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

Policy #: 090       Latest Review Date: July 2014
Category: Surgical      Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
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.

DISC nucleoplasty™
During DISC nucleoplasty™, bipolar radiofrequency energy is directed into the disc to ablate tissue. 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™.

Patients considered candidates for DISC nucleoplasty™ or laser discectomy include patients with bulging discs and sciatica. 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.

Percutaneous intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) procedure, chymopapain injection and automated percutaneous lumbar discectomy, and disc biaucuplasty are discussed in separate polices. Laser discectomy and Disc nucleoplasty are the subjects of this policy.

Policy:
Laser discectomy and radiofrequency Coblation (DISC Nucleoplasty™) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best professional judgment.

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medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
This policy was created in 2003 and updated periodically using the MEDLINE database. The most recent update was performed from June 2012 through June 3, 2014.

Randomized, controlled trials (RCTs) are considered particularly important when assessing treatment of low back pain. RCTs are necessary to minimize the impact of demographic and clinical factors that can confound outcomes, to control for the expected placebo effect and other nonspecific effects of enrollment in a trial, and also to control for the variable natural history of low back pain, which may resolve with conservative treatment alone.

**Laser Discectomy**
Laser discectomy has been practiced for more than 20 years, and a fairly extensive literature describes different techniques using different types of lasers.

**Systematic Reviews**
In 2013, Singh et al updated their 2009 systematic review of current evidence on percutaneous laser disc decompression. There were 17 observational studies and no RCTs. Due to the lack of RCTs, meta-analysis could not be conducted, and evidence was considered to be limited, when rated according to U.S. Preventive Services Task Force criteria.

In 2003, Gibson et al published a Cochrane review of surgery for lumbar disc prolapse, which included a review of laser discectomy. This review concluded that unless or until better scientific evidence is available, laser discectomy should be regarded as a research technique. Their 2007 updated Cochrane review of surgical interventions for lumbar disc prolapse included two comparative studies on laser discectomy that were reported in U.S. Congress proceedings and abstracts. One study, comparing two types of lasers, did not report comparative outcome results, and the other, which compared laser discectomy with chemonucleolysis, reported limited results favoring chemonucleolysis. The review 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.”

In a 2007 paper, Goupille et al reviewed the literature on laser disc decompression and 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.” They cite the lack of consensus regarding technique, the questionable methodology and conclusions of published studies, and the absence of a controlled study in their discussion.

**Controlled Cohort Studies**
A retrospective review reported outcomes from 500 patients with discogenic pain and herniated discs treated with microdiscectomy (1997-2001 by 6 surgeons) and 500 patients treated with percutaneous laser disc decompression (2002-2004 by a single surgeon). Patients with sequestered discs were excluded. This retrospective review found that the hospital stay (6 vs 2
days), overall recovery time (60 vs 35 days), and repeat procedure rates (7% vs 3%, all respectively) were lower in the laser group; these were not compared statistically. The percentage of patients with overall good/excellent outcomes (MacNab criteria) was found to be similar in the two groups (85.7% vs 83.8%, respectively) at the two-year assessment; quantitative outcome measures were not reported.

Observational Studies
Other than the comparative studies previously mentioned, the evidence for laser discectomy is limited to case series. In 2004, Choy described the largest series of 1275 patients treated with 2400 procedures (including cervical, thoracic, lumbar discs) over a period of 18.5 years, reporting an overall success rate, according to the MacNab criteria (measuring pain and function) of 89%. “The complication rate (only infectious discitis) was 0.4%; all 10 patients with complications were cured with appropriate antibiotics. The recurrence rate was 5% and usually due to reinjury.” Menchetti et al reported a retrospective review of 900 patients treated with laser discectomy for herniated nucleus pulposus in 2011. The success rate according to MacNab criteria at a mean of five years (range, 2-6 years) was 68%. Visual analog scores (VAS) for pain decreased from 8.5 preoperatively to 2.3 at three-year follow-up and 3.4 at five-year follow-up. There was a correlation between fair/poor results and subannular extrusion; 40% of these cases were treated with microsurgery after one to three months.

In 2009, an article describing the design for an RCT was published by investigators in the Netherlands. No results from this trial have been identified.

Section Summary
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.

Radiofrequency Coblation (Disc Nucleoplasty)
Systematic Reviews
At the time this policy was created, the literature on Disc nucleoplasty™ consisted of case series with no controlled trials. In 2009, Chou et al published a review of the evidence for nonsurgical interventions for low back pain for an American Pain Society guideline. The authors noted that one lower quality systematic review identified no RCTs, and there was insufficient evidence from small case series to evaluate efficacy. A 2013 systematic review by Manchikanti et al identified one RCT and 14 observational studies on nucleoplasty that met inclusion criteria, concluding that evidence on nucleoplasty was limited to fair.

Randomized Controlled Trials
An industry-sponsored RCT from 2010 was an unblinded multicenter comparison of coblation nucleoplasty versus two epidural steroid injections. The 85 patients included in the study had a focal disc protrusion and had failed conservative therapy. In addition, all patients had received an epidural steroid injection three weeks to six months previously with no relief, temporary relief, or partial relief of pain. At the six-month follow-up, the mean improvement in VAS for leg pain, back pain, the Oswestry Disability Index (ODI), 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. A similar percentage of patients (27% of the nucleoplasty group, 20% of the epidural steroid group) had unresolved symptoms and received a secondary procedure during the first six months of the study. At one-year follow-up, secondary procedure rates increased to 42% of the nucleoplasty group and 68% of the steroid group. By the two-year follow-up, 44% of the nucleoplasty group and 73% of patients in the steroid group had secondary procedures, including 20 patients who had crossed over from steroid treatment to nucleoplasty.

A 2012 unblinded RCT from Asia compared nucleoplasty with conservative treatment in 64 patients. VAS at 15 days after treatment was reduced from a baseline of about nine to about five. 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 following treatment, although the data were not presented in this brief report. Comparison of magnetic resonance imaging (MRI) at baseline and after treatment showed a decrease in the bulging of the disc from 5.09 mm to 1.81 mm at three months after nucleoplasty.

Controlled Cohort Studies
Bokov et al reported a nonrandomized cohort study comparing nucleoplasty and microdiscectomy in 2010. Patients undergoing nucleoplasty were divided into those with a disc protrusion (n=46) or a disc extrusion (n=27). The patients with disc extrusion chose nucleoplasty, despite a total annulus disruption. Patients were examined at 1, 3, 6, 12, and 18 months with VAS for pain and ODI. A satisfactory result was defined as a 50% decrease in VAS and a 40% decrease in ODI. 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 patients (94%). For patients with a disc extrusion, nucleoplasty had a significantly higher rate of unsatisfactory results; clinically significant improvements were observed in 12 cases (44%), and nine patients (33%) with disc extrusion treated with nucleoplasty subsequently underwent microdiscectomy for exacerbation of pain.

In 2009, Birnbaum compared outcomes from a series of 26 patients with cervical disc herniation treated with disc nucleoplasty with a group of 30 patients who received conservative treatment with bupivacaine and prednisolone acetate. Baseline VAS was 8.4 in the control group and 8.8 in the nucleoplasty group. At one week, scores were 7.3 and 3.4, respectively, and at 24 months, 5.1 and 2.3, respectively. No other outcome data were provided.

Other
Cuellar et al reported accelerated degeneration after failed nucleoplasty. Of 54 patients referred for persistent pain after nucleoplasty, 28 patients were evaluated by MRI to determine the source of their symptoms. VAS for pain in this cohort was 7.3. At a mean follow-up of 24 weeks (range, 6-52) 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 one 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 occur after nucleoplasties that were considered to be successful. Additional study of this potential adverse effect of nucleoplasty is needed.

Section Summary
Two small RCTs have been published on nucleoplasty. One was a small RCT from Asia that compared nucleoplasty with conservative therapy. The other RCT was an industry-sponsored comparison of coblation nucleoplasty versus epidural steroid injections in a group of patients who had already failed the control intervention. At six-month follow-up, scores for pain and functional status were superior for the nucleoplasty group, but a similar percentage of patients in the two groups had unresolved symptoms and received a secondary procedure. In the observational phase of the study (two-year follow-up), there was a higher percentage of patients (50%) in the control group who 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 of nucleoplasty versus microdiscectomy are needed to evaluate efficacy and time for recovery in patients with disc protrusion. Notably, one case series reported accelerated degeneration after nucleoplasty. Adequate follow-up with MRI is needed to determine if nucleoplasty accelerates disc degeneration.

Summary
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 the 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. Questions remain about the safety and efficacy of these treatments. Reconsideration of the policy position awaits 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. These procedures are considered investigational.

Practice Guidelines and Position Statements
The National Institute for Clinical Excellence (NICE) published guidance on laser lumbar discectomy in 2009, stating that current evidence “is inadequate in quantity and quality”, that this procedure should only be used with special arrangements for clinical governance, consent, and audit or research, and that patients should understand the uncertainty about the safety and efficacy of the procedure. Guidance on percutaneous disc decompression using Coblation for lower back pain was published in 2006 stating that there is some evidence of short-term efficacy; however “this is not sufficient to support the use of this procedure without special arrangements for consent and audit or research.”

A 2009 American Pain Society Clinical Practice Guideline on nonsurgical interventions for low back pain states 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.

Practice Guidelines published in 2009 and updated in 2013 by the American Society of Interventional Pain Physicians. The 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty, as described in the 2013 systematic reviews by Singh et al, and Manchikanti et al.

**Key Words:**
Coblation, Nucleoplasty, Perc-D SpineWand, chemonucleolysis, percutaneous laser discectomy, percutaneous lumbar discectomy, ArthroCare, radiofrequency, contained disc herniation, TransDiscal™ System.

**Approved by Governing Bodies:**
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 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 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

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
### Current Coding:

CPT codes:
- **22899**: Unlisted procedure, spine
  - Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous diskectomy, percutaneous laser diskectomy)
- **62287**: Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous diskectomy, percutaneous laser diskectomy)
- **64999**: Unlisted procedure, nervous system
- **77002**: Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device)
- **S2348**: Decompression procedure, percutaneous of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

### Previous Coding:

CPT codes:
- **76003**: Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device) *(Deleted effective January 1, 2007)*
- **0062T**: Percutaneous intradiscal annuloplasty, any method except electrothermal, unilateral or bilateral including fluoroscopic guidance; single level (CPT category III code) *(Deleted effective January 1, 2010)*
- **0063T**: Percutaneous intradiscal annuloplasty, any method except electrothermal, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (list separately in addition to 0062t for primary procedure) (CPT category III code) *(Deleted effective January 1, 2010)*

### References:


**Policy History:**
Medical Policy Group, January 2003, (1)
Medical Policy Administration Committee, January 2003
Available for comment February 6-March 24, 2003
Medical Policy Group, January 2005 (1)
Medical Policy Administration Committee, April 2005
Available for comment April 12-May 26, 2005
Medical Policy Group, January 2007 (1)
Medical Policy Group, July 2007 (1)
Medical Policy Administration Committee, July 2007
Available for comment July 27-September 10, 2007
Medical Policy Group, April 2008 (1)
Medical Policy Group, June 2009 (1)
Medical Policy Administration Committee, July 2009
Available for comment July 1-August 14, 2009
Medical Policy Group, July 2010, (1): Key Points updated, Description updated, Reference added
Medical Policy Group, July 2012 (4): Updated description, Key Points and References, Updated coding section, No changes to policy section were made.
Medical Policy Group, July 2013 (4): 2013 Updates to Key Points and References
Medical Policy Panel, July 2014
Medical Policy Group, July 2014 (4): Updated Key Points. No changes to the policy at this time.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.