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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_coblationOrigination:9/1991Last Review:10/2023

Description of Procedure or Service

Laser energy (laser discectomy) and radiofrequency (RF) 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.

A variety of minimally invasive techniques have been investigated 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 a variety of intradiscal electrothermal procedures that are discussed in the policy titled Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine.

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 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 according to the length of treatment, but typically the laser is activated for brief periods only.

RF 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 with an RF coblation source. 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 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. 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.

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. 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.

Related Policies

Percutaneous Intradiscal and Intraosseous Radiofrequency Procedures of the Spine Automated Percutaneous and Endoscopic Discectomy Cervical Spine Procedures Lumbar Spine Procedures

***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 covered

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

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 RF 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 three RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in one trial, 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 one 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.

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

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

<u>Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or</u> <u>Radiofrequency Coblation (Nucleoplasty)</u>

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 7/12/2012

Specialty Matched Consultant Advisory Panel – 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 7/11/2013

Specialty Matched Consultant Advisory Panel - 10/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 7/10/2014

Specialty Matched Consultant Advisory Panel - 10/2014

Medical Director review 10/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 7/9/2015

Specialty Matched Consultant Advisory Panel - 10/2015

Specialty Matched Consultant Advisory Panel - 10/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 1/12/2017

Specialty Matched Consultant Advisory Panel - 10/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 4/12/2018

Specialty Matched Consultant Advisory Panel - 10/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 4/8/2019

Specialty Matched Consultant Advisory Panel - 10/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 4/16/2020

Specialty Matched Consultant Advisory Panel - 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.93, 4/8/2021

Specialty Matched Consultant Advisory Panel - 10/2021

Specialty Matched Consultant Advisory Panel - 10/2022

Specialty Matched Consultant Advisory Panel - 10/2023

Medical Director review- 10/2023

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)

<u>Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or</u> <u>Radiofrequency Coblation (Nucleoplasty)</u>

- 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)
- 9/4/12 Reference added. (btw)
- 11/13/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. No change to policy. (btw)
- 8/27/13 Reference added. (btw)
- 11/12/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. No change to policy intent. (btw)
- 11/11/14 Reference added. Specialty Matched Consultant Advisory Panel review 10/28/2014. Medical Director review. No change to policy intent. (sk)
- 9/1/15 Reference added. (sk)
- 11/24/15 Specialty Matched Consultant Advisory Panel review 10/28/2015. (sk)
- 11/22/16 Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)
- 3/31/17 Reference added. Policy Guidelines updated. (sk)
- 11/10/17 Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)
- 7/27/18 Reference added. (sk)
- 11/9/18 Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)
- 7/16/19 Reference added. (sk)
- 11/26/19 Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)
- 8/25/20 Reference added. (sk)
- 11/10/20 Specialty Matched Consultant Advisory Panel review 10/21/2020. (sk)
- 11/16/21 Reference added. Specialty Matched Consultant Advisory Panel review 10/20/2021. (sk)
- 5/2/23 Policy review. Specialty Matched Consultant Advisory Panel review 10/19/2022. (sk)
- 11/7/23 Added Related Policies. References updated. Specialty Matched Consultant Advisory Panel review 10/2023. Medical Director review 10/2023. (ldh)

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.