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Medical Policy Manual

Topic: Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION[1]

Intradiscal annuloplasty therapies are thermal annular procedures (TAPs) that use energy sources to thermally treat discogenic low back pain arising from annular tears and other forms of internal disc derangement. In contrast with disc nucleoplasty, which ablates disc material, 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 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. PIRFT may also be referred to radiofrequency posterior annuloplasty.

A more recently developed annuloplasty procedure, referred to as intradiscal biacuplasty (Baylis Medical, Inc.), 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.

Regulatory Status

The following have U.S. Food and Drug Administration's (FDA) 510(k) approval:

- IDET™, Oratec Nucleotomy Catheter
- SpineCATH ™ Intradiscal Catheter
- Radionics RF Disc Catheter Electrode System (Radionics Inc./Tyco Healthcare)
- DiscTRODE™ RF catheter electrode system (Valleylab/Tyco Healthcare) for use with the RFG-3CPlus™ RF lesion generator (Radionics/Tyco Healthcare)
- TransDiscal ™ System (Baylis Medical) for biacuplasty
- Pain Management Cooled Probe (Baylis Medical)
- Pain Management Generator-TD (Baylis) with multi-radiofrequency (Multi-RF) mode for use in conjunction with FDA approved probes such as the TransDiscal probe or Baylis Pain Management Cooled Probe to create radiofrequency lesions in nervous tissue.

Note: This policy does not address DISC nucleoplasty™, a technique based on a device offered by ArthroCare. With the ArthroCare system, a bipolar radiofrequency device is used to provide heat 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. DISC nucleoplasty is considered in a separate medical policy (see Cross References below). .

MEDICAL POLICY CRITERIA

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty and percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **not medically necessary**.

SCIENTIFIC BACKGROUND

The principal outcomes associated with treatment of pain due to any cause may include relief of pain and improved function. Relief of pain is a subjective outcome and can be influenced by nonspecific effects, placebo response, and the natural history of the disease. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for nonspecific effects and to determine whether any treatment effect from percutaneous annuloplasty provides a significant advantage over the placebo/sham treatment or other medical or surgical management. Therefore, evidence reviewed for this policy focuses on randomized controlled trials.

In the evaluation of the risks of intradiscal thermal annuloplasty techniques, observational studies can provide data on the likelihood of potential complications. The following adverse events related to these procedures have been reported:

- Catheter breakage or migration, possibly requiring surgical removal of catheter fragment
- Nerve root injury
- Disc herniation
- Discitis
- Osteonecrosis
- Development of Grade 1 anterolisthesis
- Cauda equina syndrome
- Possible permanent ablation of traversing motor roots with techniques using radiofrequency

Literature Appraisal

Technology Assessments and Systematic Reviews

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

BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessments published in 2002[2], and updated in 2003[3] concluded that the evidence, which consisted primarily of case series, did not permit conclusions as to whether IDET and PIRFT improved health outcomes or was as beneficial as established treatments. A number of systematic reviews of IDET and PIRFT were published between 2006 and 2009.[4-9] These reviews were discussed in the 2012 systematic review summarized below. In general, conclusions varied between reviews, but most found no evidence to support a role for IDET or PIRFT. Those that did find supportive evidence included studies with significant methodologic limitations such as those without an appropriate control group.

IDET, PIRFT, and Intradiscal Biacuplasty (IDB)

- A 2012 systematic review of IDET and PIRFT identified 3 RCTs[10-12] and one observational study[13] that met their criteria.[14] Four nonrandomized controlled trials[15-18] were excluded from the review because they did not meet the minimum sample size criterion of 25 patients per group. The included evidence on the effectiveness of these procedures in relieving discogenic low back pain was found to be fair for IDET and poor for discTRODE and biacuplasty procedures.
    - Two of the randomized studies evaluated IDET.[10,11] The Pauza et al. trial, summarized below, showed weak evidence of effectiveness.[10] The Freeman et al. trial[11], 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 was considered to be a high-quality study.[12] Recruitment was discontinued when blinded interim analysis of the first 20 patients showed no significant difference between active and sham treatment at 6 and 12 months..
    - 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.

The 2013 systematic review for the American Society of Interventional Pain Physicians (ASIPP) guidelines reached the following conclusions[19]:

- Evidence related to IDET was rated limited to fair based on the evidence of 1 RCT with negative outcomes[11] that they considered to be flawed, 1 RCT with positive outcomes[10], 4 positive observational studies[20-23], and a retrospective review with indeterminate results.[13]

- The single study evaluating PIRFT showed no benefit from the procedure.[12] Therefore, the evidence was rated as limited (or poor).
- Evidence for the effectiveness of biacuplasty was rated as limited to fair based on 1 RCT that showed modest benefits.[24]

Randomized Controlled Trials (RCTs)

Intradiscal Electrothermal Annuloplasty (IDET)

- No RCTs for IDET have been published since the above 2012 and 2013 systematic reviews.

- In 2003, Pauza and colleagues published the results of a RCT which was the focus of discussion in the 2003 TEC Assessment. [10] The study included 64 patients with low back pain of greater than 6 months' duration who were randomized 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 was also significantly greater for the IDET group compared with the sham group. The improvement on the 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. While the per-protocol analyses are consistent with the study question assessing the efficacy of IDET compared with sham treatment, intent-to-treat analysis, which includes all patients randomized, is the preferred method because it is less likely to introduce bias. The Pauza study did not appear to use this method of analysis.

  Besides failing to perform intent-to-treat analyses, there are additional concerns about statistical methods used by Pauza et al. Potential confounding should be assessed and necessary adjustments should be made. 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. It is also important to report an appropriate measure of effect with an index of the precision of estimation (i.e., the confidence interval). 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 of 0.82–2.74. Although these data suggest a higher relative probability of achieving a minimally clinically significant improvement for the IDET group, this estimation lacks precision and is not clinically significant.

  It is interesting to note that, although the sham procedure consisted only of insertion of a needle into the patient's back, 38% of patients in the sham group reported improvement in pain of greater than 20 points, 33% reported greater than 50% improvement, and one patient reported complete relief of pain. These results illustrate the importance of placebo-controlled trials of pain therapies. In uncontrolled trials of pain therapies, what appear to be reasonable or promising outcomes may be the result of no more than "having a procedure."

In summary, the Pauza trial is a well-designed trial with respect to randomization, clear description of intervention, and use of valid and reliable outcomes measures. However, this single center trial did not permit conclusions about the relative effects of IDET and placebo. The study did not conduct intent to treat analysis, and it was unclear whether IDET achieved clinically and statistically significant improvements in measures of pain, disability, and quality of life.

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

No RCTs for PIRFT have been published since the above 2012 and 2013 systematic reviews.

Intradiscal Biacuplasty

As noted in the 2013 systematic review for the ASIPP, data from only one RCT has been published for IDB. Kapural and colleagues reported the results of a 2013 small industry-sponsored Phase-I double-blind RCT comparing active with sham IDB.[24] Of the 64 patients enrolled, 59 were treated. 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 improvement from baseline for the SF-36 (15.0 vs. 2.63; p=0.029), NRS (-2.19 vs. -0.64; p=0.006) and ODI (-7.43 vs. 0.53; p=0.037). 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.

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians (ASIPP)[19]

As noted above, the 2013 systematic review conducted for the ASIPP rated the evidence as limited (or poor) to fair for IDET and biacuplasty, and limited for PIRFT. Despite these lower levels of evidence, the updated guideline recommendations were that IDET and biacuplasty may be performed in a select group of patient with discogenic pain nonresponsive to conservative modalities including epidural injections.

American Pain Society[25]

A 2009 evidence-based practice guideline from the American Pain Society stated that, “There is insufficient evidence to adequately evaluate benefits of …intradiscal electrothermal therapy…for nonradicular low back pain.”

American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Medicine (ASRA)[26]

- A 2010 joint guideline recommended that IDET “be considered for young active patients with early single-level degenerative disc disease with well-maintained disc height.” However, there was disagreement between consultants, ASA members, and ASRA members on this recommendation. The brief analysis of current data in the guideline noted two sham-controlled RCTs that found no significant difference for either pain or functional outcomes between sham and active IDET. Also noted were nonrandomized, noncomparative observational trials that reported improved symptoms in the short term (6-12 months) compared with baseline. As noted previously, data from nonrandomized trials with no sham control group are unreliable because they do not control for any placebo effect.
- The guideline concluded that there is insufficient evidence to establish the efficacy of percutaneous thermal

intradiscal procedures other than IDET.

Summary

The majority of the randomized controlled trials (RCT) for intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), and intradiscal biacuplasty (IDB) techniques have found no significant difference between treatment groups compared with placebo/sham groups. The few studies that demonstrated an improvement in pain were limited by a lack of a sham treatment group to control for nonspecific effects such placebo response. Due to the RCT evidence these procedures do not result in improved health outcomes compared with sham treatment, IDET, PIRFT, and IDB are considered not medically necessary.

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CROSS REFERENCES

Thermal Capsulorrhaphy as a Treatment of Joint Instability, Surgery, Policy No. 100

Artificial Intervertebral Disc, Surgery, Policy No. 127

Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Energy (Nucleoplasty); Surgery, Policy No. 131

Automated Percutaneous Discectomy; Surgery, Policy No. 145

Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176

CODES	NUMBER	DESCRIPTION
CPT	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
HCPCS	None	