

Percutaneous Intradiscal Electrothermal Annuloplasty, RF Annuloplasty, Biacuplasty & Intraosseous Basivertebral Nerve Ablation

Medicare Advantage Medical Policy No.: MNG-008

The Health Plan reserves the right to amend this policy and procedure at any time. Exceptions to this policy and procedure will be made on a case-by-case basis at the total discretion of the Health Plan.

Effective Date: March 04, 2024

Instructions for use

This policy serves to provide guidance in determining coverage based on medical necessity. It also gives a list of resources used to create these guidelines. Medical necessity determinations will be made in accordance with generally accepted standards of medical practice, taking into account credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of the physicians practicing in relevant clinical areas, and other relevant factors, as they relate to the member's clinical circumstances.

Medicare Advantage Members

Coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: <https://www.cms.gov/medicare-coverage-database/search.aspx>. You may wish to review the Guide to the MCD Search here: <https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx>.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria will be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of the coverage criteria and is to be used by all plans and lines of business unless Federal or State law, contract language, including member or provider contracts, take precedence over the policy.

InterQual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review nurse does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.

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Basic Requirements for Clinical Appropriateness:

1. Before diagnostic or therapeutic intervention, a clinician must confirm the diagnosis or establish the likelihood based on a history and physical exam and, when appropriate, a review of laboratory studies, previous diagnostic testing and response to any prior interventions, specifically relevant to the clinical situation.
2. An alternative treatment or other appropriate intervention should not offer any greater benefit based on standards of medical practice and/or current literature.
3. The potential benefit to the patient should outweigh the risk of the diagnostic or therapeutic intervention.
4. A reasonable likelihood of the intervention changing management and/or leading to an improved outcome for the patient must exist, based on the clinical evaluation, current literature and standards of medical practice.

If these requirements are not apparent in the request for authorization, including the clinical documentation provided, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous ordering of multiple diagnostic or therapeutic interventions and/or repeated diagnostic or therapeutic interventions in the same anatomic area may be denied, unless individual circumstances support the medical necessity of performing interventions simultaneously or repeatedly. This should be apparent in the clinical documentation or in peer-to-peer conversations.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers percutaneous annuloplasty (eg, intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain to be investigational.*

Based on review of available data, the Company considers intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain to be investigational.*

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®) ‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following: CPT codes 22526, 22527, 22899, 64628, and 64629.

There are no applicable HCPCS codes.

All related ICD-10 diagnoses codes apply.

Background/Overview

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.

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A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency 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 radiofrequency 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 radiofrequency 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 radiofrequency 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 uses direct application of radiofrequency energy. With percutaneous intradiscal radiofrequency thermocoagulation, 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°C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics Radiofrequency Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty uses 2 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.

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

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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 (Relieva 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)." FDA product code: GXI.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

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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, quality of life (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

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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. These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET. 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.

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. 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

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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”.

In 2016, NICE guidance on electrothermal annuloplasty was also updated. 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.”

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in April 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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