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Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

Policy # 00077

Original Effective Date: 11/21/2001

Current Effective Date: 01/15/2014

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.

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 [IDET™]‡ annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation [PIRFT], or intradiscal biacuplasty) for the treatment of chronic discogenic back pain to be **investigational**.*

Background/Overview

Intradiscal annuloplasty therapies use energy sources to thermally treat discogenic low back pain arising from annular tears. Thermal annuloplasty techniques are designed to decrease pain arising from the annulus and enhance its structural integrity.

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 IDET annuloplasty procedure (Oratec SpineCath System), a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. The catheter is then snaked through the disc circuitously to return posteriorly. Using indirect radiofrequency (RF) 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 RF energy with IDET 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.

Another procedure, referred to as 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.

A more recently developed annuloplasty procedure, referred to as intradiscal biacuplasty (Baylis Medical, Inc., Montreal, Canada) 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 (LASE) kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty or PELA) has also been described.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

IDET, Oratec Nucleotomy Catheter, received marketing clearance through the FDA 510(k) process in 2002. The predicate device was the SpineCATH Intradiscal Catheter, which received FDA clearance for marketing in 1999. Radionics (Burlington, MA - a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance through the FDA's 510(k) process in 2000. Valleylab (Boulder, CO - another division of Tyco Healthcare) is marketing the DiscTRODE™[‡] RF catheter electrode system for use with the RFG-3CPlus™[‡] RF lesion generator in the U.S.

The Baylis Pain Management Cooled Probe received marketing clearance through the FDA's 510(k) process in 2005. It is intended for use "in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue."

Note: This policy does not address DISC Nucleoplasty™[‡], a technique based on a device offered by ArthroCare (Austin, TX). With the ArthroCare system, a bipolar RF device is used to provide lower energy 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.

Centers for Medicare and Medicaid Services (CMS)

The CMS has determined that thermal intradiscal procedures, including IDET therapy and 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 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 policy focuses on randomized controlled trials (RCTs).

Systematic Reviews

A 2013 review of the evidence for American Society of Interventional Pain Physicians guidelines found limited to fair evidence for IDET annuloplasty and biacuplasty and limited evidence for PIRFT. Based on the evidence of 1 positive randomized trial (Pauza et al., described below) and 4 positive observational studies that met the inclusion criteria, and negative evidence from another randomized trial that they considered to be flawed (Freeman et al., described below) and an observational study, the review concluded that evidence for IDET is fair. They identified one randomized trial by Kapural for biacuplasty (described below) that showed modest benefits. The single study evaluating PIRFT (Kvarstein et al., described below) showed no benefit from the procedure.



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In 2007, a systematic review of IDET and PIRFT was published that followed the criteria recommended by the Cochrane Back Review Group. Four randomized and 2 nonrandomized studies, totaling 283 patients, were included in the review (the key studies are described below). The report concluded that the available evidence does not support the efficacy or effectiveness of IDET or PIRFT and that these procedures are associated with potentially serious side effects.

A 2012 systematic review by some of the same authors identified 3 RCTs and one observational study that met their criteria on thermal annular procedures. No new controlled trials were identified. The included evidence was found to be fair for IDET and poor for discTRODE and biacuplasty procedures regarding whether they are effective in relieving discogenic low back pain. Out of the 2 randomized studies that evaluated IDET, one showed weak evidence of effectiveness, and the other one, 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 that was included in the review was considered to be a high-quality study that showed lack of efficacy. There were no high-quality studies that evaluated the efficacy of biacuplasty, although it was noted that this procedure is being investigated in 2 ongoing RCTs.

A number of other systematic reviews that focused on related issues have come to various different conclusions about the efficacy of these procedures. Freeman and Mehdiian reported that the evidence for IDET was mixed and that the evidence showed that PIRFT was ineffective for discogenic back pain. Levin concluded that IDET was modestly effective for discogenic pain in carefully selected patients. Helm et al. concluded that the literature was limited, but supported that IDET led to significant benefit in approximately half of appropriately chosen patients and that there was minimal evidence for the efficacy of intradiscal biacuplasty.

An industry-funded meta-analysis and systematic review were published that support the use of IDET. However, the quality of the studies included in these reviews was poor; 14 of the 18 studies reviewed did not have appropriate controls.

Intradiscal Electrothermal Annuloplasty

Randomized Controlled Trials

Pauza and colleagues published the results of a randomized study, which was the focus of discussion in the 2003 Technology Evaluation Centers (TEC) Assessment. The study included 64 patients with low back pain of greater than 6 months' duration who were randomly assigned to receive either IDET™ or a sham procedure. Visual analogue scale (VAS) pain was reduced by an average of 2.4 cm in the IDET 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 IDET group compared with the sham group. The improvement on the Short Form (SF)-36 Bodily Pain subscale was nearly significantly higher for the IDET group. The study also reported the percentage with a change in VAS of 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 (CI) of 0.82–2.74. In summary, the Pauza et al. trial is well-designed with respect to randomization, clear description of intervention, and use of valid and reliable outcomes measures. However, this single-center

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trial does not permit conclusions about the relative effects of IDET and placebo, and it is unclear whether IDET achieves clinically and statistically significant improvements in measures of pain, disability, and quality of life.

An industry-sponsored double-blinded randomized sham-controlled trial was published by Freeman et al. in 2005. This trial enrolled patients with chronic discogenic low back pain, marked functional disability, magnetic resonance imaging (MRI) evidence of degenerative disc disease, and failure of conservative management. Both the active IDET 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 IDET, 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. No subject in either group achieved a successful treatment response, and 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 Oswestry Disability Index (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. There were no serious adverse events reported in either group.

Non-randomized Trials

In a controlled study by Kapural et al., comparison of 21 electrothermal IDET and 21 RF procedures found significant improvements in a majority of IDET patients but not in matched RF-treated patients at 1-year follow-up; the study did not have a placebo-control group.

Percutaneous Intradiscal Radiofrequency Thermocoagulation

There is relatively minimal published data on PIRFT. In 2001, Barendse and colleagues 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. 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 1 in the treatment group. The authors concluded that PIRFT was not better than the placebo procedure in reducing pain and disability.

In 2009, Kvarstein and colleagues published 12-month follow-up from an RCT of intra-annular RF thermal disc therapy using the discTRODE[®] probe from Radionics. 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. Although this controlled study did not find evidence for a benefit of PIRFT, it may not have been powered to detect a small or moderate effect of the procedure.

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Biacuplasty

Randomized Controlled Trials

Kapural and colleagues have published several articles on the use of transdiscal RF annuloplasty using 2 transdiscal probes (biacuplasty), including a 2013 industry-sponsored small Phase I double-blind RCT (NCT00750191). Out of 1,894 patients who were screened, 1,771 (94%) did not meet inclusion criteria. 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.

Observational Studies

In 2007; Kapural et al. published a case report biacuplasty, which they reported to be the first publication with this procedure. Aside from several publications from the group of Kapural and colleagues, 1 report from Turkey was identified with a case series of 15 patients treated with biacuplasty.

One RCT has been published on the use of biacuplasty to treat chronic low back pain. In this report, only 6% of the subjects screened met the strict inclusion/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. Additional study in a broader population of patients is needed to determine with greater certainty the effect of this treatment on health outcomes.

Ongoing Clinical Trials

A search of the online site ClinicalTrials.gov in 2013 identified one industry-sponsored study on biacuplasty.

- NCT01263054 is a manufacturer-sponsored Phase IV randomized, multi-center, open-label clinical trial comparing disc biacuplasty with the TransDiscal system versus medical management for discogenic lumbar back pain. The study was scheduled to begin in December 2010 with an estimated enrollment of 136 subjects. Final data collection for the primary outcome measure is expected in 2012, with study completion in 2013.

Summary

There is limited evidence on the efficacy of intradiscal thermal annuloplasty, consisting of a small number of RCTs and case series. The two RCTs on IDET annuloplasty report different results, with one reporting benefit for IDET and the other reporting no benefit. There is a lack of evidence to support a role for RF annuloplasty with a single probe. One recent RCT on biacuplasty suggests that this procedure may provide modest benefit in a proportion of highly selected patients; confirmation of these results in a broader population is needed. Overall, evidence is insufficient to conclude that these procedures improve health outcomes. Therefore, annuloplasty (i.e., IDET, PIRFT, and biacuplasty) is considered investigational.

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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-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	80.59

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

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01/20/2010	Medical Policy Committee approval. No change to coverage. Coding revision.
01/06/2011	Medical Director review
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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.
Next Scheduled Review Date:	01/2015

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- 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:
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