

# MEDICAL POLICY



<b>SUBJECT: PERCUTANEOUS INTRADISCAL ELECTROTHERMAL ANNULOPLASTY (IDET/IDTA, PIRFT, BIACUPLASTY)</b>	<b>EFFECTIVE DATE: 10/21/99</b> <b>REVISED DATES: 12/07/00, 11/15/01, 10/16/02, 10/15/03, 08/19/04, 06/16/05, 05/18/06, 05/17/07, 04/17/08</b> <b>ARCHIVED DATE: 04/16/09</b> <b>EDITED DATE: 04/22/10, 04/21/11, 04/19/12, 04/18/13, 04/17/14</b> <b>PAGE: 1 OF: 5</b>
<b>POLICY NUMBER: 7.01.17</b> <b>CATEGORY: Technology Assessment</b>	
<ul style="list-style-type: none"><li>• <i>If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.</i></li><li>• <i>Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.</i></li><li>• <i>Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.</i></li></ul>	

## POLICY STATEMENT:

Based upon our criteria and review of the peer-reviewed literature, percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) has not been medically proven effective and is therefore considered **investigational** for the treatment of chronic discogenic back pain.

*Refer to Corporate Medical Policy #7.01.16 regarding Automated Percutaneous Discectomy.*

*Refer to Corporate Medical Policy #7.01.62 regarding Intervertebral Disc Decompression: Laser and Radiofrequency Coblation Techniques.*

*Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.*

## POLICY GUIDELINES:

- I. This policy does not address DISC nucleoplasty<sup>TM</sup>, which uses a bipolar radiofrequency device to provide heat treatment to the intervertebral disc, in order to remove tissue with minimal thermal damage to collateral tissue.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## DESCRIPTION:

Intradiscal annuloplasty therapies utilize radiofrequency energy 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.

*Intradiscal electrothermal annuloplasty (IDET<sup>TM</sup> or IDTA) is a minimally invasive treatment<sup>TM</sup> for discogenic low back pain intended to treat the protein wall of the disc and reduce the volume of disc material that causes nerve irritation. The procedure involves the insertion of a spinal catheter through a needle into the disc under fluoroscopy and then, using indirect radiofrequency energy, heating the needle to 194 degrees Fahrenheit (90 degrees centigrade) for up to 20 minutes. The heat kills the invading nerves and tightens the surrounding ligaments, creating a new seal. 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.*

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IDET™ is different from the direct application of radiofrequency energy, known as *percutaneous intradiscal thermocoagulation* (PIRFT) using the Radionics Disc Catheter System. In this procedure, the radiofrequency probe is placed into the center of the disc rather than around the annulus, and the device is activated for only 90 seconds at a temperature of 70 degrees centigrade. The mechanism of action is not precisely understood, but is thought to be related to reducing the nociceptive pain input from the free nerve ending in the outer annulus fibrosis. The Radionics Disc Catheter System is similar in concept to IDET™. However, the method of delivering the thermal energy is distinctly different between the two procedures. The proposed advantages of electrothermal delivery of energy (IDET™) compared to a radiofrequency needle (the Radionics device) is related to the fact that IDET™ provides electrothermal coagulation to a broader tissue segment and allows precise temperature control and temperature feedback.

A more recently developed annuloplasty procedure, referred to as *intradiscal biacuplasty*, involves the use of two cooled radiofrequency electrodes placed on the posterolateral sides of the intervertebral annulus fibrosis. It is proposed that by cooling the probes a larger area may be treated than with a regular needle probe.

**RATIONALE:**

The SpineCATH®/Oratec Intradiscal Electrothermal Catheter received U.S. Food and Drug Administration (FDA) 510(k) premarket notification in March 1998. The Radionics RF Disc Catheter Electrode System (Radionics, Inc., Burlington, MA) received FDA 510(k) premarket notification in 2000. It is intended to create lesions in nervous tissue, and for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The Baylis Pain Management Cooled Probe, used for intradiscal biacuplasty, (Baylis Medical, Inc., Montreal, Canada) received FDA 510(k) marketing notification in 2005. It is intended for use “in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue.” The Baylis Transdiscal™ System received FDA 510(k) premarket notification in 2006. “Used in combination with the Baylis Pain Management Generator is intended for the creation of radiofrequency (RF) lesions in nervous tissue including that which is situated in intervertebral disc material.”

Intradiscal electrothermal annuloplasty (IDET™). Published clinical trials have not provided evidence to support the efficacy of Intradiscal Electrothermal Annuloplasty. Published evidence consists mainly of case series. Results of two randomized controlled trials, each with methodological weaknesses, are inconsistent. Pauza, et al concluded that the treatment is effective, however they did not use an intention to treat analysis, and it is not clear that the reduction in reported pain is clinically significant. Freeman, et al conducted a randomized, sham controlled study; no subject in either arm met criteria for successful outcome, and no significant benefit for IDET over placebo was demonstrated.

Percutaneous intradiscal thermocoagulation (PIRFT). There is little published clinical evidence regarding PIRFT. A 2001 double-blind trial randomized 28 patients with chronic low back pain to under PIRFT or a sham control group. The primary outcome was the percentage of success at 8 weeks, measured by changes I pain level, impairment, Oswestry disability scale, and analgesics taken. At the end of 8 weeks there were two treatment successes in the sham group compared to one in the treatment group. Authors concluded that PIRFT was not better than the placebo procedure in reducing pain and disability.

A 2007 evidence-based practice guideline in the management of chronic spinal pain, from the American Society of Interventional Pain Physicians, created to provide recommendations to clinicians in the U.S., concluded that evidence is moderate for IDET in the management of chronic discogenic low back pain. Complications included catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equine syndrome, infection, epidural abscess, spinal cord damage. The same guideline concluded that evidence for radiofrequency posterior annuloplasty (PIRFT) was limited, with complications similar to IDET.

A systematic review of IDET and PIRFT was conducted following the criteria recommended by the Cochrane Back Review Group. Four randomized and two non-randomized studies, totaling 283 patients, were included in the review. The report concluded that the available evidence does not support the efficacy or effectiveness of IDET and PIRFT, and

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that these procedures are associated with potentially serious side effects. 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 IDED. Complications include catheter breakage, nerve root injuries, post-IDED disc herniation, cauda equine 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.

*Intradiscal biacuplasty.* There is extremely limited published clinical evidence regarding intradiscal biacuplasty. One small pilot study of 13 patients showed improved pain and functional capacity at 6-month follow-up.

**CODES:**      Number              Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

**CPT:**              22526 (E/I)      Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level

                         22527 (E/I)              one or more additional levels (list separately in addition to code for primary procedure)

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**HCPCS:**      No specific code(s)

**ICD9:**              722.52              Degeneration of lumbar or lumbosacral intervertebral disc

**ICD10:**              M51.36              Other Intervertebral disc degeneration, lumbar region

                         M51.37              Other Intervertebral disc degeneration, lumbosacral region

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**KEY WORDS:**

IDET, IDTA, Intradiscal Electrothermotherapy, Intradiscal Biacuplasty, Percutaneous Intradiscal Thermocoagulation, PIRFT, Radiofrequency Annuloplasty, Thermal Annuloplasty.

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## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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There is currently a National Coverage Determination (NCD) for thermal intradiscal procedures. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=324&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>