DISCOGENIC PAIN TREATMENT (FOR TENNESSEE ONLY)

Policy Number: CS031TN.L Effective Date: November 1, 2019

Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPLICATION</td>
<td>1</td>
</tr>
<tr>
<td>COVERAGE RATIONALE</td>
<td>1</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>1</td>
</tr>
<tr>
<td>DESCRIPTION OF SERVICES</td>
<td>2</td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>3</td>
</tr>
<tr>
<td>U.S. FOOD AND DRUG ADMINISTRATION</td>
<td>12</td>
</tr>
<tr>
<td>CENTERS FOR MEDICARE AND MEDICAID SERVICES</td>
<td>12</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>12</td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>15</td>
</tr>
<tr>
<td>INSTRUCTIONS FOR USE</td>
<td>15</td>
</tr>
</tbody>
</table>

APPLICATION

This Medical Policy applies to Medicaid only plans in the state of Tennessee.

COVERAGE RATIONALE

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

- Thermal intradiscal procedures (TIPS) for treating discogenic pain
- Percutaneous discectomy and decompression procedures for treating discogenic pain
- Annulus fibrosus repair following spinal surgery

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 Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22526</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level</td>
</tr>
<tr>
<td>22527</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22899</td>
<td>Unlisted procedure, spine</td>
</tr>
<tr>
<td>62287</td>
<td>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</td>
</tr>
<tr>
<td>62380</td>
<td>Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association
UnitedHealthcare

Discogenic Pain Treatment (for Tennessee Only)
UnitedHealthcare Community Plan Medical Policy

Proprietary Information of UnitedHealthcare. Copyright 2019 United HealthCare Services, Inc.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2348</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar</td>
</tr>
</tbody>
</table>

**DESCRIPTION OF SERVICES**

**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 remove unwanted tissue, such as herniated discs; create a seal to limit expression of matrix components; shrink collagen tissue; and destroy nociceptors.

**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 is inserted into the spinal disc, directly to the annulus-fibrous, 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 destroys 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 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 irritation the nerves which cause pain and weakness (North American Spine Society [NASS], 2018). There are a number of techniques described as “percutaneous discectomy,” and the 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 decompresses 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. These procedures are 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 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 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/or Interlaminar (iLESSYS®)**

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.

**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. Annual fibrous repair 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).

### CLINICAL EVIDENCE

**Thermal Intradiscal Procedures (TIPs)**

**Intradiscal Electrothermoplasty (IDET) and Intradiscal Biacuplasty (IDB)**

Desai et al. (2016) 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. Sixty-three patients who had been treated with IDB and CMM for chronic LBP of discogenic origin were originally randomized to the IDB + CMM group (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 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 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.

In a follow up to the above study (Desai et al., 2017), the original IDB + CMM study subjects were followed for a total of 12 months (N=22). 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; ODI was 42/30; BDI 8/8; PGIC 4.4/2.9 and EQ-5D 0.57/0.71. 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 randomized comparison included the lack of study subjects' blinding to the study arm within which they were randomized. Study eligibility was also restricted to patients with single-level discogenic pain.

Freeman, et al. (2005) 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.

---

Discogenic Pain Treatment (for Tennessee Only)
UnitedHealthcare Community Plan Medical Policy

Proprietary Information of UnitedHealthcare. Copyright 2019 United HealthCare Services, Inc.

Page 3 of 15
Effective 11/01/2019
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, “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.” The authors concluded that IDET was no more effective than placebo for the treatment of chronic discogenic LBP.

In a retrospective analysis 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 dependent 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. RCTs and longer outcomes are needed to further evaluate IDET.

Helm et al. (2017) conducted a systematic review of the available evidence evaluating the effectiveness 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 biaucuplasy 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, and the lack of reported patient populations.

Helm and colleagues (2012) conducted a systematic review of the available evidence evaluating the effectiveness of thermal annular procedures in treating discogenic LBP. The primary outcome measure was pain relief of at least six months. Secondary outcome measures were improvements in functional status. Three RCTs and one observation study met the inclusion criteria for thermal annular procedures. No new controlled trials were identified. Using the criteria for successful outcomes, the evidence was found to be fair for IDET and poor for use of the discTRODE probe, a device to deliver thermal energy to the disc, and IDB procedures regarding whether they are effective in relieving discogenic LBP. The limitations of this systematic review for IDET include the paucity of literature and non-availability of randomized trials.

Helm et al. (2009) conducted a systematic review of the effectiveness of thermal annular procedures in treating discogenic LBP. A total of 67 articles were reviewed of which 36 were either RCTs (n=2) or observational studies (n=34). The authors conclude that while the evidence is generally weak, IDET offers functionally significant relief in approximately one-half of appropriately chosen chronic discogenic LBP patients. There is minimal evidence supporting the use of radiofrequency annuloplasty and IDB.

A systematic review by Urrutia et al. (2007) included six studies with a total of 283 patients. Two open, nonrandomized trials (95 patients) showed positive results for IDET compared with rehabilitation and percutaneous intradiscal radiofrequency therapy (PIRFT). Results from 2 RCTs showed no differences between PIRFT and placebo, and between different PIRFT techniques. Two RCTs compared IDET with placebo. One suggested differences only in pain and in disability, while the best quality RCT showed no differences. The authors concluded that the available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of discogenic LBP.

The National Institute for Health and Care Excellence (NICE) 2016(b) 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 updated ASIPP evidence-based practice guideline in the management of chronic spinal pain (Manchikanti, et al., 2013a) states that the evidence for IDET and biaucuplasy is limited to fair.

*North American Spine Society (NASS)*

In their clinical guideline on the diagnosis and treatment of lumbar disc herniation and radiculopathy, NASS (Kreiner, et al., 2012) 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)**

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. TheVAS 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 small sample size.

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 the study. 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.

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.

**Professional Societies**

*American Society of Interventional Pain Physicians (ASIPP)*

The ASIPP 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) states that the evidence is limited for discTRODE (PIRFT). The ASIPP did not address radiofrequency posterior annuloplasty in this updated guideline.

**Percutaneous Discectomy and Disc Decompression Procedures**

*Nucleoplasty*

Klessinger (2018) conducted a retrospective observational study 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.

Nie et al. (2018) reported 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, n=147) and nucleoplasty group (group N, n=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. Study limitations include non-randomization and lack of blinding.

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. 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 among 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 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 non-randomization, small sample size, and short follow-up period.

Kuman et al. (2014) evaluated the safety and efficacy of annulo-nucleoplasty using Disc-FX for the treatment of lumbar disc pathology (n=24). All patients 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. 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.

A prospective, non-randomized, longitudinal, cohort study, 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. 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.

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.

The largest improvement in mean VAS score was reported in this follow-up study by Masala et al. (2007) who treated 72 patients affected by lumbar disk herniation were treated 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 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 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 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.

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 updated their 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 lumbar disc herniation and radiculopathy, NASS (Kreiner et al., 2012) 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)**

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 trials with 974 cases consisting of 3 RCTs, 3 prospective studies and 7 retrospective studies were included. The results suggest that patients treated with PEID experienced more 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 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. Therefore, 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.

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. 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), bed time 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.

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 end-points 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 comparable to results from other procedures. RCTs, larger patient populations, and longer-term outcomes are needed to further evaluate PETD.

Liu et al. (2018) evaluated the clinical outcomes of PETD, 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 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. Additional studies with randomization, longer outcomes, and larger patient populations are needed to further evaluate PETD.

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

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 studies were included; none of the randomized trials and 19 observational studies 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.

A systematic review by Hirsch et al. (2009) evaluated the effectiveness of APLD and concluded that it is a safe procedure which may provide relief in properly selected patients with contained disc herniation. The authors also stated that the effectiveness of APLD appears to compare favorably with the results of chymopapain injection and open discectomy, however assumptions have not been proven in randomized trials.

There is insufficient evidence in the peer-reviewed medical literature to support the safety and efficacy of APLD. Results of published studies are inconsistent and do not demonstrate long-term improvement.

**Professional Societies**

*North American Spine Society (NASS)*

In their clinical guideline on the diagnosis and treatment of LDH and radiculopathy, NASS (Kreiner, et al., 2012) 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 an updated 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)

Martins et al. (2016) conducted a review of 40 systematic reviews for the surgical treatment of LBP and analyzed their outcomes, quality, and conclusions. There was a heterogeneous group of surgical interventions, including injections, direct repair of the pars interarticularis, arthroplasty, decompression, nucleoplasty, endoscopic discectomy, and fusion. The outcome measures utilized were the AMSTAR (A Measurement Tool to Assess Systematic Reviews) score and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) questionnaires. Most systematic reviews for LBP did not reach very good or excellent quality and only 27.5% of them had evidence based conclusions. Including a meta-analysis is a significant factor to improve quality and evidence for systematic reviews and the authors suggested that researchers should concentrate efforts in performing RCTs in surgical treatment for LBP before attempting secondary studies. The authors concluded that although many systematic reviews for LBP surgical treatment are available, there is still no strong evidence favoring most of surgical procedures from an evidence-based approach and surgeons should not blindly trust systematic reviews because the validity of a significant number of them is questioned.

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. Cochran 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 with cost-effectiveness analyses are needed.

A Hayes Health Technology Brief evaluated the use of percutaneous endoscopic lumbar discectomy (PELD) for the treatment of recurrent LDH in adults. The literature search identified 6 clinical studies (n=41-401 patients). Overall, the low-quality body of evidence suggests that PELD may be inferior to comparison treatments for reducing back pain. While some studies suggest no statistically significant differences between PELD and comparator treatments for a majority of key outcomes, in a small number of studies minimally invasive transforaminal lumbar interbody fusion or microendoscopic discectomy was favored over PELD on evaluations of back pain and recurrence. The poor quality of the individual studies, small samples, and small numbers of studies evaluating individual key outcomes and comparisons, and variability in index surgeries all contributed to the low-quality body of evidence (2017; updated 2019).

A Hayes Health Technology Brief literature search identified 8 clinical studies (n=20-15,817 patients) that evaluated the efficacy and safety of PELD for primary surgical intervention for symptomatic LDH. Overall, a low-quality body of evidence suggests that PELD performs similarly to other surgical alternatives in patients with symptomatic LDH that has failed conservative management. Substantial uncertainty exists regarding appropriate patient-selection criteria. PELD has a significant learning curve, requiring specific instruction and training. The bulk of the literature with PELD is in the lower lumbar spine (L4-L5, L5-S1), with less available evidence with use of the technology in upper LDH (2017; updated 2019).

Percutaneous Laser Disc Decompression (PLDD)

In a prospective cohort study, McCormick et al. (2016) determined long-term outcomes of Dekompressor percutaneous lumbar disc decompression (PLDD) for discogenic radicular pain. Consecutive patients (N=70) with discogenic lumbar sacral 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 collected at 8 years. 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 lumbar sacral 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.
Brouwer and colleagues (2015) conducted a RCT with non-inferiority study design (n=115) to evaluate PLDD compared with conventional surgery for the treatment of LBP. The non-inferiority analysis showed that PLDD resulted in non-inferior outcomes compared with conventional surgery; however, the number of reoperations required was significantly higher in the PLDD group (38%) compared with conventional surgery group (16%).

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.

Current evidence on the safety and efficacy of thoracic PELD does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

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 PLD 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 opioid 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)]**

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 (RCTs and non-RCTs). The 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/or Interlaminar (iLESSYS®)**

Pan et al. (2016) performed a prospective cohort study to investigate the clinical outcomes of transforaminal endoscopic system (TESSYS) for discogenic LBP. 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. 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 fibrosus, 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.

In a prospective cohort study of 80 patients who underwent TESSYS for LDH, Wu et al. (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 review, 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%. 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. RCTs with larger patient populations and longer follow-up periods are needed to further evaluate this technique in the treatment of LDH.

Sanusi et al. (2015) conducted a two year retrospective assessment of patients (n=201) who underwent transfemoral 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 preoperatively 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.

**Annulus Fibrosus Repair**

Kursumovic et al. (2018) conducted a retrospective analysis of a RCT 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.

A prospective, multicenter, single-blind, RCT by Bailey et al. (2013a) 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 LHD 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 authors concluded that without a safe and effective method for closing the annulus fibrosus after discectomy, current practice has been to leave the annulus in a compromised state. This study demonstrated that, while not statistically significant, annular repair may reduce the need for subsequent reherniation surgery while retaining the benefits of discectomy with no increased risk for patients.

Bailey et al. (2013b) completed a two-year follow up evaluation to outcomes associated with repairing annulus fibrosus after lumbar discectomy. The primary outcome measure, reherniation surgery rates at 3 months, 6 months, and 2 years, did not differ statistically between the experimental and control groups. However the difference between the two groups in reoperation for disc reherniation was not seen at two years. Limitations of this study include the use of a post-hoc analysis, the lack of consecutive enrollment of participants at each site because certain individuals did not meet the inclusion/exclusion criteria and declined to participate in the randomized study, and the declining numbers of participants who were available at the two-year follow-up for inclusion in the analysis. The authors concluded that the addition of annulus fibrosus repair did not induce a significant reduction in reoperation for recurrent herniation. Additional RCTs with participants reporting statistically significant improvement in clinical outcomes and a decrease in overall complication rates are needed to determine the long term safety and efficacy of the Xclose Tissue Repair System in reducing the need for subsequent reherniation surgery after post-discectomy annular repair.

Parker et al. (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. RCTs with larger patient populations and longer-term follow-up are needed to further evaluate Barricaid.

Ledic et al. (2015) reported two-year outcomes from two prospective single-arm studies on patients treated with limited discectomy and an annular closure device. A total of 75 patients were included in this cohort 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 discectomy combined with the use of an annular 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 non-randomization and small patient population.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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. 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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). (Accessed July 1, 2019)

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 July 1, 2019)

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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm)

(Accessed July 1, 2019)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not cover Thermal Intradiscal Procedures (TIPs). Effective for services performed on or after September 29, 2008, CMS has determined that TIPs are not reasonable and necessary for the treatment of low back pain. Refer to the National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) [150.11](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). Local Coverage Determinations (LCDs) for TIPs do not exist at this time.

Medicare does not have an NCD for percutaneous discectomy and decompression procedures used to treat discogenic pain. See the LCDs for Non-Covered Services and Noncovered Services other than CPT® Category III Noncovered Services.

Medicare does not have an NCD for annulus fibrosus repair following spinal surgery. LCDs do not exist at this time.

(Accessed August 21, 2019)

REFERENCES


**POLICY HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/01/2019</td>
<td><strong>Supporting Information</strong>&lt;br&gt;• Updated Description of Services, Clinical Evidence, CMS, and References sections to reflect the most current information; no change to Coverage Rationale or Applicable Codes&lt;br&gt;• Archived previous policy version CS031TN.K</td>
</tr>
</tbody>
</table>

**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 MCG™ Care Guidelines, 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.