

Protocol

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

(70193)

Medical Benefit		Effective Date: 11/01/07	Next Review Date: 09/17
Preauthorization	No	Review Dates: 02/07, 01/08, 01/09, 01/10, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16	

This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Patients/individuals with: <ul style="list-style-type: none">• Discogenic back pain	Interventions of interest are: <ul style="list-style-type: none">• Laser discectomy• Radiofrequency coblation	Comparators of interest are: <ul style="list-style-type: none">• Conservative care• Alternative surgical procedures for discogenic back pain	Relevant outcomes include: <ul style="list-style-type: none">• Functional outcomes• Treatment-related morbidity• Symptoms

Description

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 RF energy is directed into the disc to ablate tissue.

Summary of Evidence

While numerous case series and uncontrolled studies report improvements in pain and functioning following laser discectomy, the lack of well-designed and conducted controlled trials limits interpretation of reported data. For nucleoplasty, there are two small randomized controlled trials in addition to 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. 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) that control for selection bias, the placebo effect, and variability in the natural history of low back pain are needed.

Policy

Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered **investigational** as techniques of disc decompression and treatment of associated pain.

Background

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 RF energy, referred to as a DISC nucleoplasty™.

Techniques that alter the biomechanics of the disc (disc annulus) include intradiscal electrothermal annuloplasty (i.e., the percutaneous intradiscal electrothermal annuloplasty [IDET] procedure) or percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). It should be noted that three of these procedures use radiofrequency (RF) 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, chymopapain injection, and automated percutaneous lumbar discectomy are considered in separate Protocols. Laser discectomy and DISC nucleoplasty™ are the subjects of this Protocol.

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 RF 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 RF 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 surrounding tissue.

Regulatory Status

A number of laser devices have received 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), 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. FDA product code: GEX.

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 decom-

pression of disc material to treat symptomatic patients with contained herniated discs. Smith and Nephew acquired ArthroCare in 2014. FDA product code: GEI.

Related Protocols

Automated Percutaneous and Endoscopic Discectomy

Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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