
**Subject: Intradiscal Electrothermal
Therapy (IDET™)**
Number: 0039

Effective Date: 2/15/2005
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INSTRUCTIONS FOR USE

This Medical Necessity Guideline outlines the factors CareAllies considers in determining medical necessity for this indication. Please note, the terms of a participant's particular benefit plan document or summary plan description (SPD) may differ significantly from the standard upon which this Medical Necessity Guideline is based. For example, a participant's benefit plan document or SPD may contain a specific exclusion related to the topic addressed. In the event of a conflict, a participant's benefit plan document or SPD always supercedes the information in this Medical Necessity Guideline. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document or SPD. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document or SPD in effect on the date of service; 2) any applicable laws/regulations, and; 3) the specific facts of the particular situation. Medical Necessity Guidelines are not recommendations for treatment and should never be used as treatment guidelines. ©2007 Intracorp/CareAllies

Intradiscal electrothermal therapy (IDET™) is considered experimental, investigational or unproven and thus not medically necessary.

General Background

Intradiscal electrothermal therapy (IDET™), also known as intradiscal electrothermal annuloplasty, is a minimally invasive procedure that has been proposed as an alternative to spinal fusion for the treatment of chronic discogenic low back pain. Following a provocative discogram, IDET is performed by inserting a catheter into the annulus and threading a flexible electrode through the catheter and around the inside of the disc, pressing against the posterior edge of the annulus. The electrode is then heated to a temperature of 90° F for up to 17 minutes. Analgesics and/or antibiotics are then injected and the catheter is withdrawn. The heating of the electrode denatures the collagen of the annulus and coagulates the nerve endings, with the ultimate goal of relieving back pain.

The pathophysiology of discogenic back pain is not completely understood, but internal disc disruption has been proposed as a possible cause. The loss of hydrostatic pressure associated with a degenerated lumbar disc may lead to buckling of the annular lamella that can result in increased focal segmental mobility and an increase in shear stress to the wall of the annulus. Continued mechanical loading to the degenerated disc may cause sensitization of the annulus nociceptors.

Conventional treatment of discogenic low back pain includes nonsurgical interventions such as medication, physical therapy, and epidural corticosteroid injections. These traditional conservative treatments may be ineffective, however, with some patients reporting little or no reduction in pain or improvement in functional status. When medical treatment fails, spinal fusion is the primary surgical option. IDET has been investigated as a less invasive alternative to spinal fusion.

The mechanism by which IDET is reported to relieve pain has not been established and continues to be debated. It has been theorized that the procedure addresses both the mechanical and nociceptive components of discogenic back pain. Several authors have suggested that heating the coil relieves discogenic pain by thermocoagulating annular nociceptors in the disc and mechanically modifying collagen, but these hypotheses remain unproven in the scientific literature.

U.S. Food and Drug Administration (FDA)

The spineCATH® Intradiscal Electrothermal Catheter (Oratec, Menlo Park, CA) received FDA 510(k) clearance to market in 1998. Oratec was acquired by Smith & Nephew, Endoscopy (Andover, MA) in

2002. The 510(k) approval states that the spineCATH is intended for use for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

Professional Societies/Organizations

A fact sheet published by the American Academy of Orthopaedic Surgeons (AAOS) states, "The long-term results of this procedure are still unknown. IDET was introduced in 1997 and case series without controls have reported encouraging results. However, these results need to be confirmed in prospective, randomized trials. Additionally, there is debate about how the procedure actually works." (AAOS, 2002)

According to the North American Spine Society (NASS), "Early results with IDET showed that some patients who undergo the procedure report an increased activity level, a reduced use of pain medications and improved sitting tolerance. Later published results have been less positive. At this time, long-term outcomes need to be examined and compared to other forms of pain relief. More data into the effectiveness of IDET are needed especially in the form of placebo-controlled, randomized clinical trials." (NASS, 2002)

Literature Review

Outcome measures that are frequently used in IDET studies to evaluate pain relief and disability include sitting tolerance; reduction in pain medication use, as well as scores on a ten-point (0-10) subjective visual analog pain scale (VAS); the Short-Form Health Survey (SF-36) (0-100) for pain and physical functioning; and the Oswestry Disability Scale (0-100). In most of the IDET studies, a two-point change from the baseline VAS score has been considered significant. It should be noted, however, that studies evaluating pain relief generally seek a four- to five-point change in the VAS scores to demonstrate clinical significance.

Published results of several small case series evaluating IDET report success rates (significant pain relief and improved function) ranging from 54-80%. Results, however, have been conflicting. One study concluded that the improvements achieved, while statistically significant, were too minimal to be considered clinically significant (Spruit and Jacobs, 2002). Some studies using multiple outcome instruments reported improvement in VAS scores, yet demonstrated no significant improvement in physical functioning measured by the SF-36 Survey (Gerszten, et al., 2002). None of the studies available in the published, peer-reviewed, medical literature has compared the results of IDET with those of spinal fusion.

Pauza et al. (2004) conducted a prospective, randomized, controlled trial comparing IDET with placebo. Sixty-four patients, recruited by either practice referral or through the media, were randomized to receive IDET or sham treatment. The subjects were not aware of which treatment they received. Outcome tools used were the VAS scale, the SF-36, and the Oswestry Disability Scale. It is unclear whether the post-procedure outcome examiners were blinded regarding which patients received true IDET. The modest success rates reported in this trial were much less compelling than those from previously published uncontrolled studies. The investigators reported that both groups showed improvement, with mean improvements higher in the active treatment arm. Using the visual analog scale, IDET demonstrated a 2.4-point decrease in the mean pain score. An 11-point decrease was reported in the mean Oswestry score. The baseline disability level of most of the patients was low, and recruitment methods may have led to patient selection bias. The sample size was insufficient to achieve adequate statistical power, and follow-up was limited to six months. In addition, eight patients who dropped out of the study were not included in the data analysis. While the results of this study suggest that IDET may improve outcomes for patients with discogenic low back pain, these methodological flaws make it impossible to draw valid conclusions about the efficacy of this technology.

A retrospective study by Davis et al. (2004) examined outcomes of 60 consecutive patients referred by 17 spine specialists to an ambulatory surgery center for IDET. An independent evaluation was conducted to assess patients' functional status, symptoms and subsequent treatments approximately one year after undergoing IDET. Patients were contacted by telephone and completed a self-administered questionnaire based on the National Low Back Pain Study forms A and D. An independent interviewer who was blinded to patient condition and prior treatment with IDET conducted follow-up telephone calls. Almost all patients continued to report pain. Of 44 patients who completed the interview process, additional surgery was

reported by six patients at one year post-IDET (five lumbar fusions, one discectomy) and by four patients at two years post-IDET (three lumbar fusions, one discectomy). Of 38 patients who did not receive further treatment in the year following IDET, 37 reported continued pain following the procedure. Overall, 19 patients (50%) were dissatisfied with the procedure.

A randomized, double-blind controlled trial was conducted by Freeman et al. (2005) to test the safety and efficacy of IDET compared with placebo for the treatment of chronic discogenic low back pain. Patients with one- or two-level symptomatic disc degeneration with posterior or posterolateral annular tears who failed to improve after conservative therapy were considered for the study. Patients were randomized on a 2:1 ratio to IDET (n=38) or a sham procedure (n=19). An independent technician connected the catheter to the generator and delivered electrothermal energy to only the treatment group. Surgeon, patient, and independent outcome assessor were all blinded to the treatment. Low Back Outcome Score (LBOS), Oswestry Disability Index, SF36, the Zung Depression Index (ZDI) and Modified Somatic Perceptions Questionnaire (MSPQ) were measured at baseline and at six months. Successful outcome was defined as no neurological deficit, improvement in LBOS of greater than seven points, and improvement in SF-36 subsets (i.e., physical function and bodily pain) of greater than one standard deviation. No patient in either group showed improvement of greater than seven points in LBOS or greater than one standard deviation in the specified SF-36 domains. Mean ODI was 41.42 at baseline and 39.77 at six months for the IDET group compared with 40.74 at baseline and 41.58 at six months for the placebo group. There was no significant change in ZDI or MSPQ for either group. The authors concluded that there was no significant benefit from IDET over placebo.

Freeman (2006) conducted a systematic review of the evidence of the efficacy of IDET. The review included 11 prospective cohort studies, five retrospective studies, and two randomized controlled trials. The prospective cohort studies reported on a total of 256 patients with a mean follow-up of 17.1 months (range 12–28 months). The mean improvement in the VAS for back pain was 3.4 points (range 1.4–6.5), and the mean improvement in ODI was 5.2 points (range 4.0–6.4). The five retrospective studies included 379 patients and reported that between 13 and 23% of patients subsequently underwent surgery for low back pain within the study period. The two randomized controlled trials, Pauza, 2004 and Freeman, 2005, provided inconsistent evidence, as described above. The author concluded that the evidence for efficacy of IDET remains weak and has not passed the standard of scientific proof.

The safety and efficacy of IDET in the treatment of patients with chronic discogenic low back pain has not been established in the peer-reviewed medical literature. This procedure has not been proven to achieve equivalent or improved patient outcomes compared to available and established alternatives. In addition, the long-term effect of thermal coagulation of intervertebral discs has not been determined.

Note: The Radionics discTRODE™ RF Annuloplasty system, which is used to perform percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), received FDA 510(k) clearance in 2000. The PIRFT procedure, like IDET, is used for decompression of disc material as a treatment for annular disruption of contained herniated discs. The electrode in the Radionics system, however, does not include a resistive coil, and the duration of peak heating is shorter than for IDET. Refer to the Minimally Invasive Treatment of Back Pain medical necessity guideline for details.

Summary

Intradiscal electrothermal therapy (IDET™), also known as intradiscal electrothermal annuloplasty, is a minimally invasive procedure that has been proposed as an alternative to spinal fusion for the treatment of chronic discogenic low back pain. The safety and efficacy of IDET in the treatment of patients with chronic discogenic low back pain has not been established in the peer-reviewed medical literature. This procedure has not been proven to achieve equivalent or improved patient outcomes compared to available and established alternatives.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not medically necessary:

| CPT* Codes | Description |
|------------|--|
| 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.) |

| HCPCS Codes | Description |
|-------------|------------------|
| | No specific code |

| ICD-9-CM Diagnosis Codes | Description |
|--------------------------|---|
| 722.10 | Displacement of lumbar intervertebral disc without myelopathy |
| 722.52 | Degeneration of lumbar or lumbosacral intervertebral disc |
| | All other codes |

***Current Procedural Terminology (CPT®) © 2006 American Medical Association: Chicago, IL.**

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