Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 01/17/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) is addressed separately in medical policy 00087.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty (IDEA), intradiscal radiofrequency (RF) annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain to be **investigational.***

Background/Overview

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 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 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.

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Intradiscal biacuplasty involves use of 2 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A variety of RF coagulation devices are cleared for marketing by the U.S. 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. 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 FDA through the 510(k) process. It is intended for use "in conjunction with the Radio Frequency Generator to create RF lesions in nervous tissue." FDA product code: GXI.

Note: This evidence review does not address disc nucleoplasty, a technique based on the bipolar RF device (Coblation®‡; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar RF device is used to provide lower energy treatment 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 and laser discectomy are considered separately in medical policy 00087.

Centers for Medicare and Medicaid Services (CMS)

The Centers for Medicare and Medicaid Services has determined that thermal intradiscal procedures (TIPs), including IDET and PIRFT, "are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs, which include procedures that employ the use of a RF 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."

Rationale/Source

As with any therapy for pain, a placebo effect is anticipated, and thus randomized placebo-controlled trials are necessary to investigate the extent of the placebo effect and to determine whether any improvement with annuloplasty exceeds that associated with a placebo. Therefore, evidence reviewed for this review focuses on randomized controlled trials (RCTs).

INTRADISCAL ELECTROTHERMAL PROCEDURES

A 2013 review of the evidence for American Society of Interventional Pain Physicians guidelines found limited to fair evidence for IDEA and biacuplasty, and limited evidence for PIRFT. Based on the evidence of 1 positive randomized trial (Pauza et al [2004]), and 4 positive observational studies that met inclusion criteria, and a negative randomized trial that reviewers considered flawed (Freeman et al [2005]) and a negative observational study, reviewers concluded that the evidence for IDEA was fair. They identified 1 randomized trial (Kapural et al [2013, 2015]) for biacuplasty that showed modest benefits. The single study evaluating PIRFT (Kvarstein et al [2009]) (all described below) showed no benefit from the procedure.

INTRADISCAL ELECTROTHERMAL ANNULOPLASTY

Pauza et al (2004) published the results of an RCT evaluating IDEA (referred to as IDET in this report) in patients with discogenic low back pain, which was the focus of discussion in the 2003 TEC Assessment. The trial included 64 patients with low back pain of more than 6 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.

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 evidence of degenerative disc disease, and failure of conservative management. 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 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.

Section Summary: Intradiscal Electrothermal Annuloplasty
The 2 RCTs on IDEA reported conflicting results, with 1 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
There is relatively little published data on PIRFT. In 2001, Barendse et al reported on a double-blind trial that randomized 28 patients with chronic low back pain to PIRFT or to a sham control group. The primary outcome was the percentage of success at 8 weeks, as measured by changes in pain level, impairment, ODI scores, and analgesics taken. At the end of 8 weeks, there were 2 treatment successes in the sham group and 1 in the treatment group. Trialists concluded that PIRFT was no better than placebo in reducing pain and disability.

In 2009, Kvarstein et al published 12-month follow-up from an RCT of intra-annular RF thermal disc therapy using the discTRODE probe. 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
Kapural, Desai, and colleagues have published several studies on use of transdiscal RF annuloplasty using 2 transdiscal probes (biacuplasty) in patients with discogenic lower back pain, including a 2013 industry-sponsored, phase 1, double-blind RCT and a 2016 RCT.

In the phase 1 RCT by Kapural et al (2013), of 1894 patients screened, 1771 (94%) did not meet inclusion criteria. 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 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) 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 et el reported unblinded 12-month follow-up from this phase 1 trial. 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 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). 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. 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 Biacuplasty
Two industry-sponsored RCTs have assessed use of biacuplasty to treat chronic low back pain. In 1 report, only 6% of 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 have been 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.

SUMMARY OF EVIDENCE
For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, RF annuloplasty, or biacuplasty, the evidence includes a small number of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 2 RCTs on IDEA have conflicting results, with 1 reporting benefit for IDEA and the other reporting no benefit. There is a lack of evidence to support a role for RF annuloplasty with either a single or a double (biacuplasty) probe. One sham-controlled RCT on biacuplasty has suggested that this procedure may provide modest benefit in highly select patients; confirmation of these results in a broader population is needed. 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.

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Policy History

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10/18/2001	Medical Policy Committee review
11/12/2001	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy
10/21/2003	Medical Policy Committee review. Format revision. No substance change to policy
01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review. Name of policy changed from IDET (Intradiscal Electrothermal Therapy) to Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation. Policy changed to investigational status. This

	change reflects lack of supporting clinical evidence that IDET achieves clinically and statistically significant improvements in measures of pain, disability and quality of life.
01/31/2005	Managed Care Advisory Council approval
	06/06/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
01/10/2007	Medical Director review
01/17/2007	Medical Policy Committee approval
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. Title changed from “Percutaneous Intradiscal Electrothermal Annuloplasty (IDET™) and Percutaneous Intradiscal Radiofrequency Thermoregulation” to “Percutaneous Intradiscal Electrothermal Annuloplasty (IDET™) and Percutaneous Intradiscal Radiofrequency Annuloplasty”. No change to coverage eligibility.
01/07/2010	Medical Director review
01/20/2010	Medical Policy Committee approval. No change to coverage. Coding revision.
01/06/2011	Medical Director review
01/19/2011	Medical Policy Committee approval. No change to coverage.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/08/2015	Medical Policy Committee review
01/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Title changed from “Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty” to “Percutaneous intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty.” Policy statement terminology revised to reflect the changes in the title. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2019

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	22526, 22527, 22899
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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