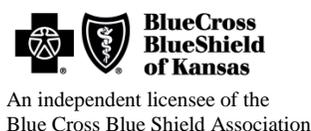


## Medical Policy



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

#### Professional

Original Effective Date: October 18, 2004  
 Revision Date(s): September 7, 2005;  
 February 21, 2006; May 6, 2006;  
 July 27, 2006; September 14, 2006;  
 October 31, 2006; January 1, 2007;  
 November 18, 2009; February 8, 2010;  
 September 20, 2011; January 1, 2012  
 November 6, 2012; October 13, 2015;  
 January 1, 2017; May 23, 2018  
 Current Effective Date: February 8, 2010

#### Institutional

Original Effective Date: July 1, 2005  
 Revision Date(s): September 7, 2005;  
 February 21, 2006; May 6, 2006;  
 July 27, 2006; September 14, 2006;  
 October 31, 2006; January 1, 2007;  
 November 18, 2009; February 8, 2010;  
 September 20, 2011; January 1, 2012;  
 November 6, 2012; October 13, 2015;  
 January 1, 2017; May 23, 2018  
 Current Effective Date: February 8, 2010

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Populations	Interventions	Comparators	Outcomes
Patients/individuals with: <ul style="list-style-type: none"> <li>With discogenic back pain or radiculopathy</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Laser discectomy</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Conservative management</li> <li>Epidural steroid injection</li> <li>Discectomy</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Symptoms</li> <li>Functional outcomes</li> <li>Treatment-related morbidity</li> </ul>

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• With discogenic back pain or radiculopathy</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Disc nucleoplasty with radiofrequency coblation</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Conservative management</li><li>• Epidural steroid injection</li><li>• Discectomy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Treatment-related morbidity</li></ul>

## **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. These minimally invasive procedures are being evaluated for the treatment of discogenic back pain.

### **Objective**

The objective of this evidence review is to evaluate whether laser discectomy or disc nucleoplasty with radiofrequency coblation improve the net health outcome in patients who have discogenic back pain.

### **Background**

#### **Discogenic Low Back Pain**

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease.

### **Treatment**

Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

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 those 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.

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 by 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 using an RF coblation source. The proposed advantage of coblation technology is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue.

### **Regulatory Status**

A number of laser devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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. Trimedynе received 510(k) clearance in 2002 for the Trimedynе® Holmium Laser System Holmium:Yttrium, Aluminum Garnet (Holmium:YAG), in 2007 RevoLix Duo™ Laser System, and in 2009 Quanta System LITHO Laser System. 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 Trimedynе® 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.

In 2001, the Perc-D SpineWand™ (ArthroCare) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent 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; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website. FDA product code: GEI.

## **POLICY**

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

## **RATIONALE**

This evidence review has been updated with searches of the MEDLINE database. The most recent update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The optimal comparators are conservative therapy with a sham control, epidural steroid injection, or conventional discectomy.

### **Laser Discectomy**

Laser discectomy has a fairly extensive literature describing different techniques using different lasers.

### **Systematic Reviews**

Singh et al (2013) updated their systematic review of current evidence on percutaneous laser disc decompression.<sup>1,2</sup> They selected 17 observational studies. Due to the lack of RCTs, meta-analysis could not be conducted, and evidence was considered limited, as rated using U.S. Preventive Services Task Force criteria. A Cochrane review (2007) of surgical interventions for lumbar disc prolapse included 2 comparative studies on laser discectomy that were reported in as proceedings and abstracts.<sup>3</sup> Reviewers concluded that clinical outcomes following automated discectomy and laser discectomy “are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged.”

### **Observational Studies**

Tassi et al (2006) compared outcomes from 500 patients who had discogenic pain and herniated discs treated using microdiscectomy (1997-2001 by 6 surgeons) with 500 patients treated using percutaneous laser disc decompression (2002-2004 by a single surgeon).<sup>4</sup> Patients with sequestered discs were excluded. This retrospective review found that the hospital stay (6 days vs 2 days), overall recovery time (60 days vs 35 days), and repeat procedure rates (7% vs 3%), all respectively, were shorter or had lower rates in the laser group than in the microdiscectomy group. No statistical comparisons were provided. The percentage of patients with overall good/excellent outcomes (Macnab criteria) was found to be similar in both groups (85.7% vs 83.8%, respectively) at the 2-year assessment; quantitative outcome measures were not reported.

Other than the comparative studies previously mentioned, the evidence for laser discectomy is limited to case series. The largest series, published by Choy (2004), included 1275 patients treated with 2400 procedures (including cervical, thoracic, lumbar discs) over 18.5 years, with an overall success rate using the Macnab criteria (measuring pain and function) of 89%.<sup>5</sup> Menchetti et al (2011) retrospectively reviewed 900 patients treated with laser discectomy for herniated nucleus pulposus.<sup>6</sup> The success rate using Macnab criteria at a mean of 5 years (range, 2-6 years) was 68%. Visual analog scale (VAS) scores for pain decreased from 8.5 preoperatively to 2.3 at the 3-year follow-up but increased to 3.4 at the 5-year follow-up. There was a correlation between fair/poor results and subannular extrusion; 40% of these cases were treated with microsurgery after 1 to 3 months.

### **Section Summary: Laser Discectomy**

Evidence on decompression of the intervertebral disc using laser energy consists of observational studies. Given the variable natural history of back pain and the possibility of placebo effects with this treatment, observational studies are insufficient to permit conclusions concerning the effect of this technology on health outcomes.

## **Disc Nucleoplasty with Radiofrequency Coblation**

### **Systematic Reviews**

The systematic review by Manchikanti et al (2013) identified an RCT (described below) and 14 observational studies on disc nucleoplasty (radiofrequency coblation) that met inclusion criteria; they concluded that the evidence was limited to fair.<sup>7</sup>

### **Randomized Controlled Trials**

Included in the systematic review was an industry-sponsored, unblinded multicenter RCT by Gerszten et al (2010); it compared coblation nucleoplasty with 2 epidural steroid injections (ESI).<sup>8</sup> Ninety patients were initially randomized (46 to coblation nucleoplasty arm and 44 to ESI arm). The intent to treat analysis was defined on the basis of 85 patients (45 in nucleoplasty group and 40 in ESI group) who ultimately underwent the assigned intervention. All patients had previously had an epidural steroid injection at 3 weeks to 6 months with no relief, temporary relief, or partial relief of pain. The primary outcome was pain reduction assessed by VAS score. At the 6-month follow-up, the mean improvement in VAS scores for leg pain, back pain, Oswestry Disability Index (ODI) scores, and 36-Item Short-Form Health Survey (SF-36) subscores were significantly greater in the nucleoplasty group. A greater percentage of patients in the nucleoplasty group also had a minimum clinically important change for leg pain, back pain, ODI, and SF-36 scores. The proportion of patients in each group with unresolved symptoms requiring

a secondary procedure during the first 6 month of the trial did not differ between groups (27% for nucleoplasty vs 20% for epidural steroid). At 1-year follow-up, secondary procedure rates increased to 42% of the nucleoplasty group and to 68% of the steroid group. All patients who requested a secondary procedure were cared for as considered appropriate by the study investigator. For the ESI and coblation nucleoplasty groups, respectively, secondary procedures that were pursued included additional ESI (5 and 13 patients), other radiofrequency ablation (2 and 2), coblation nucleoplasty (20 and 0), microdiscectomy (2 and 4), and lumbar interbody fusion (0 and 1).

An unblinded RCT by Chitragran et al (2012) from Asia compared nucleoplasty with conservative treatment in 64 patients.<sup>9</sup> VAS scores at 15 days after treatment were reduced by 4 points from a baseline (9 to 5). The nucleoplasty group was reported to have a reduction in pain and medication use compared with conservatively treated controls at 1, 3, 6, and 12 months posttreatment, although the data were not presented. Comparison of magnetic resonance images at baseline and after treatment showed a decrease in disc bulging from 5.09 mm to 1.81 mm at 3 months after nucleoplasty.

### **Cohort Studies**

Bokov et al (2010) reported a nonrandomized cohort study comparing nucleoplasty with microdiscectomy.<sup>10</sup> Patients undergoing nucleoplasty were grouped into those with a disc protrusion (n=46) or a disc extrusion (n=27). Patients were rated at 1, 3, 6, 12, and 18 months for pain VAS and ODI scores. A satisfactory result was defined as a 50% decrease in VAS score and a 40% decrease in ODI score. For patients with a disc protrusion treated with nucleoplasty, satisfactory results were obtained in 36 (78%). For patients with a disc protrusion treated with microdiscectomy, a satisfactory result was observed in 61 (94%) patients. For patients with a disc extrusion, nucleoplasty had a significantly higher rate of unsatisfactory results; clinically significant improvements were observed in 12 (44%) cases, and 9 (33%) patients with disc extrusion treated with nucleoplasty subsequently underwent microdiscectomy for exacerbation of pain.

Birnbaum (2009) compared outcomes from a series of 26 patients who had cervical disc herniation treated using disc nucleoplasty with a group of 30 patients who received conservative treatment using bupivacaine and prednisolone acetate.<sup>11</sup> Baseline VAS score was 8.4 in the control group and 8.8 in the nucleoplasty group. At 1 week, scores were 7.3 and 3.4, respectively, and at 24 months, 5.1 and 2.3, respectively. No other outcomes data were provided.

Cuellar et al (2010) reported on an observational study evaluating accelerated degeneration after failed nucleoplasty.<sup>12</sup> Of 54 patients referred for persistent pain after nucleoplasty, 28 patients were evaluated by magnetic resonance imaging to determine the source of their symptoms. VAS score for pain in this cohort was 7.3. At a mean follow-up of 24 weeks (range, 6-52 weeks) after nucleoplasty, no change was observed between baseline and postoperative magnetic resonance imaging results 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%) patients appeared to show progressive degeneration at treated levels. Of 17 lumbar procedures in 16 patients, 4 (15%) patients showed progressive degeneration. Overall, 32% of the patients in this series showed progressive degeneration at the treatment level less than 1 year after nucleoplasty. The proportion of discs showing progressive degeneration of the total nucleoplasty

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

### **Section Summary: Disc Nucleoplasty With Radiofrequency Coblation**

Two unblinded RCTs have assessed nucleoplasty. One was from Asia and compared nucleoplasty with conservative therapy. The other RCT was an industry-sponsored comparison of coblation nucleoplasty with epidural steroid injections in a group of patients who had already failed the control intervention. At 6-month follow-up, scores for pain and functional status were superior for the nucleoplasty group, but a similar percentage of patients in the 2 groups had unresolved symptoms and received a secondary procedure. In the observational phase of the trial (2-year follow-up), 50% of patients in the epidural steroid group crossed over to nucleoplasty. The manner in which alternative interventions were offered in the observational phase is uncertain. Overall, interpretation of these study results is limited. Results from a cohort study support the conclusion that nucleoplasty is not as effective as microdiscectomy for disc extrusion. Prospective controlled trials comparing nucleoplasty with microdiscectomy are needed to evaluate efficacy and time to recovery in patients with disc protrusion. Notably, a case series reported accelerated degeneration after nucleoplasty. Adequate follow-up with magnetic resonance imaging is needed to determine if nucleoplasty accelerates disc degeneration.

### **Summary of Evidence**

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 interpretation of reported data. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who have discogenic back pain or radiculopathy who receive disc nucleoplasty with radiofrequency coblation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 2 RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in one, 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 1 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 the effect of the technology on health outcomes.

### **Practice Guidelines and Position Statements**

#### **National Institute for Health and Care Excellence**

In 2016, the National Institute for Health and Care Excellence (NICE) updated its guidance on laser lumbar discectomy for the treatment of sciatica.<sup>13</sup> The guidance stated that current evidence “is inadequate in quantity and quality.”

NICE also updated its guidance on percutaneous disc decompression using coblation for lower back pain and sciatica in 2016.<sup>14</sup> NICE stated: “Current evidence on percutaneous coblation of

the intervertebral disc for low back pain and sciatica raises no major safety concerns. The evidence on efficacy is adequate and includes large numbers of patients with appropriate follow-up periods." The guidance also noted that the patient should be informed of the range of treatment options available.

### **American Pain Society**

American Pain Society practice guidelines (2009) on nonsurgical interventions for low back pain found that "there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate" a number of interventions including coblation.<sup>15,16</sup>

### **American Society of Interventional Pain Physicians**

Practice guidelines on lumbar disc compression and chronic spinal pain were published in 2009 and updated in 2013, respectively, by the American Society of Interventional Pain Physicians.<sup>17,18</sup> The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty.<sup>2,7</sup>

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in March 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

### **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

#### **CPT/HCPCS**

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 discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

- 62287 describes percutaneous needle-based decompression of intervertebral disc; therefore, based on this code alone, it might not be possible to distinguish among automated percutaneous discectomy, laser discectomy, or DISC nucleoplasty™.
- 77002 may be used to describe the radiologic guidance.
- A specific HCPCS S code is available for the radiofrequency procedure: S2348.

## DIAGNOSIS

Experimental / Investigations for all diagnoses related to this policy.

<b>REVISIONS</b>	
02-08-2010	The Decompression of the Intervertebral Disc Using Laser or Radiofrequency medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
09-20-2011	Modified Title from: "Decompression of the Intervertebral Disc Using Laser (Laser Discectomy) or Radiofrequency (DISC Nucleoplasty TM) Energy" to: "Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)"
	Description section updated
	In Policy section <ul style="list-style-type: none"> <li>▪ Revised wording from: "Laser discectomy and DISC nucleoplasty are considered experimental / investigational as techniques of disc decompression and treatment of associated pain." to: "Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered experimental / investigational as techniques of disc decompression and treatment of associated pain."</li> <li>▪ No change in policy intent was made.</li> </ul>
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Updated nomenclature for CPT code 77002.</li> </ul>
	Referenced updated.
01-01-2012	In Coding section: <ul style="list-style-type: none"> <li>▪ Revised CPT code nomenclature: 62287</li> </ul>
11-06-2012	Revision section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Removed all reference to specific diagnoses codes and replaced with the wording, "Experimental / Investigations for all diagnoses related to this policy."</li> </ul>
	References updated
10-13-2015	Description section updated
	Rationale section updated
	References updated
01-01-2017	In Coding section: <ul style="list-style-type: none"> <li>▪ Revised CPT Codes: 62287, 77002</li> </ul>
05-23-2018	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Coding notations updated</li> </ul>
	References updated

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