Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

Policy # 00087
Original Effective Date: 06/05/2002
Current Effective Date: 11/11/2024

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: Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty and Intraosseous Basivertebral Nerve Ablation are addressed separately in medical policy 00077.

Note: Percutaneous 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 laser discectomy and radiofrequency (RF) coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated 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 symptom findings, in conjunction with radiologically confirmed degenerative disc disease.

Treatment

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

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A variety of minimally invasive techniques have been investigated as treatment of low back pain related to disc disease. Techniques can be broadly divided into those designed to remove or ablate disc material, and thus decompress the disc, and those designed to alter the biomechanics of the disc annulus. The former category includes chymopapain injection, automated percutaneous lumbar discectomy, laser discectomy, and, most recently, disc decompression using radiofrequency energy, referred to as a disc nucleoplasty.

Techniques that alter the biomechanics of the disc (disc annulus) include a variety of intradiscal electrothermal procedures discussed in medical policy 00077.

A variety of different lasers have been investigated for laser discectomy, including YAG (yttrium aluminum garnet), KTP (potassium titanyl phosphate), holmium, argon, and carbon dioxide lasers. Due to differences in absorption, the energy requirements and the rates of application differ among the lasers. In addition, it is unknown how much disc material must be removed to achieve decompression. Therefore, protocols vary by the length of treatment, but typically the laser is activated for brief periods only.

Radiofrequency coblation uses bipolar low-frequency energy in an electrical conductive fluid (eg, saline) to generate a high-density plasma field around the energy source. This creates a low-temperature field of ionizing particles that break organic bonds within the target tissue. Coblation technology is used in a variety of surgical procedures, particularly related to otolaryngology. The disc nucleoplasty procedure is accomplished with a probe mounted using a radiofrequency coblation source. The proposed advantage of coblation is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of laser devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for incision, excision, resection, ablation, vaporization, and coagulation of tissue. Intended uses described in FDA summaries include a wide variety of procedures, including percutaneous discectomy. Trimedyne received 510(k) clearance in 2002 for the Trimedyne®‡ Holmium Laser System Holmium: Yttrium, Aluminum Garnet

(Holmium:YAG), in 2007 RevoLix Duo™‡ Laser System, and in 2009 Quanta System LITHO Laser System. All were cleared, based on equivalence with predicate devices for percutaneous laser disc decompression/discectomy, including foraminoplasty, percutaneous cervical disc decompression/discectomy, and percutaneous thoracic disc decompression/discectomy. The summary for the Trimedyne®‡ system states that indications for cervical and thoracic decompression/discectomy include uncomplicated ruptured or herniated discs, sensory changes, imaging consistent with findings, and symptoms unresponsive to 12 weeks of conservative treatment. Indications for treatment of cervical discs also include positive nerve conduction studies. FDA product code: GEX.

In 2001, the Perc-D SpineWand™‡ (ArthroCare) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to predicate devices. It is used in conjunction with the ArthroCare Coblation®‡ System 2000 for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs. Smith & Nephew acquired ArthroCare in 2014; as of 2024, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website. FDA product code: GEI.

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, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

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.

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Summary of Evidence
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 the 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 randomized controlled trials (RCTs), systematic reviews, and prospective and retrospective nonrandomized studies. 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.

Supplemental Information

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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American Society of Interventional Pain Physicians
In 2009, updated in 2013, the American Society of Interventional Pain Physicians issued practice guidelines on lumbar disc compression and chronic spinal pain. The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty.

National Institute for Health and Care Excellence
In 2016, NICE updated its guidance on laser lumbar discectomy for the treatment of sciatica. The guidance stated that current evidence "is inadequate in quantity and quality."

Also in 2016, NICE updated its guidance on percutaneous disc decompression using coblation for lower back pain and sciatica. NICE stated: "Current evidence on percutaneous coblation of the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods." The guidance also noted that the patient should be informed of the range of treatment options available.

North American Spine Society
In 2012, the North American Spine Society (NASS) released clinical practice guidelines on the diagnosis and treatment of lumbar disc herniation with radiculopathy. NASS stated, "there is insufficient evidence to make a recommendation for or against the use of plasma disc decompression/nucleoplasty in the treatment of patients with lumbar disc herniation with radiculopathy."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The Centers for Medicare & Medicaid Services have determined that thermal intradiscal procedures, including percutaneous (or plasma) disc decompression or coblation, are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, 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."

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The Centers for Medicare & Medicaid Services has not published a national coverage decision on laser discectomy; however, the Centers did indicate the following in its decision on laser procedures:

"Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, Medicare Administrative contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06151704	The Effect of High-power Laser Therapy on Pain, Functional Disability, Range of Motion and Pressure Pain Threshold in Subjects With Radicular Low Back Pain Due to Intervertebral Disc Herniation: A Double-blind Randomised Controlled Trial	36	Apr 2025
NCT05601791	Efficacy of Percutaneous Laser Disc Decompression Versus Epidural Steroid and Local Anesthetic Injection by Transforaminal Approach in the Treatment of Lumbar Radicular Pain	116	Jul 2024

NCT: national clinical trial.

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References

1. Singh V, Manchikanti L, Benyamin RM, et al. Percutaneous lumbar laser disc decompression: a systematic review of current evidence. Pain Physician. 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; 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. Chen CH, Chiu YP, Ji HR, et al. Analysis of the clinical and radiological outcomes of percutaneous cervical nucleoplasty: A case-control study. PLoS One. 2022; 17(12): e0278883. PMID 36508407

12. Bokov A, Skorodumov A, Isrelov A, et al. Differential treatment of nerve root compression pain caused by lumbar disc herniation applying nucleoplasty. Pain Physician. 2010; 13(5): 469-80. PMID 20859316
13. Birnbaum K. Percutaneous cervical disc decompression. Surg Radiol Anat. Jun 2009; 31(5): 379-87. PMID 19190848
14. 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
15. Manchikanti L, Derby R, Benyamin RM, et al. A systematic review of mechanical lumbar disc decompression with nucleoplasty. Pain Physician. 2009; 12(3): 561-72. PMID 19461823
16. 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
17. 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.
18. 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.
19. North American Spine Society. Clinical guidelines for diagnosis and treatment of lumbar disc herniation with radiculopathy. 2012; https://www.spine.org/Portals/0/Assets/Downloads/ResearchClinicalCare/Guidelines/LumbarDiscHerniation.pdf.
20. 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?NCDId=324.
21. 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?NCDId=69&ncdver=1&DocID=140.5&bc=gAAAAAgAAAAAAA%3D%3D.

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04/18/2002	Medical Policy Committee review
06/05/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
06/01/2004	Medical Director review
07/20/2004	Medical Policy Committee review. Format revision. Policy and name change (replaces previous Nucleoplasty policy) and expanded to include laser discectomy.
07/26/2004	Managed Care Advisory Council approval
03/09/2006	Medical Director review
03/15/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
03/12/2008	Medical Director review
03/19/2008	Medical Policy Committee approval. No change to coverage eligibility.
03/04/2009	Medical Director review
03/18/2009	Medical Policy Committee approval. No change to coverage eligibility.
03/05/2010	Medical Director review
03/19/2010	Medical Policy Committee approval. No change to coverage eligibility.
03/03/2011	Medical Director review
03/16/2011	Medical Policy Committee approval. Title changed. Coverage wording changed.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013	Coding updated
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review

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09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2024	Medical Policy Committee review
10/08/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2025

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	62287
HCPCS	S2348
ICD-10 Diagnosis	All related Diagnoses

*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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.