Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Policy # 00077
Original Effective Date: 11/21/2001
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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 (e.g., intradiscal electrothermal annuloplasty (IDEA), intradiscal radiofrequency (RF) annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic 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 symptoms findings, in conjunction with radiologically confirmed degenerative disc disease.

Treatment

Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency (RF) energy into the disc. It has

been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures and that pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

Some electrothermal intradiscal procedures are briefly described next.

With the intradiscal electrothermal annuloplasty procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect RF energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90°C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with intradiscal electrothermal annuloplasty include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Percutaneous intradiscal radiofrequency thermocoagulation uses direct application of RF energy. With percutaneous intradiscal radiofrequency thermocoagulation, the RF probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70□C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty uses 2 cooled RF electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that, by cooling the probes, a larger area may be treated than could occur with a regular needle probe.

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A variety of RF 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) RF (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.

Note: This evidence review does not address disc nucleoplasty, a technique based on the bipolar RF device (Coblation®‡; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar RF device is used to provide lower energy treatment to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. Disc nucleoplasty is closer in concept to a laser discectomy in that tissue is removed or ablated to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered 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, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 of annular tissue.

For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, radiofrequency annuloplasty, or biacuplasty, the evidence includes a small number of randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and

treatment-related morbidity. Two randomized controlled trials on intradiscal electrothermal annuloplasty have reported conflicting results, with one reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. There is a lack of evidence to support a role for radiofrequency annuloplasty with either a single or a double (biacuplasty) probe. One sham-controlled randomized controlled trials assessing biacuplasty has suggested that this procedure may provide modest benefit to highly select patients; confirmation of these results in a broader population is needed. Further study in a sham-controlled trial with a representative population of patients is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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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 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

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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
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.

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Coding

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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
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

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*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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