

DRAFT Medical Coverage Policy | Minimally Invasive Procedures for Back Pain Related to Disc Disease



EFFECTIVE DATE: 01|01|2023
POLICY LAST UPDATED: 09|07|2022

OVERVIEW

This policy addresses a variety of minimally invasive techniques that have been investigated over the years as treatment of low back pain related to disc disease. Surgical management of herniated intervertebral discs most commonly involves discectomy or microdiscectomy, performed manually through an open incision. Automated percutaneous discectomy involves placement of a probe within the intervertebral disc under image guidance with aspiration of disc material using a suction cutting device. 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. Laser energy (laser discectomy) and radiofrequency coblation (nucleoplasty) are being evaluated for decompression of the intervertebral disc. For laser discectomy under fluoroscopic guidance, a needle or catheter is inserted into the disc nucleus, and a laser beam is directed through it to vaporize tissue. For disc nucleoplasty, bipolar radiofrequency energy is directed into the disc to ablate tissue. These minimally invasive procedures are being evaluated for the treatment of discogenic back pain.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

The following services are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intrasept® system) for the treatment of vertebrogenic back pain
- Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain
- Laser discectomy and radiofrequency coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated pain.
- Automated percutaneous discectomy as a technique of intervertebral disc decompression in individuals with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter(s)/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.

The scope of the Centers for Medicare and Medicaid Services national coverage determination on TIPs includes percutaneous intradiscal techniques that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of a contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probe(s)/catheter(s), which utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction, or the annulus.

Although not intended to be an all-inclusive list, TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFI), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Each technique or device has its own protocol for application of the therapy.

The Centers for Medicare and Medicaid Services has determined that TIPs are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs, 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. Therefore, these services are not covered for Medicare Advantage Plans.

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain and radiculopathy will resolve with conservative care, surgical decompression is often considered when the pain is unimproved after several months and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of discectomy in which the extruding disc material is excised. When performed with an operating microscope, the procedure is known as a microdiscectomy.

Minimally invasive options have also been researched, in which some portion of the disc is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material. Ablative techniques include laser discectomy and radiofrequency decompression. Intradiscal electrothermal annuloplasty is another minimally invasive approach to low back pain. In this technique, radiofrequency energy is used to treat the surrounding disc annulus.

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 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 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, 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 that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain or radiculopathy who receive laser discectomy, the evidence includes systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. While numerous case series and uncontrolled studies have reported improvements in pain levels and functioning following laser discectomy, the lack of well-designed and conducted controlled trials limits interpretation of reported data. 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 or radiculopathy who receive disc nucleoplasty with radiofrequency coblation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 3 RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in 1, inadequate data reporting in the second, and low enrollment with early study termination in the third. The available evidence is insufficient to permit conclusions concerning the effect of these procedures on health outcomes due to multiple confounding factors that may bias results. High-quality randomized trials with adequate follow-up (at least 1 year), which control for selection bias, the placebo effect, and variability in the natural history of low back pain, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) are not covered for Medicare Advantage Plans when identified as Percutaneous Thermal Intradiscal Procedures (TIPs) and not medically necessary for Commercial Products:

- 22526** Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
- 22527** Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels (List separately in addition to code for primary procedure)
- 62287** Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
- 64628** Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral (New code effective 1/01/2022)
- S2348** Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

PUBLISHED:

Provider Update, November 2022
Provider Update, September 2021
Provider Update, October 2020
Provider Update, February 2020
Provider Update, January 2019

REFERENCES:

1. Singh V, Manchikanti L, Benyamin RM, et al. Percutaneous lumbar laser disc decompression: a systematic review of current evidence. *Pain Physician*. May-Jun 2009; 12(3): 573-88. PMID 19461824
2. Singh V, Manchikanti L, Calodney AK, et al. Percutaneous lumbar laser disc decompression: an update of current evidence. *Pain Physician*. Apr 2013; 16(2 Suppl): SE229-60. PMID 23615885
3. Gibson JN, Waddell G. Surgical interventions for lumbar disc prolapse. *Cochrane Database Syst Rev*. Apr 18 2007;(2): CD001350. PMID 17443505
4. Tassi GP. Comparison of results of 500 microdiscectomies and 500 percutaneous laser disc decompression procedures for lumbar disc herniation. *Photomed Laser Surg*. Dec 2006; 24(6): 694-7. PMID 17199468
5. Choy DS. Percutaneous laser disc decompression: an update. *Photomed Laser Surg*. Oct 2004; 22(5): 393-406. PMID 15671712
6. Menchetti PP, Canero G, Bini W. Percutaneous laser discectomy: experience and long term follow-up. *Acta Neurochir Suppl*. 2011; 108: 117-21. PMID 21107947
7. Manchikanti L, Falco FJ, Benyamin RM, et al. An update of the systematic assessment of mechanical lumbar disc decompression with nucleoplasty. *Pain Physician*. Apr 2013; 16(2 Suppl): SE25-54. PMID 23615886
8. Gerszten PC, Smuck M, Rathmell JP, et al. Plasma disc decompression compared with fluoroscopy-guided transforaminal epidural steroid injections for symptomatic contained lumbar disc herniation: a prospective, randomized, controlled trial. *J Neurosurg Spine*. Apr 2010; 12(4): 357-71. PMID 20201654

9. Chitragran R, Poopitaya S, Tassanawipas W. Result of percutaneous disc decompression using nucleoplasty in Thailand: a randomized controlled trial. *J Med Assoc Thai*. Oct 2012; 95 Suppl 10: S198-205. PMID 23451463
10. de Rooij J, Harhangi B, Aukes H, et al. The Effect of Percutaneous Nucleoplasty vs Anterior Discectomy in Patients with Cervical Radicular Pain due to a Single-Level Contained Soft-Disc Herniation: A Randomized Controlled Trial. *Pain Physician*. Nov 2020; 23(6): 553-564. PMID 33185372
11. Bokov A, Skorodumov A, Isrellov A, et al. Differential treatment of nerve root compression pain caused by lumbar disc herniation applying nucleoplasty. *Pain Physician*. Sep-Oct 2010; 13(5): 469-80. PMID 20859316
12. Birnbaum K. Percutaneous cervical disc decompression. *Surg Radiol Anat*. Jun 2009; 31(5): 379-87. PMID19190848
13. Cuellar VG, Cuellar JM, Vaccaro AR, et al. Accelerated degeneration after failed cervical and lumbar nucleoplasty. *J Spinal Disord Tech*. Dec 2010; 23(8): 521-4. PMID 21131800
14. National Institute for Health and Care Excellence (NICE). Epiduroscopic lumbar discectomy through sacral hiatus for sciatica [IPG570]. 2016; <https://www.nice.org.uk/guidance/ipg570>. Accessed March 10, 2022.
15. National Institute for Health and Care Excellence (NICE). Percutaneous coblation of the intervertebral disc for low back pain and sciatica [IPG543]. 2016; <https://www.nice.org.uk/guidance/ipg543>. Accessed March 11, 2022.
16. Manchikanti L, Derby R, Benyamin RM, et al. A systematic review of mechanical lumbar disc decompression with nucleoplasty. *Pain Physician*. May-Jun 2009; 12(3): 561-72. PMID 19461823
17. 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):S49-283. PMID 23615883
18. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Laser Procedures (140.5). 1997; <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCIDid=69&ncdver=1&DocID=140.5&bc=gAAAAAgAAAAAA%3D%3D>. Accessed March 11, 2022.
19. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) (150.11). 2009; <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCIDid=324>. Accessed March 12, 2022.

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

