

Protocol

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

(70172)

Medical Benefit		Effective Date: 04/01/09	Next Review Date: 09/14
Preauthorization	No	Review Dates: 02/07, 02/08, 01/09, 01/10, 01/11, 09/11, 09/12, 09/13	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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.

Background

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.

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.

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 Protocol 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. DISC Nucleoplasty and laser discectomy are considered in a separate Protocol.

Related Protocols:

Automated Percutaneous and Endoscopic Discectomy

Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

Corporate Medical Guideline

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

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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