BlueCross BlueShield of Alabama

Name of Policy:

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

Policy #: 090
Category: Surgical

Latest Review Date: May 2018
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.*

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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. For DISC nucleoplasty, bipolar RF energy is directed into the disc to ablate tissue. These minimally invasive procedures are being evaluated for the treatment of discogenic 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.

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™.

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.

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 member's contract and corporate medical policies. Physicians should always exercise their best 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 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 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 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. A 2007 Cochrane review of surgical interventions for lumbar disc prolapse included 2 comparative studies on laser discectomy that were reported in U.S. Congress proceedings and abstracts. 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."

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). 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%. Menchetti et al (2011) retrospectively reviewed 900 patients treated with laser discectomy for herniated nucleus pulposus.6 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

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

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). 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).

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 3 months after nucleoplasty.

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 (2010) reported on an observational study evaluating accelerated degeneration after failed nucleoplasty. 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: Radiofrequency Coblation (Disc Nucleoplasty)
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 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 radiofrequency coblation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 2 randomized controlled trials in addition to the uncontrolled studies, but these trials are limited by the lack of blinding, an inadequate control condition in 1 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 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
The National Institute for Health and Care Excellence guidance on laser lumbar discectomy for the treatment of sciatica was updated in December 2016. The guidance states that current evidence “is inadequate in quantity and quality.”

The guidance on percutaneous disc decompression using coblation for lower back pain and sciatica was also updated in 2016. It states: "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.

American Pain Society
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.

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

U.S Preventive Services Task Force Recommendations
Not Applicable.

Key Words:
Nucleoplasty, Perc-D SpineWand, chemonucleolysis, percutaneous laser discectomy, percutaneous lumbar discectomy, ArthroCare, radiofrequency coablation, contained disc herniation.

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), 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.

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 and 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.

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 and will be reviewed for medical necessity.

Current Coding:

CPT codes:	**22899**	Unlisted procedure, spine
	62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, 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.
	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

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Policy History:

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Medical Policy Group, December 2011 **(1):** 2012 Code Updates – Verbiage change to Code 62287
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.
Medical Policy Panel, 2015
Medical Policy Group, July 2015 (**2**): 2015 Update to Description and Key Points; no change to policy statement.
Medical Policy Group, December 2016: 2017 Annual Coding Update. Updated revised verbiage for cpt code 62287.
Medical Policy Panel, January 2017

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Medical Policy Group, January 2017 **(7):** Updates to Description and Key Points, no new References added; no change to policy statement.
Medical Policy Group, August 2017 **(7):** Removed Previous Coding Section: 76003, 0062T 0063T.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(7):** Updates to Description, Key Points, Approved by Governing Bodies and References; no change to policy statement.

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.