure. Limitations of the study include its small size and short follow-up.

In 2010, Chopko et al., reported on a one-year follow-up from an industry-sponsored multicenter study, with patients who were treated with mild® devices. All 78 patients had failed conservative medical management, with 75.9% of patients treated with conservative therapy for more than 6 months. Twenty-nine patients (50%) were discharged from the surgical facility on the same day as the procedure, and none of the patients stayed longer than 24 hours. There were no reports of major intraoperative or postoperative procedure-related adverse events. The primary outcome of patient success was defined as a 2-point improvement in VAS pain, but the percentage of patients who achieved success was not reported. VAS for pain improved from a mean of 7.4 at baseline to 4.5 at 1-year follow-up. The ODI improved from 48.6 to 36.7, and there was significant improvement on all domains of the Zurich Claudication Questionnaire and the SF-12 physical component score (from 27.4 to 33.5). The small number of study participants and its industry sponsorship limit the conclusions that can be drawn from this study.

Clinical Practice Guidelines

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations for decompression with interlaminar stabilization. ISASS concluded, based in part on a conference presentation of a study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Recommended indications and limitations were described in the article. The document did not address interspinous and interlaminar distraction devices without decompression (Guyer et al., 2016).

National Institute for Health and Care Excellence

The National Institute for Health and Clinical Excellence states that current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication (such as the X-STOP prosthesis) shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur, and further surgery may be needed. There are no major safety concerns. Therefore, these procedures may be used provided that normal arrangements are in place for clinical governance, consent, and audit. Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options (NICE, 2010).

North American Spine Society (NASS)

The 2014 revised NASS clinical guideline on interspinous process spacing devices concluded that there is insufficient evidence to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis (LSS).

Percutaneous Image-Guided Lumbar Decompression (PILD, PLDD)

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 a large RCT, a small RCT, 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 trial was unblinded and there is evidence of differing expectations and follow-up in the 2 groups, suggesting a high-risk of bias. The available evidence is insufficient to determine the efficacy of MILD compared with placebo or to determine the efficacy of image-guided minimally invasive lumbar decompression compared with open decompression. Trials with

relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

In a health technology assessment, a small body of very limited low-quality evidence is considered insufficient to determine the safety and efficacy of PLDD for lower back disc herniation (Hayes 2018, updated 2021). The assessment also suggests uncertainty regarding the comparative and long-term effectiveness of PLDD and the need for subsequent surgeries.

Brouwer and colleagues (2015, included in Hayes report above) conducted a RCT with non-inferiority study design (n = 115) to evaluate PLDD compared with conventional surgery for the treatment of LBP. The non-inferiority analysis showed that PLDD resulted in non-inferior outcomes compared with conventional surgery; however, the number of reoperations required was significantly higher in the PLDD group (38%) compared with conventional surgery group (16%). At the two year follow up, Brower and his colleagues (2017) demonstrated that although the rate of reoperation in the PLDD group was higher than expected, surgery could be avoided in 48% of those patients that were original candidates for surgery. The authors concluded the results justify the need for additional studies into the value of PLDD as an alternative to conservative treatment.

In a retrospective observational study, Klessinger (2018c) reported on the re-surgery frequency of 73 patients that received percutaneous lumbar disc decompression (PLDD) using Dekompressor. Patient data were drawn from an electronic medical record system of patients receiving PLDD between January 2005 and December 2007. A history of pain for a minimum of 3 months was mandatory. Patients had either low back pain or radicular pain with or without a sensory loss. Patients with a lumbar spine surgery in their history were excluded. All patients were seen in the practice one month after the operation for follow-up and subsequent follow up was according to the needs of the patient. In 22 patients (30.1%), the follow-up was longer than 5 years, and in five patients (6.8%) it was longer than 10 years. The mean follow-up time was 35.6 months. The results showed that one month after the intervention, excellent results were achieved in 17 patients and good results, in 32 patients, giving a short-term success rate of 67.1%; however, subsequent open surgery at the index level was necessary in 19 patients (26.0%). Most reoperations (15 patients) had to be performed during the first year after PLDD (20.5% of all patients, 78.9% of all resurgeries). These patients had a statistically significant worse outcome (26.7% versus 75.0% satisfied patients). Radicular pain was present in all patients with an early subsequent surgery, but only in 50% of patients with late surgery. The mean time between PLDD and the additional surgery was at 10.8 ±17.9 months. The author concluded that despite an initial success rate of 67%, the resurgery rate of 26% offsets that, and suggests that PLDD is not a replacement for open discectomy. Further studies are needed to compare the outcome and rate of subsequent surgery in patient populations with and without radicular symptoms to find the ideal indications for PLDD.

In a prospective cohort study, McCormick et al. (2016) determined long-term outcomes of Dekompressor percutaneous lumbar disc decompression (PLDD) for discogenic radicular pain. Consecutive patients (n = 70) with discogenic lumbosacral radicular pain who underwent PLDD with Dekompressor were included in the study. Numerical Rating Scale (NRS) leg pain score and Oswestry Disability Index (ODI) score data were collected at 6 months and 1 year. These 2 measures, 5-point Likert scale patient satisfaction, and surgical rate data were also collected at 8 years when possible. Forty and twenty-five patients were successfully contacted at 1-year and 8-year follow-up, respectively. At 1 year and 8 years, NRS leg pain scores were reduced greater than 50% in 47% and 29% of patients, respectively; ODI score improved greater than 30% in 43% and 26% of patients, respectively. Of the patients who were followed-up at 8 years, 36% had undergone surgery and the median satisfaction was "4" (interquartile range of 2 to 5). The authors concluded that while limited by loss-to-follow-up, the findings of this study suggested that treatment of discogenic lumbosacral radicular pain with Dekompressor resulted in decreased leg pain and disability and favorable satisfaction at long-term follow-up. They stated that further study with adequate follow-up retention is needed to confirm that Dekompressor spares open spinal surgery. The findings are limited by lack of comparison group and large loss to follow up.

Cong et al. (2016) conducted a systematic review to compare the effectiveness and safety of endoscopic discectomy (ED) with open discectomy (OD) for the treatment of symptomatic LDH. A search was used to identify all published RCTs up to August 2014. Cochrane methodology was used for the results of this meta-analysis. Nine relevant RCTs involving 1,092 patients were identified. Compared with OD, ED results in slightly better clinical outcomes which were evaluated by the Macnab criteria without clinical significance (ED group: 95.76%; OD group: 80%; p = 0.10), a significantly greater patient satisfaction rate (ED group: 93.21%; OD group: 86.57%; p = 0.03), lower intraoperative blood loss volume, and shorter length of hospital stay. The authors concluded that from the existing outcomes, ED surgery could be viewed as a sufficient and safe supplementation and alternative to standard open discectomy. The cost-effectiveness analyses still remain unproved from the existing data. More independent high-quality RCTs using sufficiently large sample sizes are needed.

Manchikanti et al. (2013b) conducted a systematic review on patients with radicular pain to determine effectiveness of mechanical lumbar disc decompression with nucleoplasty. Fifteen studies met the inclusion criteria, but only one was an RCT thus no meta-analysis could be performed. A total of 2,429 patients were evaluated with at least 50 patients in each study and a follow up period of one year. Patients had an average improvement of 62% in pain relief. In this limited to fair evidence, the authors concluded nucleoplasty may provide relief in patients with disc herniation. Limitations included lack of RCTs, patient loss, publication bias and a large number of placebo-control groups where utilization of local anesthetic injection was performed thus mimicking a facet joint injection.

Percutaneous Sacroplasty

A Hayes report for percutaneous sacroplasty for treatment of sacral insufficiency fractures published in 2018, indicates that the literature search identified a nonrandomized controlled study and a few uncontrolled studies of percutaneous sacroplasty. Results of these studies provide preliminary evidence that percutaneous sacroplasty improves outcomes for patients who have sacral insufficiency fractures. The best evidence supporting use of this treatment was obtained in the nonrandomized controlled study and the largest available uncontrolled trial. Both of these studies enrolled patients who could not tolerate or failed to respond to conservative nonsurgical therapy. Comparing pre-surgery with post-surgery, percutaneous sacroplasty provided statistically significant reductions in pain and improvements in mobility and activities of daily living. Two smaller uncontrolled studies of percutaneous sacroplasty do not provide reliable evidence of efficacy since the investigators did not report whether patients underwent nonsurgical treatments for sacral insufficiency fractures before sacroplasty. Further controlled studies with long-term assessment of the results of percutaneous sacroplasty are needed to confirm that it is a safe and effective procedure for sacral insufficiency fractures. The January 2021 Hayes update indicates that the evidence regarding efficacy is unchanged since publication of the 2018 Health Technology Brief (Hayes, 2018; updated January 2021).

Frey et al. (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs. nonsurgical management. This prospective, observational cohort study spanned ten years and comprised 240 patients with sacral insufficiency fractures. Thirty-four patients were treated with nonsurgical methods, and 210 patients were treated with sacroplasty. Pain, as measured by VAS, was recorded before treatment and at several follow-ups. Mean pretreatment VAS for the sacroplasty group was 8.29; for the nonsurgical treatment group, it was 7.47. Both forms of treatment resulted in significant VAS improvement from pretreatment to the 2-year follow-up. However, the sacroplasty treatment group experienced significant VAS score improvement consistently at many of the follow-up points (pretreatment to post; posttreatment through 2 weeks; 12 weeks through 24 weeks; 24 weeks through 1 year. Meanwhile, the group with nonsurgical treatment only experienced one significant pain improvement score − at the 2-week follow-up post-treatment. One major limitation of this study was that the nonsurgical treatment group was not followed up with at the 10-year mark whereas the sacroplasty group did receive follow-up.

Dougherty et al. (2014) retrospectively evaluated outcomes of consecutive patients with SIF treated by percutaneous sacroplasty in an electronic database. The study included 57 patients (75% women; age 61 to 85 years, median 74 for men or 75 for women; duration of pain 2 to 5 weeks. Pain was measured at rest and, sometimes, during activity on an 11-point NRS (higher values = greater pain) or described by patients, opioid use was also evaluated before and at 1 to 5 weeks (median, 2.5) after sacroplasty. The study is limited by retrospective design, small sample size, lack of a control group, subjective outcome measures, inconsistent evaluation of pain, and short follow-up.

Kortman et al. (2013, included in Hayes report above) retrospectively examined outcomes of patients with painful SIF or symptomatic sacral lesions treated by percutaneous sacroplasty at any of six participating U.S. centers. Patients were included in the study if they had severe sacral pain refractory to standard conservative management (defined as any combination of bed rest, analgesics, partial weight bearing, and orthosis), imaging evidence of bilateral or unilateral SIF or focal or infiltrating sacral lesions, and symptoms attributable to sacral pathology. The SIF group consisted of 204 patients. The group with sacral lesions (SL group) included 39 patients. Sacroplasty entailed the long- or short-axis approach and PMMA or bioceramic cement, but the rate of each approach and the trade names for cement and other devices were not reported. Pain was evaluated by self-report, a VAS, and analgesic use before and at 1 month after sacroplasty. All patients with SIF were followed for ≥ 1 year. Compared with pretreatment values, mean VAS scores improved significantly after sacroplasty in patients with bilateral SIF, patients with unilateral SIF, and patients with sacral lesions. In the entire group with SIF and the group with sacral lesions, respectively, 31% and 18% experienced complete pain relief and 3.0% and 10% experienced no significant pain relief. Use of narcotic, non-narcotic, and over-the-counter analgesics decreased markedly after versus before sacroplasty in both groups but data for analgesic use were not reported. The study is limited by retrospective design, lack of a control group, and use of subjective outcome measures.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

A variety of endoscopes and associated surgical instruments and devices have received marketing clearance through the FDA's 510(k) process. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

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Policy History/Revision Information

Date	Summary of Changes
06/01/2025	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) criteria for substance use disorder (SUD) services, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies that have been approved by the Kansas Department of Health and Environment. The UnitedHealthcare Medical Policies are intended to be used in

connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.