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

Policy # 00087
Original Effective Date: 06/05/2002
Current Effective Date: 10/17/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Percutaneous Discectomy is addressed separately in medical policy 00208.

Note: Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty are addressed separately in medical policy 00077.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers laser discectomy and radiofrequency (RF) coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated pain to be **investigational.***

Background/Overview

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 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.

Techniques that alter the biomechanics of the disc (disc annulus) include a variety of intradiscal electrothermal procedures discussed in medical policy 00077.

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 (e.g., 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 is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of laser devices have been cleared for marketing by the U.S. 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. Trimedyne received 510(k) clearance in 2002 for the Trimedyne®‡ 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 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. 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.

Centers for Medicare and Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services have determined that thermal intradiscal procedures, including percutaneous (or plasma) disc decompression or coblation, are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, which include procedures that "employ the use of a RF energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered."

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The Centers for Medicare & Medicaid Services has not published a national coverage decision on laser discectomy; however, the Centers did indicate the following in its decision on laser procedures:

> "Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the FDA, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered."

Rationale/Source

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. 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. 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). 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. 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 (RF coblation) that met inclusion criteria; they concluded that the evidence 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 RF 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. 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. 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. 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. 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 ESI 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 RF 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.

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Policy History

Original Effective Date:	06/05/2002
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04/18/2002	Medical Policy Committee review
06/05/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
06/01/2004	Medical Director review
07/20/2004	Medical Policy Committee review. Format revision. Policy and name change (replaces previous Nucleoplasty policy) and expanded to include laser discectomy.
07/26/2004	Managed Care Advisory Council approval
03/09/2006	Medical Director review
03/15/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
03/12/2008	Medical Director review
03/19/2008	Medical Policy Committee approval. No change to coverage eligibility.
03/04/2009	Medical Director review
03/18/2009	Medical Policy Committee approval. No change to coverage eligibility.
03/05/2010	Medical Director review
03/19/2010	Medical Policy Committee approval. No change to coverage eligibility.
03/03/2011	Medical Director review
03/16/2011	Medical Policy Committee approval. Title changed. Coverage wording changed.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013	Coding updated
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014	Medical Policy Committee review
04/23/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date:	10/2019

Coding

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Louisiana

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code			
CPT	62287			
HCPCS	S2348			
ICD-10 Diagnosis	M46.40-M46.49	M50.00-M50.03	M50.20-M50.23	M50.30-M50.33
	M50.80-M50.83	M50.90-M50.93	M51.04-M51.06	M51.24-M51.27
	M51.34-M51.37	M51.44-M51.47	M51.84-M51.87	M51.9
	M96.1			

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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