Minimally Invasive Spine Surgery Procedures

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

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 to S1 vertebral bodies
- Percutaneous Image-Guided Lumbar Decompression (PILD)
- Percutaneous sacral augmentation (Sacroplasty), with or without a balloon or bone cement
- Automated Percutaneous Lumbar Discectomy (APLD) for intervertebral disc decompression
- Percutaneous Endoscopic Lumbar Discectomy (PELD) for intervertebral disc decompression
- Minimally Invasive Lumbar Decompression (MILD®)
- Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)
- Transforaminal Lumbar Interbody Fusion (TLIF), which uses only endoscopy visualization (such as a percutaneous incision with video visualization)

Definitions

Automated Percutaneous Lumbar Discectomy (APLD): The percutaneous (through the skin, membrane, and/or tissue) removal of protruding disc material using a large-bore needle that is inserted directly into the disc space [North American Spine Society (NASS), 2025].

Axial Lumbar Interbody Fusion (AxiaLIF): Also called trans-sacral, transaxial, or paracoccygeal Interbody Fusion and is a minimally invasive technique that is used in L5 to 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: An Endoscope is a diagnostic instrument that is equipped with illumination and designed for direct visualization of internal anatomical structures (Animated Dissection of Anatomy for Medicine, 2025).

Endoscopic Discectomy: A minimally invasive surgical procedure that removes herniated disc material from the spine using an Endoscope (NASS, 2025).

Fluoroscopy: The use of radiological imaging to position instruments during diagnostic and surgical procedures (NASS, 2025).

Image-Guided Minimally Invasive Lumbar Decompression (MILD®): Minimally Invasive Lumbar Decompression is a minimally invasive, image-guided procedure that is used to decompress the lumbar spine in cases in which central canal stenosis is caused by a thickened ligamentum flavum (Zhang et al., 2025).

Interbody Fusion: The fusing of two vertebral segments in the space between discs with grafting bone (NASS, 2025).

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF): Laparoscopic Anterior Lumbar Interbody Fusion is a minimally invasive surgical procedure that is used to fuse painful or unstable vertebrae together in the lumbar region. The procedure uses several small incisions in the abdomen to provide endoscopic access to the anterior spine [Decker et al., 2025; American Academy of Orthopaedic Surgeons (AAOS), 2025].

Open Spine Surgery: Open Spine Surgery involves making a long incision to expose the surgical area, providing the surgeon with direct visualization and access to the underlying anatomy (AAOS, 2025).

Percutaneous Endoscopic Lumbar Discectomy (PELD): Percutaneous Endoscopic Lumbar Discectomy is a minimally invasive surgical procedure for treating lumbar disc herniation. The procedure incorporates a linear lumbar skin incision and an advanced camera system to magnify the operative field, allowing the surgeon to remove the herniated disc material with clear visualization and safeguard nerve structures throughout the procedure (Ruan et al., 2016).

Percutaneous Image-Guided Lumbar Decompression (PILD): Percutaneous Image-Guided Lumbar Decompression is a minimally invasive surgical procedure that is used to treat individuals with symptomatic posterior lumbar spinal stenosis. This technique involves the removal of thickened tissue to enlarge the spinal canal, thereby relieving nerve compression. The procedure uses imaging guidance rather than direct visualization of the surgical area and is performed through a percutaneous (through the skin) approach (Hayes, 2025).

Posterior Lumbar Spine Surgery: Posterior Lumbar Spine Surgery is the surgical approach to access an individual's lumbar spine through the back of the body (AAOS, 2025).

Presacral: Anterior to the sacrum (Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, 2023).

Sacroplasty: Sacroplasty is a minimally invasive procedure that involves the placement of polymethyl methacrylate cement into the site of a sacral insufficiency fracture to provide mechanical stabilization and pain relief. The procedure can be performed via multiple approaches, including bilateral short axis, bilateral long axis, coaxial vision, transiliac, interpedicular, and balloon assisted (Singh et al., 2024).

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 a minimally invasive surgery approach using tubular dilators and a microscope or Endoscope. The more common decompressive procedures include laminectomy and foraminotomy [American Association of Neurological Surgeons (AANS), 2022; updated 2024].

Transforaminal Lumbar Interbody Fusion: Transforaminal Lumbar Interbody Fusion is a modification of posterior lumbar Interbody Fusion that involves approaching the intervertebral body from the side, performing a complete removal of the disc, and placing a bone graft through the transforaminal route (Yang et al., 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 the member specific benefit plan document 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
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, 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
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)
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

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.

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 that is used to treat individuals with chronic lower back pain. This procedure is an alternative to traditional fusion techniques that use 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

Automated Percutaneous Lumbar Discectomy

Systematic reviews have assessed automated percutaneous discectomy compared with other interventions; however, the majority of these reviews contained observational studies that were published more than a decade ago, with generally small populations of individuals and inconsistent results. There is insufficient evidence that has been obtained from well-designed and -executed randomized controlled trials (RCTs) to evaluate the impact of automated percutaneous discectomy on net health outcome.

Feng et al. (2017) conducted a meta-analysis of RCTs to evaluate the clinical results of seven surgical interventions for the treatment of lumbar disc herniation. The eligible RCTs were identified, and data from three outcomes (success, complications, and reoperation rate) were independently extracted by two authors. A total of 29 RCTs, including 3,146 individuals, were included in this meta-analysis. For the success rate, the rank probability (from best to worst) included percutaneous endoscopic lumbar discectomy (PELD) > standard open discectomy > standard open microsurgical discectomy > chemonucleolysis > microendoscopic discectomy (MED) > percutaneous laser disc decompression > automated percutaneous lumbar discectomy (APLD). The limitations of this network meta-analysis include the range of study populations and inconformity of the follow-up times and outcome measurements. The authors concluded that this meta-analysis provides evidence that PELD might be the best choice to increase the success rate and decrease the complication rate; moreover, standard open microsurgical discectomy might be the best option to drop the reoperation rate. APLD might lead to the lowest success rate and the highest complication and reoperation rates. Higher-quality RCTs and direct head-to-head trials are needed to confirm these results.

Manchikanti et al. (2013c) conducted a systematic review of APLD for the contained herniated disc. Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, opioid intake, and return to work. Short-term effectiveness was defined as 1 year or less, whereas long-term effectiveness was defined as greater than 1 year. Overall, 19 observational studies and no RCTs were included and met the inclusion criteria for methodological quality assessment. Overall, 5,515 individuals were studied, with 4,412 individuals (80%) having positive results that lasted 1 year or longer. Based on U.S. Preventive Services Task Force criteria, the indicated evidence for APLD is limited for short- and long-term relief. A study limitation is the paucity of RCTs in the literature that describe APLD.

Clinical Practice Guidelines

American College of Occupational and Environmental Medicine (ACOEM)

The 2021 ACOEM evidence-based practice guidelines on invasive treatments for low back disorders state that there is no quality evidence that automated percutaneous discectomy is an effective treatment for any back or radicular pain problem; thus, this treatment is not recommended (Hegmann et al., 2021).

American Society of Interventional Pain Physicians (ASIPP)

In the section on percutaneous disc decompression in the evidence-based guideline, the ASIPP found limited evidence for the use of APLD for the treatment of lumbar disc compression (Manchikanti et al., 2013a).

North American Spine Society (NASS)

The 2012 practice guidelines from NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommend that percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (poor-quality evidence). However, a separate recommendation states that evidence is insufficient to recommend for or against use of automated percutaneous discectomy compared with open discectomy.

Axial Lumbar Interbody Fusion

Although this method may be considered an emerging, minimally invasive surgical approach, no RCTs that evaluate axial lumbar interbody fusion (AxiaLIF) as a minimally invasive or percutaneous surgical procedure for the treatment of L5 to S1 conditions were found in the peer-reviewed, published scientific literature that supported safety and efficacy. Improvement in net health outcomes has not been clearly demonstrated compared with 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- and long-term clinical benefits, possible

complications, failure rates, relief of symptoms, and 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 a case series in one systematic review and one additional case series (not in the systematic review) is at too high of a risk of bias to support conclusions on the safety and effectiveness of one-level lumbar interbody fusion or L5 to S1 spondylolisthesis or spondylosis with AxiaLIF. RCTs that compare individual-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 for patients treated with the AxiaLIF Technique (AxiaLIF, AMS Group) using a minimally invasive presacral approach. From 2013 to 2018, a total of 52 patients had been treated (12 male, 40 female; mean age, 46.3 years). The diagnosis included L5 isthmic spondylolisthesis, low-grade dysplasia, and primary and secondary degenerative disc disease. Overall, 43 patients had been followed up 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 visual analog scale (VAS) and Oswestry Disability Index (ODI) at baseline through the last follow-up. Clinical results showed good pain resolution. VAS back demonstrated an average reduction over baseline of 50%, 57%, 71%, and 77% at 3, 6, 12, and 24 months, respectively ($p < 0.001$). The 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 and partial fusion in 30%; 5% were in the absence of bony bridges that were visible radiographically. Two major complications were noted, one retroperitoneal hematoma and one spondylodiscitis, with one minor complication, which was a superficial infection of the surgical wound. The authors concluded that the surgical treatment of degenerative disc disease at L5 to S1 with the minimally invasive technique AxiaLIF showed good radiographic and clinical outcomes, with an acceptable rate of complications. Moreover, shorter hospitalization and faster functional recovery are additional factors that support 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 anterior lumbar interbody fusion (ALIF) patients vs AxiaLIF patients in terms of clinical and radiographic outcomes. Adult patients who (1) had spinal deformity; (2) were treated with circumferential minimally invasive surgery (MIS) techniques, with at least a 2-year follow-up; and (3) 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), and pelvic incidence–LL mismatch as well as 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 to S1 were seen, all in the AxiaLIF group. The authors concluded that ALIF patients had more favorable radiographic correction parameters and lower rates of pseudarthrosis, major complications, and revision surgeries. ALIF is the preferred strategy for L5 to S1 arthrodesis at the 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 RCTs, is needed to validate these findings.

The National Institute for Health and Care Excellence guidance states 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. The National Institute for Health and Care Excellence encourages further research into transaxial interbody lumbosacral fusion (NICE, 2018).

Zeilstra et al. (2013) reported their 6-year, single-center experience with L5 to S1 AxiaLIF. Overall, 131 individuals with symptomatic degenerative disc disease that was refractory to nonsurgical treatment were treated with AxiaLIF at L5 to S1 and followed up for a minimum of 1 year. Main outcomes included back and leg pain severity, ODI score, working status, analgesic medication use, individual 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 with baseline. The authors concluded that single-level AxiaLIF is a safe and effective means to achieve lumbosacral fusion in individuals with symptomatic degenerative disc disease. Moreover, they noted, "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 postmarketing surveillance study, Gundanna et al. (2011) reported complications associated with axial presacral lumbar interbody fusion in 9,152 individuals. A single-level L5 to S1 fusion was performed in 8,034 individuals (88%), and a two-level L4 to S1 fusion was performed in 1,118 individuals (12%). Complications were reported in 1.3% of individuals, with the most commonly reported complications being bowel injury (0.6%) and transient intraoperative hypotension (0.2%). Other complications that were noted included 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 the 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 compared 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)

The AANS and CNS have jointly published a series of guidelines that address 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; therefore, it is not recommended.

North American Spine Society (NASS)

NASS (2014b) published guidelines on the treatment of degenerative spondylolisthesis. 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 with traditional open surgical treatments for degenerative lumbar spondylolisthesis. This guideline did not specifically address AxiaLIF.

Laparoscopic Anterior Lumbar Interbody Fusion

Evidence in the peer-reviewed scientific literature that evaluates laparoscopic anterior lumbar interbody fusion (LALIF) 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 individuals. Many studies are outdated, with the average being over 20 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 with open spinal fusion.

Minimally invasive alternatives to the mini-open ALIF approach include LALIF and robotic-assisted anterior lumbar interbody fusion (R-ALIF). In a 2025 systematic review, Decker et al. summarized the existing literature on both L- and R-ALIF, focusing on current practices as well as future objectives. In total, 48 studies met the criteria for inclusion; 42 focused on LALIF (37 of these were published prior to 2004), while six assessed R-ALIF. Compared with mini-open ALIF procedures, LALIF produced similar outcomes; however, LALIF had longer operative times, higher technical demands, and a potentially higher rate of complications. The researchers indicated that based on the evidence identified in the review, LALIF is now rarely used. Evidence specific to R-ALIF, although limited, revealed potential reductions in complications, such as nerve injury and retrograde ejaculation, as well as shorter recovery times, but additional training requirements, logistical challenges due to the large robotic operating systems, and higher cost present potential barriers. Although these data are encouraging, several limitations were noted. These include the high volume of retrospective studies in the analysis, exclusion of studies that were not published in English, and significant level of heterogeneity among the studies reviewed, limiting data interpretation. In addition, only six studies that focused on R-ALIF were identified for the review, most of which had been published in the past 2 years. Lastly, because of the limitations noted above, no quantitative analysis of the publications was carried out. Further high-quality clinical studies that substantiate the utility of R-ALIF in spinal surgery are required before this technology can be incorporated into standard models of care.

Minimally Invasive Lumbar Decompression

Available studies have limitations that include noncontrolled trials, case series, nonblinded studies, and a small number of individuals. Well-designed studies that include a larger number of individuals at multicenters, use of clear participant selection criteria, measures of outcomes using standardized tools, comparison with conservative management, comparison with and without an anesthetic agent, and longer-term outcomes are needed to validate the use, safety, and effectiveness of this technology.

Zhang et al. (2025) conducted a systematic review and meta-analysis to evaluate the efficacy of the Minimally Invasive Lumbar Decompression (MILD®) procedure for the treatment of lumbar spinal stenosis due to a hypertrophied ligamentum flavum. Pain relief, measured via the VAS or ODI, was the primary outcome of this analysis; scores were measured at baseline, less than 6 months post treatment, 6 months or less post treatment, less than 1 year post treatment, and greater than 1 year post treatment. Postoperative complications were assessed as a secondary outcome. Information from 500 individuals, enrolled in 12 clinical trials, was examined. The analysis revealed a significant decrease in mean pain score after MILD® treatment compared with baseline ($p < 0.01$). In addition, the rate of adverse events was low (8.2%) compared with those of other surgical decompression techniques. The authors concluded that based on these findings, MILD® appears to be a safe and effective surgical technique for individuals with stenosis that is secondary to a hypertrophied ligamentum flavum. However, the review has several notable limitations. The clinical trials that were evaluated in this study (some of which were retrospective) did not have consistent exclusion and inclusion criteria. Heterogeneity across the included trials was high, and publication bias was likely. While all clinical trials that were included in the analysis incorporated conservative treatments prior to MILD®, neither treatment modalities nor duration of treatment were standardized. VAS and ODI scores were used; these are subjective and may have introduced bias. Additional large, well-designed, prospective studies are needed to confirm the findings of this review and analysis. (Publications by Mekhail et al., 2021, and Chopko et al., 2013, which were previously cited in this policy, are included in this systematic review.)

ECRI (2021a) performed a literature review of the Vertos mild® Device Kit. Evidence from studies synthesized in systematic reviews showed that the mild® procedure is safe and relieves lumbar spinal stenosis symptoms at up to 1 year of follow-up. Evidence from additional studies suggests that the mild® procedure may be as effective as but safer than laminectomy (three nonrandomized studies) and may be more effective than epidural steroid injections (ESIs; one RCT), 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 that of other decompression procedures. Large multicenter studies that assess the mild® procedure's long-term effectiveness (i.e., 5 years or longer) are also needed.

Merkow et al. (2020) published the results of a systematic review that evaluated outcomes with both MILD® and Superion (intraspinous process device), separately, as treatments for 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 the treatment of lumbar spinal stenosis, based primarily on the study by Staats et al. (2018), which showed 2-year outcomes. (This study is included in the 2025 Hayes Health Technology Assessment discussed below.)

Aldahshory et al. (2020) evaluated and compared the clinical outcomes with 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 in 50 participants with degenerative LCS. The study compared two cohorts; in group A, 25 participants underwent classic lumbar laminectomy with posterolateral transpedicular fixation, and in group B, 25 participants underwent MILD. There were no statistically significant differences between both treatment modalities in the VAS for leg pain and back pain, Patient Satisfaction Index, and ODI 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 include a 1-year follow-up, which is not sufficient to assess the reoperation rate in case of adding fusion. Other limitations include a small sample size and lack of information about the body mass index of each participant and the associated comorbidities.

In 2019, Deer et al. published consensus guidelines for minimally invasive spine treatment for lumbar spinal stenosis. The U.S. Preventive Services Task Force criteria for evidence level and degree of recommendation were used, along with strength of consensus for development of the guidelines. In this guideline regarding percutaneous image-guided lumbar decompression (PILD), the authors concluded that the available evidence is level 1 and is supportive of PILD. In addition to retrospective and prospective studies that were reviewed by the consensus group, there were two comparative prospective trials that led to reimbursement approval by the Centers for Medicare and Medicaid Services, both being noted as level 1 (Brown, 2012; Staats et al., 2018, detailed below); both compared PILD with lumbar ESIs and not with open decompression. The recommendation by the authors is grade A (good evidence that the measure is effective and that benefits outweigh harms), level 1 (at least one controlled and randomized trial, properly designed), and a strong consensus (> 80% consensus).

Staats et al. (2018, included in the 2021a ECRI literature review and the 2025 Hayes Health Technology Assessment discussed elsewhere in this policy) reported the results of a prospective multicenter RCT. This study evaluated the long-term durability of the MILD procedure in terms of functional improvement and pain reduction in participants with lumbar

spinal stenosis and neurogenic claudication due to a hypertrophic ligamentum flavum. Follow-up occurred at 6 months and 1 year for the randomized phase and at 2 years for MILD participants only. The ODI, 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 the 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 individuals with central spinal stenosis, neurogenic claudication symptoms, and a hypertrophic ligamentum flavum. Despite the above findings, the study has limitations, including the lack of a control group at the 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 participant group only. This study did not compare efficacy directly with open surgical approaches, including lumbar decompression, fusion, and spacers.

Brown (2012) reported the results of a double-blinded, randomized, prospective study of ESIs and the mild® procedure at a single pain management center. A total of 38 participants with symptomatic lumbar spinal stenosis participated in the study and were randomized into two treatment groups: 21 participants in the mild® arm and 17 participants in the ESI arm. Outcome measures were reported using the VAS, ODI, and Zurich Claudication Questionnaire 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 of follow-up. Using the ODI, at 6 weeks of follow-up, participants in the mild® group had 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 of 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 the participants in the ESI group had the mild® procedure. A total of 14 of the 17 participants in the crossover 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. (This study is included in the Hayes 2025 Health Technology Assessment and the systematic review by Zhang et al., 2025, discussed above.)

Clinical Practice Guidelines

International Society for the Advancement of Spine Surgery (ISASS)

In 2016, the ISASS published recommendations for decompression with interlaminar stabilization. The 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 are described in the article. The document did not address interspinous and interlaminar distraction devices without decompression (Guyer et al., 2016).

North American Spine Society (NASS)

The 2011 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.

Percutaneous Image-Guided Lumbar Decompression

This evidence review addresses posterior decompression of lumbar spinal stenosis with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided MILD 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 two groups, suggesting a high risk of bias. The available evidence is insufficient to determine the efficacy of MILD compared with that of placebo or to determine the efficacy of image-guided MILD compared with that of 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.

A Hayes Health Technology Assessment (2025) evaluated the effectiveness and safety of the PILD procedure in adults (≥ 18 years old) with posterior lumbar spinal stenosis. The evidence in the assessment included 11 relevant studies and focused on individuals with lumbar spinal stenosis that was primarily due to hypertrophy of the ligamentum flavum. PILD was performed via the mild® procedure using a proprietary surgical kit (mild®; Vertos Medical, Inc.) in most of the published literature. Overall, Hayes determined that the body of evidence was low quality, and while statistically and clinically significant improvements in symptoms of pain, disability, and function that lasted for up to 1 to 2 years were observed, substantial uncertainty remains regarding long-term durability of benefit and effectiveness compared with other minimally invasive procedures.

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

Brouwer et al. (2015, included in the Hayes report above) conducted an RCT with a noninferiority study design (n = 115) to evaluate percutaneous laser disc decompression compared with conventional surgery for the treatment of low back pain. The noninferiority analysis showed that percutaneous laser disc decompression resulted in noninferior outcomes compared with conventional surgery; however, the number of reoperations that were required was significantly higher in the percutaneous laser disc decompression group (38%) than the conventional surgery group (16%).

At the 2-year follow-up, Brouwer et al. (2017) demonstrated that although the rate of reoperation in the percutaneous laser disc decompression group was higher than expected, surgery could be avoided in 48% of those participants who were original candidates for surgery. The authors concluded that the results justify the need for additional studies into the value of percutaneous laser disc decompression as an alternative to conservative treatment.

In a retrospective observational study, Klessinger (2018) reported on the resurgery frequency in 73 patients who received percutaneous lumbar disc decompression (PLDD) using the Dekompressor. Patient data were drawn from an electronic medical record system for patients who were 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 lumbar spine surgery in their history were excluded. All patients were seen in the practice 1 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 1 month after the intervention, excellent results were achieved in 17 patients, and good results were achieved 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% vs 75.0% satisfied patients). Radicular pain was present in all patients with early subsequent surgery but was present in only 50% of patients with late surgery. The mean time between PLDD and the additional surgery was 10.8 ±17.9 months. The author concluded that despite an initial success rate of 67%, the resurgery rate of 26% offsets that, suggesting that PLDD is not a replacement for open discectomy. Further studies are needed to compare the outcome with and rate of subsequent surgery in populations of individuals with or without radicular symptoms to find the ideal indications for PLDD.

In a prospective cohort study, McCormick et al. (2016) determined long-term outcomes with Dekompressor PLDD for discogenic radicular pain. Consecutive participants (n = 70) with discogenic lumbosacral radicular pain who underwent PLDD with Dekompressor were included in the study. The Numeric Rating Scale leg pain score and ODI score data were collected at 6 months and 1 year. These two measures, 5-point Likert scale participant satisfaction, and surgical rate data were also collected at 8 years when possible. Overall, 40 and 25 participants were successfully contacted at the 1-year and 8-year follow-ups, respectively. At 1 year and 8 years, Numeric Rating Scale leg pain scores were reduced greater than 50% in 47% and 29% of participants, respectively; ODI score improved greater than 30% in 43% and 26% of participants, respectively. Of the participants who were followed up at 8 years, 36% had undergone surgery, and the median satisfaction was 4 (IQR, 2-5). 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 the 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 the lack of a 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 with those of open discectomy for the treatment of symptomatic lumbar disc herniation. 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 individuals, were identified. Compared with open discectomy, endoscopic discectomy resulted in slightly better clinical outcomes, which were evaluated by the Macnab criteria, without clinical significance (endoscopic discectomy group: 95.76%; open discectomy group: 80%; p = 0.10), a significantly greater individual satisfaction rate (endoscopic discectomy group: 93.21%; open discectomy 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, endoscopic discectomy 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 that include sufficiently large sample sizes are needed.

Manchikanti et al. (2013b) conducted a systematic review in individuals with radicular pain to determine the effectiveness of mechanical lumbar disc decompression with nucleoplasty. Fifteen studies met the inclusion criteria, but only one was an RCT; therefore, no meta-analysis could be performed. A total of 2,429 individuals were evaluated, with at least 50 individuals in each study and a follow-up period of 1 year. Individuals had an average improvement of 62% in pain relief. In this limited-to-fair evidence, the authors concluded that nucleoplasty may provide relief in individuals with disc herniation. Limitations include the lack of RCTs, patient loss, publication bias, and large number of placebo-control groups in which a local anesthetic injection was performed, thus mimicking a facet joint injection.

Percutaneous Endoscopic Lumbar Discectomy

The primary beneficial outcomes of interest for the treatment of spinal pain are relief of pain and improved function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, large, blinded RCTs, with long-term follow-up, are necessary to establish the safety and efficacy of percutaneous endoscopic discectomy compared with those of open surgical discectomy, which is the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of percutaneous endoscopic discectomy outweigh any risks and provide a significant advantage over conventional open discectomy techniques.

Xu et al. (2020) conducted a meta-analysis on the efficacy of PELD vs that of MED; the authors specifically focused on the mid- and long-term outcomes. A total of 487 studies were identified, with only nine articles meeting the inclusion criteria and high-quality standards. Only one of these was an RCT; the others were observational studies. In the results analysis, both PELD and MED obtained satisfactory mid- and long-term clinical efficacy; however, the PELD group obtained better outcomes in scores for low back pain after 2 years post operation compared with the MED group. The authors concluded that the PELD individuals had overwhelming superiority in the length of incision, postoperative time in bed, and hospital length of stay, which supported PELD as less invasive and resulting in faster rehabilitation. Further well-defined, large, randomized trials are needed to validate and increase the strength of these findings. Limitations include the lack of randomization in most included studies; lack of detailed surgical methods for several studies, thus limiting an additional subgroup analysis; and high heterogeneity.

The results of a recent meta-analysis that investigated the effect of PELD compared with that of other surgeries for the treatment of lumbar disc herniation support that similar complications occurred with PELD; however, it was also associated with a significantly higher rate of recurrent disc herniation (Bai et al., 2021). The authors' analysis included 14 studies, involving 2,528 individuals (10 cohorts, four RCTs); the other surgeries for comparison included open lumbar microdiscectomy, MED, minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF), and PELD. Success rates in the PELD and other surgical intervention groups were 90.1% and 88.0%, respectively, and recurrence rates in the PELD and other surgical intervention groups were 7.57% and 4.38%. The authors acknowledged that additional large-scale, well-performed, randomized trials are needed to verify their findings.

An ECRI report for the Vertebris System for Interlaminar Endoscopic Lumbar Discectomy indicated that the interlaminar endoscopic lumbar discectomy with the Vertebris System reduces pain and improves functional status in individuals with lumbar disc herniation, based on evidence from three nonrandomized comparison studies and four before-and-after studies; however, the studies are at too high of a risk of bias to be conclusive about how well the system works and how it compares with other lumbar discectomy approaches (ECRI, 2021b).

In a Health Technology Brief document published by Hayes, eight studies were reviewed that evaluated the safety and efficacy of PELD as a treatment of primary lumbar disc herniation. Hayes concluded that although the body of evidence was low quality overall, the evidence consistently suggests that PELD performs similarly to other surgical alternatives for decompression when there is failure of conservative management. However, Hayes acknowledged that "substantial uncertainty exists due to the overall quality of the body of evidence and additional studies are needed to evaluate comparative effectiveness and determine patient selection criteria when employed for primary disc herniation." In a second Health Technology Brief document, Hayes evaluated PELD as a treatment for recurrent lumbar disc herniation. A total of six studies were included in the review. According to the report, a low-quality body of evidence suggests that PELD may be inferior to comparison treatments for decreasing back pain and that PELD may have higher recurrence rates than comparison treatments (Hayes, 2019c).

Alvi et al. (2018) conducted a meta-analysis that included 14 RCTs or quasirandomized trials and compared open discectomy with microdiscectomy vs minimally invasive procedures, including percutaneous discectomy, percutaneous endoscopic discectomy, and tubular discectomy for lumbar disc herniation. All the studies were determined to have a serious risk of bias and were judged to be of low or very low quality. No differences were seen between groups for VAS score. Open procedures were also associated with longer hospital stays and greater blood loss.

Ruan et al. (2016) conducted a systematic review and meta-analysis to compare PELD and open lumbar microdiscectomy for the treatment of lumbar disc herniation. A total of seven studies (1,389 individuals) were included (two RCTs and five observational studies). The authors concluded that existing evidence indicates that no superiority exists between the two surgical approaches for the treatment of lumbar disc herniation in terms of functional outcome, complication rate, and reoperation rate, despite the PELD surgical group achieving shorter operation time and hospital stay than the open lumbar microdiscectomy surgical group. This review is limited by a low number of RCTs and unknown follow-up periods.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

In 2013, a task force of the ASIPP published updated guidelines for interventional techniques in the management of chronic spinal pain. The evidence for percutaneous lumbar discectomy was rated as limited for short- and long-term relief based on all observational studies. An evidence rating of "limited" is defined as evidence that is insufficient to assess the effects on health outcomes because of a limited number or inadequate power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or execution, gaps in the chain of evidence, or lack of information on important health outcomes. The ASIPP concluded that this technique may be performed when indicated but did not provide patient selection criteria. The recommendation was not graded; the authors indicated that this recommendation was only based on "individual experience and the large amount of literature." Therefore, this recommendation is not considered evidence based.

North American Spine Society (NASS)

The 2012 practice guidelines from NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommend that endoscopic percutaneous discectomy or automated percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (poor-quality evidence). However, a separate recommendation stated that evidence is insufficient to recommend for or against the use of automated percutaneous discectomy compared with open discectomy.

Percutaneous Sacroplasty

There is insufficient and low-quality evidence demonstrating the safety and clinical efficacy of percutaneous sacral augmentation or percutaneous sacroplasty for sacral insufficiency fractures from causes other than osteoporosis or malignancy. Further research is necessary to establish the value of this procedure, with recommended larger RCTs that are geared to establish the safety and long-term effectiveness of this procedure for unilateral or bilateral sacral insufficiency fractures.

A 2023 (updated November 2024) Hayes evolving Evidence Report for percutaneous sacroplasty for the treatment of sacral insufficiency fractures (SIFs) due to causes other than malignancy indicates that there is minimal support for using percutaneous sacroplasty for the treatment of SIFs. In addition, based on a review of full-text clinical practice guidelines and position statements, guidance appears to confer no/unclear support for sacroplasty for the treatment of SIFs. In the report, Hayes concluded that the overall body of evidence is poor, and additional research is needed to establish the value and role of sacroplasty for the treatment of SIFs.

Andresen et al. (2022) conducted a retrospective study to compare the outcomes of conservative, interventional, and surgical treatment of fragility fractures of the sacrum (FFS). The study spanned 2 years and contained 292 patients who had confirmed FFS. The individual treatment concepts were determined by using fracture morphology, pain, concomitant diseases, and the will of the patient. Patients who had a pain level of ≤ 5 benefited from the conventional treatment measures; patients with pain levels of > 5 notably delayed the development of mobility. Post sacroplasty, patients' pain levels were found to be reduced significantly, which produced a swift improvement in mobility without any noteworthy difference between vertebro-, balloon, radiofrequency, and cement sacroplasty. The study also found that the patients who benefited from osteosynthesis took longer in pain reduction and mobilization due to compound fracture types with lumbopelvic stabilization. Mortality rates were at 21.7% after 12 months in patients who underwent conservative treatment, while the rate in those who sought interventional treatment was 8.4%; patients who underwent surgical therapy were found to be at 13.6%. The mortality rate increased to 24.3% in the group of patients who underwent conservative therapy and were problematic to mobilize due to pain. Over the course of 2 years, patients attained the greatest independence after sacroplasty. Patients who chose sacroplasty followed by osteosynthesis and conservative treatment achieved subjective satisfaction during 12 and 24 months. Vitamin D deficiency was noted in all patients. The authors concluded that patients with FFS and low pain levels could be treated conservatively, whereas patients with interminable, immobilizing pain had a notable increase in complications and mortality. In patients with nondislocated fractures and an unacceptable level of pain, sacroplasty was significantly beneficial. Surgically treated patients with sacroplasty or osteosynthesis benefited in independence and lower mortality. The treatment of different fracture types and bias due to

the selection of the type of treatment (surgical vs interventional) are limitations, in addition to the retrospective study design.

Chandra et al. (2019) conducted a systematic review and meta-analysis that evaluated the safety and effectiveness of sacroplasty for the treatment of osteoporotic and malignant sacral fractures. Overall, 19 studies (n = 861) met the inclusion criteria and were used in this analysis. The main outcome measures that were extracted included technical success rate, clinical success rate, complication rate, and pain score, as measured by the VAS. The study identified that 98.9% of individuals achieved technical success with sacroplasty and clinical success of 95.7%. The primary complication was cement leakage at 0.3%, which required surgical decompression. The VAS pain level prior to the procedure and at 24 to 48 hours, 6 months, and 12 months was demonstrated by cumulative pain scores of 8.32 ±0.01, 3.55 ±0.01, 1.48 ±0.01, and 0.923 ±0.01, respectively. The authors concluded that sacroplasty appears safe and effective for pain relief in individuals with osteoporotic or malignant sacral fractures, with statistically significant, sustained improvement in VAS pain scores up to 12 months. Limitations of this study are those intrinsic to systematic reviews. Techniques, selection of individuals, and follow-up were not standardized across the studies. In addition, the bulk of studies that were involved in this meta-analysis were retrospective and prospective case series, and there were no RCTs that met the inclusion criteria. Additionally, other metrics of clinical benefit were not analyzed, including individuals' mobility after the procedure, individuals' satisfaction, and individuals' use of narcotics. To summarize, the meta-analysis supported that sacroplasty seems safe and effective for the treatment of osteoporotic or malignant sacral fractures, with statistically considerable experienced improvement in VAS pain scores up to 12 months. The results of the study may be used as an incentive for upcoming RCTs that compare sacroplasty with conservative management or sham procedures. (Frey et al., 2017, which was previously cited in this policy, is included in this systematic review.)

Transforaminal Lumbar Interbody Fusion

Evidence in the peer-reviewed scientific literature that evaluates percutaneous endoscopic fusion is limited to case series that involve small sample populations. Published trials that compare this approach with open conventional approaches are lacking, and strong conclusions regarding safety and efficacy cannot be made. Further studies are needed to establish the safety and efficacy of this approach to lumbar fusion.

In a 2025 systematic review and meta-analysis, Hu et al. summarized the existing literature and performed a comparative assessment of the clinical effectiveness, complications, and fusion rates of two surgical techniques: biportal endoscopic lumbar interbody fusion (BE-LIF) and MIS-TLIF. In total, ten studies, including 736 individuals, were included in the analysis. While certain clinical outcomes were similar (leg pain VAS scores, complication rates, and fusion rates), BE-LIF was found to have better early postoperative back pain VAS scores, faster recovery after surgery, less intraoperative blood loss, and shorter duration of postoperative hospitalization than MIS-TLIF. Although this investigation suggested that BE-LIF presents apparent benefits compared with MIS-TLIF, significant limitations are noteworthy: (1) only retrospective studies were included; (2) studies were restricted to specific ethnic populations; (3) sample sizes were small, and duration of follow-up was limited; and (4) bias in the measurement of some study parameters was likely. The authors recommended the pursuit of large, well-designed, prospective trials to validate the findings of this review and analysis.

A 2025 ECRI Clinical Evidence Assessment on dualPortal (Amplify Surgical, Inc.) for lumbar fusions was conducted. dualPortal is a biportal endoscopic surgery method that includes various instruments that are planned to assist surgeons in completing a multitude of spinal procedures, including posterior lumbar interbody fusion (PLIF), lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion (TLIF). It was concluded that the available evidence is insufficient to determine the efficacy of dualPortal compared with other lumbar spinal fusion methods for reducing pain and enhancing physical function and quality of life. The analysis included one systematic review, one nonrandomized comparison study, and a case series. The nonrandomized comparison study concluded that there is no change in back or leg pain and functional status between dualPortal and microscopic, minimally invasive TLIF; however, this study offers very low-quality evidence and does not permit conclusions. A systematic review and case series reported advancements with dualPortal; however, these studies lack comparative data and findings that cannot be interpreted due to the lack of a control group.

Yang et al. (2022) conducted an RCT to evaluate the effectiveness, safety, and usability of a novel MIS bone graft delivery device. Overall, 73 consecutive participants with lumbar spondylosis, degenerative disc disease, spondylolisthesis, scoliosis, or trauma were enrolled in this RCT. Group 1 comprised 39 participants who were treated with the novel MIS bone graft delivery device. Group 2 consisted of 34 participants who were treated with the conventional system. The primary objective of the study was the assessment of the amount of bone graft delivery using the device. The secondary objectives were the effect of the device on operative time, pain relief, disability improvement, and bone fusion grade. The bone delivery amount was higher in the MIS device group (6.7 ±2.9 mL) than the conventional group (2.3 ±0.5 mL) ($p < 0.001$). Regarding the operation time, the MIS device group was associated lower duration compared with the conventional group ($p < 0.001$). After a 3-month follow-up, 39.5% of the participants in the MIS device group and 3.5% of the participants in the conventional group were observed to achieve grade I fusion (complete fusion). There was a notable

difference in fusion success rates ($p < 0.01$). The authors concluded that the novel MIS bone graft delivery device was associated with successful bone delivery and stated that the MIS device provides a promising modality, with less operative time and higher bone fusion rates than conventional modalities. Long-term evaluations of the results and prospective randomized studies are still needed.

Song et al. (2022) conducted a meta-analysis to compare the safety and clinical effectiveness of percutaneous endoscopic transforaminal lumbar interbody fusion (PE-TLIF) and MIS-TLIF in treating lumbar degenerative disease. Based on inclusion criteria, the authors selected eight studies for meta-analysis. A total of 229 individuals underwent PE-TLIF, and 258 underwent MIS-TLIF. MIS-TLIF and PE-TLIF have similar effectiveness in relieving leg pain and improving the ODI. However, PE-TLIF is superior in relieving back pain. The pooled data of fusion, postoperative analgesic, and complication rates were comparable between the two groups. The pooled operation and intraoperative fluoroscopic times were both higher in the PE-TLIF group than the MIS-TLIF group. The pooled intraoperative blood loss, incision length, duration from surgery to ambulation, and hospital stay were significantly lower in the PE-TLIF group than the MIS-TLIF group. Most of the end points revealed significant heterogeneity. The end points of operation time and intraoperative blood loss revealed significant publication bias. Both PE-TLIF and MIS-TLIF are safe and effective interventions for individuals with lumbar degenerative disease. The authors concluded that when compared, although MIS-TLIF results in reduced operative time, less intraoperative blood loss and enhanced postoperative recovery can be achieved by PE-TLIF. The findings of this study need to be validated by well-designed studies. Further investigation is needed before the clinical usefulness of this procedure is proven.

Luan et al. (2022) conducted a single-center retrospective study to analyze the clinical efficacy of TLIF in the treatment of continuous double-level lumbar spondylolisthesis with sagittal imbalance. The clinical data from 36 patients with double-level spondylolisthesis who were treated with TLIF were included and divided into the L3/L4 double spondylolisthesis group and L4/L5 double spondylolisthesis group, according to the site of spondylolisthesis. The sagittal parameters in the patients were measured by standing anteroposterior and lateral x-rays of the whole spine, and the VAS for lumbar and lower limb pain, Japanese Orthopaedic Association (JOA), and ODI were recorded. The imaging parameters and clinical parameters in the patients before surgery, after surgery, and at the last follow-up were compared and statistically analyzed. A total of 36 patients were included in the study, and all had sagittal imbalance. Among them, there were 21 cases of L3 and L4 spondylolisthesis and six male and 15 female patients, with an average age of 64.7 ±9.4 years; there were 15 cases of L4 and L5 spondylolisthesis and four male and 11 female patients, with an average age of 66.5 ±8.0 years. In total, 36 patients completed the operation; the operation time was 190.28 ±6.12 minutes, and intraoperative blood loss was 345 ±11 ml. Compared with prior to the operation, there were differences in sagittal vertical axis, T1 pelvic angle, T1 spinopelvic inclination, LL, pelvic inclination, sacral inclination, pelvic incidence minus LL, slip distance, slip angle, and slip percentage between patients after surgery and at the last follow-up ($p < 0.05$). Compared with prior to the operation, VAS score, JOA score, and ODI of the waist and lower limbs were improved after the operation and at the last follow-up, and a difference was observed ($p < 0.05$). The authors concluded that TLIF can effectively relieve the symptoms in individuals with continuous double-level lumbar spondylolisthesis, restore LL and sagittal spinal sequence, and improve the quality of life of individuals. Limitations include a small sample size and lack of a control. Well-designed, comparative studies, with larger populations of individuals, are needed to further describe safety and clinical outcomes.

Giordan et al. (2021) performed a systematic review and meta-analysis to assess transforaminal endoscopic lumbar foraminotomy (TELF) outcomes in the treatment of lumbar foraminal stenosis consequent to bony stenosis or lateral disc herniation. Multiple databases were searched for studies that were published in the English language and involved individuals older than 18 years who underwent endoscopic foraminotomy. Outcomes included the rate of individuals who had excellent and good postoperative improvement, decreased leg pain, and improved ODI scores. A total of 14 studies that included 600 individuals were included in the analysis. Approximately 85% of individuals improved significantly after TELF, without significant differences among different groups and with almost negligible adverse events rates. Mean leg pain decreased an average of 5.2 points, and ODI scores improved by 41.2%. Individuals with previous spine surgery or failed back surgery syndrome had higher postoperative leg dysesthesia rates after TELF (14% vs 1%, respectively). The investigators concluded that TELF is a useful and safe method to achieve decompression in foraminal stenosis. According to the investigators, the main limitation in this analysis is the lack of individual patient data, making predictive analysis subject to confounding bias. Also, six studies were estimated to have an elevated risk of bias. The investigators indicated that (1) this systematic review and meta-analysis lacks randomized studies and that (2) the level of evidence is relatively low (mostly level III); however, this is the best that is currently available from the literature.

In a systematic review and meta-analysis, Kou et al. (2021) compared the clinical efficacy and safety of endoscopic lumbar interbody fusion (Endo-LIF) and MIS-TLIF in the treatment of lumbar degenerative diseases. A literature search was performed using multiple databases. Studies published up to November 15, 2020, that compared Endo-LIF with MIS-TLIF for treating lumbar degenerative diseases were retrieved. Data were extracted according to predefined clinical outcome measures. The primary outcomes were preoperative and postoperative VAS for leg and back pain and ODI

scores. The secondary outcomes were operative time and intraoperative blood loss; length of hospitalization; and complication, reoperation, and fusion rates. A data analysis was conducted with statistical software. The meta-analysis included six studies, comprising 480 individuals. Results of the merged analysis revealed similar complication, reoperation, and fusion rates and preoperative and postoperative VAS for leg and back pain and ODI scores for Endo-LIF and MIS-TLIF. Nevertheless, except for longer operative time, Endo-LIF compared favorably with MIS-TLIF, with less intraoperative blood loss, shorter hospital stay, and better long-term functional outcomes. Based on the evidence that was provided by this study, the investigators concluded that there is no significant difference in clinical efficacy and safety between Endo-LIF and MIS-TLIF in the treatment of lumbar degenerative diseases. Although Endo-LIF has a longer operative time, it has the advantages of less tissue trauma and rapid recovery after operation. This systematic review and meta-analysis has some limitations. First, it included six articles, and several of these articles had methodological defects. Therefore, the validity of the available data may lead to unsatisfactory results. Second, the total number of individuals included is relatively small, which may have an impact on the study results due to the limited statistical capacity of the data. Third, because of the small number of current relevant studies, with most of the follow-up periods lasting approximately 12 months, a comparison of the long-term clinical outcomes with the two surgical techniques could not be obtained. Therefore, more studies, with longer follow-ups, are needed to compare the long-term clinical outcomes with Endo-LIF vs those with MIS-TLIF.

Zhu et al. (2021) conducted a systematic review and meta-analysis to compare the clinical outcomes and complications with PE-TLIF and MIS-TLIF in treating degenerative lumbar disease. A comprehensive search of multiple databases was performed to identify related studies that reported the outcomes and complications with PE-TLIF and MIS-TLIF for degenerative lumbar disease. The clinical outcomes were assessed by the VAS and ODI. In addition, operative time, intraoperative blood loss, time to ambulation, length of hospital stay, fusion rate, and surgery-related complications were summarized. Forest plots were constructed to investigate the results. A total of 28 studies, involving 1,475 individuals, were included in this meta-analysis. PE-TLIF significantly reduced operative time, intraoperative blood loss, time to ambulation, and length of hospital stay compared with MIS-TLIF. Moreover, PE-TLIF was superior to MIS-TLIF in the early postoperative relief of back pain. However, there were no significant differences in medium- to long-term clinical outcomes, fusion rate, and incidence of complications between PE-TLIF and MIS-TLIF. The investigators concluded that medium- to long-term clinical outcomes and complication rates with PE-TLIF were similar to those with MIS-TLIF for the treatment of degenerative lumbar disease. However, PE-TLIF has advantages, including less surgical trauma, faster recovery, and early postoperative relief of back pain. This systematic review and meta-analysis has some limitations. First, there is a high degree of statistical heterogeneity among the included studies. Another limitation is that most of the included studies are nonrandomized controlled trials. RCTs are needed to confirm the results of this analysis.

Zhao et al. (2021) compared the clinical efficacy of percutaneous full-endoscopic transforaminal lumbar interbody fusion (Endo-TLIF) with percutaneous pedicle screws performed using a visualization system with that of MIS-TLIF for the treatment of degenerative lumbar spinal stenosis. From June 2017 to May 2018, data from 78 patients who met the selection criteria were retrospectively reviewed and were divided into the Endo-TLIF group (40 cases) and the MIS-TLIF group (38 cases) according to the surgical method used. The VAS and JOA scale were administered prior to the operation and at the 1-week, 3-month, and 1- to 2-year follow-ups. The fusion rate and major complications, including revision, were also recorded. All the patients were followed up for 24 to 34 months, with an average follow-up of 30.7 months. The intraoperative blood loss and length of hospital stay in the Endo-TLIF group were statistically significantly lower than those in the MIS-TLIF group. The VAS and JOA scores in the patients in the two groups at postoperative 1 week, 3 months, 1 year, and 2 years were statistically significantly improved from the preoperative scores. The VAS and JOA scores in the Endo-TLIF group were statistically significantly better than those in the MIS-TLIF group at 3 months and 1 year after surgery. There were no statistically significant differences in the scores between the two groups at any of the other time points. There was no significant difference in the intervertebral altitude between the two groups at the 3-month and final follow-ups. Dural tears, cerebrospinal fluid leakage, infection, and neurological injury did not occur. Both groups had good intervertebral fusion at the last follow-up. The intervertebral fusion rate was 97.5% in the Endo-TLIF group and 94.7% in the MIS-TLIF group, with no statistically significant difference between the two groups. The authors concluded that Endo-TLIF with percutaneous pedicle screws performed using a visualization system for lumbar degenerative disease may be regarded as an efficient alternative surgery for degenerative lumbar spinal stenosis. It is a safe and minimally invasive way to perform this surgery and has shown satisfactory clinical outcomes. This is a retrospective study with a small sample size. Long-term follow-up and multicenter RCTs are needed to verify the results of this study.

Chang et al. (2021) conducted a systematic review and meta-analysis to compare oblique lumbar interbody fusion (OLIF) with TLIF as an interbody fusion technique in lumbar fusion surgery for individuals with degenerative spondylolisthesis. Among the 3,022 articles, three studies were identified and met the inclusion criteria. In terms of radiological outcome, the amount of disc height restoration was greater in the OLIF group than in the TLIF group, but there was no difference between the two surgical techniques ($p = 0.18$). For clinical outcomes, the pain improvement was not different between the two surgical techniques. In terms of surgical outcomes, OLIF resulted in a shorter length of hospital stay and less

blood loss than TLIF ($p < 0.0001$ and $p = 0.02$, respectively). This meta-analysis indicated no difference in clinical and radiological outcomes and surgical time between TLIF and OLIF for degenerative spondylolisthesis, but the length of hospital stay and blood loss were better with OLIF than TLIF. Although encouraging, these findings were based on low-quality evidence from a small number of retrospective studies that were prone to bias. The findings of this study need to be validated by well-designed studies. Further investigation is needed before the clinical usefulness of this procedure is proven.

Kang et al. (2021) conducted a retrospective comparison study of BE-LIF. The clinical and radiological outcomes with biportal endoscopic TLIF were analyzed. There are three biportal endoscopic TLIF techniques. In the available literature, the postoperative 1-year outcomes with biportal endoscopic TLIF were comparable to those with PLIF and MIS-TLIF. Clinical parameters were improved after biportal endoscopic TLIF. Compared with PLIF or MIS-TLIF, biportal endoscopic TLIF may have the advantage of a faster recovery. Biportal endoscopic TLIF showed no inferiority in fusion rates compared with PLIF or MIS-TLIF. The postoperative complications were usually minor. The authors concluded that the postoperative 1-year clinical and radiological outcomes with biportal endoscopic TLIF were favorable compared with those with PLIF and MIS-TLIF. However, long-term outcomes need to be investigated through prospective RCTs in the future.

ECRI (2019) conducted a clinical evidence review of the Transforaminal Endoscopic Spine System. They concluded that low-quality studies at a high risk of bias and RCTs provided mixed evidence on efficacy and compared different procedures at different time points, which prevents drawing efficacy conclusions for percutaneous transforaminal endoscopic discectomy with the Transforaminal Endoscopic Spine System and determining how it compares with other MISs for lumbar repair. The nonrandomized comparisons are at a high risk of bias due to the lack of randomization, retrospective design, and/or single-center focus; the case series and cohort study are at a high risk of bias due to the lack of randomization, small size, and single-center focus. Studies primarily measured efficacy using subjective measures of pain relief and disability.

Lan et al. (2018) compared the efficacy and safety in the management of lumbar diseases, which was performed by either PLIF or TLIF. Overall, 16 studies, involving 1,502 individuals, were included in the meta-analysis. The authors found that while TLIF was superior to PLIF, both achieved similar outcomes. While interbody fusion is considered the gold standard, both PLIF and TLIF have been promoted as promising techniques; however, the authors indicated that these techniques remain controversial. Limitations of the study include the need for additional, well-designed RCTs, with long-term outcomes and larger sample sizes.

A retrospective study by Price et al. (2018) compared the clinical results of and radiographic outcomes with MIS vs open techniques for TLIF. A consecutive series of 452 one- or two-level TLIF patients at a single institution between 2002 and 2008 was analyzed. A total of 148 were MIS patients, and 304 were open. ODI and VAS pain scores were documented prior to and post operation. Fusion was at a minimum of 1 year of follow-up. The authors concluded that MIS-TLIF produces comparable clinical and radiological outcomes to open TLIF, with the benefits of decreased intraoperative blood loss, shorter operative times, shorter hospital stays, and fewer deep wound infections. Results are limited by the study design and lack of a control. Further prospective studies that investigate long-term functional results are required to assess the definitive merits of percutaneous instrumentation of the lumbar spine.

Clinical Practice Guidelines

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

The AANS/CNS published a guideline update in 2014 on the performance of fusion procedures for degenerative disease of the lumbar spine, with part of the guideline update focused on interbody techniques for lumbar fusion. This guideline did not offer any specific recommendations that pertained to TLIF in general or MIS-TLIF specifically. The authors indicated that there was no conclusive evidence of superior clinical or radiographic outcomes based on technique when performing interbody fusion. Therefore, no general recommendations were offered regarding the technique that should be used to achieve interbody fusion. The authors also noted that they did not analyze any comparisons of MIS vs traditional open surgery in this report (Mummaneni et al., 2014).

North American Spine Society (NASS)

NASS published clinical guidelines on the treatment of adult isthmic spondylolisthesis (NASS, 2014a) and degenerative spondylolisthesis (NASS, 2014b). These guidelines did not offer any specific recommendations that pertained to the use of MIS-TLIF vs open TLIF procedures. However, both guidelines recommend the development of RCTs and prospective comparative studies that compare MIS vs traditional open surgical techniques in adult patients with these conditions.

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 the device name section: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed October 22, 2025)

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Policy History/Revision Information

Date	Summary of Changes

02/01/2026	**Definitions**
	• Added definition of "Transforaminal Lumbar Interbody Fusion"
	• Removed definition of:
	  ○ Interlaminar Lumbar Instrumented Fusion (ILIF)
	  ○ Nucleoplasty
	  ○ Percutaneous or Endoscopic Lumbar Fusion
	  ○ Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems
	  ○ Tubular Retractor
	• Updated definition of:
	  ○ Automated Percutaneous Lumbar Discectomy (APLD)
	  ○ Axial Lumbar Interbody Fusion (AxiaLIF)
	  ○ Endoscope
	  ○ Endoscopic Discectomy
	  ○ Fluoroscopy
	  ○ Image-Guided Minimally Invasive Lumbar Decompression (MILD®)
	  ○ Interbody Fusion
	  ○ Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)
	  ○ Open Spine Surgery
	  ○ Percutaneous Endoscopic Lumbar Discectomy (PELD)
	  ○ Percutaneous Image-Guided Lumbar Decompression (PILD)
	  ○ Posterior Lumbar Spine Surgery
	  ○ Sacroplasty
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
	• Archived previous policy version 2026T0640G

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. 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.