Corporate Medical Policy

Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine

File Name: percutaneous_intradiscal_and_intrasosseous_radiofrequency_procedures_of_the_spine
Origination: 9/1991
Last Review: 5/2023

Description of Procedure or Service

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 is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease. 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 of the electrothermal intradiscal procedures are briefly described.

With the intradiscal electrothermal annuloplasty (IDEA) 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 degrees centigrade; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of radiofrequency energy with IDEA 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 (PIRFT) uses direct application of radiofrequency energy. With PIRFT, 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 degrees centigrade. 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 involves the use of two 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.

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Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve (BVN) enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the BVN, has been purported to occur with endplate damage or degeneration.

Regulatory Status

A variety of radiofrequency (RF) coagulation devices are 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 the U.S. Food and Drug Administration (FDA) through the 510(k) process. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. Radionics (a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance through FDA's 510(k) process in 2000.

The Baylis Pain Management Cooled Probe received marketing clearance through the FDA's 510(k) process in 2005. It is intended for use "in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue."

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 six months duration that has not responded to at least six 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)."

Note: This policy does not address disc nucleoplasty, a technique based on the bipolar RF device (Coblation®; ArthroCare, Austin, TX, acquired by Smith and 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 in an effort to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered separately in the policy entitled, Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty).

Related Policies:

Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)
Automated Percutaneous and Endoscopic Discectomy

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine

Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine for the treatment of chronic back pain are considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine are covered

Not applicable

When Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine are not covered

Intradiscal annuloplasty for the treatment of chronic discogenic back pain is considered investigational for all levels of the spine (i.e., cervical, thoracic, lumbar and sacral), whether performed percutaneously or using an open incision. This includes, but is not limited to, the following:

- Intradiscal electrothermal annuloplasty (IDEA)
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- Intradiscal biacuplasty

Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain is considered investigational.

Policy Guidelines

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 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 two 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 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 two industry-sponsored RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One trial reported significant improvements at 6 months posttreatment, but not at 1 and 3 months. The other trial also showed a significant reduction in visual analog scale (VAS) 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 pain who receive intraosseous ablation of basivertebral nerves, the evidence includes two RCTs (SMART and INTRACEPT trials). Relevant outcomes are symptoms, functional outcomes, quality of life 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 three months using an intent-to-treat analysis. Although the per protocol analysis showed a significant difference; results for the per protocol population at twelve months were not significantly different. Additionally, 73% of patients in this trial crossed over to the active treatment group at twelve 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 three months. Comparative data at six 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 six months are not available. Additional limitations to this RCT include lack of a sham control. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 22526, 22527, 22899, 64628, 64629

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual, 7.01.72 – 5/31/01

Consultant review – 7/8/2001

Specialty Matched Consultant Advisory Panel – 8/2001

Specialty Matched Consultant Advisory Panel – 8/2002

BCBSA Medical Policy Reference Manual, 7.01.72, 7/12/02

Specialty Matched Consultant Advisory Panel – 7/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 11/9/04

ECRI Target Report. #767. (2004, March). Intradiscal electrothermal therapy (IDET) for discogenic pain. Retrieved 1/26/05 from www.Target.ecri.org/summary/detail.aspx?doc_id=1154&q=IDET&anm=Wynne.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 4/1/2005

Specialty Matched Consultant Advisory Panel – 6/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 12/12/2006

Specialty Matched Consultant Advisory Panel – 5/2007

Freeman BJ and Mehdian R. Intradiscal electrothermal therapy, percutaneous discectomy, and nucleoplasty: what is the current evidence? Curr Pain Headache Rep 2008; 12(1):14-21.

National Institute for Clinical Excellence (NICE). Percutaneous intradiscal electrothermotherapy for low back pain. August 2004. Retrieved 3/9/09 from http://www.nice.org.uk/nicemedia/pdf/ip/IPG081guidance.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 4/24/09

Specialty Matched Consultant Advisory Panel – 5/2009

National Institute for Health and Clinical Excellence. (NICE) IPG319 Percutaneous intradiscal electrothermal therapy for low back pain: guidance. 2009; Last reviewed March 29, 2011 at: http://guidance.nice.org.uk/IPG319/Guidance/pdf/English .

National Institute for Health and Clinical Excellence. IPG83 Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 2004; Last reviewed March 29,2011 at: http://guidance.nice.org.uk/IPG83 .

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 8/12/10

Specialty Matched Consultant Advisory Panel – 5/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 7/14/2011

Specialty Matched Consultant Advisory Panel – 5/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 7/12/12

Specialty Matched Consultant Advisory Panel – 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 7/11/2013

Senior Medical Director – 8/2013

Specialty Matched Consultant Advisory Panel – 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 7/10/2014

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 7/9/2015

Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 1/12/2017

Specialty Matched Consultant Advisory Panel – 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 1/11/2018

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 4/8/2019

Specialty Matched Consultant Advisory Panel – 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 4/16/2020

Specialty Matched Consultant Advisory Panel – 5/2020

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 [published online ahead of print, 2020 May 25]. *Eur Spine J*. 2020;10.1007/s00586-020-06448-x.

Fischgrund JS, Rhyne A, 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. International Journal of Spine Surgery 2019; 13: 110-119

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. The Spine Journal 2019; 19: 1620-1632.

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*. 2018;27(5):1146-1156.

Medical Director review

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.72, 4/8/2021

Specialty Matched Consultant Advisory Panel – 5/2021

Specialty Matched Consultant Advisory Panel – 5/2022

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.

Specialty Matched Consultant Advisory Panel – 5/2023

Policy Implementation/Update Information

Intradiscal Electrothermal (IDET) Annuloplasty

7/6/09 Herniated Lumbar Disc, Percutaneous policy separated into individual policies by topic. No change to policy statement. Description revised. Updated rationale in the "Policy Guidelines" section. References added. (btw)

1/5/10 Deleted HCPCS codes 0062T and 0063T from the "Coding/Billing" section. (btw)

6/22/10 Policy Number(s) removed (amw)

Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

6/21/11 Combined Intradiscal Electrothermal annuloplasty and Percutaneous Intradiscal Radiofrequency annuloplasty. Renamed "Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty". Specialty Matched Consultant Advisory Panel review 5/25/2011. Updated "Description" and "Policy" statements to reflect these services. No change to policy intent. "Intradiscal annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures." References added. (btw)

8/30/11 Reference added. (btw)

5/29/12 Specialty Matched Consultant Advisory Panel review 5/16/2012. Policy Guidelines updated. No change to policy statement. Removed deleted CPT code, 62288. (btw)

8/21/12 Removed deleted CPT codes 0062T and 0063T from Billing/Coding section (btw)

9/18/12 Reference added. (btw)

7/1/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. Policy Guidelines updated. No change to policy intent. (btw)

9/10/13 Policy Guidelines section updated. Removed HCPCS code S2348 from Coding/Billing section as it does not pertain to this policy. Senior Medical Director review 8/29/2013. Reference added. (btw)

6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. No change to policy. (btw)

11/11/14 Reference added. (sk)

7/1/15 Specialty Matched Consultant Advisory Panel review 5/26/2015. (sk)

9/1/15 Reference added. Codes 62292 and 64640 removed from Billing/Coding Section. (sk)

7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)

3/31/17 Reference added. Description section and Policy Guidelines Section revised. Title changed from Intradiscal Electrothermal (IDET) 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 but policy intent is unchanged. (sk)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)

3/9/18 Reference added. (sk)

6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)

12/14/18 Codes C9752 and C9753 added to Billing/Coding section for effective date 1/1/2019. (sk)

6/11/19 Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)

6/9/20 Reference added. Policy guidelines updated. Specialty Matched Consultant Advisory Panel review 5/20/2020. (bb)

7/14/20 References added. Regulatory Status updated. Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain added to When Not Covered section. Policy Guidelines updated. Code 22899 added to Billing/Coding section. Title changed from Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty to "Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine". Medical Director review. (sk)

6/15/21 Reference added. Specialty Matched Consultant Advisory Panel review 5/19/2021. (sk)

12/30/21 Added codes 64628 and 64629 to Billing/Coding section. (sk)

6/14/22 Policy Guidelines updated. Removed deleted codes C9752 and C9753 from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 5/18/2022. (sk)

6/30/23 Policy Guidelines updated. Regulatory Status updated. Reference added. Specialty Matched Consultant Advisory Panel review 5/17/2023. (sk)