
Medical Policy



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***Current Policy Effective Date: 7/1/26**
(See policy history boxes for previous effective dates)

Title: Spinal Surgery: Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

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 annular tissue.

Medical Policy Statement

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, and intradiscal biacuplasty) for the treatment of chronic discogenic back pain is experimental/investigational. The evidence is insufficient to determine the effects of the technology on health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

22526

22527

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.

Treatment

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.

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 radiofrequency energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90 degrees centigrade; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of radiofrequency energy with IDEA include precise temperature feedback and control, and the ability to provide electro thermocoagulation 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 degrees centigrade. 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 the 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 or PELA) has also been described as a treatment option for discogenic low back pain.

SUMMARY OF EVIDENCE

For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, radiofrequency annuloplasty, or biacuplasty, the evidence includes a small number of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 2 RCTs on intradiscal electrothermal annuloplasty have conflicting results, with 1 reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. Further study in a sham-controlled trial with a representative population of patients is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have discogenic back pain who receive intradiscal radiofrequency annuloplasty, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Neither RCT found evidence of benefit with the treatment. More sham-controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have discogenic back pain who receive intradiscal biacuplasty, the evidence includes 2 industry-sponsored RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One trial reported significant improvements at 6 months posttreatment, but not at 1 and 3 months. The other trial also showed a significant reduction in VAS scores at 6 months that appeared to continue to the 12-month follow-up; however, it is unclear whether this trial was sufficiently powered. The evidence is insufficient to determine the effects of the technology on health outcomes.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

Intradiscal Electrothermal Annuloplasty

Clinical Context and Therapy Purpose

The purpose of percutaneous intradiscal electrothermal annuloplasty (IDEA) in individuals who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Review of Evidence

Randomized Controlled Trials

Pauza et al (2004)³ published the results of an RCT evaluating IDEA (referred to as intradiscal electrothermal therapy [IDET] in this report) which was the focus of discussion in the 2003 TEC Assessment. The trial included 64 patients with low back pain of greater than 6 months'

duration who were randomly assigned to IDEA or to a sham procedure. Visual analogue scale (VAS) 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 Scale (ODS) was also significantly greater for the IDEA group compared with the sham group. The improvement on the Short Form Health Survey (SF)-36 bodily pain subscale score was slightly higher for the IDEA group. The trial also reported the percentage with a change in VAS score more than 2.0 cm, which is greater than the minimally clinically significant improvement of 1.8–1.9. When the VAS is dichotomized in this way, a relative risk of 1.5 is observed with a 95% confidence interval of 0.82–2.74. 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. The study did not conduct intent-to-treat analysis, and it is unclear whether IDEA achieves clinically and statistically significant improvements in measures of pain, disability, and quality of life.

In 2005, Freeman et al 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 (MRI) evidence of degenerative disc disease, and failure of conservative management.⁴ 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 7 points; and 3) improvements in the SF-36 physical functioning and bodily pain scales of at least 1 standard deviation. The authors reported that IDET™ was no more effective than sham stimulation on any of the outcomes. Outcomes were similar between the IDET and sham groups on the LBOS (38.31 vs. 37.45), the ODI (39.77 vs. 41.58), the SF-36 subscales (35.10 vs. 30.40), the Zung Depression Index (ZDI, 41.39 vs. 40.82), and the Modified Somatic Perception Questionnaire (MSPQ, 8.67 vs. 8.67, IDET vs. sham, all respectively). None of the sub-group analyses showed statistically or clinically significant differences in the study outcomes. No serious adverse events were reported in either group.

Section Summary: Intradiscal Electrothermal Annuloplasty

Two RCTs on IDEA have reported conflicting results, with one finding a benefit for IDEA and the other no benefit. The most recent RCT identified was from 2005. No recent literature on IDEA has been identified.

Percutaneous Intradiscal Radiofrequency Annuloplasty

Clinical Context and Therapy Purpose

The purpose of percutaneous intradiscal radiofrequency annuloplasty in individuals who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Review of Evidence

Randomized Controlled Trials

There is relatively little published data on PIRFT. In 2001, Barendse et al reported on a double-blind trial that randomly assigned 28 patients with chronic low back pain to undergo PIRFT or to a sham control group.⁵ The primary outcome was the percentage of success at 8 weeks, as measured by changes in pain level, impairment, ODS, and analgesics taken. At the end of 8 weeks, there were 2 treatment successes in the sham group compared to one in the treatment group. The authors concluded that PIRFT was not better than the placebo procedure in reducing pain and disability.

In 2009, Kvarstein et al published 12-month follow-up from an RCT of intra-annular radiofrequency thermal disc therapy using the discTRODE™ probe.⁶ Recruitment was discontinued when blinded interim analysis of the first 20 patients showed no trend toward overall effect or difference in pain intensity between active and sham treatment at 6 months. At 12 months, there was a reduction from baseline pain but no significant difference between the 2 groups. Two patients from each group reported an increase in pain.

Section Summary: Percutaneous Intradiscal Radiofrequency Annuloplasty

Two sham-controlled RCTs showed no evidence of a benefit with PIRFT. One study found that only 1 of 14 patients was considered a treatment success. The other was terminated after blinded interim analysis showed no trend to benefit compared to sham.

Intradiscal Radiofrequency Biacuplasty

Clinical Context and Therapy Purpose

The purpose of intradiscal radiofrequency biacuplasty in individuals who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Review of Evidence

Randomized Controlled Trials

Kapural et al (2013), Desai et al (2016) and colleagues have published several articles on the use of transdiscal radiofrequency annuloplasty using 2 transdiscal probes (biacuplasty), including a 2013 industry-sponsored small Phase I double-blind RCT and a 2016 RCT.⁷⁻¹⁰

In the phase 1 RCT by Kapural et al (2013), of 1,894 patients who were screened, 1,771 (94%) did not meet inclusion criteria.⁷ Sixty-four subjects were consented and enrolled in the study. Outcome measures were the SF-36 physical functioning subscore (0-100), the numerical rating scale (NRS) for pain (0-10), and the ODI (0-100). There were no significant differences between the groups at 1 month or 3 months. At 6 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). 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 the 2 groups.

In 2015 Kapural et al reported unblinded 12-month follow-up from this phase 1 trial.⁸ Improvements continued through 12 months, with a change from baseline to post treatment 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 of 4.4 remains 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 was not significantly decreased (53.47 mg at baseline to 34.07 mg at follow-up, $p=0.23$).

In the 2016 RCT by Desai et al, 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 ($n=34$).⁹ 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.¹⁰ 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 6 months, patients randomized to medical management were allowed to receive intradiscal biacuplasty and were followed for another 6 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.

Section Summary: Intradiscal Radiofrequency Biacuplasty

Two industry-sponsored RCTs have assessed the use of biacuplasty to treat chronic low back pain. In 1 report, only 6% of the subjects screened met the strict inclusion and exclusion criteria for the study. Significant differences in outcomes were observed at 6 months, but not at 1 month or 3 months, and the definition of successful treatment appears to be post hoc. In the second multicenter RCT, 63 patients met inclusion criteria, which included a positive result on provocation discography. There was a significant effect of treatment for the primary outcome measure, but not the secondary outcome measures. This trial was not sham-controlled, and it was not reported if it was adequately powered. Additional sham-controlled trials in a broader population of patients are needed to determine the effect of this treatment with greater certainty.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Society of Interventional Pain Physicians (ASIPP)

A 2013 review of the evidence for American Society of Interventional Pain Physicians guidelines found limited to fair evidence for intradiscal electrothermal annuloplasty (IDET; another term for intradiscal electrothermal annuloplasty) and biacuplasty and limited evidence for percutaneous intradiscal radiofrequency thermocoagulation (PIRFT).¹³ This update of 2007

guidelines concluded that the evidence is moderate for management of chronic discogenic low back pain with IDET. Complications include catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage. The evidence for radiofrequency posterior annuloplasty (PIRFT) was reported to be limited, with complications similar to IDET.¹⁴

National Institute for Health and Care Excellence (NICE)

A National Institute for Health and Care Excellence guidance, updated in 2016, indicated that the evidence on safety and efficacy of PIRFT for low back pain was “limited” and should only be used by “special arrangement”.¹⁵

The NICE guidance on electrothermal annuloplasty was also updated in 2016.¹⁶ NICE considered evidence on the efficacy of PIRFT for low back pain to be inconsistent and of poor quality, although no major safety concerns were identified. NICE recommended PIRFT only with special arrangements for clinical governance, and audit or research.

International Society for the Advancement of Spine Surgery

In 2022, the International Society for the Advancement of Spine Surgery published updated guidelines on intraosseous basivertebral nerve ablation.¹⁷ The guideline was informed by a systematic review which included 2 randomized controlled trials (RCTs) and additional single-arm studies. The guideline authors concluded that intraosseous ablation of the basivertebral nerve from the L3 through S1 vertebrae may be considered medically indicated for individuals with chronic low back pain when all the following criteria are met:

- Chronic low back pain of at least 6 months duration.
- Failure to respond to at least 6 months of nonsurgical management.
- Magnetic resonance imaging-demonstrated MC1 or MC2 in at least 1 vertebral endplate at 1 or more levels from L3 to S1. (*Endplate changes, inflammation, edema, disruption, and/or fissuring.)
- Fibrovascular bone marrow changes (hypointense signal for Modic type 1).
- Fatty bone marrow changes (hyperintense signal for Modic type 2).

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov did not identify any ongoing or unpublished trials that would likely influence this review.

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. In 2002, the Oratec Nucleotomy Catheter (ORATEC Interventions, Menlo Park, CA, acquired by Smith & Nephew in 2002) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. Radionics (a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance through FDA’s 510(k) process in 2000. FDA product code: GEI.

In 2005, the Baylis Pain Management Cooled Probe was cleared for marketing by the FDA through the 510(k) process. It is intended for use “in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue.” FDA product code: GXI

Note: This policy does not address disc nucleoplasty, a technique based on the bipolar RF device (Coblation®; ArthroCare, Austin, treatment, acquired by Smith and Nephew, 2014). With the coblation system, a bipolar RF device is used to provide lower energy treatment (Coblation®) to the intervertebral disc, which is designed to provide lower energy treatment to the intervertebral disc, which 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 and laser discectomy are considered separately in another policy.

Government Regulations

National:

National Coverage Determination, 150.11, publishing number 100-3, effective 9/29/2008.

The Centers for Medicare and Medicaid Services has determined that thermal intradiscal procedures (TIPS), including Intradiscal electrothermal therapy (IDET) and percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) “are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, which include procedures that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered.”¹⁸

Local:

There is no WPS local policy determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Spinal Surgery: Automated Percutaneous and Endoscopic Discectomy
 - Spinal Surgery: Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD, MELD) for Lumbar Stenosis
 - Spinal Surgery: Percutaneous Disc Decompression Using Laser Energy (Laser Discectomy) or Radiofrequency Ablation (DISC Nucleoplasty™)
 - Radiofrequency Ablation of Basivertebral Nerve for Low Back Pain (i.e., Intrasept)
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References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/31/02	7/31/02	8/9/02	Joint medical policy established
5/14/04	5/14/04	5/27/04	Scheduled review of non-covered procedure; updated resources
11/23/04	11/23/04	11/23/04	Updated coding (effective 7/1/04); deleted previous S codes.
1/1/07	11/1/06	11/13/06	Routine maintenance
11/1/08	8/19/08	10/30/08	Code changes; Deleted 0062T, 0063T, Added 22526, 22527
11/1/09	8/18/09	8/18/09	Updated Medicare non-coverage. Effective 3/1/12, this policy is consolidated into another policy, "Spinal Surgery-Percutaneous, Endoscopic, Laser and/or Radiofrequency Decompression"
3/1/12	12/13/11	12/21/11	Refer to joint policy, "Spinal Surgery-Percutaneous, Endoscopic, Laser and/or Radiofrequency Decompression"
11/1/13	8/22/13	8/27/13	IDET policy split back out from consolidated spinal surgery policy to mirror BCBSA policy.
5/1/15	2/17/15	2/27/15	Routine update of non-established procedure. No change in policy status.
7/1/16	4/19/16	4/19/16	Routine policy maintenance no change in policy status.
7/1/17	4/18/17	4/18/17	Routine maintenance. Policy title changed to mirror BCBSA title. No change in policy status.
7/1/18	4/17/18	4/17/18	Routine policy maintenance, no change in policy status.
7/1/19	4/16/19		Routine policy maintenance, no change in policy status.
7/1/20	4/14/20		Routine policy maintenance, no change in policy status.
7/1/21	4/20/21		Routine policy maintenance, no change in policy status.

7/1/22	4/19/22		Routine policy maintenance, no change in policy status.
7/1/23	4/18/23		Routine policy maintenance, no change in policy status. Vendor Managed-Turning Point OR-1039 (ds)
7/1/24	4/16/24		Updated rationale, added references 11-17 & 21. Vendor managed: Turning Point OR-1039. (ds)
7/1/25	4/15/25		Routine policy maintenance, no change in status. Vendor managed: Turning Point OR-1039. (ds)
7/1/26	4/21/26		Rationale updated several references removed, removed all sections related to Intracept, no change in policy status. Turning Point OR-1039. (ds)

Next Review Date: 2nd Qtr. 2027

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SPINAL SURGERY: PERCUTANEOUS INTRADISCAL ELECTROTHERMAL (IDET)
ANNULOPLASTY AND RADIOFREQUENCY ANNULOPLASTY, BIACUPLASTY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.