

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: 09/14
Preauthorization	No	Review Dates: 02/07, 01/08, 01/09, 01/10, 09/10, 09/11, 09/12, 09/13	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel the service is medically necessary; supporting documentation must be submitted to Utilization Management.** 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.*

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.

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 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 percutaneous intradiscal electrothermal annuloplasty [IDET] procedure) or percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). It should be noted that three 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, 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 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 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. Trimeddyne, Inc. received 510(k) clearance in 2002 for the Trimeddyne® Holmium Laser System Ho1mium:Yttrium Aluminum Garnet (Ho1mium: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 Trimeddyne 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 Protocols:

Automated Percutaneous and Endoscopic Discectomy

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

Corporate Medical Guideline

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

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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