Discogenic Pain Treatment (for North Carolina Only)

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➲ Instructions for Use

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Related Policies

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

Application

This Medical Policy only applies to the state of North Carolina.

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 North Carolina 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 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 codefor primary procedure)

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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

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

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.

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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.

Wang et al. (2023) 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 7 RCTs and 8 observational studies which included a total of 2,161 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.

A Hayes Technology Assessment was conducted on 9 studies that met the inclusion criteria for implantation of an annular closure device (ACD) to close sizable defects (typically ≥ 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 6 weeks of conservative care, or they had contraindications to conservative treatment strategies (such as neurological deficits). It was concluded that overall, the quality of evidence evaluating the safety and efficacy of ACD is low quality. Only one study demonstrated good quality. Limitations of the individual studies included retrospective design, use of historical controls, small sample sizes, and insufficient follow-up time to determine the long-term outcomes. Additionally, it was noted that numerous studies involved overlapping authors and research groups, which may result in the analysis of duplicate patient data (Hayes 2023).

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 (SR) with meta-analysis of data from 2 randomized controlled trials (RCTs) and 2 nonrandomized comparison studies, it was determined the evidence is somewhat favorable. The studies included 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 2023).

Thomé et al. (2021) reported 5-year results on patients that received an annular closure with a bone-anchored implant (Barricaid) for lumbar disc herniation. Participants included in the study were aged between 21 and 75 years, had a single-level disc herniation between L1 and S1, had a large annular defect (4 to 6 mm tall and 6 to 10 mm wide), leg pain and failure of conservative treatment for at least 6 weeks prior to surgery. MRI confirmed disc herniation prior to surgery. 550 patients from 21 sites were randomized into two groups; the device group (n = 272) had lumbar microdiscectomy with the Barricaid device and the control group (n = 278) had lumbar microdiscectomy only. Patient reported outcomes included Oswestry Disability Index (ODI), leg pain, and quality of life. Patients were followed up at 6 weeks, 3 months, 6 months, and annually for 5 years. The authors found the addition of the Barricaid device during surgery lowered the patient's risk of recurrence and reoperation; when compared to other similar studies, these findings suggest promising long-term results. Limitations included lack of blinding contributed to performance bias, approximately 25% of participants lost to follow-up and inability to apply the results to patients with small annular defects.

In an ongoing prospective, randomized, multicenter study of 554 patients in 21 centers in Europe, a total of 276 patients were randomized to the annual closure device (ACD) group and 278 patients to the control group (CG) to demonstrate the superiority of the Barricaid device to a discectomy for primary lumbar disc herniation (Clinicaltrial.gov NCT01283438). Three-year results (Kienzler et al., 2019, included in the 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

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safety profile was similar between the two groups. Nada et al. (2019, also included in the 2020 ECRI and 2021 Hayes assessments) reported the four-year results on the risk of lumbar disc reherniation and reoperation rate for lumbar discectomy in patients with large annular defects following single level lumbar discectomy. Clinical follow-up occurred at 6 weeks, 3 months, 6 months, and annually for 4 years. The results showed the risk of reoperation was 14.4% for those who received the device, and 21.1% for the controls. The reoperation rate was not significantly affected by age, sex, body mass index, smoking status, level of herniation, leg pain or ODI scores. Additionally, the percentage of patients who achieved the minimal clinically important difference without a reoperation was proportionally higher in the ACD group compared to the control group for leg pain. The authors concluded that the addition of a bone anchored ACD reduces the risk of reoperation and provides better long-term pain and disability relief. The authors acknowledged that this trial has several limitations; only patients with large post-discectomy annular defects were included and there are additional patient characteristics that were crucial to achieving positive results and included adequate disc height and non-osteoporotic bone mineral density (BMD) of the lumbar spine. Additionally, the decision to re-operate involved shared decision-making between the patient and surgeon resulting in a potential for bias in the reported re-operation rates. In 2021, Kienzler et al. analyzed the data from this same trial to report the risk factors for early reherniation after lumbar discectomy with or without annual closure. The results showed four (1.5%) symptomatic reherniations in the ACG group and 18 (6.5%) in the control group. A significant correlation was found with recurrent herniation for disc degeneration, and a trend for current smoker status. In the control group, age ≥ 50 years and disc degeneration were predictive factors for reherniation. The authors concluded that these were predictive factors for early disc herniation after lumbar surgery and suggest that the ACD reduced the risk.

In a prospective RCT on sixty patients, Cho et al. (2019, included in the 2023 Hayes assessment above) compared the recurrence and re-operation outcomes for conventional lumbar discectomy (CLD) with that of a discectomy utilizing the Barricaid® annular closure device (ACD). The participants were aged 18 to 75 years and suffering from sciatica that was unresponsive to conservative treatment for at least 6 weeks; no restrictions were placed on defect height, size or width except as defined by the manufacturer's instructions for use. In the ACD group, a limited discectomy was followed by implantation of the Barricaid device. In the CLD group, patients received CLD alone. Study outcomes included patient-reported pain as measured with the visual analog scale (VAS), disability with the Oswestry Disability Index (ODI), and quality of life using the Medical Outcomes Study 12-item Short-Form health survey (SF-12) scale. Patients were assessed postoperatively at 1 week and again at 1, 3, 6, 12, and 24 months. The authors found that while both ACD and CLD groups showed positive results in scores for VAS, ODI and SF-12, no significant difference was found between the two groups themselves. It was concluded that the Barricaid® ACD was associated with excellent clinical scores and thus compelling evidence to support its use, however; limitations include small sample size, large loss to follow-up and lack of long-term outcomes.

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

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authors concluded that in patients with large annular defects following limited lumbar discectomy, additional implantation with a bone-anchored ACD reduces risk of postoperative complications despite a greater frequency of VEPC. VEPC were associated with higher risk of symptomatic reherniation in patients treated with limited lumbar discectomy, but not in those who received additional ACD implantation. Additional RCTs are needed to validate these findings.

Parker et al. (2016, included in both 2023 ECRI and 2023 Hayes assessments above) conducted a prospective cohort study to evaluate whether an annular closure device (Barricaid®) could be implanted safely to reduce same-level recurrent disk herniation, or attenuate disk height loss and improve the outcome after lumbar discectomy. Forty-six consecutive patients undergoing lumbar discectomy for single-level herniated disk at 2 institutions were followed prospectively with clinical and radiographic evaluations at 6 weeks, and 3, 6, 12, and 24 months (control cohort). A second consecutive cohort of 30 patients undergoing 31 lumbar discectomies with implantation of an annular closure device was followed similarly. Incidence of recurrent disk herniation, disk height loss, the leg and back pain VAS, and the ODI were assessed at each follow-up. By 2 years of follow-up, symptomatic recurrent same-level disk herniation occurred in 3 (6.5%) patients in the control cohort versus 0 (0%) patients in the annular repair cohort ($p = 0.27$). A trend of greater preservation of disk height was observed in the annular repair versus the control cohort 3 months (7.9 vs. 7.27 mm, $p = 0.08$), 6 months (7.81 vs. 7.18 mm, $p = 0.09$), and 12 months (7.63 vs. 6.9 mm, $p = 0.06$) postoperatively. The annular closure cohort reported less leg pain (VAS-LP: 5 vs. 16, $p < 0.01$), back pain (VAS-BP: 13 vs. 22, $p < 0.05$), and disability (ODI: 16 vs. 22, $p < 0.05$) 1 year postoperatively. The authors conclude that closure of annular defect after lumbar discectomy may help preserve the physiological disk function and prevent long-term disk height loss and associated back and leg pain. The study is limited by the lack of randomization between interventions, which could have introduced a bias. RCTs with larger patient populations and longer-term follow-up are needed to further evaluate Barricaid.

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 6 weeks and maintained over the course of study. There was a single symptomatic reherniation requiring surgical intervention within this series. According to the authors, limited lumbar diskectomy combined with the use of an annular 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.

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

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

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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)

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). 45 patients were divided into two separate groups; one group received the intervention for a duration of 7 minutes and the other group received the intervention for a duration of 15 minutes. The outcomes were measured using the Numeric Rating Scale (NRS-11) for pain and the Oswestry Disability Index (ODI). Data was collected at baseline, 2- and 6-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 7 or 15 minutes. The authors found both the ODI and NRS scores for the participants were lower at both the 2- and 6-week follow-up appointments. At 6 months, 12 of the 17 patients in the 7-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 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 Dallas discogram score (DDS) during discography, and the presence of a high intensity zone (HIZ) on magnetic resonance imaging (MRI) was noted. The primary outcome measure was assessment of back pain severity based on the VAS; function was assessed by the ODI. Follow-up examinations for ODI and VAS scores were assessed at 1-, 6-, and 12-months post-treatment. Outcomes were discussed with respect to morphological changes in intervertebral discs on discogram. There was an average 57.39% and 47.16% improvement in VAS and ODI scores, respectively, between pre-treatment 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 2 RCTs showing efficacy, with no negative trials, the authors identified Level I, or strong, evidence of the efficacy of biacuplasty in the treatment of chronic, refractory discogenic pain. Based upon one high-quality RCT showing efficacy and one moderate-quality RCT interpreted as showing no benefit, Level III, or moderate, evidence supporting the use of intradiscal electrothermal therapy (IDET) in treating chronic, refractory discogenic pain was identified. The evidence supporting the use of discTRODE is level V, or limited. This systematic review is limited by the low number of RCTs that met the inclusion criteria, small sample size, and the lack of clarity on the statistical significance of the findings.

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

Desai et al. (2016, included in the Helm systematic review cited above) conducted a prospective, randomized, crossover, multicenter trial to evaluate comparative effectiveness of intradiscal biacuplasty (IDB) versus conventional medical management (CMM) in the treatment of lumbar discogenic pain. The primary outcome measure was the change in visual analog scale (VAS) after the initiation of each method from baseline to 6 months. Secondary outcome measures included treatment "responders" (the proportion of subjects with a 2-point or 30% decrease in VAS scores), the short form (SF) 36-Physical Functioning (SF36-PF), Oswestry Disability Index (ODI), Beck's Depression Index (BDI), Patient Global Impression of Change (PGIC) and Quality of Life (QOL) Index (EQ-5D), and back pain related medication usage. CMM included physical therapy, pharmacological management, interventional procedures (lumbar epidural injections, sacroiliac

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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.

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

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.

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.

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,

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as well as lack of a comparator group. Additional studies are necessary to definitively evaluate the safety and efficacy of the L'DISQ device for treatment of lumbar discogenic pain.

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

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

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.

International Society for the Advancement of Spine Surgery (ISASS)

In a detailed review of the evidence by Lorio et al. (2019), the ISASS identifies scientific evidence that supports the use of bone-anchored annual closure devices in patients with large annular defects for treatment of LDH. Current "evidence demonstrates that, in appropriately selected patient populations, implantation of a bone-anchored ACD reduces the risk of symptom recurrence and revision surgery compared to discectomy alone.

North American Spine Society (NASS)

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

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

U.S. Food and Drug Administration (FDA)

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

The Center for Biologics Evaluation and Research (CBER) regulates cellular therapy products, human gene therapy products, and certain devices related to cell and gene therapy. CBER uses both the Public Health Service Act and the Federal Food Drug and Cosmetic Act as enabling statutes for oversight. Cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including 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 29, 2024)

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)

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- Product code: GAT (suture, nonabsorbable, synthetic, polyethylene)

(Accessed August 29, 2024)

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 27, 2024)

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 27, 2024)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2025	• Created state-specific policy version for the state of North Carolina (no change to coverage guidelines)
02/01/2025	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS031.R

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