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

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 09/01/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) is addressed separately in medical policy 00087.

Note: Automated Percutaneous and Percutaneous Endoscopic Discectomy is addressed separately in medical policy 00208.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider thermal destruction of the lumbar intraosseous basivertebral nerve (BVN) for the treatment of select chronic low back pain to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for thermal destruction of the lumbar intraosseous BVN for the treatment of select chronic low back pain will be considered in individuals who meet **ALL** the following criteria:

- Skeletally mature patient; **AND**
- History of chronic lumbar back pain for at least 6 months with a minimum Visual Analogue Scale (VAS) score of ≥ 4 on most days; **AND**

- Associated significant functional impairment as measured by an Oswestry Disability Index (ODI) ≥ 30; **AND**
- Documented failure to respond to at least 6 consecutive months of non-surgical management; **AND**
- All other possible pain sources including, but not limited to, fracture, tumor, infection, or significant spinal deformity have been ruled out; **AND**
- Imaging studies confirm **BOTH** of the following:
    - Evidence of Modic Type I changes on MRI (i.e., hypointense T1 and hyperintense T2) or Type I and Type II changes on MRI (hyperintense T1 and hyperintense T2) in the endplates of 1 or more vertebrae from L3-S1; **AND**
    - Absence of non-vertebrogenic pathology that could explain the source of the patient's pain including, but not limited to, fracture, tumor, or infection; **AND**
- Statement from a primary care physician, neurologist, physiatrist, psychiatrist, psychologist, or other licensed behavioral and/or medical health care provider attesting to the absence of untreated, underlying mental health conditions/issues (e.g., depression, drug abuse, alcohol abuse) as a major contributor to chronic back pain.
- Absence of all situations considered investigational (see below).

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 (e.g., 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) when coverage criteria are not met and in **ANY** of the following situations to be **investigational*:**

- Skeletally immature patients (generally <18 years of age); **OR**
- Patients with severe cardiac or pulmonary compromise; **OR**

- Concurrent vertebral augmentation procedures at the intended levels; **OR**
- MRI evidence of Modic changes at levels other than L3-S1; **OR**
- Radicular pain (defined as nerve pain following a dermatomal distribution and that correlates with nerve compression in imaging); **OR**
- Previous lumbar spine surgery at the intended treatment level (discectomy/laminectomy allowed if > 6 months prior to baseline and radicular pain resolved); **OR**
- Symptomatic spinal stenosis (defined as the presence of neurogenic claudication confirmed by imaging); **OR**
- Diagnosed osteoporosis (T-score of -2.5 or less), metabolic bone disease, spine fragility fracture history, or trauma/compression fracture at intended level, or spinal cancer; **OR**
- Spine infection, active systemic infection, bleeding diathesis; **OR**
- Radiographic evidence of other pain etiology:
    - Disc extrusion or protrusion > 5 mm at levels L3-S1; **OR**
    - Spondylolisthesis > 2 mm at any level; **OR**
    - Spondylolysis at any level; **OR**
    - Facet arthrosis/effusion correlated with facet-mediated LBP at levels L3-S1; **OR**
- Current use of extended-release opioids with addiction behaviors; **OR**
- BMI > 40; **OR**
- Contraindicated to MRI, allergies to components of the device, or active implantable devices; **OR**
- Pregnant or lactating women; **OR**
- Repeat procedure at the same level of a prior intraosseous ablation.

Policy Guidelines

The Oswestry Disability Index (ODI) is a validated, quick, and easily administered tool to quantify and monitor functional abilities such as lifting, walking, sitting, standing, social life, and traveling. Baseline and periodic use of the ODI can be useful to observe concordance with the clinical assessment, establish baseline level of function, determine work capabilities, and monitor recovery.

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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.

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 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)." FDA product code: GXI.

Note: This medical policy 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 medical policy 00087.

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 lack of a sham control.

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.[7] 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".

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 February 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Carelon Medical Benefits Management, Inc., Clinical Appropriateness Guidelines for Musculoskeletal Appropriate Use Criteria: Interventional Pain Management, "Paravertebral Facet Injection/Medial Branch Nerve Block/Neurolysis-Intraosseous Basivertebral Nerve Ablation ", June 30, 2024.
2. The Oswestry Disability Index - PubMed (nih.gov)
3. https://www.aaos.org/globalassets/quality-and-practice-resources/patient-reported-outcome-measures/spine/oswestry-2.pdf
4. U.S. Food & Drug Administration. K213836 Intracept Intraosseous Nerve Ablation System 510k Summary. 2022. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213836.
5. Pauza KJ, Howell S, Dreyfuss P, et al. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. Spine J. 2004; 4(1): 27-35. PMID 14749191
6. Freeman BJ, Fraser RD, Cain CM, et al. A randomized, double-blind, controlled trial: intradiscal electrothermal therapy versus placebo for the treatment of chronic discogenic low back pain. Spine (Phila Pa 1976). Nov 01 2005; 30(21): 2369-77; discussion 2378. PMID 16261111
7. Barendse GA, van Den Berg SG, Kessels AH, et al. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70 C lesion. Spine (Phila Pa 1976). Feb 01 2001; 26(3): 287-92. PMID 11224865
8. Kvarstein G, Måwe L, Indahl A, et al. A randomized double-blind controlled trial of intra-annular radiofrequency thermal disc therapy--a 12-month follow-up. Pain. Oct 2009; 145(3): 279-286. PMID 19647940

9. Kapural L, Vrooman B, Sarwar S, et al. A randomized, placebo-controlled trial of transdiscal radiofrequency, biacuplasty for treatment of discogenic lower back pain. Pain Med. Mar 2013; 14(3): 362-73. PMID 23279658
10. Kapural L, Vrooman B, Sarwar S, et al. Radiofrequency intradiscal biacuplasty for treatment of discogenic lower back pain: a 12-month follow-up. Pain Med. Mar 2015; 16(3): 425-31. PMID 25339501
11. Desai MJ, Kapural L, Petersohn JD, et al. A Prospective, Randomized, Multicenter, Open-label Clinical Trial Comparing Intradiscal Biacuplasty to Conventional Medical Management for Discogenic Lumbar Back Pain. Spine (Phila Pa 1976). Jul 01 2016; 41(13): 1065-1074. PMID 26689579
12. Desai MJ, Kapural L, Petersohn JD, et al. Twelve-Month Follow-up of a Randomized Clinical Trial Comparing Intradiscal Biacuplasty to Conventional Medical Management for Discogenic Lumbar Back Pain. Pain Med. Apr 01 2017; 18(4): 751-763. PMID 27570246
13. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. May 2018; 27(5): 1146-1156. PMID 29423885
14. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain: 2-Year Results From a Prospective Randomized Double-Blind Sham-Controlled Multicenter Study. Int J Spine Surg. Apr 2019; 13(2): 110-119. PMID 31131209
15. Fischgrund JS, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. Aug 2020; 29(8): 1925-1934. PMID 32451777
16. Khalil JG, Smuck M, Koreckij T, et al. A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Spine J. Oct 2019; 19(10): 1620-1632. PMID 31229663
17. Smuck M, Khalil J, Barrette K, et al. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. Aug 2021; 46(8): 683-693. PMID 34031220

18. Koreckij T, Kreiner S, Khalil JG, et al. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-Month treatment arm results. N Am Spine Soc J. Dec 2021; 8: 100089. PMID 35141653
19. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician. Apr 2013; 16(2 Suppl): S49-283. PMID 23615883
20. Boswell MV, Trescot AM, Datta S, et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. Pain Physician. Jan 2007; 10(1): 7-111. PMID 17256025
21. Lorio M, Clerk-Lamalice O, Rivera M, et al. ISASS Policy Statement 2022: Literature Review of Intraosseous Basivertebral Nerve Ablation. Int J Spine Surg. Dec 2022; 16(6): 1084-1094. PMID 36266051
22. National Institute for Health and Care Excellence. Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain [IPG545]. 2016; https://www.nice.org.uk/guidance/ipg545.
23. National Institute for Health and Care Excellence. Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica [IPG544]. 2016; https://www.nice.org.uk/guidance/IPG544.
24. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) (150.11). 2008; https://www.cms.gov/medicare-coverage-database/details/ncd- details.aspx?ncdid=324&ver=1

Policy History

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Current Effective Date: 09/01/2024

10/18/2001	Medical Policy Committee review
11/12/2001	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy
10/21/2003	Medical Policy Committee review. Format revision. No substance change to policy
01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review

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01/18/2005	Medical Policy Committee review. Name of policy changed from IDET (Intradiscal Electrothermal Therapy) to Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation. Policy changed to investigational status. This change reflects lack of supporting clinical evidence that IDET achieves clinically and statistically significant improvements in measures of pain, disability and quality of life.
01/31/2005	Managed Care Advisory Council approval
06/06/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
01/10/2007	Medical Director review
01/17/2007	Medical Policy Committee approval
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. Title changed from "Percutaneous Intradiscal Electrothermal Annuloplasty (IDET™) and Percutaneous Intradiscal Radiofrequency Thermoregulation" to "Percutaneous Intradiscal Electrothermal Annuloplasty (IDET™) and Percutaneous Intradiscal Radiofrequency Annuloplasty". No change to coverage eligibility.
01/07/2010	Medical Director review
01/20/2010	Medical Policy Committee approval. No change to coverage. Coding revision.
01/06/2011	Medical Director review
01/19/2011	Medical Policy Committee approval. No change to coverage.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/08/2015	Medical Policy Committee review

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01/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Title changed from "Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty" to "Percutaneous intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty." Policy statement terminology revised to reflect the changes in the title. Coverage eligibility unchanged.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2020	Medical Policy Committee review
01/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Added an investigational statement for intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®‡ system) for the treatment of vertebrogenic back pain .
12/20/2021	Coding update

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01/05/2022	Coding Update
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2024	Medical Policy Committee review
01/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Added coverage with criteria for thermal destruction of the lumbar intraosseous basivertebral nerve (BVN) for the treatment of select chronic low back pain. Added situations to the investigational statement for intraosseous radiofrequency ablation of the basivertebral nerve (e.g. Intracept®‡ system) when coverage criteria are not met. Added a coverage criteria bullet for absence of all investigational situations. Added a Policy Guidelines section.

Next Scheduled Review Date: 06/2025

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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Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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:

Code Type	Code
CPT	22526, 22527, 22899, 64628, 64629
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 09/01/2024

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.