

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

# Medical Policv Percutaneous Intradiscal Electrothermal Annuloplasty. Radiofrequency Annuloplasty, and Biacuplasty

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# **Table of Contents**

- **Policy: Commercial**
- **Policy: Medicare**
- Authorization Information
- Description • **Policy History** 
  - References •

Information Pertaining to All Policies

# Policy Number: 482

BCBSA Reference Number: 7.01.72 NCD/LCD: National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) (150.11)

Coding Information

## **Related Policies**

- Automated Percutaneous and Percutaneous Endoscopic Discectomy, #231
- Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty), #271

# **Policv**

# Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Percutaneous annuloplasty (eg, intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **INVESTIGATIONAL.** 

# Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determinations (NCDs)

National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) (150.11)

Note: To review the specific NCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

# **Prior Authorization Information**

## Inpatient

For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>sM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>sm</sup>	This is <b>not</b> a covered service.

## **CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

#### The following CPT and HCPCS codes are considered investigational for <u>Commercial Members:</u> <u>Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:</u>

#### **CPT Codes**

CPT codes:	Code Description
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional level

#### HCPCS Codes

HCPCS	
codes:	Code Description
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc,
	using radiofrequency energy, single or multiple levels, lumbar

### **Description**

#### **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 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 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.

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.

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

## **Summary**

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 electrothermal annuloplasty, the evidence includes a small number of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty reported conflicting results, with one 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 the effects of the technology on health outcomes.

For individuals who have discogenic back pain who receive intradiscal radiofrequency annuloplasty, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 the effects of the technology on health outcomes.

For individuals who have discogenic back pain who receive intradiscal biacuplasty, the evidence includes 2 industry-sponsored RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 the effects of the technology on health outcomes.

Date	Action
6/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
2/2018	New references from BCBSA National medical policy.

## **Policy History**

3/2017	BCBSA National medical policy review.
	Title changed. Policy statement terminology revised to reflect the changes in the title
	but the intent is unchanged. New references added. 3/1/2017.
12/2015	Added coding language.
8/2015	New references from BCBSA National medical policy.
10/2013	New references from BCBSA National medical policy.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
4/2012	No changes to policy statements.
6/2011	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
7/2010	BCBSA National medical policy review.
	No changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
5/2009	BCBSA National medical policy review.
	No changes to policy statements.
7/2008	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
5/2008	BCBSA National medical policy review.
	Changes to policy statements.
12/2007	BCBSA National medical policy review.
	No changes to policy statements.

# Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u>

Medical Technology Assessment Guidelines

## References

- 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
- Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain. TEC Assessments. Nov 6 2003;Volume 18:Tab 19. PMID 15043079
- 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. Jan-Feb 2004;4(1):27-35. PMID 14749191
- 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 1 2005;30(21):2369-2377; discussion 2378. PMID 16261111
- 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

- Kvarstein G, Mawe 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
- 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
- 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
- 9. 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
- 10. 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 1 2017;18(4):751-763. PMID 27570246
- 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-S283. PMID 23615883
- 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
- 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. Accessed March 4, 2020.
- 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 March 4, 2020.
- 15. 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. Accessed March 4, 2020.