

Corporate Medical Policy

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

File Name:	decompression_intervertebral_disc_using_laser_energy_or_radiofrequency_coblation
Origination:	9/1991
Last CAP Review:	11/2011
Next CAP Review:	11/2012
Last Review:	11/2011

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.

A variety of minimally invasive techniques have been investigated over the years as a 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™.

Techniques that alter the biomechanics of the disc (disc annulus) include intradiscal electrothermal annuloplasty (i.e., the IDET procedure) or percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). It should be noted that 3 of these procedures use radiofrequency energy—disc nucleoplasty, IDET, and PIRFT—but apply the energy in distinctly different ways such that the procedures are unique.

Patients considered candidates for DISC nucleoplasty™ or laser discectomy include patients with bulging discs and sciatica. In contrast, the presence of a herniated disc is typically considered a contraindication for the IDET or PIRFT procedure. The IDET and PIRFT procedures and automated percutaneous lumbar discectomy are considered in separate policies. Laser discectomy and DISC nucleoplasty™ are the subjects of this policy. 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.

The Disc nucleoplasty™ procedure uses bipolar radiofrequency energy in a process referred to as coblation technology. The technique consists of small, multiple electrodes that emit a fraction of the energy required by traditional radiofrequency energy systems. The result is that a portion of nucleus tissue is ablated not with heat, but with a low-temperature plasma field of ionized particles. These particles have sufficient energy to break organic molecular bonds within tissue, creating small channels in the disc. The proposed advantage of this coblation technology is that the procedure provides for a controlled and highly localized ablation, resulting in minimal therapy damage to

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surrounding tissue.

Regulatory Status

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. Trimedyn, Inc. received 510(k) clearance in 2002 for the Trimedyn Holmium Laser System Holmium: Yttrium Aluminum Garnet (Holmium: YAG), Lisa Laser Products for 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 Trimedyn 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.

Arthrocare's Perc-D SpineWand received 510(k) clearance in 2001 based on equivalence 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.

Related Policies

Percutaneous Lumbar Discectomy
Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

*****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

Radiofrequency Coblation (Disc Nucleoplasty) and Laser Discectomy are considered investigational for all applications. 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 Radiofrequency Coblation (Disc Nucleoplasty) and Laser Discectomy is

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Not applicable

When Radiofrequency Coblation (Disc Nucleoplasty) and Laser Discectomy is not covered

Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered investigational as techniques of disc decompression and treatment of associated pain for all levels of the spine (i.e., cervical, thoracic, lumbar and sacral), whether performed percutaneously or using an open incision.

Policy Guidelines

While numerous case series and uncontrolled studies report improvements in pain and functioning following laser discectomy and nucleoplasty, the lack of well-designed and conducted controlled trials limits interpretation of reported data. Questions remain about the safety and efficacy of these treatments. Further evaluation of effectiveness requires randomized trials with adequate follow-up that control for selection bias, the placebo effect, and variability in the natural history of low back pain. These procedures are considered investigational.

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: 62287, S2348

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

Consultant review - 7/8/2001

Specialty Matched Consultant Advisory Panel - 8/2001

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

Specialty Matched Consultant Advisory Panel - 8/2002

Disc Nucleoplasty and Laser Discectomy

Specialty Matched Consultant Advisory Panel - 7/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 10/9/03

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 3/15/2005

Specialty Matched Consultant Advisory Panel - 6/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 3/7/2006

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.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 3/12/09

Specialty Matched Consultant Advisory Panel - 5/2009

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 6/10/2010

Specialty Matched Consultant Advisory Panel – 11/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 7/14/2011

Medical Director - 8/2011

Specialty Matched Consultant Advisory Panel – 11/2011

Policy Implementation/Update Information

Disc Nucleoplasty and Laser Discectomy

7/20/09 Herniated Lumbar Disc, Percutaneous policy separated into individual policies by topic. Disc Nucleoplasty and Laser Discectomy are considered investigational. Specialty Matched Consultant Panel review 5/28/09. "Description" section revised. Laser Discectomy added as appropriate throughout policy. Rationale in "Policy Guidelines" revised. References added. (btw)

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

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- 12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/2010. Policy name changed from “Disc Nucleoplasty and Laser Discectomy” to “Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)”. “Description” section revised. “When Not Covered” section revised from Disc Nucleoplasty and Laser Discectomy are considered investigational for all levels of the spine (i.e., cervical, thoracic, lumbar and sacral), whether performed percutaneously or using an open incision. BCBSNC does not provide coverage for investigational procedures.” to “Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered investigational as techniques of disc decompression and treatment of associated pain for all levels of the spine (i.e., cervical, thoracic, lumbar and sacral), whether performed percutaneously or using an open incision.” “Policy Guidelines” updated. References added. (btw)
- 9/13/11 “Description” section updated. “Policy Guidelines” updated. No change to policy intent. Medical Director review 8/27/2011. Reference added. (btw)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/30/2011. No change to policy. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.