Name of Policy:  
Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Annuloplasty

Policy #:  041       Latest Review Date:  July 2014
Category: Surgical       Policy Grade:  A

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
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 intradiscal electrothermal annuloplasty procedure (IDET™, 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 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 IDET 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 radiofrequency needle.

Another procedure, referred to as percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), uses direct application of radiofrequency energy. With PIRFT, the radiofrequency 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 radiofrequency 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.

Policy:
Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best
medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:  
This policy is based in part on TEC Assessments from 2002 and 2003, with periodic updates of the literature using the MEDLINE database. The most recent literature search was performed through June 2014. 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).

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

In 2007, a systematic review of intradiscal electrothermal annuloplasty (IDET) and percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) was published that followed the criteria recommended by the Cochrane Back Review Group. Four randomized and two nonrandomized studies, totaling 283 patients, were included in the review (the key studies are described below).

A 2012 systematic review by some of the same authors identified three 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 two 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 two ongoing randomized controlled trials.

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 Mehdian 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 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 (IDET™)**

Pauza et al published the results of a randomized study, which was the focus of discussion in the 2003 TEC Assessment. The study included 64 patients with low back pain of greater than six 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 trial does not permit conclusions about the relative effects of IDET and placebo. The study did not conduct intent-to-treat analysis, 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 (RCT) 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 placebos) had been enrolled. Follow-up was for six 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 scales of at least one standard deviation. The authors reported that IDET™ was no more effective than sham stimulation on any of the outcomes. No subject in either group achieved a successful treatment response, as defined previously. There were no differences 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), or 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 differences in the study outcomes. There were no serious adverse events reported in either group.
In another controlled study, comparison of 21 electrothermal (IDET) and 21 radiofrequency procedures found significant improvements in a majority of IDET patients but not in matched radiofrequency-treated patients at one year follow-up; the study did not have a placebo-control group.

**Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)**
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 eight weeks, as measured by changes in pain level, impairment, ODS, and analgesics taken. At the end of eight weeks, there were two 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 and colleagues published 12-month follow-up from an RCT of intra-annular radiofrequency 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 six months. At 12 months, there was a reduction from baseline pain but no significant difference between the two 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.

**Biacuplasty**
One case report of transdiscal radiofrequency annuloplasty using two transdiscal probes (biacuplasty) was identified in 2007; the authors indicate this to be the first publication with this procedure. In 2010, investigators from Turkey published a case series of 15 patients treated with biacuplasty.

**Biacuplasty**
**Randomized Controlled Trials**
Kapural and colleagues have published several articles on the use of transdiscal radiofrequency annuloplasty using two 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 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). 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 two 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 two groups.
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 six months, but not at one month or three 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.

**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 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 radiofrequency 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.

**Practice Guidelines and Position Statements**

Evidence-based guidelines from the American Society of Interventional Pain Physicians 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.

The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) guidance, published in 2004, indicates that the current evidence on safety and efficacy of percutaneous intradiscal percutaneous radiofrequency thermocoagulation for lower back pain does not appear adequate to support its use.

NICE guidance on electrothermal annuloplasty was updated in 2009. NICE considers current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain to be inconsistent. NICE recommends that this procedure only be used with special arrangements for clinical governance, consent, and audit or research.

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

**Key Words:**

Intradiscal annuloplasty, annuloplasty, electrothermal annuloplasty, IDET, intradiscal electrothermal therapy, percutaneous intradiskal radiofrequency, PIRFT, Oratec SpineCath System, Radionics RF Disc Catheter System, disc biacuplasty, TransDiscal™ System, DiscTRODE™, radiofrequency posterior annuloplasty
Approved by Governing Bodies:
IDET™, Oratec Nucleotomy Catheter received marketing clearance through the U.S. Food and Drug Administration’s (FDA) 510(k) process in 2002. The predicate device was the SpineCATH Intradiscal Catheter, which received FDA clearance for marketing in 1999.

Radionics (a division of Tyco Healthcare group) RF Disc Catheter System received marketing clearance through the FDA’s 510(k) process in 2000. Valleylab, a 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.”

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
Health South contracts: Covered
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification/Pre-determination requirements: Not applicable.

Coding:
CPT code:
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

The following codes should not be used to report IDET:
CPT code:
62290 Injection procedure for diskography, each level: lumbar
62291 Injection procedure for diskography, each level: cervical
62292 Injection procedure for chemonucleolysis, including diskography, single or multiple levels, lumbar
64640 Destruction by neurolytic agent; peripheral nerve or branch
62288 Injection of substance other than anesthetic, antispasmodic, contrast, or neurolytic agents
72285 Diskography, cervical, radiological supervision and interpretation
72295 Diskography, lumbar, radiological supervision and interpretation
References:
5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intradiscal electrothermal therapy for chronic low back pain. TEC Assessments 2002; volume 17, Tab 11.
9. Cooper AR. Disc biacuplasty for treatment of axial discogenic low back pain – Initial case series. Pain Relief Clinic, Causeway Hospital, Coleraine, N Ireland, UK.
31. Saal J. and Saal J. Intradiscal electrothermal treatment for chronic discogenic low back pain: a prospective outcome study with minimum two-year follow-up, SOAR Physiatry Medical Group; Menlo Park, CA.
35. Swenson R. Lower back pain: differential diagnosis a reasonable clinical approach, Neurologic Clinics:17(1); 1999.

**Policy History:**
Medical Review Committee, January 1999
TEC, August 2000
Medical Policy Group, February 2002
Medical Review Committee, February 2002
Medical Review Committee, March 2002
Available for Comment April 15-May 29, 2002
Medical Policy Group, May 2003 (2)
Medical Review Committee, June 2003
Medical Policy Administration Committee, August 2003
Available for comment August 12-September 26, 2003
Medical Policy Group, January 2006 (2)
Medical Policy Group, January 2007 (2)
Medical Policy Group, July 2007 (1)
Medical Policy Administration Committee, July 2007
Available for comment July 27-September 10, 2007
Medical Policy Group, April 2008 (1)
Medical Policy Panel, April 2009
Medical Policy Group, July 2009 (2)
Medical Policy Panel, August 2010
Medical Policy Group, September 2010 (2)
Medical Policy Group, August 2011; Updated Key Points & References
Medical Policy Panel, July 2012
Medical Policy Group, July 2012 (2); Updated Key Points, Key Words, &References
Medical Policy Panel, July 2013
Medical Policy Group, July 2013 (2): 2013 Update to Key Points and References; no change in policy statement
Medical Policy Panel, July 2014
Medical Policy Group, July 2014 (4); Updated Key Points. No change to the policy statement at this time.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.