MEDICAL POLICY – 7.01.72

Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

BCBSA Ref. Policy: 7.01.72

SELECT A HYPERLINK BELOW TO BE DIRECTED TO THAT SECTION.

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Introduction

Between each vertebra (bone) of the spine is a round, flat disc. The discs act as cushions between the vertebrae, help hold them together, and also provide a gap between the vertebrae where nerves can enter and leave the spinal cord. The discs also provide stability and allow a wide range of motion. Discs are made up of an inner portion and an outer portion. The outer portion is tough and fibrous. The inner portion contains a gel-like substance and fibers. Should the discs break down, pain and nerve problems may result. Typical treatment for damaged discs includes physical therapy and/or pain medications. In more severe cases, surgery may be needed. In recent years, a number of methods involving heat to seal or treat the outer portion of the disc have been proposed as a way to stabilize the disc(s) and prevent pain. All of these methods are investigational (unproven). More and larger studies are needed to determine if these techniques are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

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

Coding

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
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<tr>
<td>22526</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level</td>
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<tr>
<td>22527</td>
<td>1 or more additional levels (list separately in addition to code for primary procedure)</td>
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Related Information

Benefit Application

Intradiscal electrothermal therapy may be performed in the setting of a pain management clinic.

Evidence Review
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 the annular tissue.

Background

**Discogenic Low Back Pain**

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease.

Treatment

Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency (RF) energy into the disc. 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.

Some electrothermal intradiscal procedures are briefly described next.

With the intradiscal electrothermal annuloplasty procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect RF energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90°C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with intradiscal electrothermal annuloplasty include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Percutaneous intradiscal radiofrequency thermocoagulation uses direct application of RF energy. With percutaneous intradiscal radiofrequency thermocoagulation, the RF probe is placed into
the center of the disc and the device is activated for only 90 seconds at a temperature of 70°C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty involves use of 2 cooled RF 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 kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

Summary of Evidence

For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, the evidence includes a small number of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty reported conflicting results, with one reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. 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.

For individuals who have discogenic back pain who receive intradiscal radiofrequency annuloplasty, the evidence includes two RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Neither RCT found evidence of benefit with the treatment. More sham-controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have discogenic back pain who receive intradiscal biacuplasty, the evidence includes two industry-sponsored RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One trial reported significant improvements at 6 months post-treatment, but not at 1 and 3 months. The other trial also showed a significant reduction in visual analog scale scores at 6 months that appeared to continue to the 12 month follow-up; however, it is unclear whether this trial was sufficiently powered. More sham-controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.
Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in February 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

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).\textsuperscript{11} These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET.\textsuperscript{12} Complications include catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage. The evidence for PIRFT was reported to be limited, with complications similar to IDET.\textsuperscript{12}

National Institute for Health and Clinical Excellence

A 2016 guidance update by the National Institute for Health and Care Excellence (NICE) indicated that the evidence on safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for low back pain was “limited” and should only be used by “special arrangement”.\textsuperscript{13}

In 2016, NICE guidance on electrothermal annuloplasty was updated in 2016.\textsuperscript{14} NICE considered evidence on the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation 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.
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 electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are non-covered.”15

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 the 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 the FDA thorough the 510(k) process in 2000. FDA product code: GEI.

In 2005, the Baylis Pain Management Cooled Probe was also cleared for marketing by the FDA through the FDA’s 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 policy 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 in an effort to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered separately in another policy (see Related Policies).

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intradiscal electrothermal therapy for chronic low back pain. TEC Assessments Apr 2002;Volume 17:Tab 11. PMID 11010675


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**History**

<table>
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<tr>
<td>05/11/04</td>
<td>Add to Surgery Section - New Policy, replaces PR.7.01.514—effective September 15, 2004</td>
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<tr>
<td>03/14/06</td>
<td>Replace Policy - Policy updated with literature search; no change in policy statement.</td>
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<td>05/13/08</td>
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<td>07/08/08</td>
<td>Code Update - 62310 and 62311 added, deleted 62288, no other changes.</td>
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<td>10/14/08</td>
<td>Cross Reference Update - No other changes.</td>
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<td>Codes Updates - Deleted codes 0062T and 0063T removed from policy.</td>
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<td>04/17/12</td>
<td>Related Policies updated; the title of 7.01.18 now includes endoscopic discectomy.</td>
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<td>09/08/15</td>
<td>Annual Review. Policy updated with literature review through June 10, 2015; reference 17 added. Policy statement unchanged. Removed CPT codes 62290-92, 62310-11, 64690, 72285 and 72295; these are not utilized for review and do not directly pertain to the policy.</td>
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<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. No changes to policy statements. Literature review through April 18, 2016.</td>
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<td>04/01/17</td>
<td>Annual Review, approved March 14, 2017. 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 biaucuplasy.” Policy statement terminology revised to reflect the changes in the title but the intent is unchanged.</td>
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  - Qualified sign language interpreters
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有關於重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Daytoy a pakdaa mabalin nga adda ket naglaon iti napateg nga impomarsion. Daytoy a pakdaa mabalin nga adda ket naglaon iti napateg nga impomarsion maipanggep iti aksiyasoyi unso coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaa. Mabalin nga adda rumbeng nga aramiyone nga addang sakkay dagiti particulik a naituding nga aildaw tapno mapagtalaineyi ti coverage ti salun-atyo wenno tong daga tagadii gastos. Adda karbenganyo a mangala iti daytoy nga impomarsion ken tong daga bukodyo a pagasasio nga awan ti bayadangyo. Tumawagi ti numero nga 800-722-1471 (TTY: 800-842-5357).

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Thông báo này có thông tin quan trọng về quyền lợi của bạn. Nếu bạn không biết đến các ngày quan trọng, việc mua thêm bảo hiểm hoặc quyết định mua bảo hiểm mới, thì bạn có thể mất quyền lợi.

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