

Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:

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

Policy #: 090

Latest Review Date: April 2023

Category: Surgical

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;*
- 2. Not experimental or investigational*;*
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - Furnished in a setting appropriate to the patient's medical needs and condition;*
 - Ordered and furnished by qualified personnel;*
 - One that meets, but does not exceed, the patient's medical need; and*
 - At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **laser discectomy and radiofrequency coblation (DISC Nucleoplasty™)** as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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 variety of minimally invasive techniques have been investigated over the years as treatment of low back pain related to disc disease. Techniques can be broadly divided into techniques that are 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™.

A variety of different lasers have been investigated for laser discectomy, including YAG, KTP, holmium, argon, and carbon dioxide lasers. Due to differences in absorption, the energy requirements and the rate of application differ among the lasers. In addition, it is unknown how much disc material must be removed to achieve decompression. Therefore, protocols vary according to 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 (e.g., 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 an RF 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.

KEY POINTS:

This policy was created in 2003 and updated periodically using the MEDLINE database. The most recent update was performed through February 14, 2023.

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 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 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 randomized controlled trials in addition to the uncontrolled studies, but these trials are limited by the lack of blinding, an inadequate control condition in one trial, and 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.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence guidance on laser lumbar discectomy for the treatment of sciatica was updated in December 2016. The guidance states that current evidence “is inadequate in quantity and quality.”

The guidance on percutaneous disc decompression using coblation for lower back pain and sciatica was also updated in 2016. It states: “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.

American Society of Interventional Pain Physicians

Practice guidelines on lumbar disc compression and chronic spinal pain were published in 2009 and updated in 2013, respectively, by the American Society of Interventional Pain Physicians.

The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty.

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.

KEY WORDS:

Nucleoplasty, Perc-D SpineWand, chemonucleolysis, percutaneous laser discectomy, percutaneous lumbar discectomy, ArthroCare, radiofrequency coablation, contained disc herniation.

APPROVED BY GOVERNING BODIES:

A number of laser devices have received U.S. Food and Drug Administration (FDA) 510(k) clearance 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, Inc. received 510(k) clearance in 2002 for the Trimedyne® Holmium Laser System Holmium:Yttrium Aluminum Garnet (Holmium:YAG), Revolix Duo™ Laser System in 2007, and Quanta System LITHO Laser System in 2009. 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.

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 and Nephew acquired ArthroCare in 2014; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:**CPT codes:**

22899	Unlisted procedure, spine
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, 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.
64999	Unlisted procedure, nervous system
77002	Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device)
S2348	Decompression procedure, percutaneous of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005

Available for comment May 1-June 14, 2005
Medical Policy Group, January 2007
Medical Policy Group, July 2007
Available for comment July 27-September 10, 2007
Medical Policy Group, March 2008
Medical Policy Group, June 2009
Available for comment July 1-August 14, 2009
Medical Policy Group, June 2010
Medical Policy Group, July 2011
Medical Policy Group, December 2011
Medical Policy Group, July 2012
Medical Policy Group, July 2013
Medical Policy Group, July 2014
Medical Policy Group, July 2015
Medical Policy Group, December 2016
Medical Policy Group, January 2017
Medical Policy Group, August 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, May 2020
Medical Policy Group, April 2021
Medical Policy Group, April 2022
Medical Policy Group, April 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.