MEDICAL POLICY

POLICY TITLE	**PERCUTANEOUS INTRADISCAL ELECTROTHERMAL ANNULOPLASTY, RADIOFREQUENCY ANNULOPLASTY, AND BIACUPLASTY**
POLICY NUMBER	**MP-1.124**

Original Issue Date (Created):	**12/1/2011**
Most Recent Review Date (Revised):	**7/20/2018**
Effective Date:	**9/1/2018**

I. POLICY

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP-1.123 Automated Percutaneous and Percutaneous Endoscopic Discectomy
MP-1.125 Decompression of the Intervertebral Disc Using Laser Energy Discectomy or Radiofrequency Coblation Nucleoplasty

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.72, Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

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III. DESCRIPTION/BACKGROUND

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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.

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.

REGULATORY STATUS

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 separately in MP-1.125.

IV. RATIONALE

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SUMMARY OF EVIDENCE

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 (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 2 RCTs on intradiscal electrothermal annuloplasty have conflicting results, with 1 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 RCT on biacuplasty has suggested that this procedure may provide modest benefit in 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.

V. DEFINITIONS

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ANNULAR LAMELLAE are circular plates of collagen fibers found in secondary (mature, adult) bone.

INTERVERTEBRAL DISC is the fibrocartilaginous tissue between the vertebral bodies. The outer portion is the annulus fibrosus; the inner portion is the nucleus pulposus. The disc is the shock absorber, or cushion, and permits movement.

MINIMALLY INVASIVE PROCEDURES also called minimal access procedures used to perform spinal surgeries. These may include the following: (Note; this is not an all-inclusive list.)

- ALIF – anterior lumbar interbody fusion
- AxiaLIF – axial approach to interbody fusion which is performed perpendicular to the long axis of the spine with access through the sacrum. Also called anterior para-axial, trans-sacral or paracoccygeal interbody fusion performed with the AxiaLIF® and AxiaLIF 2 Level systems.
- DLIF - Direct lateral interbody fusion
- IDET – intradiscal electrothermal annuloplasty
- IG-MLD – image-guided minimally invasive lumbar decompression.
- LASE – annuloplasty using a laser-assisted spinal endoscopy
- LTIF – lateral transpsoas interbody fusion
- MEDL – microendoscopic decompressive laminotomy
- MILD – microscopic muscle-preserving interlaminar decompression involves a small skin incision at the interspinous level and partial drilling of the spinous process.
- PELA – percutaneous endoscopic laser annuloplasty.
- PLD – percutaneous lumbar discectomy
- PIRFT – percutaneous intradiscal radiofrequency thermocoagulation
- PLIF – posterior lumbar interbody fusion

- TLIF – transforaminal interbody fusion
- XLIF –Extreme lateral interbody fusion

NOCICEPTORS are free nerve endings that are receptors for painful stimuli**.**

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, and therefore not covered:

CPT Codes ®							
22526	22527						

IX. REFERENCES

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1. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intradiscal electrothermal therapy for chronic low back pain. TEC Assessments Apr 2002;Volume 17:Tab 11. PMID 11010675*
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6. *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 1 2001;26(3):287-292. PMID 11224865*
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8. *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):362-373. PMID 23279658*
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11. *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):425-431. PMID 25339501*

12. *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*
13. *National Institute for Health and Clinical Excellence. Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain [IPG83]. 2004; http://guidance.nice.org.uk/IPG83. Accessed July 20, 2018.*
14. *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. Accessed July 20, 2018.*
15. *Centers for Medicare and 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. Accessed July 20, 2018.*
16. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.72. Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty and Biacuplasty. January 2018.*

X. POLICY HISTORY

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MP 1.124	**CAC 7/26/11** New policy, Adopt BCBSA. BCBSA language adoption did not change intent of policy statements. Other minimally invasive procedures extracted from CBC MP-1.021 Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis (formerly Minimally Invasive Disc Procedures) and separated into individual policies. See MP 1.123 Automated Percutaneous Discectomy, MP 1.125 Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) and MP 1.126 Minimally Invasive Lumbar Interbody Fusion.
	CAC 10/30/12 Consensus review. References updated; no changes to the policy statements. FEP variation revised to refer to the FEP policy manual. Codes reviewed 10/18/2012
	CAC 11/26/13 Consensus review. References updated; no changes to the policy statements. Rationale added.
	CAC 11/25/14 Consensus review. No change to policy statements. References and rationale updated. Coding Reviewed 11/07/2014
	CAC 11/24/15 Consensus review. No change to the policy statements. Reference and rationale update. Coding reviewed.
	CAC 11/29/16 Consensus review. No change to the policy statements. References

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	updated**.** Variations reformatted. Coding reviewed.
	CAC 11/28/17 Consensus review. Title changed to "Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty." Policy statement terminology revised to reflect the changes in the title, but the intent is unchanged. Cross-Reference, Description/Background, Rationale and Reference sections updated.
	7/20/18 Consensus review. No change to policy statements. References reviewed. Rationale condensed.

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