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FEP Medical Policy Manual

FEP 7.01.72 Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Annual Effective Policy Date: January 1, 2024

Original Policy Date: December 2011

Related Policies:

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

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

Description

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 annular tissue.

OBJECTIVE

The objective of this evidence review is to evaluate whether intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, intradiscal biacuplasty, and intraosseous basivertebral nerve ablation improve net health outcomes in individuals with discogenic or vertebrogenic back pain.

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**.

Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept system) for the treatment of vertebrogenic back pain is considered **investigational.**

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

A variety of radiofrequency 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) 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.

The Intracept Intraosseous Nerve Ablation System "is intended to be used in conjunction with radiofrequency (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 evidence review does not address disc nucleoplasty, a technique based on the bipolar radiofrequency device (Coblation; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar radiofrequency 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.

RATIONALE

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). Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty reported conflicting results, with 1 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 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 2 RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, 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 2 industry-sponsored RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, 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 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 2 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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 percutaneous intradiscal radiofrequency thermocoagulation.[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 percutaneous intradiscal radiofrequency thermocoagulation 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 2 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 6 months duration.
- Failure to respond to at least 6 months of nonsurgical management.
- Magnetic resonance imaging-demonstrated MC1 or 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 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".[19,]

In 2016, NICE guidance on electrothermal annuloplasty was also updated.[20,] NICE considered evidence on the 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 percutaneous intradiscal radiofrequency thermocoagulation 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, including IDET and percutaneous intradiscal radiofrequency thermocoagulation, "are not reasonable and necessary for the treatment of low back pain. Therefore, TIPS [thermal intradiscal procedures], 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 noncovered."[21,]

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed to read not medically necessary. Related policies added.
September 2013	Replace policy	Policy updated with literature search; references 3, 5, 16, 18, 19 and 21 added; policy statement unchanged.
September 2014	Replace policy	Policy updated with literature review, policy statement unchanged.
September 2015	Replace policy	Policy updated with literature review; reference 17 added. Policy statement unchanged.
March 2017	Replace 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	Replace policy	Policy updated with literature review through November 21, 2017; no references added; note 13 updated. Policy statement unchanged.
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through February 11, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through February 23, 2021; no references added. Policy statements unchanged.
December 2021	Replace policy	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.
December 2022	Replace policy	Policy updated with literature review through September 16, 2022; references added. Policy statements unchanged.
December 2023	Replace policy - correction only	Removed spinal decompression from comparators for intraosseous basiverterbral nerve ablation (Rationale section, Indication 4); policy statement unchanged.