

## ***Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty***

**Effective:** June 1, 2022

**Next Review:** February 2023

**Last Review:** April 2022

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are designed to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening of annular tissue.

### **MEDICAL POLICY CRITERIA**

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **not medically necessary**.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

1. [Artificial Intervertebral Disc](#), Surgery, Policy No. 127
2. [Decompression of Intervertebral Discs Using Laser Energy \(Laser Discectomy\) or Radiofrequency Energy \(Nucleoplasty\)](#); Surgery, Policy No. 131
3. [Automated Percutaneous Discectomy](#); Surgery, Policy No. 145

## BACKGROUND

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease. Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency (RF) energy into the disc. It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures and that pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

Some of the electrothermal intradiscal procedures are briefly described.

With the intradiscal electrothermal annuloplasty (IDEA) procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect RF energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90°C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with IDEA include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) uses direct application of RF energy. With PIRFT, the RF probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70°C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty involves use of two cooled RF electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that by cooling the probes a larger area may be treated than could occur with a regular needle probe.

Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

## REGULATORY STATUS

A variety of radiofrequency (RF) coagulation devices are cleared for marketing by the U.S. Food and Drug Administration (FDA), some of which are designed for disc nucleotomy. The following are examples of devices which have U.S. Food and Drug Administration's (FDA) 510(k) approval:

- IDET™, Oratec Nucleotomy Catheter
- SpineCATH™ Intradiscal Catheter
- Radionics RF Disc Catheter Electrode System (Radionics Inc./Tyco Healthcare)
- DiscTRODE™ RF catheter electrode system (Valleylab/Tyco Healthcare) for use with the RFG-3CPlus™ RF lesion generator (Radionics/Tyco Healthcare)

- TransDiscal™ System (Baylis Medical) for biacuplasty
- Pain Management Cooled Probe (Baylis Medical)
- Pain Management Generator-TD (Baylis Medical) with multi-radiofrequency (Multi-RF) mode for use in conjunction with FDA approved probes such as the TransDiscal probe or Baylis Pain Management Cooled Probe to create radiofrequency lesions in nervous tissue.
- Duocool Pain Management Probe (Baylis Medical)

Note: This policy does not address DISC nucleoplasty™, a technique based on a device offered by ArthroCare. With the ArthroCare system, a bipolar radiofrequency device is used to provide heat treatment (Coblation®) to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. DISC nucleoplasty is closer in concept to a laser discectomy, in that tissue is removed or ablated in an effort to provide decompression of a bulging disc. DISC nucleoplasty is considered in a separate medical policy (see Cross References above).

## EVIDENCE SUMMARY

The principal outcomes associated with treatment of pain due to any cause may include relief of pain and improved function. Relief of pain is a subjective outcome and can be influenced by nonspecific effects, placebo response, and the natural history of the disease. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for nonspecific effects and to determine whether any treatment effect from percutaneous annuloplasty provides a significant advantage over the placebo/sham treatment or other medical or surgical management. Therefore, evidence reviewed for this policy focuses on randomized controlled trials.

In the evaluation of the risks of intradiscal thermal annuloplasty techniques, observational studies can provide data on the likelihood of potential complications. The following adverse events related to these procedures have been reported:

- Catheter breakage or migration, possibly requiring surgical removal of catheter fragment
- Nerve root injury
- Disc herniation
- Discitis
- Osteonecrosis
- Development of Grade 1 anterolisthesis
- Cauda equina syndrome
- Possible permanent ablation of traversing motor roots with techniques using radiofrequency

## SYSTEMATIC REVIEWS

### Percutaneous Annuloplasty Procedures

A 2013 systematic review for the American Society of Interventional Pain Physicians (ASIPP) guidelines found limited to fair evidence for intradiscal electrothermal annuloplasty (IDET) and biacuplasty, and limited evidence for percutaneous intradiscal radiofrequency thermocoagulation (PIRFT):<sup>[1]</sup>

- Evidence related to IDET was rated limited to fair based on the evidence of 1 RCT with negative outcomes<sup>[2]</sup> that they considered to be flawed, 1 RCT with positive outcomes<sup>[3]</sup>, 4 positive observational studies<sup>[4-7]</sup>, and a retrospective review with indeterminate results.<sup>[8]</sup>

- The single study evaluating PIRFT showed no benefit from the procedure.<sup>[9]</sup> Therefore, the evidence was rated as limited (or poor).
- Evidence for the effectiveness of biacuplasty was rated as limited to fair based on 1 RCT that showed modest benefits.<sup>[10]</sup>

A 2012 systematic review of IDET and PIRFT identified three RCTs<sup>[2, 3, 9]</sup> and one observational study<sup>[8]</sup> that met their criteria.<sup>[11]</sup> Four nonrandomized controlled trials<sup>[12-15]</sup> were excluded from the review because they did not meet the minimum sample size criterion of 25 patients per group. The included evidence on the effectiveness of these procedures in relieving discogenic low back pain was found to be fair for IDET and poor for discTRODE and biacuplasty procedures. Two of the randomized studies evaluated IDET.<sup>[2, 3]</sup> The Pauza trial, summarized below, showed weak evidence of effectiveness.<sup>[3]</sup> The Freeman trial<sup>[2]</sup>, which reported no improvement in either the active or sham treatment group, was rejected for methodologic shortcomings. The single randomized trial with the discTRODE device was considered to be a high-quality study.<sup>[9]</sup> Recruitment was discontinued when blinded interim analysis of the first 20 patients showed no significant difference between active and sham treatment at 6 and 12 months. There were no high-quality studies that evaluated the efficacy of biacuplasty, although it was noted that this procedure is being investigated in two ongoing randomized controlled trials.

A number of systematic reviews of IDET and PIRFT were published between 2006 and 2009.<sup>[16-21]</sup> These reviews were also discussed in the 2012 systematic review summarized above. In general, conclusions varied between reviews, but most found no evidence to support a role for IDET or PIRFT. Those that did find supportive evidence included studies with significant methodologic limitations such as those without an appropriate control group.

## **RANDOMIZED CONTROLLED TRIALS**

### **Intradiscal Electrothermal Annuloplasty (IDET)**

No additional RCTs for IDET have been published since the above 2012 and 2013 systematic reviews.

In 2005, Freeman reported on an industry-sponsored, double-blinded, sham-controlled randomized trial evaluating IDEA (referred to as IDET in this report) in patients with chronic discogenic low back pain, marked functional disability, magnetic resonance imaging evidence of degenerative disc disease, and failure of conservative management.<sup>[2]</sup> Both the active IDEA and sham groups had an intradiscal catheter that was navigated to cover at least 75% of the posterior annulus. Planned enrollment based on power analysis was for 75 patients; however, the trial was stopped early due to slower than expected recruitment after 57 patients (38 IDEA, 19 placebo) had been enrolled. Follow-up was for 6 months, and the outcome measure was successful treatment response, as defined by all of the following: (1) no neurologic deficit; (2) an increase on the Low Back Outcome Score (LBOS) of at least seven points; and (3) improvements in the SF-36 physical functioning and bodily pain subscales scores of at least 1 SD. No subject in either group achieved a successful treatment response. Outcomes were similar between the IDET and sham groups on the LBOS (38.31 vs 37.45), ODI score (39.77 vs 41.58), SF-36 subscales score (35.10 vs 30.40), the Zung Depression Index score (41.39 vs 40.82), and the Modified Somatic Perception Questionnaire (8.67 vs 8.6), respectively. None of the subgroup analyses showed statistically or clinically significant differences in study outcomes. No serious adverse events were reported in either group.

In 2004, Pauz published the results of a RCT which was the focus of discussion in the 2003 TEC Assessment.<sup>[3]</sup> The trial included 64 patients with low back pain of more than six months in duration who were randomized to IDEA or to sham procedure. Visual analog scale (VAS) score for pain was reduced by an average of 2.4 cm in the IDEA group compared with 1.1 cm in the sham group, a significant difference between groups ( $p=0.045$ ). The mean change in the Oswestry Disability Index (ODI) score was also significantly greater for the IDEA group than for the sham group. The improvement on the 36-Item Short-Form Health Survey (SF-36) bodily pain subscale score was slightly higher for the IDEA group. The trial also reported the percent change in VAS score more than 2.0 cm, which is greater than the minimally clinically significant improvement of 1.8 to 1.9. When the VAS score was dichotomized in this way, a relative risk of 1.5 was observed with a 95% confidence interval of 0.82 to 2.74. While this single-center trial was well-designed with respect to randomization, clear description of intervention, and use of valid and reliable outcomes measures, it does not permit conclusions about the relative effects of IDEA and placebo, and it is unclear whether IDEA achieves clinically and statistically significant improvements in measures of pain, disability, and quality of life.

### **Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)**

No RCTs for PIRFT have been published since the above 2012 and 2013 systematic reviews.

### **Intradiscal Biacuplasty**

Kapural, Desai, and colleagues have published several studies on use of transdiscal radiofrequency annuloplasty using two transdiscal probes (biacuplasty) in patients with discogenic lower back pain, including a 2013 industry-sponsored, phase 1, double-blind RCT and a 2016 RCT.<sup>[10, 22-24]</sup>

In the phase 1 RCT by Kapural (2013), of 1894 patients screened, 1771 (94%) did not meet inclusion criteria.<sup>[10]</sup> Sixty-four subjects consented and were enrolled in the study. Outcome measures were the SF-36 physical functioning subscale (0-100), a numeric rating scale (NRS) for pain (0-10), and the ODI (0-100). There were no significant differences between the groups at one month or three months. At six months, the biacuplasty group showed a significantly greater change from baseline for the SF-36 (15.0 vs 2.63), NRS (-2.19 vs -0.64), and ODI (-7.43 vs 0.53) scores. Mean SF-36 and NRS scores were considered to be clinically significant, but mean ODI scores did not achieve the minimally important difference of 10 points. With clinical success defined post hoc as a 15-point increase in physical function together with a greater-than-2-point decrease in pain, 30% of biacuplasty patients and 3% of sham-treated patients were considered successful. There was no significant difference in opioid use between groups.

In 2015, Kapural reported unblinded 12-month follow-up from this phase 1 trial.<sup>[24]</sup> Improvements continued through 12 months, with a change from baseline to posttreatment of 47.0 to 68.9 (of 100) on the SF-36 physical functioning subscale ( $p<0.01$ ) and 7.1 to 4.4 (of 10) on the NRS ( $p<0.01$ ). Although the change in NRS score was statistically significant, the magnitude of the decrease was modest and a final NRS score (4.4) remained high. The change in ODI score (from 40.37 at baseline to 32.44 at 12 months) was also modest ( $p=0.05$ ). Opioid usage did not decrease significantly (53.47 mg at baseline to 34.07 mg at follow-up,  $p=0.23$ ).

In the 2016 RCT by Desai, 63 patients with lumbar discogenic pain diagnosed by provocation discography were randomized to intradiscal biacuplasty plus conservative medical management (n=29) or medical management alone (n=34).<sup>[23]</sup> Another 234 patients were scheduled for diagnostic discography but did not meet inclusion criteria. The primary outcome (the mean reduction in VAS score for pain at 6 months) was significantly greater in the biacuplasty group (-2.4) than in the medical management group (-0.56; p=0.02). The secondary outcomes were not statistically significant, which included the proportion of responders, defined as a 2-point or 30% decrease in VAS scores, which was achieved in 50% of the biacuplasty group compared to 18% of controls (p=0.073). Investigators did not report whether the trial was adequately powered. Another limitation of this industry-sponsored trial was the lack of a sham control and patient blinding, which could contribute to a placebo effect in the subjective pain outcomes.

Of the 29 patients originally randomized to intradiscal biacuplasty, 22 (76%) were available for 12-month follow-up.<sup>[22]</sup> Mean 12-month change in VAS score was -2.2 (from 6.7 at baseline to 4.4 at 12 months, p=0.001). After six months, patients randomized to medical management were allowed to receive intradiscal biacuplasty and were followed for another six months; 25 of 34 patients crossed over. VAS score improved from 7.0 to 4.7 (p<0.001) in the crossover group, and 55% were considered to be responders.

## PRACTICE GUIDELINE SUMMARY

### **AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS (ASIPP)<sup>[1]</sup>**

As noted above, the 2013 systematic review conducted for the ASIPP rated the evidence as limited (or poor) to fair for IDET and biacuplasty, and limited for PIRFT. Despite these lower levels of evidence, the updated guideline recommendations were that IDET and biacuplasty may be performed in a select group of patient with discogenic pain nonresponsive to conservative modalities including epidural injections.

### **AMERICAN PAIN SOCIETY<sup>[25]</sup>**

A 2009 evidence-based practice guideline from the American Pain Society stated that, “There is insufficient evidence to adequately evaluate benefits of ...intradiscal electrothermal therapy...for nonradicular low back pain.”

### **AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) AND THE AMERICAN SOCIETY OF REGIONAL ANESTHESIA AND PAIN MEDICINE (ASRA)<sup>[26]</sup>**

A 2010 joint guideline recommended that IDET “be considered for young active patients with early single-level degenerative disc disease with well-maintained disc height.” However, there was disagreement between consultants, ASA members, and ASRA members on this recommendation. The brief analysis of current data in the guideline noted two sham-controlled RCTs that found no significant difference for either pain or functional outcomes between sham and active IDET. Also noted were nonrandomized, noncomparative observational trials that reported improved symptoms in the short term (6-12 months) compared with baseline. As noted previously, data from nonrandomized trials with no sham control group are unreliable because they do not control for any placebo effect. The guideline concluded that there is insufficient evidence to establish the efficacy of percutaneous thermal intradiscal procedures other than IDET.

## SUMMARY

The high-quality research for intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), and intradiscal biacuplasty (IDB) techniques have showed no significant improvements compared to no treatment or other treatments. The research that demonstrated an improvement in pain had significant limitations. Based on the high-quality research, these procedures do not result in improved health outcomes compared with sham treatment. Although, practice guidelines recommend the use of IDET and IDB in certain clinical scenarios, they acknowledge that there are significant limitations to the research. Therefore, IDET, PIRFT, and IDB are considered not medically necessary for all indications.

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## CODES

<b>Codes</b>	<b>Number</b>	<b>Description</b>
CPT	22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
	22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels (list separately in addition to code for primary procedure)
	22899	Unlisted procedure, spine
HCPCS	C1754	Catheter, intradiscal

*Date of Origin: March 1999*