DISCOGENIC PAIN TREATMENT

Guideline Number: MMG033.K **Effective Date**: December 1, 2018

Instructions for Use

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Related Medical Management Guideline

- Surgical Treatment for Spine Pain

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 guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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

HCPCS Code	Description
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

DESCRIPTION OF SERVICES

A number of diagnostic and therapeutic injections and other interventional and surgical treatments have been proposed for the treatment back pain.

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. 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 low back pain. 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 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 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 irritating 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 Medical Instruments Corporation) 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. Annulus fibrosus 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 Electrothermal Therapy (IDET) and Intradiscal Biacuplasty (IDB)

A prospective, randomized, crossover, multicenter trial for the evaluation of comparative effectiveness of intradiscal biacuplasty (IDB) versus conventional medical management (CMM) in the treatment of lumbar discogenic pain was conducted. The primary outcome measure was the change in visual analog scale (VAS) 12-months after the initiation of each method. Secondary outcome measures included the SF36-Physical Functioning (SF36-PF), Oswestry Disability Index (ODI), Beck's Depression Index (BDI), Patient Global Impression of Change (PGIC) and Quality of Life Index (EQ-5D). 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 low back pain 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 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. Desai et al. (2017) 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.

In follow-up of an earlier randomized controlled trial (Kapural et al., 2005), the same investigators evaluated the use of radiofrequency intradiscal biacuplasty for the treatment of discogenic back pain over a period of 12 months (Kapural et al., 2015). This clinical study evaluated a small patient population (n=27) and evaluate physical functioning, pain relief, and disability. A total of 22 of 27 were followed for 12 months. These patients had clinically meaningful improvements in physical function and pain, and results were durable at 9 and 12 months. Of the 30 patients who were in the sham group, 24 crossed over into the treatment group, and20 of these patients completed the follow-up period at 6 months. However, patients in the crossover group did not experience statistically significant improvements in physical functioning and pain when compared with patients in the initial treatment group. The study was limited by the small number of patients followed, which may have limited the overall power of the study to accurately detect differences between groups.

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 low back pain 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, low back pain outcome score (LBOS), Oswestry Disability Index (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 in either arm of the study occurred, without defining serious adverse events. 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 low back pain.

A small, double-blind, randomized, controlled trial by Kapural et al. (2005) comparing IDET (n=38) to sham catheter (n=19) found that six months after treatment, neither group had experienced statistically significant improvement from baseline. The investigators concluded that IDET was safe, but not demonstrably better than placebo. There was no improvement in pain over sham treatment.

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 DDS during discography, and the presence of a high intensity zone (HIZ) on magnetic resonance (MR) imaging 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 MR imaging ($p < 0.0001$). 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. Randomized clinical trials and longer outcomes are needed to further evaluate IDET.

Helm et al. (2017) conducted a systematic review of thermal annular procedures in treating discogenic low back pain. 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, 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 low back pain. The primary outcome measure was pain relief of at least six months. Secondary outcome measures were improvements in functional status. Three randomized controlled trials 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 low back pain. The limitations of this systematic review for IDET include the paucity of literature and non-availability of randomized trials.

Helm at al. (2009) conducted a systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. A total of 67 articles were reviewed of which 36 were either randomized controlled trials (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 low back pain 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 low back pain.

A meta-analysis by Appleby et al. (2006) was conducted to determine the representative outcomes of intradiscal electrothermal therapy (IDET) for pain relief, reduction of disability, and risk of complications. The outcomes analyzed were the visual analog scale (VAS) assessment of pain, the bodily pain, and physical functioning subscales of the SF-36 health survey, and the Oswestry disability index. From 1998 to March 2005, 62 peer-reviewed articles were identified regarding the IDET procedure. The authors concluded that although variation exists in the reported outcomes among the various studies of the IDET procedure, the pooled results of the published studies provide

compelling evidence of the relative efficacy and safety of the IDET procedure. However, the studies that were included in this meta-analysis used subjective evaluation of improvement as key outcome measures.

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 low back pain and sciatica raises no major safety concerns but the evidence on efficacy is inconsistent and of poor quality.
The safety, efficacy, and long-term outcomes of intradiscal electrothermal annuloplasty in the treatment of patients with chronic discogenic low back pain have not been established in the published medical literature. This procedure has not been proven to achieve equivalent or improved patient outcomes compared to available and established alternatives. In addition, the long-term effect of thermal coagulation of intervertebral discs has not been determined.

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 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., 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 with radiculopathy (Grade of Recommendation: I [Insufficient Evidence]).

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

In a prospective, parallel, randomized and gender stratified, double-blind placebo-controlled study, 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.

Kapural et al. (2005) performed a prospective matched controlled trial of intradiscal thermal annuloplasty versus intradiscal radiofrequency ablation for treatment of discogenic pain. They matched 42 patients with 21 having IDET and 21 having radiofrequency annuloplasty. They reported the IDET group had significantly lower mean pain scores than the radiofrequency annuloplasty group however; there was improvement noted in both groups. VAS pain scores decreased from 6.6 + 2.0 before to 4.4 + 2.4 at one year after radiofrequency annuloplasty, whereas in IDET group the average VAS pain score decreased from 7.4 + 1.9 before IDET to 1.4 + 1.9 at 1-year follow-up. Similarly, pain disability index scores in the IDET group had a significantly larger improvement than those for patients who received radiofrequency annuloplasty.

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. The visual analog scale 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 Oswestry Disability Index also decreased in treated patients but not in control group subjects. This study is limited by small sample size.

Urrutia et al. (2007) conducted a systematic review to evaluate the evidence for the percutaneous thermocoagulation intradiscal techniques IDET and PIRFT in the treatment of discogenic low back pain. Six studies with a total of 283 patients were included. Two randomized controlled trials showed no differences between PIRFT and placebo and between different PIRFT techniques. The authors stated that, although previous case reports and nonrandomized trials suggested positive results, results from randomized clinical trials show that PIRFT is not effective for the treatment of discogenic low back pain.

Zhang and colleagues (2016) investigated the safety and efficacy of PIRFT for the treatment of discogenic low back pain (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 visual analog scale

(VAS) score and the Oswestry Disability Index (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 National Institute for Health and Care Excellence (NICE) 2016(c) guideline on PIRFT of the intervertebral disc nucleus for low back pain, 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 percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. 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 quality of life. Long-term follow-up data should include details of any subsequent procedures.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of PIRFT. There is no evidence that this procedure is as effective as established alternatives for the treatment of back pain.

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 low back pain (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

Nie et al. (2018) reported 5-year outcomes from a comparison of therapeutic efficacy of radiofrequency target disc decompression and nucleoplasty for lumbar disc herniation. Two hundred sixty patients with lumbar disc herniation were divided into two groups: target disc decompression group (group T, n = 147) and nucleoplasty group (group N, n = 113). Visual analogue scale (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 randomized controlled trial to compare CT-guided nucleoplasty, CT-guided nucleoplasty combined with nerve root injection, and CT-guided transforaminal lumbar epidural injections for patients with lumbar disk herniation and leg pain (n=97). 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 low back pain (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 Visual Analogue Scale (VAS) and the percentage reduction in pain score was calculated at each postoperative visit. The Oswestry Disability Index (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 low back pain 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 lumbar disc herniation. Health outcomes included the VAS, Oswestry Disability Index, and the Short Form-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 lumbar disc herniation, 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 quality of life (QOL) in 67 patients with radicular leg and back pain who underwent nucleoplasty-based percutaneous disc decompression. Pain relief, functioning, and quality of life (QOL) were evaluated. Patients completed the Medical Outcomes Study 36-Item Short Form (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.

A randomized controlled trial was performed by Nardi et al. (2005) who assigned 50 patients to nucleoplasty and 20 patients to conventional therapy with anti-inflammatory medications and physical therapy. Unlike most of the other available studies of nucleoplasty, this trial enrolled patients who had herniated or protruding cervical discs rather than damaged lumbar discs. At 60 days post-treatment, complete resolution of cervical and radicular pain was reported by 40 (80%) patients in the nucleoplasty group and by 4 (20%) patients in the conventional group. MRI findings at 4 months after nucleoplasty appeared to correlate with clinical resolution. In contrast, no spontaneous regression of disc herniation was observed in MRI exams of patients in the conventional group. Nardi et al. reported that clinical improvements were statistically significant in the nucleoplasty group but not in the conventional group; however, these investigators do not appear to have performed an intergroup analysis.

An uncontrolled study of nucleoplasty was performed by Alexandre et al. (2005) who assessed outcomes for 1390 patients treated for lumbalgia or lumbosciatica due to disc bulging or partially contained disc herniation. Alexandre et al. reported few details of demographics and no information concerning fraction of patients lost to follow-up. Based on Japanese Orthopedic Association scores, at 1 year of follow-up, improvements were excellent for 56% of patients, good for 25%, scanty for 12%, and none for 7%. No clear trend was observed when outcomes at 15 days, 1 month, 6 months, and 1 year were compared. Findings on MRI and/or CT at 6 months after nucleoplasty showed the elimination of disc bulging in 34% of patients, a reduction in 48%, and no change in 18%. The study is limited by uncontrolled study design.

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 postprocedure 6 months and to 2.1 at the latest follow-up. Mean Oswestry index 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.

The National Institute for Health and Care Excellence (NICE) (2016a) evaluated percutaneous coblation of the intervertebral disc for low back pain 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.

The safety, efficacy and long-term outcomes of nucleoplasty have not been demonstrated in the published medical literature. In addition, the long-term consequences of thermal denervation and tissue damage associated with this procedure are unknown.

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 lumber 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 lumbar disc herniation with radiculopathy.

Percutaneous Endoscopic Transforaminal Discectomy (PETD)

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 Visual Analogue Scale and Oswestri Disability Index 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. Randomized controlled trials, 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 lumbar disc herniation (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 automated percutaneous mechanical lumbar discectomy is limited for short- and long-term relief. A study limitation is the paucity of randomized controlled trials 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 lumber disc herniation and radiculopathy, NASS (Kreiner, et al., 2012) recommended that automated percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy (Grade of Recommendation: C). However, they concluded that there is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy in the treatment of patients with lumbar disc herniation 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 low back pain (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 randomized clinical trials in surgical treatment for LBP before attempting secondary studies. Martins and colleagues 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 lumbar disc herniation (LDH). A search was used to identify all published randomized controlled trials (RCT) 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 conclude 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 2017 Hayes Health Technology Brief evaluated the use of percutaneous endoscopic lumbar discectomy (PELD) for the treatment of recurrent lumbar disc herniation 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, small numbers of studies evaluating individual key outcomes and comparisons, and variability in index surgeries all contributed to the low-quality body of evidence.

A Hayes (2017) Health Technology Brief literature search identified 8 clinical studies (n=20-15,817 patients) that evaluated the efficacy and safety of percutaneous endoscopic lumbar discectomy (PELD) for primary surgical intervention for symptomatic lumbar disc herniation (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.

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 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 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.

Percutaneous Laser Disc Decompression (PLDD)

Brouwer and colleagues (2015) conducted a randomized controlled trial with non-inferiority study design (n=115) to evaluate PLDD compared with conventional surgery for the treatment of low back pain. 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 quality of life (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 percutaneous endoscopic laser thoracic discectomy 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 further research to evaluate safety and efficacy to reduce uncertainty of this procedure.

Professional Societies

American Society of Interventional Pain Physicians (ASIPP) (Updated 2013)

The ASIPP practice guideline for the management of chronic spinal pain stated that the evidence for percutaneous laser discectomy 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 percutaneous endoscopic discectomy may be considered as an option for the treatment of lumbar disc herniation 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 percutaneous endoscopic lumbar discectomy (PELD) and open lumbar microdiscectomy (OLM) for the treatment of lumbar disc herniation (LDH). A total of 7 studies (1389 patients) were included (randomized and non-randomized controlled trials). 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 randomized controlled trials, and unknown follow-up periods.

No professional society guidelines were identified.

Transforaminal (TESSYS®) and/or Interlaminar (iLESSYS®) [transforaminal and interlaminar approach]

Pan et al. (2016) performed a prospective cohort study to investigate the clinical outcomes of transforaminal endoscopic system (TESSYS) for discogenic low back pain (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 visual analog scale (VAS) was used for back pain, the Oswestry Disability Index (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(AF), posterior longitudinal ligament(PLL) 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. Randomized controlled trials with larger patient populations and longer follow-up periods are needed to further evaluate this technique in the treatment of lumbar disc herniation.

Sanusi et al. (2015) conducted a two year retrospective assessment of patients (n=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 visual acuity score 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 CSF 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.

No professional society guidelines were identified.

Annulus Fibrosus Repair

Kursumovic et al. (2018) conducted a retrospective analysis of a randomized controlled trial 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 adverse event (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 randomized controlled trials are needed to validate these findings.

A prospective, multicenter, single-blind, randomized, controlled clinical study by Bailey (2013a) et.al. 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 herniated lumbar discs 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 visual analogue scales for leg and back pain, Oswestry Disability Index, and Short Form-12 Health Survey. Adverse events 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 randomized controlled studies 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 Oswestry Disability Index 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 (Oswestry Disability Index: 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. Randomized controlled trials 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 diskectomy and an anular 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 diskectomy combined with the use of an 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 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 (Accessed May 22, 2018)

Additional information for marketed devices indicated for closure of the annulus fibrosus can be found under the following product codes:
Product code: FTL (surgical mesh, polymeric)
Product code: FTM (mesh, surgical)
Product code: GAT (suture, nonabsorbable, synthetic, polyethylene)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm (Accessed May 22, 2018)

FDA approved electrosurgical cutting and coagulation devices and accessories can be found under product codes GEI, GXI, HRX, BSO and BSP, is available at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm (Accessed May 22, 2018)

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GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	• Simplified coverage rationale (no change to guidelines) • Archived previous policy version MMG033.J

INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any

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