

Corporate Medical Policy

Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

File Name:	intradiscal_electrothermal_annuloplasty
Origination:	9/1991
Last CAP Review:	5/2011
Next CAP Review:	5/2012
Last Review:	8/2011

Description of Procedure or Service

Intradiscal annuloplasty therapies use radiofrequency energy to thermally treat discogenic low back pain arising from annular tears and other forms of internal disc derangement 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 electrothermo-coagulation 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 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 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 separately in the policy entitled, Disc Nucleoplasty and Laser Discectomy.

Related Policies:

Disc Nucleoplasty and Laser Discectomy
Percutaneous Lumbar Discectomy

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Intradiscal annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Intradiscal Annuloplasty is covered

Not applicable

When Intradiscal Annuloplasty is not covered

Intradiscal annuloplasty is considered investigational for all levels of the spine (i.e., cervical, thoracic, lumbar and sacral), whether performed percutaneously or using an open incision. This includes, but is not limited to, the following:

- Intradiscal electrothermal annuloplasty (IDET)
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) Intradiscal biacuplasty

Policy Guidelines

Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

Intradiscal Electrothermal Annuloplasty (IDET™)

The 2003 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 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 2005 study by Freeman et al. demonstrated a double-blind controlled trial that compared IDET to placebo. IDET did not appear more effective than placebo and neither group had a successful outcome. In a study by Kapural et al. IDET was compared to radiofrequency procedures and IDET patients demonstrated a significant improvement. However, the study did not have a control group.

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

In 2001 there was a double-blind trial that randomized 28 patients with chronic low back pain. From this trial Barendse and colleagues reported 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 a 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 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.

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.

A search of ClinicalTrials.gov identified a small Phase I randomized double-blind placebo-controlled trial of transdiscal radiofrequency annuloplasty using 2 transdiscal probes (NCT00750191) by the same principal investigator as above. The posting lists an estimated enrollment of 8 subjects with a final study collection date of September 2010 for the primary 12-month outcome measure.

NICE guidance published in 2004 indicates that the current evidence on safety and efficacy of the percutaneous intradiscal electrothermal therapy 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. Evidence is insufficient to conclude that these procedures improve health outcomes.

Billing/Coding/Physician Documentation Information

Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 22526, 22527, 62288, 62292, 64640, 0062T, 0063T, S2348

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual, 7.01.72 - 5/31/01

Consultant review - 7/8/2001

Specialty Matched Consultant Advisory Panel - 8/2001

Specialty Matched Consultant Advisory Panel - 8/2002

BCBSA Medical Policy Reference Manual, 7.01.72, 7/12/02

Specialty Matched Consultant Advisory Panel - 7/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 11/9/04

ECRI Target Report. #767. (2004, March). Intradiscal electrothermal therapy (IDET) for discogenic pain. Retrieved 1/26/05 from www.Target.ecri.org/summary/detail.aspx?doc_id=1154&q=IDET&anm=Wynne.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 4/1/2005

Specialty Matched Consultant Advisory Panel - 6/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 12/12/2006

Specialty Matched Consultant Advisory Panel - 5/2007

Freeman BJ and Mehdian R. Intradiscal electrothermal therapy, percutaneous discectomy, and nucleoplasty: what is the current evidence? *Curr Pain Headache Rep* 2008; 12(1):14-21.

National Institute for Clinical Excellence (NICE). Percutaneous intradiscal electrothermotherapy for low back pain. August 2004. Retrieved 3/9/09 from <http://www.nice.org.uk/nicemedia/pdf/ip/IPG081guidance.pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 4/24/09

Specialty Matched Consultant Advisory Panel - 5/2009

National Institute for Health and Clinical Excellence.(NICE) IPG319 Percutaneous intradiscal electrothermal therapy for low back pain: guidance. 2009; Last reviewed March 29,2011 at: <http://guidance.nice.org.uk/IPG319/Guidance/pdf/English> .

Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

National Institute for Health and Clinical Excellence. IPG83 Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 2004; Last reviewed March 29,2011 at: <http://guidance.nice.org.uk/IPG83> .

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 8/12/10

Specialty Matched Consultant Advisory Panel – 5/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 7/14/2011

Policy Implementation/Update Information

Intradiscal Electrothermal (IDET) Annuloplasty

- 7/6/09 Herniated Lumbar Disc, Percutaneous policy separated into individual policies by topic. No change to policy statement. Description revised. Updated rationale in the "Policy Guidelines" section. References added. (btw)
- 1/5/10 Deleted HCPCS codes 0062T and 0063T from the "Coding/Billing" section. (btw)
- 6/22/10 Policy Number(s) removed (amw)

Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

- 6/21/11 Combined Intradiscal Electrothermal annuloplasty and Percutaneous Intradiscal Radiofrequency annuloplasty. Renamed "Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty". Specialty Matched Consultant Advisory Panel review 5/25/2011. Updated "Description" and "Policy" statements to reflect these services. No change to policy intent. "Intradiscal annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures." References added. (btw)
- 8/30/11 Reference added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.