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

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023

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.

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.*

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.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty
and Intrarosseous Basivertebral Nerve Ablation

Policy #  00077
Original Effective Date:  11/21/2001
Current Effective Date:  02/13/2023

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 intrarosseous nerves. The basivertebral nerve enters the posterior vertebral body and sends branches to the superior
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023

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.
Percautaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Policy #  00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023

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.

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

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023

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 was unable to show a significant improvement in the Oswestry Disability Index with basivertebral nerve ablation compared to sham control at 3 months postrandomization in the intent-to-treat population. The INTRACEPT trial showed a significant improvement in the Oswestry Disability Index with basivertebral nerve ablation compared to standard care at 3 and 6 months postrandomization; however, the trial is limited by its lack of sham control. Both trials are further limited by the fact that the majority of patients assigned to control crossed over to receive active treatment, thus, long-term comparative data are not available. 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.
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Policy #  00077
Original Effective Date:  11/21/2001
Current Effective Date:  02/13/2023

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. 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 2020, the International Society for the Advancement of Spine Surgery published guidelines on intraosseous ablation of the basivertebral nerve for relief of chronic low back pain. The guidelines suggest that basivertebral nerve ablation is an appropriate treatment for chronic low back pain in select patients who meet the following additional criteria:

- "CLBP (chronic low back pain) of at least 6 months duration,
- Failure to respond to at least 6 months of nonsurgical management, and
- MRI (magnetic resonance imaging)-demonstrated MC1 or MC2 in at least 1 vertebral endplate at 1 or more levels from L3 to S1."

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

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023

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 September 2022 did not identify any ongoing or unpublished trials that would likely influence this review.

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

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023


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

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023


Policy History
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023
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
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
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Policy #  00077
Original Effective Date:  11/21/2001
Current Effective Date:  02/13/2023

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
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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023

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
01/03/2020 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., Intrasept® system) for the treatment of vertebrogenic back pain.
12/20/2021 Coding update
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
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Policy #  00077
Original Effective Date:  11/21/2001
Current Effective Date:  02/13/2023

01/11/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date:  01/2024

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 2022 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross 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.
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Policy # 00077
Original Effective Date: 11/21/2001
Current Effective Date: 02/13/2023

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>22526, 22527, 22899, 64628, 64629</td>
</tr>
<tr>
<td>HCPCS</td>
<td>Delete codes effective 1/1/2022: C9752, C9753</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*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.

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

Policy #  00077
Original Effective Date:  11/21/2001
Current Effective Date:  02/13/2023

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.