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MEDICAL POLICY – 7.01.72

Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty, and Intraosseous Basivertebral Nerve Ablation

BCBSA Ref. Policy:	7.01.72
Effective Date:	July 1, 2024
Last Revised:	June 10, 2024
Replaces:	7.01.514

RELATED MEDICAL POLICIES:

7.01.18 Automated Percutaneous and Percutaneous Endoscopic Discectomy

Select a hyperlink below to be directed to that section.

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EVIDENCE REVIEW | REFERENCES | HISTORY

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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 (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered investigational.** **Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept system) for the treatment of vertebrogenic back pain is considered investigational.**

Coding

Code	Description
CPT	
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	1 or more additional levels (list separately in addition to code for primary procedure)
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (list separately in addition to code for primary procedure)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

Intradiscal electrothermal therapy (IDET) 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 symptom 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. Pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

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. Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) uses direct application of RF energy. With PIRFT, 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 uses two 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.

Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the basivertebral nerve, has been purported to occur with endplate damage or degeneration. In intraosseous radiofrequency ablation a bipolar probe is inserted into the posterior half of the vertebral body, connected to the RF generator, and then energy is applied to destroy the basivertebral nerve to stop the transmission of pain signals.

Summary of Evidence

For individuals who have discogenic back pain who receive intradiscal electrothermal annuloplasty, the evidence includes a small number of randomized controlled trials (RCTs). The 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 individuals is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain who receive intradiscal radiofrequency annuloplasty, the evidence includes two RCTs. The 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 that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain who receive intradiscal biacuplasty, the evidence includes two industry-sponsored RCTs. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One trial reported significant improvements at six months post-treatment, but not at one and three months. The other trial also showed a significant reduction in visual analog scale scores at six 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 that the technology results in an improvement in the net health outcome.

For individuals who have vertebrogenic back pain who receive intraosseous ablation of basivertebral nerves, the evidence includes two RCTs (the SMART and INTRACEPT trials). Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The SMART trial did not find a difference in the Oswestry Disability Index between patients treated with basivertebral nerve ablation or sham control at 3 months using an intent-to-treat analysis. Although the per protocol analysis showed a significant difference; results for the per protocol population at 12 months were not significantly different. Additionally, 73% of patients in this trial crossed over to the active treatment group at 12 months and therefore, long-term comparative data are not available. The INTRACEPT trial found a significant difference in the Oswestry Disability Index and other pain scores between patients treated with basivertebral nerve ablation and standard care at 3 months. Comparative data at 6 months postrandomization showed similar results. However, 92% of patients initially assigned to standard care elected to cross over to receive early basivertebral nerve ablation, thus, long-term comparative data beyond 6 months are not available. Additional limitations to this RCT include lack of a sham control. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in February 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Interventional Pain Physicians

A 2013 systematic review 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 PIRFT.[16] These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET.[17] 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.[17]

International Society for the Advancement of Spine Surgery

In 2022, the International Society for the Advancement of Spine Surgery published updated guidelines on intraosseous basivertebral nerve ablation.[18] The guideline was informed by a systematic review which included two randomized controlled trials (RCTs) and additional single-arm studies. The guideline authors concluded that intraosseous ablation of the basivertebral nerve from the L3 through S1 vertebrae may be considered medically indicated for individuals with chronic low back pain when all the following criteria are met:

- Chronic low back pain of at least six months duration
- Failure to respond to at least six months of nonsurgical management
- Magnetic resonance imaging-demonstrated Modic Change 1 (MC1) or Modic Change 2 (MC2) in at least 1 vertebral endplate at 1 or more levels from L3 to S1 (*Endplate changes, inflammation, edema, disruption, and/or fissuring.)

- Fibrovascular bone marrow changes (hypointense signal for Modic type 1).
- Fatty bone marrow changes (hyperintense signal for Modic type 2).

National Institute for Health and Care Excellence

A 2016 guidance update by NICE indicated that the evidence on safety and efficacy of PIRFT for low back pain was "limited" and should only be used by "special arrangement".[19]

In 2016, NICE guidance on electrothermal annuloplasty was also updated.[20] 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.

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 RF 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."[21]

Regulatory Status

A variety of RF coagulation devices have been cleared for marketing by the US 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 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.

The Intracept Intraosseous Nerve Ablation System "is intended to be used in conjunction with RF generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least 6 months of conservative care". FDA reviewed the device and issued a substantially equivalent designation in August 2017 (K170827). In March of 2022, FDA issued a substantially equivalent designation for an additional Intracept Intraosseous Nerve Ablation System (Relievant Medsystems, Inc.; K213836). The prior device (K170827) is listed as the reference access instrument and the new indication adds a description of accompanying use case features, "...is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change)."[1] 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 to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered separately in another policy (see **Related Policies**).

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History

Date	Comments
05/11/04	Add to Surgery Section - New Policy, replaces PR.7.01.514—effective September 15, 2004
03/14/06	Replace Policy - Policy updated with literature search; no change in policy statement.
06/09/06	Disclaimer and Scope update - No further changes.
12/12/06	Replace Policy - Policy updated with literature review; references added; no change in policy statement.
05/13/08	Replace Policy - Policy updated with literature search. Policy statement revised to include biacuplasty as investigational. Title updated to add "annuloplasty" and deleted "thermocoagulation". References added.
07/08/08	Code Update - 62310 and 62311 added, deleted 62288, no other changes.
10/14/08	Cross Reference Update - No other changes.
06/09/09	Replace Policy - Policy updated with literature search; no change in policy statement. References added.
10/12/10	Replace Policy - Policy updated with literature review through June 2010. References have been added and reordered; the policy statement remains unchanged.
04/08/11	Codes Updates - Deleted codes 0062T and 0063T removed from policy.
09/15/11	Replace Policy – Policy updated with literature search through May 2011; reference 13 added and references reordered; policy statement unchanged.
04/17/12	Related Policies updated; the title of 7.01.18 now includes endoscopic discectomy.
09/11/12	Replace policy. Rationale section revised based on literature search through May 2012. Reference 4 added and other references renumbered. Policy statement unchanged.
09/27/13	Replace policy. Rationale updated based on a literature review through June 2013. References 3, 16 added; others renumbered/removed. Policy statement unchanged.
09/23/14	Annual Review. A literature review through June 3, 2014 did not prompt the addition of new references. Policy statement unchanged.
09/08/15	Annual Review. Policy updated with literature review through June 10, 2015; reference 17 added. Policy statement unchanged. Removed CPT codes 62290-92, 62310-11,

Date	Comments
	64690, 72285 and 72295; these are not utilized for review and do not directly pertain to the policy.
06/01/16	Annual Review, approved May 10, 2016. No changes to policy statements. Literature review through April 18, 2016.
04/01/17	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 biacuplasty." Policy statement terminology revised to reflect the changes in the title but the intent is unchanged.
10/24/17	Policy moved to new format; no change to policy statements.
04/01/18	Annual Review, approved March 20, 2018. Policy updated with literature review through November 2017; no references added; note 13 updated. Policy statement unchanged. Removed CPT code 64999.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. Policy statement unchanged.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through February 2020; no references added. Policy statements unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 23, 2021; no references added. Policy statements unchanged. Related Policies updated; removed policy 7.01.93 as it has been archived.
01/01/22	Interim Review, approved December 2, 2021. Policy title changed to Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty, and Intraosseous Basivertebral Nerve Ablation. Policy updated with literature review through September 5, 2021; references added. Policy statements updated to include that Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept system) for the treatment of vertebrogenic back pain is considered investigational. Added new CPT codes 64628 & 64629 effective 1/1/2021.
01/01/23	Annual Review, approved December 12, 2022. Policy updated with literature review through September 16, 2022; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Removed new code statement from CPT code 64628 and 64629.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through March 27, 2023; reference added. Policy statements unchanged.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 20, 2024; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and

local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.