Discogenic Pain Treatment (for Louisiana Only)

Policy Number: CS031LA.~~L~~M
Effective Date: ~~December 1,~~TBD ~~2020~~

➲ Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

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

- ~~Annulus fibrosus repair following spinal surgery~~
- **Annular Closure Devices (ACDs)**
- ~~Percutaneous discectomy~~~~Percutaneous discectomy and decompression procedures for treating discogenic pain~~
- **Percutaneous injection of allogeneic cellular/tissue-based products**
- **Thermal intradiscal procedures (TIPs)** ~~Thermal intradiscal procedures (TIPs)~~ for treating discogenic pain

Note: For percutaneous discectomy for the treatment of axial or radicular pain see the Minimally Invasive Spine Surgery Procedures (for Louisiana Only) medical policy

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
***0627T**	**Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level**
***0628T**	**Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar;each additional level (List separately in addition to code for primary procedure)**
***0629T**	**Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level**
***0630T**	**Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar;each additional level (List separately in addition to code for primary procedure)**
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)
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~~
~~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
*****S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

Codes labeled with an asterisk (*) are not on the Louisiana Medicaid Fee Schedule and therefore may not be covered by the state of Louisiana Medicaid Program.

Description of Services

Annular Closure Devices

~~Annulus Fibrosus Repair~~

The annulus fibrosus is a ring of fibrocartilage and fibrous tissue around the intervertebral disc, surrounding the nucleus pulposus of the spine. During a surgical

discectomy or ~~some~~ other spine surgeries, an open pathway or hole (defect) is made in the annulus fibrosus, which is then left to heal. Annulus fibrosus repair **devices** ~~systems~~ are designed to reinforce or bridge material to form a strong flexible wall between the annulus and nucleus of the herniated region to close the defect and repair the annulus fibrosus of the intervertebral disc~~. Current annulus fibrosus repair strategies include sutures, plugs, adhesives and hydrogels~~ (Long et al., 2016).

~~Percutaneous Discectomy Procedures~~

~~A discectomy is a procedure in which part of a herniated disc is removed. The goal of the surgery is to make the herniated disc stop pressing on and irritating the nerves which cause pain and weakness (North American Spine Society [NASS], discectomy2018). There are a number of techniques described as "percutaneous discectomy,", including nucleoplasty, laser discectomy, Yeung Endoscopic Spinal Surgery (YESS), Transforaminal (TESSYS®) and Interlaminar (iLESSYS®) Endoscopic Surgical Systems.~~ ~~Variations on each of these techniques are numerous.~~

~~*Nucleoplasty*~~

~~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 (coablate) 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. Typically, individuals are awake during the procedure. Nucleoplasty is performed on an outpatient basis with minimal anesthesia requirements.~~

~~*Laser Discectomy*~~

~~Laser discectomy [also known as laser disc decompression (PLDD), laser-assisted disc decompression (LADD),) or percutaneous endoscopic discectomy, with or without laser (PELD)] is a minimally-invasive procedure proposed as an alternative to discectomy or microdiscectomy. This procedure is performed under local anesthesia since an individual's cooperation is required during the procedure. The disc space is punctured with a cannula and the tip of the needle is placed into the center of the disc. A second cannula is placed on the opposite lateral side of the disc. Parts of the nucleus pulposus are removed to allow for examination. The remaining disc material is vaporized using a laser.~~

~~*Yeung Endoscopic Spinal Surgery (YESS)*~~

~~Yeung Endoscopic Spinal Surgeryendoscopic spinal surgery (YESS) [also known as arthroscopic microdiscectomy (AMD) or percutaneous endoscopic discectomy (PELD)], is a minimally-invasive discectomy procedure designed to relieve symptoms caused by herniated discs pressing on nerves. The YESS system uses an endoscopic approach to selectively remove the nucleus pulposus within annular tears. This is an outpatient procedure utilizing either sedative or local anesthesia. The Yeung Endoscopic Spine System (Richard Wolf Medical Instruments Corporation, IL) is a specialized endoscope developed for percutaneous spinal endoscopy and discectomy. This endoscope has multichannel inflow and outflow ports, allowing visualization through one port and suction or other therapeutic services through the working port.~~

~~*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.~~

Thermal Intradiscal Procedures (TIPs)

In general, percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter or probe into the spinal disc, under fluoroscopic guidance, to produce or apply heat within the disc to relieve low back pain (LBP). TIPs is thought to remove unwanted tissue, such as herniated discs; create a seal to limit expression of matrix components; shrink collagen tissue; and destroy nociceptors. To date, three types of TIPs have been used: Intradiscal Electrothermal Therapy (IDET), Intradiscal Biacuplasty (IDB) or Biacuplasty, and Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT).

Intradiscal Electrothermal Therapy (IDET)

Intradiscal electrothermal therapy (IDET) is one type of TIP. Since degeneration of the intervertebral disc can be the source of severe LBP, IDET has been proposed as an alternative treatment to spinal fusion for those individuals with symptomatic internal disc disruption, who are nonresponsive to conservative medical care. IDET is a minimally invasive, outpatient procedure, during which individuals are administered local anesthesia and mild sedation. Under x-ray imaging (fluoroscopy), a disposable flexible catheter and a heating element are inserted into the spinal disc, directly to the annulus fibrosus, the outer component of the intervertebral discs. IDET destroys the nerve fibers and "toughens" the disc tissue, sealing any small tears. The heating of the electrode denatures the collagen of the annulus and coagulates the nerve endings with the goal of alleviating pain.

Intradiscal Biacuplasty (IDB) or Biacuplasty

Intradiscal biacuplasty (IDB) or biacuplasty is a modification of IDET that aims to destroy the nerve fibers that generate pain sensations. IDB is a minimally invasive outpatient procedure that requires local anesthesia or mild sedation. IDB uses radiofrequency energy to heat the tissue, while circulating water is used to cool the tissue near the disc. This bilateral approach is intended to facilitate controlled lesioning between the electrodes in the disc.

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) is a minimally invasive method similar to IDET. PIRFT is also known as intradiscal electrothermal annuloplasty (IEA), intradiscal radiofrequency thermomodulation, radiofrequency (RF) annuloplasty, or radiofrequency posterior annuloplasty. Compared with IDET, PIRFT uses a radiofrequency probe that is placed into the center of the disc, rather than around the annulus. The device is activated for 90 seconds at a temperature of 70° Celsius. PIRFT does not ablate the disc material, but instead alters the biomechanics of the disc or destroys nociceptive pain fibers.

Percutaneous Injection of Allogeneic Cellular/Tissue-Based Products

Allogeneic cellular/tissue-based products are cell therapies injected through the skin into discs of the lumbar spine to stimulate tissue repair.

Clinical Evidence

Annular Closure Devices (ACDs)

~~Annulus Fibrosus Repair~~

There is insufficient **high-quality** ~~qulaity~~ evidence to support annulus fibrosus repair **devices as an adjunct** for **discectomy. Overall quality of evidence is low and does not allow sufficient follow-up time to determine long-term outcomes** ~~treating discogenic pain~~. Further research with randomized controlled studies, larger patient sample sizes and long-term outcomes are required to demonstrate its safety and efficacy.

A 2021 Hayes Technology Assessment was conducted on 9 studies that met the inclusion criteria for implantation of an annular closure device (ACD) to close sizable defects (typically ≥ 6mm), for the prevention of recurrent lumbar disc herniation (LDH) following lumbar discectomy. All included studies recruited and treated patients who had symptomatic radiculopathy caused by LDH. In most cases, either the patients had LDH that had failed to respond to more than 6 weeks of conservative care, or they had contraindications to conservative treatment strategies (such as neurological deficits). It was concluded that overall, the quality of evidence evaluating the safety and efficacy of ACD is low quality. Only one study demonstrated good quality. Limitations of the individual studies included retrospective design, use of historical controls, small sample sizes, and insufficient follow-up time to determine the long-term outcomes. Additionally, it was noted that numerous studies involved overlapping authors and research groups, which may result in the analysis of duplicate patient data.

In a 2020 Clinical Evidence Assessment, ECRI reported the findings on the Barricaid annular closure device (Intrinsic Therapeutics, Inc.) for preventing recurrent vertebral disc herniation after lumbar discectomy versus lumbar discectomy alone for preventing disc reherniation and reoperation. Based on the results of a systematic review (SR) with meta-analysis of data from 2 randomized controlled trials (RCTs) and 2 nonrandomized comparison studies, it was determined the evidence is somewhat favorable. The studies included were conducted in Europe and South Korea and data may not be directly applicable to healthcare systems in other countries, and additional randomized controlled trials conducted in the United States would be useful in confirming these results. There are currently no registered clinical trials in the United States.

In an ongoing prospective, randomized, multicenter study of 554 patients in 21 centers in Europe), a total of 276 patients were randomized to the annual closure device (ACD) group and 278 patients to the control group (CG) to demonstrate the superiority of the Barricaid device to a discectomy for primary lumbar disc herniation (Clinicaltrial.gov NCT01283438). Three-year results (Kienzler et al., 2019, included in the 2020 ECRI and 2021 Hayes assessments) showed Barricaid was superior to discectomy alone for symptomatic reherniation, reoperation, leg pain, back pain, Oswestry Disability Index (ODI), and Physical Component Study (PCS). There were specific risks associated with ACD group such as implantation difficulties, radiographic evidence of migration, mesh detachment, and vertebral endplate changes (VEPC), however the safety profile was similar between the two groups. Nada et al. (2019, also included in the 2020 ECRI and 2021 Hayes assessments) reported the four-year results on the risk of lumbar disc reherniation and reoperation rate for lumbar discectomy in patients with large annular defects following single level lumbar discectomy. Clinical follow-up occurred at 6 weeks, 3 months, 6 months, and annually for 4 years. The results showed the risk of reoperation was 14.4% for those who received the device, and 21.1% for the controls. The reoperation rate was not significantly affected by age, sex, body mass index, smoking status, level of herniation,

leg pain or ODI scores. Additionally, the percentage of patients who achieved the minimal clinically important difference without a reoperation was proportionally higher in the ACD group compared to the control group for leg pain. The authors concluded that the addition of a bone anchored ACD reduces the risk of reoperation and provides better long-term pain and disability relief. The authors acknowledged that this trial has several limitations; only patients with large post-discectomy annular defects were included and there are additional patient characteristics that were crucial to achieving positive results and included adequate disc height and non-osteoporotic bone mineral density (BMD) of the lumbar spine. Additionally, the decision to re-operate involved shared decision-making between the patient and surgeon resulting in a potential for bias in the reported re-operation rates. In 2021, Kienzler et al. analyzed the data from this same trial to report the risk factors for early reherniation after lumbar discectomy with or without annual closure. The results showed four (1.5%) symptomatic reherniations in the ACG group and 18 (6.5%) in the control group. A significant correlation was found with recurrent herniation for disc degeneration, and a trend for current smoker status. In the control group, age ≥ 50 years and disc degeneration were predictive factors for reherniation. The authors concluded that these were predictive factors for early disc herniation after lumbar surgery and suggest that the ACD reduced the risk.

Thomé, et al. (2018**, included in both 2020 ECRI and 2021 Hayes assessments above**) reported the findings of an RCT testing whether bone-anchored annular closure device, in addition to lumbar microdiscectomy, resulted in lower reherniation and reoperation rates plus increased overall success compared with lumbar microdiscectomy alone. Participants with symptoms of lumbar disc herniation for at least 6 weeks and a large annular defect (6-10 mm width) after lumbar microdiscectomy were included in the study and randomized to bone-anchored annular closure device (n=276) or lumbar microdiscectomy only (control; n=278). Based on modified intention-to-treat analyses, participants in the annular closure device treatment arm were less likely to have recurrent herniation (50% vs. 70%, P<.001) and more likely to meet the composite end point success (27% vs. 18%, P=.02). The frequency of reoperations to address recurrent herniation was 5% with annular closure device and 13% in controls (P=.001). Scores for back pain, leg pain, Oswestry Disability Index, and health-related quality of life at regular visits were comparable between groups over 2-year follow-up. The findings are limited by lack of masking of the participants and investigators to the intervention, which could have introduced biases in the findings, and possible conflicts of interest in this industry-sponsored study.

Kuršumović et al. (2018**, included in the 2021 Hayes assessment above**) conducted a retrospective analysis of the **Thomé (2018)** RCT described above ~~(Thomé, et al., 2018)~~ to characterize the morphology and clinical relevance of vertebral endplate changes (VEPC) following limited lumbar discectomy with or without implantation of a bone-anchored annular closure device (ACD). Of 554 randomized patients, the as-treated population consisted of 550 patients (267 ACD, 283 Controls). VEPC were preoperatively identified in 18% of patients in the ACD group and in 15% of Controls. At 2 years, VEPC frequency increased to 85% with ACD and 33% in Controls. Device- or procedure-related serious AEs (8% vs. 17%, P=0.001) and secondary surgical intervention (5% vs. 13%, P < 0.001) favored the ACD group over Controls. In the ACD group, clinical outcomes were comparable in patients with and without VEPC at 2 years follow-up. In the Control group, patients with VEPC at 2 years had higher risk of symptomatic reherniation versus patients without VEPC (35% vs. 19%, P<0.01) The authors concluded that in patients with large annular defects following limited lumbar discectomy, additional implantation with a bone-anchored ACD reduces risk of postoperative complications despite a greater frequency of VEPC. VEPC were associated with higher risk of symptomatic reherniation in patients treated with

limited lumbar discectomy, but not in those who received additional ACD implantation. Additional RCTs are needed to validate these findings.

Parker et al. **(2016, included in both 2020 ECRI and 2021 Hayes assessments above** ~~(2016~~) conducted a prospective cohort study to evaluate whether an annular closure device (Barricaid®) could be implanted safely to reduce same-level recurrent disk herniation, or attenuate disk height loss and improve the outcome after lumbar discectomy. Forty-six consecutive patients undergoing lumbar discectomy for single-level herniated disk at 2 institutions were followed prospectively with clinical and radiographic evaluations at 6 weeks, and 3, 6, 12, and 24 months (control cohort). A second consecutive cohort of 30 patients undergoing 31 lumbar discectomies with implantation of an annular closure device was followed similarly. Incidence of recurrent disk herniation, disk height loss, the leg and back pain VAS, and the ODI were assessed at each follow-up. By 2 years of follow-up, symptomatic recurrent same-level disk herniation occurred in 3 (6.5%) patients in the control cohort versus 0 (0%) patients in the annular repair cohort (P=0.27). A trend of greater preservation of disk height was observed in the annular repair versus the control cohort 3 months (7.9 vs. 7.27 mm, P=0.08), 6 months (7.81 vs. 7.18 mm, P=0.09), and 12 months (7.63 vs. 6.9 mm, P=0.06) postoperatively. The annular closure cohort reported less leg pain (VAS-LP: 5 vs. 16, P<0.01), back pain (VAS-BP: 13 vs. 22, P<0.05), and disability (ODI: 16 vs. 22, P<0.05) 1 year postoperatively. The authors conclude that closure of annular defect after lumbar discectomy may help preserve the physiological disk function and prevent long-term disk height loss and associated back and leg pain. The study is limited by the lack of randomization between interventions, which could have **introduced** ~~intrpduced~~ a bias. RCTs with larger patient populations and longer-term follow-up are needed to further evaluate Barricaid.

~~A prospective, multicenter, single-blind, RCT by Bailey et al. (2013) compared outcomes associated with repairing the annulus fibrosus after lumbar discectomy for the surgical management of herniated nucleus pulposus. A total of 750 patients were treated for LDH and randomly assigned in a 2:1 ratio to discectomy with the Xclose Tissue Repair System (Anulex Technologies, Minnetonka, MN) for annular repair or discectomy without annular repair. Patient self-reported measures included VAS for leg and back pain, ODI, and SF-12 Health Survey. AEs and subsequent reherniation surgical procedures were documented. Preoperative outcome measures were compared with follow-up visits at 2 weeks, 6 months, 1 year, and 2 years. The study failed to show any group difference in patient-reported outcome, but a non-statistically signficant reduction in need for subsequent reherniation surgery with annulus repair. The authors concluded that the addition of annulus fibrosus repair did not induce a significant reduction in reoperation for recurrent herniation.~~

Ledic et al. (2015**, included in the 2020 ECRI assessment above**) reported two-year outcomes from two prospective case series of patients treated with limited diskectomy and an **annular** ~~anular~~ closure device. A total of 75 patients were included in this study consisting of 40 men and 35 women with an average age of 40 years. Disk height maintenance within the group overall was 90% at 24 months. Overall, 97% of the treated disks demonstrated disk height maintenance of at least 75% of preoperative levels at 12 months and 92% at 24 months. Disk height maintenance was correlated with less nucleus removal. Patient disability, back pain, and leg pain were significantly improved from preoperative levels at 6 weeks and maintained over the course of study. There was a single symptomatic reherniation requiring surgical intervention within this series. According to the authors, limited lumbar diskectomy combined with the use of an **annular** ~~anular~~ closure device provided very low rates of disk reherniation and exhibited excellent disk height maintenance and sustained disability, leg pain, and back pain

improvement within a 24-month postoperative study period. Study limitations include lack of comparison group and small patient population.

Percutaneous Discectomy and Disc Decompression Procedures

There is insufficient quality evidence to support the use of percutaneous discectomy and disc compression procedures for treating discogenic pain. Further research with randomized controlled studies, larger patient sample sizes and long-term outcomes are required to demonstrate their safety and efficacy.

Nucleoplasty

Klessinger (2018) conducted a retrospective case series to investigate the frequency of an additional open surgery after percutaneous cervical nucleoplasty (PCN) up to 10 years. The follow-up time was longer than 5 years in 31.6% of patients and longer than 10 years in 6.0% of patients. One hundred thirty-three patients who underwent PCN between 2005 and 2007 were included. Patient satisfaction was evaluated using McNab's outcome criteria. The necessity of an additional open surgery at the cervical spine, the period between PCN and the fusion, and the treated levels were analyzed. The results showed a short-term success rate (1 month) of 70.7%; however, subsequent surgery was performed in 19.5% of patients. Overall, 57.7 % of reoperations were performed during the first year after PCN. In patients with a good result after PCN, subsequent surgery was less frequent, and the interval between PCN and additional surgery was longer. The data from this study suggest that PCN is a poor replacement for conventional open surgery. Degeneration of the disc is progressive despite or because of PCN. Findings are limited by the lack of comparisoncomarison group.

Nie et al. (2018) reported in a retrospectiverestrospective cohort study 5-year outcomes from a comparison of therapeutic efficacy of radiofrequency target disc decompression and nucleoplasty for LDH. Two hundred sixty patients with LDH were divided into two groups: target disc decompression group (group T, Nn=147) and nucleoplasty group (group N, Nn=113). VAS and functional rating index (FRI) were measured at one, three, six, 12, 24, and 60 months after the surgery. Hospitalization time, operation time, complications, and recurrence/invalid were compared between the two groups. Compared with the pre-operation, the VAS and FRI in both groups were significantly decreased in post-operation ($P < 0.01$). There was no significant difference of the occurrence of complications and disease recurrence/invalid during the follow-up between the two groups. Logistic regression analysis showed that operation time was an independent factor in the prognosis. The authors concluded there was no significant difference between between the two methods used and that both can significantly alleviate pain and improve quality of life. The study is limited by lack of randomization and a retrospective design.

Wu et al. (2015) conducted a RCT to compare CT-guided nucleoplasty, CT-guided nucleoplasty combined with nerve root injection, and CT-guided transforaminal lumbar epidural injections in 97 patients with lumbar disk herniation and leg pain. Results of the study demonstrated that the combination of nucleoplasty with nerve root injection produced a significantly greater reduction in the pain score and disability score when compare with only nucleoplasty in the short term, at 1 week, as well at 1 month. The study limitations included lack of blinding and relatively small patient populations.

Ren et al. (2015) evaluated the efficacy of percutaneous nucleoplasty using coblation technique for the treatment of chronic nonspecific LBP, after 5 years of follow-up. Forty-one patients who underwent percutaneous nucleoplasty for chronic LBP were assessed preoperatively and at 1 week, 1 year, 3 years, and 5 years postoperatively in this case series. Pain was graded using a 10-cm VAS and the percentage reduction in pain score was

~~calculated at each postoperative visit. The ODI was used to assess disability related to lumbar spine degeneration, and patient satisfaction was assessed using the modified MacNab criteria. There were significant differences between the preoperative, 1-week postoperative, and 3-year postoperative VAS and ODI scores, but not between the 3-and 5-year postoperative scores. Excellent or good patient satisfaction was achieved in 87.9% of patients after 1 week, 72.4% after 1 year, 67.7% after 3 years, and 63.4% at the last follow-up. The authors concluded although previously published short and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, the long-term follow-up results showed a significant decline in patient satisfaction over time. This is an uncontrolled study with a small sample size.~~

~~In a retrospective review, Liliang et al. (2016) reported outcomes from a case series of 47 patients who underwent nucleoplasty for degenerative LBP using VAS scores. At 10-months, 21 patients (67.7%) experienced substantial pain relief. The most common side effects following nucleoplasty were soreness at the needle puncture site (64.5%), numbness in the lower leg (12.9%), and increased intensity of back pain (9.7%). All side effects were transient. Multivariate analysis revealed that the discography results were the most critical predictor for substantial pain relief of nucleoplasty (P=0.03). The sensitivity and specificity of discography were 92.8% and 62.5%, respectively. Limitations of this study include lack of comparison to a different intervention, non-randomization, small sample size, and short follow-up period.~~

~~KumarKuman et al. (2014) evaluated the safety and efficacy of annulannulo-nucleoplasty using Disc-FX for the treatment of lumbar disc pathology (Nn=24). All patients in this case series were non-responsive to non-operative treatment measures. A total of 12 patients had degenerative disc disease and 12 patients had contained LDH. Health outcomes included the VAS, ODI, and the SF-36 scores evaluated before and after the procedure. Study authors reported significant improvement in outcomes relative to baseline. The overall rate of re-intervention for symptoms that continued to persist was about 18%; in the group of patients with LDH, the rate was about 36%. The study was limited by lack of appropriate comparator groups, lack of randomization, and relatively limited follow-up.~~

~~Zhu et al. (2011) evaluated longer-term efficacy over a 2-year follow-up of coblation nucleoplasty treatment for protruded lumbar intervertebral disc in a case series. A total of 42 cases of protruded lumbar intervertebral disc treated by coblation nucleoplasty followed-up for 2 years were analyzed. Relief of LBP, leg pain and numbness after the operation were assessed by VAS. Function of lower limb and daily living of patients were evaluated by the ODI. The authors concluded that coblation nucleoplasty may have satisfactory clinical outcomes for treatment of protruded lumbar intervertebral disc for as long as 2-year follow up, but longer-term benefit still needs verification. The findings are limited by lack of relevant comparison group.~~

~~In a case series, Masala et al. (2007) treated 72 patients affected by lumbar disk herniation with nucleoplasty coblation. Average preprocedural pain level for all patients was 8.2, while the average pain level at 12 months follow-up was 4.1. At the 1-year evaluation, 79% of patients demonstrated a statistically significant improvement in numeric pain scores: 17% (12 patients) were completely satisfied with complete resolution of symptoms, and 62% (43 patients) obtained a good result with a decrease from 8.2 at baseline to 4.1 (4.1 points). The study is limited by lack of comparion group and subjective outcomes with only a 50% decrease in pain and no documentation of improvement in functional status.~~

~~Mirzai et al. (2007) evaluated outcomes 2 weeks, 6 months, and 1 year after nucleoplasty in a case series of 52 consecutive patients with leg pain and MRI evidence of small and medium-sized herniated discs. Thirty-four patients had one and 18 had two discs treated; a total of 70 procedures were performed. Mean VAS reduced from preprocedure 7.5 to 3.1 at post procedure 6 months and to 2.1 at the latest follow-up. Mean ODI decreased from 42.2 to 24.8 at 6 months and to 20.5 at the latest examination. Analgesic consumption was stopped or reduced in 42 patients (85%) at 6 months and in 46 patients (94%) 1 year after the procedure. Overall patient satisfaction was 81% at 2 weeks, 85% at 6 months, and 88% at the latest follow-up. The study is limited by subjective outcomes.~~

~~A prospective case series, Gerszten et al. (2006) assessed pain, functioning, and QOL in 67 patients with radicular leg and back pain who underwent nucleoplasty-based percutaneous disc decompression. Pain relief, functioning, and QOL were evaluated. Patients completed the SF-36 Health Survey, EuroQol 5D (EQ5D), and a VAS for pain preoperatively, and at 3 and 6 months after surgery. Compared with pre-operative QOL, there was a statistically significant improvement in QOL at 3 months as measured using the SF-36 Physical Component Summary (PCS) scale, the EQ5D and the VAS for pain. Six-month results in 36 patients continued to reflect improvement as measured using the SF-36 PCS and the EQ5D. The authors concluded that nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves QOL as measured by the SF-36, EQ5D, and VAS for pain, three generic QOL outcome instruments. They also concluded that nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc herniations. They noted that further follow-up evaluation is underway to determine the durability of QOL improvement after nucleoplasty. The study is however limited by lack of relevant comparison group.~~

~~Bhagia et al. (2006) reported the short-term side effects and complications after percutaneous disc decompression utilizing coblation technology (nucleoplasty) in a retrospective study on 53 patients. The authors reported statistically significant reductions in VAS scores for both back and leg pain. The procedure was associated at 24 hours with short- term increased pain at the needle insertion site (76%), new numbness or tingling (26%), increased preprocedure back pain (15%) and new areas of back pain (15%). By 2 weeks no patients had soreness at injection site or new areas of back pain, and only 2 had increased intensity of preprocedure back pain, while new numbness or tingling was present in 15% of patients. The study is limited by retrospective study design, subjective outcomes and new symptoms in 15% of study participants.~~

~~NICE (2016a) evaluated percutaneous coblation of the intervertebral disc for LBP and concluded that this procedure may be used for patients with pain caused by contained herniated discs that have not responded to conservative treatment, when open surgery is not suitable.~~

~~Professional Societies~~

~~*American Society of Interventional Pain Physicians (ASIPP)*~~

~~The ASIPP performed a systematic assessment of mechanical lumbar disc decompression with nucleoplasty. They concluded that the clinical effectiveness of nucleoplasty is limited to fair and is recommended only in select cases (Manchikanti et al., 2013b).~~

~~*North American Spine Society (NASS)*~~

~~In their clinical guideline on the diagnosis and treatment of lumber disc herniation and radiculopathy, NASS (Kreiner et al., 2014) concluded that there is insufficient evidence~~

~~to make a recommendation for or against the use of plasma disc decompression/nucleoplasty in the treatment of patients with LDH with radiculopathy.~~

~~Percutaneous Endoscopic Transforaminal Discectomy (PETD)~~

~~Tacconi et al. (2020) compared surgical invasiveness between two procedures: transforaminal full endoscopic lumbar discectomy (FELD) and open discectomy (OD). 50 patients with a single-level lumbar foraminal herniation were randomly assigned to either have a FELD or OD procedure. Pre- and postoperative leg and back pain data were collected using a visual analog scale (VAS). A satisfactory postoperative outcome was defined by a decrease in the leg pain score by ≥3 points from the preoperative leg VAS score. The VAS scores for back pain were recorded ≥6 hours after the procedure or at mobilization. Additional assessment of back pain was not performed later during follow-up period due to potential risk of back pain occurring secondarily to spinal instability or a degenerative disc. There were no intraoperative or postoperative surgical complications. For the OD group, the median VAS score for leg pain had decreased from 7 preoperatively to 2 at six months postoperatively. In the FELD group, the median VAS score for leg pain had decreased from 8 preoperatively to 2 at six months postoperatively. The authors concluded even though the VAS scores for leg pain were not significantly different between the two groups, the period for patient mobilization along with the VAS scores for back pain immediately postoperatively were significantly lower for the FELD group. Limitations included a relatively small number of participants.~~

~~In a 2019 meta-analysis, Huang et al. sought to systematically review and compare the safety and effectiveness of PETD versus percutaneous endoscopic interlaminar discectomy (PEID) for the treatment of LDH. A total of 13 studies with 974 cases consisting of 3 RCTs, 3 prospective studies and 7 retrospective studies were included. The agrate results, based on observational studies and randomized controlled~~~~controled~~ ~~trials, suggest that patients treated with PEID experienced significant advantages with shorter operation time, less intraoperative blood loss and less intraoperative fluoroscopy times but more complications than those treated with PETD; however, the two operative approaches did not significantly differ in terms of LDH recurrence, hospital stay, ODI scores, VAS scores, Japanese Orthopedic~~~~Orthopaedic~~ ~~Association (JOA) scores and MacNab criteria at the final follow-up. The authors concluded that PEID may be superior to PETD in certain ways, some of its advantages have yet to be verified and the two interventions were not significantly different in terms of relief of symptoms and functional recovery. They also concluded that PEID would be recommended for treating LDH especially at L5/S1 under certain conditions, but a prudent attitude is necessary to choose between the two operative approaches before a large sample and high quality RCTs have been performed. Limitations included lack of separation between randomized and non-randomized studies in the aggregate~~~~agregate~~ ~~estimates, which could introduce biases, clinical heterogeneity and short-term follow-up.~~

~~Mo et al. (2019) evaluated percutaneous endoscopic transforaminal diskectomy (PETD) in comparison with percutaneous endoscopic interlaminar diskectomy (PEID) for herniation at L5-S1. 80 participants were recruited and randomly assigned to two different groups - either PETD or PEID. All procedures were performed by the same physician. Even though the operation time in the PEID group was significantly shorter than the PETD group, no significant differences were noticed during the postoperative period. All patients were followed for 9-22 months, with an average follow-up of 16.59 ± 4.10 months in the PETD group and 16.71± 3.72 months in the PEID group. The Oswestry Disability Index (ODI) and visual analog scale (VAS) scores with similar with no significant differences between the two groups. The authors concluded PETD has a similar clinical effect to that of PEID. Limitations included single-center study, low number~~

~~of participants and analysis based on as treated rather than intent to treat approach. Larger sample size and tracking of long-term results are still warranted.~~

~~Yu et al. (2019) compared the clinical outcomes for percutaneous transforaminal endoscopic discectomy (PTED) and micro-endoscopic discectomy (MED) as alternative minimally invasive procedures for lumbar disc herniation. A literature search provided eight studies in the final analysis totaling 805 patients. Only one of these studies was a randomized controlled trial, while the others were observational studies. From the data extracted, visual analog scale (VAS) and Oswestry Disability Index (ODI) were considered the primary outcomes. The author's analysis concluded that PTED resulted in a shorter hospital length of stay, but MED was superior for intraoperative fluoroscopy and total cost. Significant lower back pain was found in the PTED group short term and at one year postoperatively. No differences were found regarding the pain score or ODI. The authors' meta-analysis concluded that both the PTED and MED are safe and effective in treating lumbar disc herniation. Limitations included small number of studies included for review and findings based mainly on observational studies. Furthermore, different methodologies contributed to heterogeneity in the analyses and the surgeon skill level may have introduced bias.~~

~~Chen et al (2018) conducted a systematic review and meta-analysis to compare efficacy and safety between PETD and PEID for L5-S1 LDH. Nine studies involving 621 patients met inclusion criteria. Only three of these studies were reported to be randomized controlled trials. The results indicated that PETD was significantly associated with greater fluoroscopy times (mean difference 9.28 times); and longer operative time (mean difference 16.51 minutes) compared with PEID. However, there were no distinct differences between PETD and PEID in estimated blood loss (P = 0.24), bedtime after surgery (P = 0.32), hospitalization time (P = 0.27), or MacNab evaluation (P = 0.78). Similarly, no obvious differences were detected between PETD and PEID regarding VAS, JOA score, or ODI when measured preoperatively, 1 day postoperatively, 3 months postoperatively, or at the last follow up. In addition, no significant difference was found regarding overall incidence of complications between PETD and PEID (P = 0.14). Nevertheless, a significantly lower incidence rate of dural tear was observed in PETD compared with PEID (P = 0.04). The authors concluded that PETD had comparable clinical efficacy and safety compared with PEID; however, PEID was superior to PETD regarding fluoroscopy times and operative time. Therefore, PEID might be a better surgical procedure for L5-S1 LDH. The findings are limited by lack of separation in the analysis between randomized controlled trials and observational studies.~~

~~In a retrospective review, Tacconi et al. (2018) reported outcomes and complications in 270 patients who underwent PETD. All patients have a minimum follow-up of 6 months. Primary study endpoints were evaluation of outcomes using the VAS and ODI pre-operatively and at 3, 6 and 12 months, as well as the complications and the recurrence rates. The authors reported positive outcomes of approximately 93%. In their opinion, the complication rate of 5.5%, and recurrence rate of 4.1% are compare to results from other procedures. The findings are limited by lack of comarison group. RCTs, larger patient populations, and longer-term outcomes are needed to further evaluate PETD.~~

~~Liu et al. (2018, included in the Yu systematic review cited above) evaluated the clinical outcomes of PETD, micro endoscopic~~~~microendoscopic~~ ~~discectomy (MED), and microdiscectomy (MD) for treatment of symptomatic LDH. One hundred ninety-two patients with symptomatic LDH at L3-4 and L4-5 were included in this retrospective cohort study. The patients were divided into groups as follows: group A was treated with PETD and included 60 patients (31 men and 29 women) with a mean age of 36.2 years; group B was~~

~~treated with MED and included 63 patients (32 men and 31 women) with a mean age of 33.1 years; and group C was treated with MD and included 69 patients (36 men and 33 women) with a mean age of 34.0 years. There were no significant differences in mean preoperative ODI score, and VAS scores for LBP and leg pain among groups A, B, and C. Incision length, duration of the operation, blood loss, creatine phosphokinase, length of hospital stay, and postoperative incision pain according to the VAS were best in the PETD group (p < 0.05). Fifty-five (91.6%), 59 (93.7%), and 62 patients (89.9%) had at least 2 years of follow-up in groups A, B, and C, respectively. At the last follow-up, VAS scores of LBP and leg pain, and ODI scores were significantly better than preoperative correlates in all groups. The authors concluded that PETD, MED, and MD were all reliable techniques for the treatment of symptomatic LDH. With a restricted indication, PETD can result in rapid recovery and better clinical results after at least 2 years of follow-up. Findings are limited by the observational and retrospective design of the study. Additional studies with randomization, longer outcomes, and larger patient populations are needed to further evaluate PETD.~~

~~*Automated Percutaneous Lumbar Discectomy (APLD)/Automated Percutaneous Nucleotomy*~~

~~A Hayes report concluded that while there is a sufficient amount of evidence published to evaluate APLD for lumbar disc disease, there are a limited number of publications at this time to conclude the safety and efficacy of this technology (Hayes 2020).~~

~~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 one year or less, whereas long-term effectiveness was defined as greater than one year. Nineteen observational studies and no randomized controlled~~~~controled~~ ~~trial were included~~~~;~~ ~~and met inclusion criteria for methodological quality assessment. Overall, 5,515 patients were studied with 4,412 patients (80%) showing positive results lasting one year or longer. Based on USPSTF 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 describing APLD.~~

~~Professional Societies~~

~~*North American Spine Society (NASS)*~~

~~In their clinical guideline on the diagnosis and treatment of LDH and radiculopathy, NASS (Kreiner, et al., 2014) recommended that APLD may be considered for the treatment of LDH with radiculopathy (Grade of Recommendation: C). However, they concluded that there is insufficient evidence to make a recommendation for or against the use of APLD compared with open discectomy in the treatment of patients with LDH with radiculopathy (Grade of Recommendation: I [Insufficient Evidence]).~~

~~*American Society of Interventional Pain Physicians (ASIPP)*~~

~~In a comprehensive evidence-based guideline for interventional techniques in chronic spinal pain, the ASIPP (Manchikanti et al., 2013a) concludes that the level of evidence for automated percutaneous mechanical lumbar disc decompression is limited for short- and long-term relief based on all observational studies.~~

~~*Percutaneous Lumbar Discectomy (PLD)*~~

~~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.~~

~~*Percutaneous Laser Disc Decompression (PLDD)*~~

~~In a health technology assessment, a small body of very limited low--quality evidence is were considered insufficient to determine the safety and efficacy of PLDD for lower back disc herniation (Hayes 2018, updated 2021).2020). 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 (Nn=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 colleaguescolleguces (2017) demonstrated that although the rate of reoperation in the PLDD group was higher than expected, surgerysugery 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 2003, NICE evaluated the safety and efficacy of endoscopic laser foraminoplasty and found the evidence inadequate to support the use of this procedure. They recommend that further research to evaluate safety and efficacy to reduce uncertainty of this procedure.~~

~~Professional Societies~~

~~*American Society of Interventional Pain Physicians (ASIPP)*~~

~~The ASIPP practice guidelines for the management of chronic spinal pain stated that the evidence for percutaneous disc decompression is moderate for short-term relief and limited for long-term relief (Manchikanti et al., 2013b).~~

~~*North American Spine Society (NASS)*~~

~~In their evidence-based guideline, NASS states that PELD may be considered as an option for the treatment of LDH and radiculopathy to reduce early postoperative disability and opiod use compared with open discectomy (Grade of Recommendation - B[fair-quality evidence]) (Kreiner et al., 2012).~~

~~Yeung Endoscopic Spinal Surgery (YESS)/[Arthroscopic Microdiscectomy or Percutaneous Endoscopic Discectomy (PELD)]~~

~~Xu et al. (2020) conducted a meta-analysis on the efficacy of percutaneous endoscopic lumbar discectomy (PELD) versus micro endoscopic~~~~microendoscopic~~ ~~discectomy (MED); the authors specifically focused on the midterm and long-term outcomes. A total of 487 studies were identified with only 9 articles meeting the inclusion criteria and high-quality standards. Only one of these was a randomized controlled~~~~controled~~ ~~trial, the other were observational studies. In the results analysis, both PELD and MED obtained satisfactory midterm and long-term clinical efficacy, however the PELD group obtained better outcomes in scores for low back pain after 2 years postoperatively compared with the MED group. The authors concluded that the PELD patients exhibited overwhelming superiority in length of incision, postoperative time in bed and hospital length of stay which supported PELD as less invasive and faster rehabilitation. Further well-defined large, randomized trials are needed to validate and increase the strength of these findings. Limitations included lack of randomization in most included studies, lack of detailed surgical methods for several studies thus limiting additional subgroup analysis and high heterogeneity.~~

~~Ruan et al. (2016) conducted a systematic review and meta-analysis to compare PELD and open lumbar microdiscectomy (OLM) for the treatment of LDH. A total of 7 studies (1389 patients) were included (2 RCTs and 5 observational studies). The authors concluded that existing evidence indicates that no superiority exists between the two surgical approaches for the treatment of LDH in terms of functional outcome, complication rate and reoperation rate, in spite of the PELD surgical group can achieve shorter operation time and hospital stay than OLM surgical group. This review is limited by a low number of RCTs, and unknown follow-up periods.~~

~~Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems~~

~~In a prospective cohort study of 80 patients who underwent TESSYS for LDH, Wu et al. (2018, included in 2019 ECRI assessment above~~~~(2018)~~ ~~evaluated outcome predictors in 36 men and 44 women with a mean age of 48.76±15.60 years (range: 24-78 years). The mean follow-up time was 25.15±9.76 months (range: 12-48 months). LDH with older age (odds ratio [OR]: 6.621; 95% confidence interval [CI], 0.632-20.846; $p=0.019$), high-intensity zone (HIZ) (OR: 8.152; 95% CI, 0.827-4.380; $p=0.003$), and larger disk herniation (OR: 6.819; 95% CI, 0.113-4.825; $p=0.017$) were the most significant negative outcome predictors.~~ ~~The study is limited by its lack of randomization and small patient population.~~

~~In a retrospective case series, Kosztowski et al. (2018) evaluated the risk for reherniation in the first year after transforaminal endoscopic decompression in 46 consecutive male and 38 female patients. Four patients required microdiscectomy due to reherniation at 5 months, 8 months, 9 months, and 10 months postoperatively. All the patients in the series reportedly improved immediately following their endoscopic procedures, and no patients presented with symptoms suggestive of reherniation until 5 months after their initial endoscopic surgery. Patients with reherniation tended to be young: 31, 45, 48, and 49 years of age: all less than the average patient age who underwent endoscopic surgery. The 1-year reherniation rate in this study is 4.7%. According to the authors, this suggests that the benefit of this technique may be that it is ultra-minimally invasive, but it may only be equal, not superior to microdiscectomy in its rate of reherniation. The study was limited by lack of comparison group and loss to follow up. RCTs with larger patient populations and longer follow-up periods are needed to further evaluate this technique in the treatment of LDH.~~

~~Pan et al. (2016, included in 2019 ECRI assessment above) performed a prospective case series to investigate the clinical outcomes of transforaminal endoscopic system (TESSYS) for discogenic lLBP (DLBP). Consecutive patients (N=62) with one-level DLBP underwent TESSYS from January 2010 to December 2013 with a mean follow-up of 26.8 ± 4.2 months. The VAS was used for back pain, the ODI for lumbar function, and the modified MacNab criteria for clinical global outcomes. Twenty-four patients showed only inflammatory granuloma on annulus tear tissues (Group A), 16 patients showed no annulus tear but adhesion and inflammatory granuloma among the intracanal annulus fibrous posterior longitudinal ligament and the abdomen side of the dura sac (Group B) and 22 patients showed both (Group C). The success rate of group C was much higher than A and B. The whole success rate was 75.8%. Of the 4 patients with poor result, 2 refused further surgical treatment and showed either no improvement or worsening. The remaining 2 patients had spinal fusion surgery and achieved better results. VAS and ODI had significantly improved after surgery (P < 0.01). No unexpected complications were seen. The authors concluded that TESSYS is an effective method in treating DLBP. The findings of this study need to be validated by well-designed studies and are limited by lack of comparison group.~~

~~Sanusi et al. (2015) conducted a two-year retrospective case series of patients (Nn=201) who underwent transforaminal endoscopic discectomy at a tertiary neurosurgical center in the United Kingdom by a single surgeon. Mean time of onset of symptoms was 5.5 months and the most common level was L4/5 (53%). All endoscopic discectomies were performed under local anesthesia. The VAS of the pain dropped from an average of 7/10 pre-operatively to 0-1/10 in 95% of patients two weeks post operatively. Eighty-seven percent of the patients went back to their normal daily activities within two weeks. There were no cases of cerebrospinal fluid leak, hematoma formation or wound infection. One percent of patients developed a nerve root injury. 6% of patients had recurrent herniation and required microdiscectomy. The authors concluded that endoscopic discectomy can be an alternative approach to microdiscectomy, and the data shows that the far lateral endoscopic discectomy using the TESSYS technique has comparable outcomes to microdiscectomy. The study is limited by its retrospective observations and lack of comparison group.~~

Percutaneous Injection of Allogeneic Cellular/Tissue-Based Products

There is insufficient high-quality evidence to support percutaneous injection of allogeneic cellular/tissue-based products for treating discogenic pain. Further research with robust RCTs, larger patient sample sizes and long-term outcomes are required to demonstrate its safety and efficacy.

In 2021, Beall et al. reported the one year results of the VAST RCT below. A total of 218 patients with chronic low back pain secondary to single-level or 2-level degenerative disc disease were blinded and randomized to receive intradiscal injections of either viable disc allograft or saline, or continued with nonsurgical management (NSM) and assessed at 6 and 12 months. After 3 months, the NSM group could crossover to the allograft group. The results showed at 12 months, clinically meaningful improvements in VASPI and ODI scores in both groups, with 76% responders in the allograft group compared to 57% in the saline group. Limitations of this study include a relatively small number of participants as well as the loss of 36 participants to follow up. Furthermore, future studies are needed using a more accurate neutral comparator than saline to better understand the therapeutic effects.

Beall et al. (2020) reported the preliminary results of the first 24 patients from an ongoing prospective parallel-arm, multicenter randomized controlled trial for individuals with degenerative disc disease who received the VIADISC™ NP (VIVEX Biologics, Inc.) allograft. Individuals were randomized to receive allograft or saline at either 1 or 2 levels, or continue nonsurgical management (NSM); outcomes were assessed using a visual analog scale (VAS) and Oswestry Disability Index (ODI). At 12 months, the VAS score improved from 54.81, 55.25, and 62.255 in the allograft, saline, and NSM subjects, to 12.27, 19.67, and 6.0 at 12 months. The ODI score improved from 53.73, 49.25, and 55.75 in the allograft, placebo, and NSM subjects, to 15.67, 9.33, and 11.0 at 12 months. At 3 months, participants from both groups were given the option to cross over to the allograft treatment and all subjects chose that option. Adverse events were short-lived and resolved in all cohorts. The trial has completed recruitment of 218 of the 220 planned participants, and follow-up will continue for 36 months. ~~Currently, the evidence is insufficient to determine that the technology results in improvement in health outcomes.~~
~~Additional clinical trial information can be found at: https://www.clinicaltrials.gov/ct2/home; ClinicalTrials.gov number NCT03709901; ClinicalTrials.gov number NCT03347708~~

Thermal Intradiscal Procedures (TIPs)

There is insufficient quality evidence to support the use of thermal intradiscal procedures (TIPs) for treating discogenic pain. Further research with randomized controlled studies, larger patient sample sizes and long-term outcomes are required to demonstrate their safety and efficacy.

Intradiscal Electrothermal Therapy (IDET) and Intradiscal Biacuplasty (IDB)

In a retrospective case series of patients undergoing IDET for discogenic back pain, Kircelli et al. (2017) evaluated 12-month pain and functional outcomes and predictors of clinical success (N=120). The degree of disc degeneration was graded using the Dallas discogram score (DDS) during discography, and the presence of a high intensity zone (HIZ) on magnetic resonance imaging (MRI) was noted. The primary outcome measure was assessment of back pain severity based on the VAS; function was assessed by the ODI. Follow-up examinations for ODI and VAS scores were assessed at 1-~~,~~ 6-~~,~~ and 12-~~—~~months post-treatment. Outcomes were discussed with respect to morphological changes in intervertebral discs on discogram. There was an average 57.39% and 47.16% improvement in VAS and ODI scores, respectively, between pretreatment and 12 months follow-up ($p < 0.0001$ for both comparisons). Predictors of 12-month clinical success was depended on DDS ($p < 0.0001$), a HIZ on MRI ($p < 0.0001$). In the authors' opinion, durable clinical improvements can be realized after IDET in select surgical candidates with mild disc degeneration and HIZ, discography, and low-grade DDS, with more effective treatment results. RCT and longer outcomes are needed to further evaluate IDET. The study is

limited by a lack of **comparison** ~~comaprison~~ group undergoing a different therapeutic approach.

Helm et al. (2017) conducted a systematic review of thermal annular procedures in treating discogenic LBP. Four RCTs were included; there were no observational studies which met the inclusion criteria. Based upon 2 RCTs showing efficacy, with no negative trials, the authors identified Level I, or strong, evidence of the efficacy of biacuplasty in the treatment of chronic, refractory discogenic pain. Based upon one high-quality RCT showing efficacy and one moderate-quality RCT interpreted as showing no benefit, Level III, or moderate, evidence supporting the use of intradiscal electrothermal therapy (IDET) in treating chronic, refractory discogenic pain was identified. The evidence supporting the use of discTRODE is level V, or limited. This systematic review is limited by the low number of RCTs that met the inclusion criteria, small sample size, and the lack of clarity on the statistical **significance** ~~signficance~~ of the findings.

Desai et al. (2017) reported 12-~~-~~month outcomes on the subjects treated in the Desai et al. (2016) study cited below, including the participants who were allowed to cross-over to the surgery arm of the original RCT after six months of conservative treatment. Study eligibility was restricted to patients with single-level discogenic pain. The VAS mean baseline score was 6.7 and at 12 months the mean score was 4.4. The SF36-PF mean baseline score was 48 and at 12 months 62. The authors concluded that pain reduction at 12 months was statistically significant and clinically meaningful in the original IDB + CMM group compared to baseline. Limitations of this study included lack of comparison groups after the original six months of the study, lack of study subjects' blinding to the study arm within which they were randomized, and lack of sham intervention.

Desai et al. (2016, included in the Helm systematic review cited above) conducted a prospective, randomized, crossover; multicenter trial to evaluate comparative effectiveness of intradiscal biacuplasty (IDB) versus conventional medical management (CMM) in the treatment of lumbar discogenic pain. The primary outcome measure was the change in visual analog scale (VAS) after the initiation of each method from baseline to 6 months. Secondary outcome measures included treatment "responders" (the proportion of subjects with a 2-point or 30% decrease in VAS scores), the short form (SF) 36-Physical Functioning (SF36-PF), Oswestry Disability Index (ODI), Beck's Depression Index (BDI), Patient Global Impression of Change (PGIC) and Quality of Life (QOL) Index (EQ-5D), and back pain related medication usage. CMM included physical therapy, pharmacological management, interventional procedures (lumbar epidural injections, sacroiliac joint injections, and facet interventions), and lifestyle changes such as behavioral therapy, weight loss, and acupuncture. Out of 67 randomized participants who had been treated with IDB and CMM for chronic LBP of discogenic origin, 63-underwent IDB + CMM (N=29) or CMM-alone (N=34). Six months following continuous CMM-alone treatment, participants in this study group were permitted to "cross-over" to IDB + CMM (N=25), and followed for an additional 6 months. The six-month results showed in the IDB cohort, the mean VAS score reduction exceeded that in the CMM cohort (-2.4 vs. -0.56; P=0.02), and the proportion of treatment responders was substantially greater (50% vs. 18%). Differences in secondary measures favored IDB. No differences in opioid utilization were however noted between groups. The authors concluded that the superior performance of IDB with respect to all study outcomes suggests that it is a more effective treatment for discogenic pain than CMM-alone. Randomized controlled trials (RCTs) with larger patient populations are required to validate these results. The findings are limited by a lack of **comparison** ~~comaprison~~ to a sham procedure and, consequently~~consquently~~, a possible placebo effect of the invasive procedure, compared to CMM. The findings are also limited by a loss to

follow up of more than 20% at six month, which could have introduced a bias, considering the relatively small initial sample size and a possible **differential** ~~differencial~~ loss to follow up.

Freeman et al. (2005, included in the Helm systematic review cited above) reported results of 57 patients who were randomized to either IDET (N=38) or sham (N=19). The objective of the study was to test the safety of IDET compared with sham treatment for LBP of at least 3 months duration. Study participants were chosen from consecutive patients of 3 spine surgeons if they satisfied eligibility criteria. Randomization occurred after catheter placement via sealed envelope by an independent technician who covertly connected the catheter if the patient was to receive active treatment. All subjects followed a common rehabilitation program. Patient evaluations occurred at 6 weeks and 6 months by an independent investigator. Outcomes measures were recorded at baseline and 6 months and included the VAS, LBP outcome score (LBOS), ODI, SF-36, Zung Depression index, the modified somatic perception questionnaire, sitting tolerance, work tolerance, medication, and the presence of any neurologic deficit. Success was defined a priori as a composite measure: no neurologic deficit resulting from the procedure, an improvement in the LBOS of 7 or more points, and an improvement in the SF-36 subscales of bodily pain and physical functioning of greater than 1 standard deviation from the mean. Sample size was calculated before the study and using a 2:1 allocation with 80 % power, 75 patients were required. The authors reported that no serious adverse events (AEs) occurred in either arm of the study, without defining serious AEs. The authors also reported, that "Transient radiculopathy (less than 6 weeks) was reported in 4 study participants who underwent IDET and in 1 study participant who underwent the sham procedure" and that no subject in either arm met criteria for successful outcome. The authors concluded that IDET was no more effective than placebo for the treatment of chronic discogenic LBP.

The National Institute for Health and Care Excellence (NICE, 2016b) recommendation states that the current evidence on percutaneous electrothermal treatment of the intervertebral disc annulus for LBP and sciatica raises no major safety concerns, but the evidence on efficacy is inconsistent and of poor quality.

~~Professional Societies~~

~~*American Society of Interventional Pain Physicians (ASIPP)*~~

~~An ASIPP evidence-based practice guideline in the management of chronic spinal pain (Manchikanti, et al., 2013a) states that the evidence for IDET and biacuplasty is limited to fair.~~

~~*North American Spine Society (NASS)*~~

~~In their clinical guideline on the diagnosis and treatment of lumber disc herniation and radiculopathy, NASS (Kreiner, et al., 2014) concluded that there is insufficient evidence to make a recommendation for or against the use of percutaneous electrothermal disc decompression in the treatment of patients with lumbar disc herniation (LDH) with radiculopathy (Grade of Recommendation: I).~~

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

Zhang and colleagues (2016) investigated the safety and efficacy of PIRFT for the treatment of discogenic LBP. Twenty-three patients with LBP who were treated with single-level bipolar radiofrequency thermocoagulation (RFTC) were included in this case series. The patients were assessed before the procedure and at 1 week, 1 month, 3 months, 6 months, and 1 year after the procedure. The primary outcome included the VAS score and

the ODI score. The secondary outcome included pain relief, reduction of analgesic dose, and patient satisfaction. VAS and ODI scores were reported as significantly decreased after bipolar RFTC treatment at all-time points of follow-up ($p<0.05$). A significant change was also reported in all secondary measures, such as pain relief, reduction of analgesic dose, and patient satisfaction. Three patients experienced mild short-term post-dural puncture headache, but the symptom disappeared within 1 week. No serious complications, such as nerve injuries, discitis, and hematoma, or neurological sequelae occurred in any of the patients. The authors concluded that bipolar RFTC treatment can significantly reduce pain and improve the function of patients with discogenic LBP. Limitations of this study include lack of a control group and the small sample size.

Lee et al. (2015) conducted a small pilot study to evaluate the safety and effectiveness of the L'DISQ device in patients with lumbar discogenic pain (N=20). Preliminary results of the L'DISQ device showed that at 48 weeks, the VAS improved, while the disability index, range of motion, and QOL index decreased significantly when compared with baseline values. However, the study was limited by the before-and-after study design, lack of randomization, and blinding, as well as lack of a comparator group. Additional studies are necessary to definitively evaluate the safety and efficacy of the L'DISQ device for treatment of lumbar discogenic pain.

In a prospective, parallel, gender stratified, double-blind placebo RCT, Kvarstein et al. (2009) evaluated the long-term effect and safety aspects of PIRFT with the discTRODE probe. A total of 20 patients with chronic LBP and a positive 1-level pressure-controlled provocation discography were randomized to either intra-annular PIRFT or intra-annular sham treatment. A blinded interim analysis was performed when 20 patients had been followed for 6 months. The 6-month analysis did not reveal any trend towards overall effect or difference between active and sham treatment for the primary endpoint: change in pain intensity (0 to 10). The inclusion of patients was therefore discontinued. After 12 months, the overall reduction from baseline pain had reached statistical significance, but there was no significant difference between the groups. The functional outcome measures (ODI, and SF 36 subscales and the relative change in pain) appeared more promising but did not reach statistical significance when compared with sham treatment. Two actively treated and 2 sham-treated patients reported increased pain levels, and in both groups a higher number was unemployed after 12 months. The study did not find evidence for a benefit of PIRFT, although it cannot rule out a moderate effect. The authors stated that considering the high number reporting increased pain in this study, they would not recommend intra-annular thermal therapy with the discTRODE probe.

Finch et al. (2005) studied 31 patients by heating of their annular tears with a flexible radiofrequency electrode placed across the posterior annulus and compared 15 patients with conservative management in a cohort study. The VAS decreased significantly after the radiofrequency treatment and this decrease persisted at 12 months follow-up. The VAS did not change over 12 months in untreated controlled subjects. The ODI also decreased in treated patients but not in control group subjects. This study is limited by lack of randomization, lack of sham procedure, and small sample size.

The NICE (2016c) guideline on PIRFT of the intervertebral disc nucleus for LBP, states that current evidence raises no major safety concerns. The evidence on its efficacy is limited in quantity and quality. NICE encourages further research into PIRFT of the intervertebral disc nucleus for LBP. Further research should include details of patient selection, the duration of patients' symptoms, and a precise account of the technique used for treatment. Outcome measures should include pain relief and QOL. Long-term follow-up data should include details of any subsequent procedures.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

In an~~Professional Societies~~

~~*American Society of Interventional Pain Physicians (ASIPP)*~~

~~The~~ ASIPP **Interventional Pain Management** ~~practice guidelines on interventional techniques in the management of chronic spinal pain concludes that the evidence for radiofrequency posterior annuloplasty was limited for short- term improvement, and indeterminate for long-term improvement in managing chronic discogenic LBP (Boswell et al., 2007).~~

~~An updated ASIPP evidence-based practice~~ guideline ~~in the management of chronic spinal pain (Manchikanti, et al., 2013a)~~**, the authors performed a systematic assessment of the literature and concluded** ~~the following: states~~ **that the evidence is** limited to fair for intradiscal electrothermal therapy ~~for discTRODE (PIRFT). The ASIPP did not address radiofrequency posterior annuloplasty in this updated guideline.~~

North American Spine Society (NASS)

In the 2012 clinical guidelines on the diagnosis and treatment of lumbar disc herniation with radiculopathy, NASS states that there is insufficient evidence for or against the use of percutaneous electrothermal disc decompression in the treatment of patients with lumbar disc herniation with radiculopathy.

~~*North American Spine Society (NASS)*~~

In their 2020 clinical guideline on the diagnosis and treatment of low back pain, NASS concluded that there is insufficient evidence to make a recommendation for or against the use of percutaneous intradiscal radiofrequency thermocoagulation.

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.

The Center for Biologics Evaluation and Research (CBER) regulates cellular therapy products, human gene therapy products, and certain devices related to cell and gene therapy. CBER uses both the Public Health Service Act and the Federal Food Drug and Cosmetic Act as enabling statutes for oversight. Cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including hematopoetic stem cells and adult and embryonic stem cells. See the following website for further information: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products. (Accessed ~~November 23, 2021~~**September 27, 2022).**

~~Percutaneous endoscopic lumbar discectomy (PELD) is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. See~~~~Please see~~ ~~the following website for more information on devices used for PELD (search by product code HRX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 20, 2021~~~~September 8, 2020)~~

Additional information for marketed devices indicated for closure of the annulus fibrosus can be found at **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm**

~~http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm~~ under the following product codes:

- Product code: FTL (surgical mesh, polymeric)
- Product code: FTM (mesh, surgical)
- Product code: GAT (suture, nonabsorbable, synthetic, polyethylene)

(Accessed ~~September 8, 2020~~**September 27, 2022)**

On February~~September~~ 8, **2019, the Barricaid® Anular Closure Device (Intrinsic Therapeutics, Inc.) received FDA premarket approval, and is indicated for reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level** ~~2020)~~
between L4 and S1. Additional information can be found at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K201676
~~https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=QES&min_report_year=2019.~~
(Accessed September 27, 2022)

FDA approved electrosurgical cutting and coagulation devices and accessories can be found ~~(~~under product codes GEI, GXI, HRX, BSO and BSP~~)~~ at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed **September 27, 2022**~~September 8, 2020~~)

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Policy History/Revision Information

Date	Summary of Changes
TBD	**Coverage Rationale** • **Revised list of unproven and not medically necessary procedures:** ○ **Added:**

	▪ Annular closure devices (ACDs) ▪ Percutaneous injection of allogeneic cellular/tissue-based products ○ Removed: ▪ Annulus fibrosus repair following spinal surgery • Added instruction to refer to the Medical Policy titled *Minimally Invasive Spine Surgery Procedures (for Louisiana Only)* for percutaneous discectomy for the treatment of axial or radicular pain **Applicable Codes** • Added CPT codes 0627T, 0628T, 0629T, and 0630T • Removed CPT codes 62287 and 62380 • Added language to indicate CPT/HCPCS codes 0627T, 0628T, 0629T, 0630T, and S2348 are not on the State of Louisiana Fee Schedule and therefore are not covered by the State of Louisiana Medicaid Program **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS031LA.L

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