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: 10/18/2017

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 (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty 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 is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease. 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 that are discussed in medical policy 00077 as noted above.

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 by the length of treatment, but typically the laser is activated for brief periods only.
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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 with a 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.

The ArthroCare SpineWand used coblation technology (ArthroCare, Austin, TX). ArthroCare was acquired by Smith & Nephew in 2014; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website.

**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 Inc. 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/discrancy. 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. FDA product code: GEI.

Centers for Medicare and Medicaid Services (CMS)
The CMS has 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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CMS has not published a national coverage decision on laser discectomy; however, CMS states 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
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 to control for the variable natural history of low back pain, which may resolve with conservative treatment alone. The optimal comparators, therefore, 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
In 2013, Singh et al 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, 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 disc decompression 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 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 days vs 2 days), overall recovery time (60 days vs 35 days), and repeat procedure rates (7% vs 3%), all respectively, were lower 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
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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 3-year follow-up but increased to 3.4 at 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 1 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 a 2010, industry-sponsored RCT, an unblinded multicenter comparison of coblation nucleoplasty and 2 epidural steroid injections. The 85 patients included in the study had a focal disc protrusion and had failed conservative therapy. All patients had previously also had an epidural steroid injection at 3 weeks to 6 months with no relief, temporary relief, or partial relief of pain. 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 study 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. By the 2-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 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 in this report. 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.
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Controlled Cohort Studies
Bokov et al reported a nonrandomized cohort study comparing nucleoplasty with microdiscectomy in 2010. 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.

In 2009, Birnbaum compared outcomes from a series of 26 patients with cervical disc herniation treated with disc nucleoplasty to a group of 30 patients who received conservative treatment with 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.

Other
Cuellar et al (2010) reported accelerated degeneration after failed nucleoplasty. Of 54 patients referred for persistent pain after nucleoplasty, 28 patients were evaluated by magnetic resonance imaging (MRI) 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 MRI 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, 26% 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 effect 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 to 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 study (2-year follow-up), a higher percentage of patients (50%) in the control 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
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extrusion. Prospective controlled trials of nucleoplasty versus microdiscectomy are needed to evaluate efficacy and time to recovery in patients with disc protrusion. Notably, 1 case series reported accelerated degeneration after nucleoplasty. Adequate follow-up with MRI 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 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.

References

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**Policy History**

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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

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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
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015 Medical Policy Committee review
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.
Next Scheduled Review Date: 10/2018

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*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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