Medical Policy

BlueCross BlueShield of Kansas
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Title: Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

Professional
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DESCRIPTION

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.

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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 nocioceptors 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 electrothermocoagulation 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.

Regulatory Status

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 (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.

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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 radiofrequency 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.

POLICY

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **experimental / investigational**.

RATIONALE

This policy is based in part on TEC Assessments from 2002 and 2003, with periodic updates of the literature using the MEDLINE database. (1, 2) The most recent literature search was performed for the period of June 2011 through May 2012. 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).

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. (3) 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. (4) 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, (5, 6) 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. (7) 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 randomized controlled trials.

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A number of other systematic reviews that focused on related issues have come to various different conclusions about the efficacy of these procedures. (8-10) Freeman and Mehdian reported that the evidence for IDET was mixed and that the evidence showed that PIRFT was ineffective for discogenic back pain. (8) Levin concluded that IDET was modestly effective for discogenic pain in carefully selected patients. (9) 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. (10)

Intradiscal Electrothermal Annuloplasty (IDET™)

Pauza and colleagues published the results of a randomized study, (5) which was the focus of discussion in the 2003 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 authors stated that per-protocol analyses were conducted, which excluded data from 8 patients, 5 from the IDET group and 3 from the sham group. One patient died, 1 was lost to follow-up, 1 had unsatisfactory electrode placement, 1 had post-treatment bone fracture, and 2 had new injuries unrelated to low back pain and were excluded due to compensation claims or opioids. Besides failing to perform intent-to-treat analyses, there are additional concerns about statistical methods used by Pauza et al. (4) The report noted that the analysis of SF-36 Role Physical scores adjusted for differences at baseline, but whether the comparison used adjustment and statistical techniques was not specified. The technique for comparing group scores on continuous variables was described only as a t test, suggesting simple comparison of mean change at follow-up. More appropriate techniques for comparing changes between groups include analysis of covariance and repeated measure analysis of variance. The comparison of means on the VAS for pain and the ODS for disability do not readily reveal how often patients achieve a clinically significant improvement. Minimally significant improvement in VAS has been estimated at 1.8–1.9 cm, and by this estimate, the mean change in VAS of 2.4 cm for IDET would be considered clinically significant. However, a small number of extreme values can influence this measure. 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.

A second double-blinded randomized sham-controlled trial (RCT) was published by Freeman et al. in 2005. (6) 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. Planned enrollment 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

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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. 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, the Oswestry Disability Index (ODI), the SF-36 subscales, the Zung Depression Index (ZDI), or the Modified Somatic Perception Questionnaire (MSPQ). 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 1-year follow-up; the study did not have a placebo-control group. (11)

Evidence-based guidelines from the American Society of Interventional Pain Physicians in 2007 concluded that the evidence is moderate for management of chronic discogenic low back pain with IDET. (12) Complications include catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage.
An industry-funded meta-analysis and systematic review were published that support the use of IDET. (13, 14) However, the quality of the studies included in these reviews was poor; 14 of the 18 studies reviewed did not have appropriate controls.

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. (15) 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 and colleagues published 12-month follow-up from an RCT of intra-annular radiofrequency thermal disc therapy using the discTRODE™ probe from Radionics. (7) 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.

Evidence-based guidelines from the American Society of Interventional Pain Physicians in 2007 found the evidence for radiofrequency posterior annuloplasty (PIRFT) to be limited, with complications similar to IDET (catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage). (12)

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Biacuplasty

One case report of transdiscal radiofrequency annuloplasty using 2 transdiscal probes (biacuplasty) was identified in 2007; the authors indicate this to be the first publication with this procedure. (16) In 2010, investigators from Turkey published a case series of 15 patients treated with biacuplasty. (17) No published RCTs were identified.

Ongoing Clinical Trials

A search of the online site ClinicalTrials.gov in June 2012 identified two industry-sponsored studies on biacuplasty.

- NCT00750191 is a small Phase I randomized double-blind placebo-controlled trial of transdiscal radiofrequency annuloplasty using 2 transdiscal probes by the same principal investigator as in the 2007 report above. (16) The study is currently recruiting with an estimated enrollment of 64 subjects and completion expected in 2012.
- 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 report different results, with one reporting benefit for IDET and the other reporting no benefit. Systematic reviews of the available evidence have generally found limited to no evidence to support a role for radiofrequency annuloplasty or biacuplasty. This 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™. (12) 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. (18)

NICE guidance on electrothermal annuloplasty was updated in 2009. (19) 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.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral, including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)
62290	Injection procedure for discography, each level: lumbar
62291	Injection procedure for discography, each level: cervical or thoracic
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar
62310	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic
62311	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)
64640	Destruction by neurolytic agent; peripheral nerve or branch
64999	Unlisted procedure, nervous system
72285	Discography, cervical or thoracic, radiological supervision and interpretation
72295	Discography, lumbar, radiological supervision and interpretation

- Effective January 1, 2007, there are 2 CPT category I codes specific to this procedure: 22526 and 22527.

DIAGNOSIS

Experimental / Investigational for all diagnoses related to this policy.

REVISIONS

02-08-2010	The Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
12-01-2011	Description section updated
	Rationale section updated
	References updated
01-01-2012	In Coding section: ▪ Revised CPT code nomenclature: 62310, 62311

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11-06-2012	Rational section updated
	In Coding section: Revised CPT code nomenclature: 62292
	References updated

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