

## **Medical Policy Manual**

**Topic:** Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Energy (Nucleoplasty)

**Date of Origin:** December 2003

**Section:** Surgery

**Last Reviewed Date:** July 2014

**Policy No:** 131

**Effective Date:** October 1, 2014

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Ablation of the nucleus pulposus using laser energy (laser discectomy) and radiofrequency energy (coblation or nucleoplasty) is being evaluated as a technique for decompression of the intervertebral disc. Patients considered candidates for laser discectomy or disc nucleoplasty include those patients with bulging discs and sciatica.

#### **Laser Discectomy**

A variety of different lasers have been investigated for laser discectomy, including YAG, KTP, holmium, argon and carbon dioxide lasers. Regardless of the type of laser, the procedure involves vaporization (also referred to as ablation or coagulation) of disc tissue using laser energy delivered via a needle or catheter inserted into the disc nucleus under fluoroscopic guidance. Due to differences in absorption, the energy requirements and the rate of application differ among the lasers. Additionally, 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.

#### **Disc Nucleoplasty**

The disc nucleoplasty procedure uses bipolar radiofrequency energy directed into the disc to ablate disc tissue in a process commonly 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.

### **Chemonucleolysis as an Adjunct to Disc Nucleoplasty**

After FDA approval in 1982, chemonucleolysis was used for a number of years in the United States as a stand-alone procedure to ablate or dissolve disc material. In this procedure, chymopapain, a protein-dissolving enzyme derived from papaya, is injected into a ruptured or bulging disc. However, it largely fell out of favor following disclosure of neurological sequelae and other complications. More recently, chemonucleolysis has been proposed to pre-treat a disc prior to percutaneous disc decompression procedures including disc nucleoplasty.

### **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 SpineWands™ 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 & Nephew acquired ArthroCare in 2014.

**Note:** This policy does *not* address intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), or percutaneous and endoscopic discectomy which are considered in separate medical policies (see Cross References below).

## **MEDICAL POLICY CRITERIA**

- I. Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered **investigational** for all indications, including but not limited to disc decompression and treatment of associated pain.

- II. Chemonucleolysis as an adjunct to percutaneous disc decompression procedures including, but not limited to disc nucleoplasty, is considered **investigational**.

## SCIENTIFIC EVIDENCE

The most clinically relevant outcomes of treatments of back pain are improvements in pain and/or function. Both of these outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of back pain. Therefore, large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to compare ablative disc decompression with open surgical disc decompression, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of the ablative techniques outweigh any risks and provide a significant advantage over conventional open techniques.

### Literature Appraisal

The focus of the following literature review is on systematic reviews, randomized controlled clinical trials, prospective comparative trials, and clinical practice guidelines.

#### Laser Discectomy

Although laser discectomy has been practiced for over a decade, and there is fairly extensive literature describing different techniques using different types of lasers, most of the evidence in the published literature is from case series, retrospective reviews, and a number of review articles.

#### *Systematic Reviews*

- In a 2007 update of a 2003 Cochrane review<sup>[1]</sup> of surgery for lumbar disc prolapse, Gibson and Waddell noted the generally poor methodological quality of the available studies.<sup>[2]</sup> Only three small randomized controlled trials of laser discectomy were found. The authors concluded that these data did not provide conclusive evidence of its efficacy, and that clinical outcomes following laser discectomy “are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged.”
- In a 2007 meta-analysis, Goupille and colleagues concluded that “although the concept of laser disc nucleotomy is appealing, this treatment cannot be considered validated for disc herniation-associated radiculopathy resistant to medical treatment”.<sup>[3]</sup> They cited the lack of consensus regarding technique, that methodology and conclusions of published studies are questionable, and absence of a controlled study.
- In a 2013 update<sup>[4]</sup> of their 2009 systematic review<sup>[5]</sup> Singh et al. rated the current evidence for percutaneous lumbar laser disc decompression for short- and long-term relief of pain as “limited” or poor when rated according to U.S. Preventive Services Task Force (USPSTF) criteria. There were 17 observational studies and no RCTs. Due to the lack of RCTs, meta-analysis could not be conducted. There was a lack of standardization of both selection and outcome criteria. In addition, the authors noted that the lack of a control group in observational studies limited the conclusions that could be made on efficacy.

#### *Randomized Controlled Trials and Nonrandomized Comparative Trials*

No RCTs or nonrandomized comparative trials have been published since publication of the systematic reviews above. Observational, nonrandomized, studies are insufficient to permit conclusions concerning the effect of this technology on health outcomes due to methodologic limitations such as the lack of randomized treatment allocation, small study size, short-term follow-up (generally one year or less), and the lack of a control group for comparison.

### *Adverse Effects*

Few adverse effects have been reported. Choy et al reported complications in 10 of 1275 patients who had 2400 procedures over an 18 year period.<sup>[6]</sup> The only complication was infections discitis which was cured with antibiotics in all 10 patients. Other adverse effects have included instrument failures, nerve damage, reflex sympathetic dystrophy (RSD), sigmoid artery injury, anomalous iliolumbar artery injury, spondylodiscitis, and cauda equina syndrome.<sup>[7]</sup> Reoperation with conventional surgical disc decompression following laser decompression was reported in up to 40% of cases.<sup>[8,9]</sup>

### Radiofrequency Coblation (Disc Nucleoplasty)

#### *Systematic Reviews*

- In 2009, Chou et al. published a review of the evidence for nonsurgical interventions for low back pain for an American Pain Society guideline.<sup>[10]</sup> The authors noted that one lower quality systematic review identified no randomized controlled trials, and there was insufficient evidence from small case series to evaluate efficacy.
- A 2013 systematic review by Manchikanti et al. identified one RCT, rated as moderate in quality, and 14 observational studies on nucleoplasty that included at least 50 subjects and had at least one-year follow-up.<sup>[11]</sup> The available evidence was ranked as “limited to fair” when rated according to USPSTF criteria.

#### *Randomized Controlled Trials and Comparative Trials*

No RCTs or nonrandomized comparative trials for disc nucleoplasty have been published since publication of the systematic reviews above. For the reasons noted above, observational studies are insufficient to permit conclusions concerning the effect of this technology on health outcomes.

### *Adverse Effects*

Adverse effects and reoperation rates have not been consistently reported in the available published literature.

One trial was found in which Cuellar et al. reported accelerated degeneration after failed nucleoplasty.<sup>[12]</sup> Of 54 patients referred for persistent pain after nucleoplasty, 28 patients were evaluated by MRI to determine the source of their symptoms. The total number of procedures performed could not be determined. At a mean follow-up of 24 weeks (range, 6 to 52) after nucleoplasty, no change was observed between the baseline and postoperative MRI for increased signal hydration, disc space height improvement, or shrinkage of the preoperative disc bulge. Of 17 cervical levels treated in 12 patients, 5 (42% of patients) appeared to show progressive degeneration at treated levels. Of 17 lumbar procedures in 16 patients, 4 (15% of patients) showed progressive degeneration. Overall, a total of 26% of the patients in this series showed progressive degeneration at the treated level less than 1 year after nucleoplasty. The proportion of discs showing progressive degeneration out of the total nucleoplasty

procedures performed cannot be determined from this study. It is also unknown whether any morphologic changes occurred after nucleoplasties that were considered to be successful. Additional study of this potential adverse effect of nucleoplasty is needed.

One case of transient epidural fibrosis 3 months post nucleoplasty has also been reported.<sup>[13]</sup>

### Chemonucleolysis as Pre-treatment for Percutaneous Discectomy

No clinical trials were found in which chemonucleolysis was combined with laser discectomy or nucleoplasty procedures.

## **Clinical Practice Guidelines**

### American Society of Interventional Pain Physicians (ASIPP)

In 2013 a task force of the ASIPP updated guidelines for interventional techniques in the management of chronic spinal pain.<sup>[14]</sup> The guidelines reported limited evidence for percutaneous laser disc decompression and fair evidence for nucleoplasty, as described in the 2013 systematic reviews by Singh et al., and Manchikanti et al. summarized above.

- For percutaneous laser discectomy, the guidelines reported Level II-2 evidence for short-term and long-term relief of pain, citing the review by Singe<sup>[5]</sup> which is summarized above.<sup>[7]</sup> Level II-2 evidence was defined as evidence from at least one properly designed small diagnostic accuracy study. The recommendation for use of percutaneous lumbar laser discectomy was graded as 1C, defined as a strong recommendation from low-quality or very low-quality evidence from observational studies or case series. The 1C definition further states that this recommendation “may change when higher quality evidence becomes available.” The authors noted that “these guidelines do not represent a “standard of care.”
- For radiofrequency disc nucleoplasty in managing predominantly lower extremity pain attributable to contained disc herniation a grade 2B weak recommendation was given based on Level II-3 evidence (i.e., “multiple time series with or without the intervention”). No recommendation for nucleoplasty was given regarding managing axial low back pain because no related evidence was found.

### American Pain Society (APS)

A 2009 APS clinical practice guideline found insufficient evidence to evaluate alternative surgical methods, including laser- or endoscopic-assisted techniques, various percutaneous techniques, coblation nucleoplasty, or the Disc Decompressor compared with standard open discectomy and microdiscectomy.<sup>[15]</sup>

## **Summary**

Current evidence is insufficient to determine whether laser discectomy or radiofrequency disc nucleoplasty performed with or without chemolysis is as safe and effective as open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. In addition, there are no evidence-based clinical practice guidelines from U.S. professional societies that recommend these techniques. Therefore, laser discectomy and radiofrequency disc nucleoplasty for disc decompression, with or without chemonucleolysis, are considered investigational.

## REFERENCES

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16. BlueCross BlueShield Association Medical Policy Reference Manual "Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)." Policy No. 7.01.93

## CROSS REFERENCES

[Percutaneous Intradiscal Electrothermal Annuloplasty \(IDET\) and Percutaneous Intradiscal Radiofrequency Thermocoagulation](#), Surgery, Policy No. 118

[Automated Percutaneous and Endoscopic Discectomy](#), Surgery, Policy No. 145

[Image-Guided Minimally Invasive Spinal Decompression \(IG-MSD\) for Spinal Stenosis](#), Surgery, Policy No. 176

CODES	NUMBER	DESCRIPTION
CPT	62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
	62292	Injection procedure for chemonucleolysis including discography, intervertebral disc, single or multiple levels, lumbar
HCPCS	S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar