Discogenic Pain Treatment (for Kentucky Only)

Policy Number: CS031KY.06
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➲ Instructions for Use

Table of Contents **Page**

Related Policies

- Ablative Treatment for Spinal Pain (for Kentucky Only)
- Minimally Invasive Spine Surgery Procedures (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

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

- Annular closure devices (ACDs)
- Percutaneous injection of allogeneic cellular/tissue based products
- Thermal intradiscal procedures (TIPs) for treating discogenic pain

Note: For percutaneous discectomy for the treatment of axial or radicular pain, refer to the Medical Policy titled Minimally Invasive Spine Surgery Procedures (for Kentucky Only).

Applicable Codes

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

CPT Code	Description
0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)

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
63032	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone-anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure)

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

Description of Services

Annular Closure Devices

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 other spine surgeries, an open pathway or hole (defect) is made in the annulus fibrosus, which is then left to heal. Annulus fibrosus repair devices 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 (Long et al., 2016).

Thermal Intradiscal Procedures (TIPs)

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

Intradiscal Electrothermal Therapy (IDET)

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

Intradiscal Biacuplasty (IDB) or Biacuplasty

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

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

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

Percutaneous Injection of Allogeneic Cellular/Tissue-Based Products

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

Clinical Evidence

Annular Closure Devices (ACDs)

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

Dalal et al. (2025) conducted a meta-analysis to evaluate long-term postoperative outcomes following the use of the Barricaid annular closure device. The meta-analysis included five studies (two RCTs, two retrospective studies and one prospective cohort study) that had a minimum of two years of follow-up (mean 2.6 years) and had data on reherniation and complication rates. There were 332 patients in the ACD cohort and 354 patients in the non-ACD cohort. The authors reported that symptomatic reherniation rates in the ACD populations ranged from 3% to 18.8% with a 53% lower risk of symptomatic disk reherniation when compared to the non-ACD population. The authors also reported that there were no significant differences found in reoperation rates and that, in the four studies that reported patient-reported outcome measures (PROMs) data, all of the studies observed relative improvement in each cohort, although pooled analysis did not find significant differences between ACD and non-ACD groups for the Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS) – leg pain at 2-year follow-up. According to the authors, non-ACD patients were found to have a significantly lower risk of complications than the ACD group. The authors concluded that the Barricaid device was effective in reducing symptomatic reherniation but did not appear to alter postoperative PROMs or reoperation rates. Limitations of the meta-analysis include the heterogeneity of the study protocols, inclusion criteria, and surgical techniques, the small number of studies available for inclusion and the potential for bias from the conflicts of interests disclosed in four of the included studies. The Thome et al (2021), Parker et al. (2016) and Cho et al. (2019) studies previously summarized in this policy were included in this meta-analysis.

Wang et al. (2024) conducted a meta-analysis aimed at summarizing the clinical efficacy and safety of the various annular defect repair methods that have emerged in recent years. The analysis included seven RCTs and eight observational studies which included a total of 2161 participants. The authors found by adding the annular repair technique to the surgical procedure for lumbar disc herniation (LDH), a reduction was seen in the postoperative recurrence rate, reoperation rate, and loss of intervertebral height. Furthermore, a subgroup analysis identified the Barricaid Annular Closure Device (ACD) more effective than the annulus fibrosus suture in preventing re-protrusion and reducing reoperation rates. All 15 studies reported reherniation rates as a follow-up endpoint and all suggested that the postop recurrence rate in the annular repair group was significantly lower than that in the control group. Serious adverse events included dural injury/spinal fluid leakage, epidural hematoma, and wound-related adverse events (such as infection, dehiscence, and delayed healing) and were reported in 12 studies, but only participants from four studies had experienced any of these. It was concluded that lumbar discectomy combined with an annular closure device could effectively reduce the postop recurrence and reoperation rates in patients with lumbar disc herniation. This study was included in the ECRI 2023 updated report summarized below.

A Hayes Technology Assessment was conducted on nine studies that met the inclusion criteria for implantation of an annular closure device (ACD) to close sizable defects (typically ≥ 6 mm), for the prevention of recurrent lumbar disc herniation (LDH) following lumbar discectomy. All included studies recruited and treated patients who had symptomatic radiculopathy caused by LDH. In most cases, either the patients had LDH that had failed to respond to more than six weeks of conservative care, or they had contraindications to conservative treatment strategies (such as neurological deficits). It was concluded that overall, the quality of evidence evaluating the safety and efficacy of ACD is low quality. Only one study demonstrated good quality. Limitations of the individual studies included retrospective design, use of historical controls, small sample sizes, and insufficient follow-up time to determine the long-term outcomes. Additionally, it was noted that numerous studies involved overlapping authors and research groups, which may result in the analysis of duplicate patient data. In their 2025 updated report, Hayes stated that, based on a review of abstracts, there were no relevant newly published studies that met the inclusion criteria set out in the original report (Hayes 2024; updated 2025).

In a Clinical Evidence Assessment, ECRI reported the findings on the Barricaid annular closure device (Intrinsic Therapeutics, Inc.) for preventing recurrent vertebral disc herniation after lumbar discectomy versus lumbar discectomy alone for preventing disc reherniation and reoperation. Based on the results of a systematic review with meta-analysis of data from two randomized controlled trials (RCTs) and two nonrandomized comparison studies, it was determined the

evidence is somewhat favorable. In their 2025 update, ECRI included a review of the Wang et al. 2024 systematic review and meta-analysis summarized above. ECRI stated that this systematic review was at some risk of bias because eight of the 15 included studies (four of six studies assessing Barricaid) were nonrandomized comparisons at risk of bias from lack of randomization and blinding. The studies included in this report were conducted in Europe and South Korea and data may not be directly applicable to healthcare systems in other countries; additional randomized controlled trials conducted in the United States would be useful in confirming these results (ECRI 2020, updated 2023).

In an ongoing prospective, randomized, industry sponsored, multicenter study of 554 patients in 21 centers in Europe, a total of 276 patients were randomized to the annual closure device (ACD) group and 278 patients to the control group (CG) to demonstrate the superiority of the Barricaid device to a discectomy for primary lumbar disc herniation (Clinicaltrial.gov NCT01283438). Three year results (Kienzler et al., 2019, included in the 2023 ECRI and 2023 Hayes assessments) showed Barricaid was superior to discectomy alone for symptomatic reherniation, reoperation, leg pain, back pain, Oswestry Disability Index (ODI), and Physical Component Study (PCS). There were specific risks associated with ACD group such as implantation difficulties, radiographic evidence of migration, mesh detachment, and vertebral endplate changes (VEPC). However the safety profile was similar between the two groups. Nada et al. (2019, also included in the 2020 ECRI and 2021 Hayes assessments) reported the four year results on the risk of lumbar disc reherniation and reoperation rate for lumbar discectomy in patients with large annular defects following single level lumbar discectomy. Clinical follow-up occurred at six weeks, three months, six months, and annually for four years. The results showed the risk of reoperation was 14.4% for those who received the device, and 21.1% for the controls. The reoperation rate was not significantly affected by age, sex, body mass index, smoking status, level of herniation, leg pain or ODI scores. Additionally, the percentage of patients who achieved the minimal clinically important difference without a reoperation was proportionally higher in the ACD group compared to the control group for leg pain. The authors concluded that the addition of a bone anchored ACD reduces the risk of reoperation and provides better long term pain and disability relief. The authors acknowledged that this trial has several limitations; only patients with large post-discectomy annular defects were included and there are additional patient characteristics that were crucial to achieving positive results and included adequate disc height and non-osteoporotic bone mineral density (BMD) of the lumbar spine. Additionally, the decision to re-operate involved shared decision-making between the patient and surgeon resulting in a potential for bias in the reported re-operation rates. In 2021, Kienzler et al. analyzed the data from this same trial to report the risk factors for early reherniation after lumbar discectomy with or without annual closure. The results showed four (1.5%) symptomatic reherniations in the ACG group and 18 (6.5%) in the control group. A significant correlation was found with recurrent herniation for disc degeneration, and a trend for current smoker status. In the control group, age ≥ 50 years and disc degeneration were predictive factors for reherniation. The authors concluded that these were predictive factors for early disc herniation after lumbar surgery and suggest that the ACD reduced the risk.

Thomé, et al. (2018, included in both 2023 ECRI and 2023 Hayes assessments above) reported the findings of an industry sponsored RCT testing whether bone-anchored annular closure device, in addition to lumbar microdiscectomy, resulted in lower reherniation and reoperation rates plus increased overall success compared with lumbar microdiscectomy alone. Participants with symptoms of lumbar disc herniation for at least 6 weeks and a large annular defect (6–10 mm width) after lumbar microdiscectomy were included in the study and randomized to bone-anchored annular closure device (n = 276) or lumbar microdiscectomy only (control; n = 278). Based on modified intention-to-treat analyses, participants in the annular closure device treatment arm were less likely to have recurrent herniation (50% vs. 70%, p < .001) and more likely to meet the composite end point success (27% vs. 18%, p = .02). The frequency of reoperations to address recurrent herniation was 5% with annular closure device and 13% in controls (p = .001). Scores for back pain, leg pain, Oswestry Disability Index, and health-related quality of life at regular visits were comparable between groups over 2-year follow-up. In 2021, the same author reported the final outcomes over 5 years. In this secondary analysis with related results, the authors found implantation of an annular closure device with a bone-anchored implant significantly reduced the risk of recurrent herniation and reoperation; 40 patients underwent 53 reoperations in the device group, and 58 patients underwent 82 reoperations in the control group. Serious adverse events were comparable and were less frequent in the device group. The findings are limited by lack of masking of the participants and investigators to the intervention, which could have introduced biases in the findings, and possible conflicts of interest in this industry-sponsored study.

Kuršumović et al. (2018, included in the 2023 Hayes assessment above) conducted a retrospective analysis of the Thomé (2018) RCT described above 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.

Ledic et al. (2015, included in the 2023 ECRI assessment above) reported two-year outcomes from two prospective case series of patients treated with limited diskectomy and an annular closure device. A total of 75 patients were included in this study consisting of 40 men and 35 women with an average age of 40 years. Disk height maintenance within the group overall was 90% at 24 months. Overall, 97% of the treated disks demonstrated disk height maintenance of at least 75% of preoperative levels at 12 months and 92% at 24 months. Disk height maintenance was correlated with less nucleus removal. Patient disability, back pain, and leg pain were significantly improved from preoperative levels at six weeks and maintained over the course of study. There was a single symptomatic reherniation requiring surgical intervention within this series. According to the authors, limited lumbar diskectomy combined with the use of an annular closure device provided very low rates of disk reherniation and exhibited excellent disk height maintenance and sustained disability, leg pain, and back pain improvement within a 24-month postoperative study period. Study limitations include lack of comparison group and small patient population.

Percutaneous Injection of Allogeneic Cellular/Tissue-Based Products

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

Costandi et al. (2025) conducted a prospective, single-arm multi-center feasibility study with 28 adults with chronic discogenic pain (mean age 44 +13 years, 43% female) to determine the degree of improvement in lumbar discogenic pain severity and associated back impairment in individuals with chronic axial low back pain treated with intradiscally delivered allogeneic nucleus pulposus (NP) at up to two vertebral levels (L1-S1). Back pain severity was evaluated using an 11-point numeric rating scale (NRS) and back function using the ODI while minimal clinically important difference (MCID) was set at > 30% over baseline, and substantial clinical benefit (SCB) was set at > 50% over baseline. The patient acceptable symptom state (PASS) threshold for pain severity was set at ≤ 3. Twenty-two participants completed the 24-month post-procedure evaluations. The authors reported that the average overall improvement in back pain severity was 43% across all post-procedure follow up intervals, while approximately 64% (14 of 22) of participants achieved or exceeded both the MCID and SCB in back pain at 24 months. The authors also reported that almost 55% (12 of 22) of participants reported a 24-month back pain severity score of ≤ 3 along with an average decrease in ODI values of 53% with 73% (16 of 22) of participants having achieved the MCID. Approximately 82% (23 of 28) of participants reported severe or crippled back impairment at baseline compared to 18% (4 of 22) at 24 months. The authors concluded that this study provided evidence of clinically significant pain relief and functional improvement through 24 months of follow-up after a single allogeneic NP supplementation procedure in individuals with lumbar discogenic pain. Limitations of this industry-sponsored study included the small sample size, the lack of a comparator or placebo group, the heterogeneity of the levels treated and the variability in the number of vertebral levels treated.

Hayes published an Evolving Evidence Review (2022, updated 2024) that evaluated the published evidence for Via Disc NP (Vivex Biologics Inc.) for treatment of intervertebral disc degeneration symptoms. The report identified a single, fair-quality RCT (Beall et al. 2021 summarized below) that did not report clear benefits or advantages in patient-oriented outcomes and that showed no statistically significant differences between this product and placebo (saline) treatment groups for improvements in pain intensity, function or the proportion of patients that achieved response on the VAS for pain intensity at < 12 months although the study did show a statistically significant difference in favor of Via Disc NP over placebo in achieving a reduction of at least 15 points on the ODI. The Hayes report conferred a no/unclear level of support for clinical studies, systematic reviews, and clinical practice guidelines for Via Disc NP as there was only one RCT and no systematic reviews or relevant or related guidelines identified. Hayes did not report finding any additional published studies, systematic reviews or relevant or related guidelines in their 2024 update.

ECRI's Clinical Evidence Assessment of the Via Disc NP Allograft (2021, updated 2025) identified one RCT with insufficient evidence for them to determine whether the product reduced pain or improved back function more than placebo or nonsurgical management for patients with lumbar degenerative disc disease (DDD) at 12-month follow-up. In their 2025 update, ECRI included a before-and-after study that reported improvements in pain and back function after treatment with Via Disc at up to two years post procedure. ECRI concluded that additional independent RCTs are needed to validate study findings. The Beall et al. 2021 and Constandi et al. 2025 studies summarized in this policy are included in this ECRI report.

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

Beall et al. (2020) reported the preliminary results of the first 24 patients from an ongoing prospective parallel-arm, multicenter randomized controlled trial for individuals with degenerative disc disease who received the VIADISC™ NP (VIVEX Biologics, Inc.) allograft. Individuals were randomized to receive allograft or saline at either 1 or 2 levels or continue nonsurgical management (NSM); outcomes were assessed using a VAS and the ODI. At 12 months, the VAS score improved from 54.81, 55.25, and 62.255 in the allograft, saline, and NSM subjects, to 12.27, 19.67, and 6.0 at 12 months. The ODI score improved from 53.73, 49.25, and 55.75 in the allograft, placebo, and NSM subjects, to 15.67, 9.33, and 11.0 at 12 months. At 3 months, participants from both groups were given the option to cross over to the allograft treatment and all subjects chose that option. Adverse events were short-lived and resolved in all cohorts. The trial has completed recruitment of 218 of the 220 planned participants, and follow-up will continue for 36 months.

Thermal Intradiscal Procedures (TIPs)

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

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

Yoo et al. (2024) performed a retrospective, single-center cohort study to evaluate the effectiveness of percutaneous lumbar nucleoplasty (PLN) and IDET and the positive predictive factors associated with intradiscal procedures. The study included an analysis of medical records of 142 adults (aged 20 to 85 years, 62.7% female) with LBP for more than three months, predominant axial LBP, and an NRS score of four or higher after at least three months of conservative treatment who underwent IDET or PLN for treatment of discogenic low back pain (D-LBP). Success was defined as ≥ 50% pain relief on the NRS pain score at the six-month follow-up visit, no increase in analgesics, and no additional treatment of D-LBP over the entire follow-up period. The authors reported that 86 (60.5%) of the 142 patients (89 who underwent PLN, and 53 who underwent IDET) experienced a successful outcome, and that success was more substantial in the PLN group (n = 61/89, 68.5%) than in the IDET group (n = 25/53, 47.2%). The authors also reported that the high-grade Modified Dallas discogram scale (DDS) in provocation discography and a procedure at the L3/L4 spinal level were independent positive predictors of successful outcomes while coexisting psychiatric disorders, such as depression and anxiety, were negative predictors of successful treatment. The authors concluded that PLN and IDET might be effective for managing D-LBP from internal disc disruption. Limitations of this study include the retrospective, single-center design, the heterogeneity of the level of operated discs and number of discs operated on, and the lack of information regarding other comorbidities.

Medina-Pérez et al. (2023) conducted a single-center, prospective crossover clinical trial with adults who underwent IDB by cooled radiofrequency treatment (CRT) for the management of discogenic low back pain to evaluate its effectiveness in the treatment of radicular pain secondary to a lumbar hernia. The study included 74 participants (mean age 49.03 ±15.15 years, 66.22% female) with a total of 134 herniated intervertebral lumbar discs who had received previous conservative treatment and a month of physiotherapy without achieving adequate pain control. Comorbidities included type 2 diabetes mellitus (n = 8), systemic arterial hypertension (n = 20) and overweight/obesity (n = 21). The distribution of hernias consisted of 14 (13.33%) at the L3-L4 levels, 49 (46.66%) at the L4-L5 levels, and 42 (40%) at the L5-S1 level. After IDP, participants were followed up between one and six months, with a mean follow-up of 2.42 ±1.29 months. The authors reported that participants showed an average improvement in discogenic pain of 79.92% in 98.64% of cases when comparing the pre-operative perception of LBP to the post-operative perception of LBP with the VAS and Oswestry low back pain disability scale (OLBPDS). The authors concluded that IDB by CRT was a considerable treatment for lumbar radiculopathy and that postoperative results demonstrated the safety and efficacy of the procedure for the management of radicular pain without significant adverse effects. This study was limited by the small number of participants, the single-center design, the lack of a comparison or control group, and the short follow-up period.

Yang et al. (2023) conducted a prospective, single-center, single surgeon case series to evaluate the general and radiographic features that may serve as markers for predicting the therapeutic outcome of IDB for the treatment of lumbar

DDD. The study included 37 adults (23-74 years old) with chronic discogenic LBP for more than six months that was unresponsive to conservative care with disc height preservation of more than 50% compared to the adjacent disc who presented with axial back pain more frequently than leg pain who had evidence of disc degeneration at three or less levels with positive reproducible pain. Each participant received lumbar cool radiofrequency IDB and completed follow-up questionnaires at one, three, six, and 12 months. Surgical outcomes were reported using the VAS, the ODI, and the consumption of nonsteroidal anti-inflammatory drugs (NSAID). Prognostic factors associated with pain relief from age, gender, body mass index (BMI), and pre-operative lumbar magnetic resonance imaging reading were calculated using a univariate analysis. One participant was lost to follow-up at one year and three participants received a second surgery at four, eight and nine months, respectively. The authors reported that significant reductions were found on both VAS and ODI at the post-operative period at one, three, six and 12 months with most participants (33/40) had at least 50% VAS improvement at the six-month follow-up. The authors also reported that the NSAID dosage was significantly decreased at three-month and six-month follow-up. The univariate analyses by the authors indicated that the prognosis of IDB was not related to disc height, Pfirrmann grading or Modic endplate change, although disc extrusions were associated with promising outcomes (VAS improvement ≥ 50%) on pain relief. The authors concluded that IDB was a good alternative choice for treating lumbar DDD in adults who failed conservative treatment. This study was limited by the single-center design, the lack of randomization or a control or comparison group, the small sample size, the short follow-up period, and the lack of long-term evaluation of the prognostic factors.

Park et al. (2020) investigated the effects of percutaneous monopolar Intradiscal pulsed radiofrequency (ID-PRF) application on patients with chronic discogenic low back pain (LBP). Forty-five patients were divided into two separate groups; one group received the intervention for a duration of seven minutes and the other group received the intervention for a duration of 15 minutes. The outcomes were measured using the NRS-11 for pain and the ODI. Data was collected at baseline, two- and six-weeks. Success was defined as a 50% or greater reduction in the NRS score or 40% or more reduction in the ODI score. The participants received single needle placement into the affected disc with application of frequency of 5 Hz, a pulse width of 5 ms, amplitude of 60V, and a maximum temperature of 42°C, for either seven or 15 minutes. The authors found both the ODI and NRS scores for the participants were lower at both the two- and six-week follow-up appointments. At six months, 12 of the 17 patients in the seven-minute group and 20 of the 28 patients in the 15-minute group reported more than 50% reduction in their pain score. No complications were found in either group. The authors' concluded that the application of ID-PRF can achieve pain relief in patients with discogenic LBP. Limitations included small sample size and lack of control group; additional well-designed and well-controlled studies are needed to fully assess the efficacy of ID-PRF.

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

Helm et al. (2017) conducted a systematic review of thermal annular procedures in treating discogenic LBP. Four RCTs were included; there were no observational studies which met the inclusion criteria. Based upon two RCTs showing efficacy, with no negative trials, the authors identified Level I, or strong, evidence of the efficacy of biacuplasty in the treatment of chronic, refractory discogenic pain. Based upon one high-quality RCT showing efficacy and one moderate-quality RCT interpreted as showing no benefit, Level III, or moderate, evidence supporting the use of intradiscal electrothermal therapy (IDET) in treating chronic, refractory discogenic pain was identified. The evidence supporting the use of discTRODE is level V or limited. This systematic review is limited by the low number of RCTs that met the inclusion criteria, small sample size, and the lack of clarity on the statistical significance of the findings. The Freeman et al. (2005) study previously summarized in this policy was included in this systematic review.

Desai et al. (2017) reported 12 month outcomes on the subjects treated in the Desai et al. (2016) study cited below, including the participants who were allowed to cross-over to the surgery arm of the original RCT after six months of conservative treatment. Study eligibility was restricted to patients with single level discogenic pain. The VAS mean baseline score was 6.7 and at 12 months the mean score was 4.4. The SF36-PF mean baseline score was 48 and at 12 months 62. The authors concluded that pain reduction at 12 months was statistically significant and clinically meaningful

in the original IDB + CMM group compared to baseline. Limitations of this study included lack of comparison groups after the original six months of the study, lack of study subjects' blinding to the study arm within which they were randomized, and lack of sham intervention.

Desai et al. (2016, included in the Helm systematic review cited above) conducted a prospective, randomized, crossover; multicenter trial to evaluate comparative effectiveness of intradiscal biacuplasty (IDB) versus conventional medical management (CMM) in the treatment of lumbar discogenic pain. The primary outcome measure was the change in visual analog scale (VAS) after the initiation of each method from baseline to 6 months. Secondary outcome measures included treatment “responders” (the proportion of subjects with a two-point or 30% decrease in VAS scores), the short form (SF) 36-Physical Functioning (SF36-PF), ODI, Beck’s Depression Index (BDI), Patient Global Impression of Change (PGIC) and Quality of Life (QOL) Index (EQ-5D), and back pain related medication usage. CMM included physical therapy, pharmacological management, interventional procedures (lumbar epidural injections, sacroiliac joint injections, and facet interventions), and lifestyle changes such as behavioral therapy, weight loss, and acupuncture. Out of 67 randomized participants who had been treated with IDB and CMM for chronic LBP of discogenic origin, 63-underwent IDB + CMM (n = 29) or CMM-alone (n = 34). Six months following continuous CMM-alone treatment, participants in this study group were permitted to "cross-over" to IDB + CMM (n = 25) and followed for an additional 6 months. The six-month results showed in the IDB cohort, the mean VAS score reduction exceeded that in the CMM cohort (-2.4 vs. -0.56; p = 0.02), and the proportion of treatment responders was substantially greater (50% vs. 18%). Differences in secondary measures favored IDB. No differences in opioid utilization were, however, noted between groups. The authors concluded that the superior performance of IDB with respect to all study outcomes suggests that it is a more effective treatment for discogenic pain than CMM-alone. Randomized controlled trials (RCTs) with larger patient populations are required to validate these results. The findings are limited by a lack of comparison to a sham procedure and, consequently, a possible placebo effect of the invasive procedure, compared to CMM. The findings are also limited by a loss to follow up of more than 20% at six months, which could have introduced a bias, considering the relatively small initial sample size and a possible differential loss to follow up.

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

Zhang and colleagues (2016) investigated the safety and efficacy of PIRFT for the treatment of discogenic LBP. Twenty-three patients with LBP who were treated with single-level bipolar radiofrequency thermocoagulation (RFTC) were included in this case series. The patients were assessed before the procedure and at 1 week, 1 month, 3 months, 6 months, and 1 year after the procedure. The primary outcome included the VAS score and the ODI score. The secondary outcome included pain relief, reduction of analgesic dose, and patient satisfaction. VAS and ODI scores were reported as significantly decreased after bipolar RFTC treatment at all-time points of follow-up ($p < 0.05$). A notable change was also reported in all secondary measures, such as pain relief, reduction of analgesic dose, and patient satisfaction. Three patients experienced mild short-term post-dural puncture headache, but the symptom disappeared within 1 week. No serious complications, such as nerve injuries, discitis, and hematoma, or neurological sequelae occurred in any of the patients. The authors concluded that bipolar RFTC treatment can significantly reduce pain and improve the function of patients with discogenic LBP. Limitations of this study include lack of a control group and the small sample size.

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

In a prospective, parallel, gender stratified, double-blind placebo RCT, Kvarstein et al. (2009) evaluated the long-term effect and safety aspects of PIRFT with the discTRODE probe. A total of 20 patients with chronic LBP and a positive 1-level pressure-controlled provocation discography were randomized to either intra-annular PIRFT or intra-annular sham treatment. A blinded interim analysis was performed when 20 patients had been followed for six months. The six-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 two 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 the 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.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

In an ASIPP Interventional Pain Management guideline, the authors performed a systematic assessment of the literature and concluded that the evidence is limited to fair for intradiscal electrothermal therapy (Manchikanti et al., 2013).

International Society for the Advancement of Spine Surgery (ISASS)

In their 2025 updated review by Lorio et al. (2025) with recommendations and coverage criteria for bone-anchored annular defect closure following lumbar discectomy, ISASS stated that the current evidence for bone-anchored annular closure is derived from nine unique studies and 1,311 patients (annular closure device: n = 931; control: n = 380) and that eight meta-analyses or systematic reviews all concluded that bone-anchored annular closure reduces the risk for recurrent LDH and reoperation. ISASS concluded that this evidence indicates a positive benefit-risk ratio for lumbar discectomy patients with large annular defects based on significant reductions in symptomatic recurrent LDH and revision surgery in an at-risk population. Based on this evidence, ISASS reiterated its position that, in patients with symptomatic LDH with radiculopathy undergoing primary discectomy with large (≥ 6 mm wide) annular defects, bone-anchored annular closure may be used to sustain the treatment benefits of discectomy by reducing the risk of recurring LDH and the need for reoperation.

National Institute for Health and Care Excellence (NICE)

The NICE (2016a) 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.

The NICE (2016b) 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.

North American Spine Society (NASS)

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

U.S. Food and Drug Administration (FDA)

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

The Center for Biologics Evaluation and Research (CBER) regulates cellular therapy products, human gene therapy products, and certain devices related to cell and gene therapy. CBER uses both the Public Health Service Act and the Federal Food Drug and Cosmetic Act as enabling statutes for oversight. Cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including hematopoietic stem cells and adult and embryonic stem cells. Refer to the following website for further information: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products.
(Accessed August 21, 2025)

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 under the following product codes:

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

(Accessed August 21, 2025)

On February 8, 2019, the Barricaid® Annular Closure Device (Intrinsic Therapeutics, Inc.) received FDA premarket approval, and is indicated for reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated

intervertebral disc) at a single level between L4 and S1. Additional information can be found at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K201676. (Accessed August 21, 2025)

FDA approved electrosurgical cutting and coagulation devices and accessories can be found under product codes GEI, GXI, HRX, BSO and BSP at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 21, 2025)

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Policy History/Revision Information

Date	Summary of Changes
02/01/2026	**Applicable Codes** • Updated list of applicable CPT codes to reflect annual edits; added 63032 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS031KY.05

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, 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.

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