

FEP 7.01.72 Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Effective Date: April 15, 2018

Related Policies:

7.01.18 Automated Percutaneous Discectomy
7.01.93 Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Description

Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are designed to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening of annular tissue.

FDA REGULATORY STATUS

A variety of RF coagulation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA), some of which are designed for disc nucleotomy. In 2002, the Oratec Nucleotomy Catheter (ORATEC Interventions, Menlo Park, CA, acquired by Smith & Nephew in 2002) was cleared for marketing by FDA through the 510(k) process. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. The Radionics (a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance by FDA through the 510(k) process in 2000. FDA product code: GEI.

In 2005, the Baylis Pain Management Cooled Probe was also cleared for marketing by FDA through the 510(k) process. It is intended for use “in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue.” FDA product code: GXI.

Note: This evidence review does not address disc nucleoplasty, a technique based on the bipolar RF device (Coblation®; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar RF device is used to provide lower energy treatment 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 to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered in evidence review 7.01.93.

POLICY STATEMENT

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

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BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, radiofrequency annuloplasty, or biacuplasty, the evidence includes a small number of randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty have reported conflicting results, with one reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. There is a lack of evidence to support a role for radiofrequency annuloplasty with either a single or a double (biacuplasty) probe. One sham-controlled randomized controlled trials assessing biacuplasty has suggested that this procedure may provide modest benefit to highly select patients; confirmation of these results in a broader population is needed. Further study in a sham-controlled trial with a representative population of patients is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

A 2013 review of the evidence informing American Society of Interventional Pain Physicians guidelines found limited-to-fair evidence for intradiscal electrothermal therapy (IDET; another term for intradiscal electrothermal annuloplasty) and biacuplasty and limited evidence for percutaneous intradiscal radiofrequency thermocoagulation (PIRFT).¹¹ These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET.¹² Complications included catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage. The evidence for PIRFT was limited, with complications similar to IDET.¹²

National Institute for Health and Care Excellence

A National Institute for Health and Care Excellence (NICE) guidance, updated in 2016, indicated that the evidence on safety and efficacy of PIRFT for low back pain was “limited” and should only be used by “special arrangement”.¹³

The NICE guidance on electrothermal annuloplasty was also updated in 2016.¹⁴ NICE considered evidence on the efficacy of PIRFT for low back pain to be inconsistent and of poor quality, although no major safety concerns were identified. NICE recommended PIRFT only with special arrangements for clinical governance, consent, and audit or research.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services has determined that thermal intradiscal procedures (TIPs), including IDET and PIRFT, “are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs, which include procedures that employ the use of a radiofrequency energy source or

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electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered.”¹⁵

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POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
June 2012	Update Policy	Policy statement changed to read not medically necessary. Related policies added.
September 2013	Update Policy	Policy updated with literature search; references 3, 5, 16, 18, 19 and 21 added; policy statement unchanged.
September 2014	Update Policy	Policy updated with literature review, policy statement unchanged.

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September 2015	Update Policy	Policy updated with literature review; reference 17 added. Policy statement unchanged.
March 2017	Update Policy	Policy updated with literature review through November 1, 2016; references 9-10 added; reference 14 updated; some references removed. Title changed to "Percutaneous intradiscal electrothermal annuloplasty, radiofrequency annuloplasty, and biacuplasty." Policy statement terminology revised to reflect the changes in the title but the intent is unchanged.
March 2018	Update Policy	Policy updated with literature review through November 21, 2017; no references added; note 13 updated. Policy statement unchanged.

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