



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

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: 04/23/2014

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; 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 coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated pain to be **investigational**.*

Background/Overview

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 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.

Techniques that alter the biomechanics of the disc (disc annulus) include intradiscal electrothermal annuloplasty (i.e., the percutaneous intradiscal electrothermal annuloplasty [IDET] procedure) or percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). It should be noted that 3 of these procedures use radiofrequency energy—disc nucleoplasty, IDET, and PIRFT—but apply the energy in distinctly different ways such that the procedures are unique.

Patients considered candidates for DISC nucleoplasty or laser discectomy include patients with bulging discs and sciatica. In contrast, the presence of a herniated disc is typically considered a contraindication for the IDET or PIRFT procedure. Laser discectomy and DISC nucleoplasty are the subjects of this policy.



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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of laser devices have received U.S. 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. Trimedyn, Inc. received 510(k) clearance in 2002 for the Trimedyn 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 Trimedyn 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.

Centers for Medicare and Medicaid Services (CMS)

The CMS has determined that thermal intradiscal procedures, including percutaneous (or plasma) disc decompression (PDD) 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 radiofrequency 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.

The CMS has not published a national coverage decision regarding laser discectomy; however, it states the following in its decision on laser procedures: "Medicare recognizes the use of lasers for many medical



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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. Randomized, controlled trials are necessary to minimize the impact of demographic and clinical factors that can confound outcomes, to control for the expected placebo effect and other non-specific 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 randomized trials. 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 (USPSTF) criteria.

In 2003, Gibson and colleagues 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 2 comparative studies on laser discectomy that were reported in U.S. Congress proceedings and abstracts. One study, comparing 2 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



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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 2 groups (85.7% vs. 83.8%, respectively) at the 2-year assessment; quantitative outcome measures were not reported.

Observational Studies

Other than the comparative studies mentioned above, the evidence for laser discectomy is limited to case series. In 2004, Choy described the largest series of 1,275 patients treated with 2,400 procedures (including cervical, thoracic, and lumbar discs) over a period of 18 1/2 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 and colleagues 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 5 years (range, 2-6 years) was 68%. Visual analog scores (VAS) for pain decreased from 8.5 preoperatively to 2.3 at 3-year follow-up and 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 1-3 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 1 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 multi-center comparison of coblation nucleoplasty versus 2 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 3 weeks to 6 months previously with no relief, temporary relief, or partial relief of pain. At the 6-month follow-up, the



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mean improvement in VAS for leg pain, back pain, the Oswestry Disability Index (ODI), and Short Form (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 and 20% of the epidural steroid group) had unresolved symptoms and received a secondary procedure during the first 6 months of the study. At 1-year follow-up, secondary procedure rates increased to 42% of the nucleoplasty group and 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 from a baseline of about 9 to about 5. The nucleoplasty group was reported to have a reduction in pain and medication use compared to 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.

Controlled Cohort Studies

Bokov and colleagues reported a non-randomized 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 9 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 1 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 MRI to determine the source of their symptoms. Visual analog scores for pain in this cohort was 7.3. At a mean follow-up of 24 weeks (range, 6 to 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



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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 1 year after nucleoplasty. The proportion of discs showing progressive degeneration out 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 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), 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 vs. 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.

Ongoing Clinical Trials

A search of the online site www.clinicaltrials.gov in June 2013 identified 1 new trial from Europe that will compare nucleoplasty with pulsed radiofrequency of the nerve or dorsal root ganglion (DRG) (NCT01797172). Thirty-eight patients will be enrolled with completion expected in 2014.

Two recent trials are listed as completed but no publications have been identified:

- An industry-sponsored randomized controlled trial of nucleoplasty compared to conservative care (NCT00940810). The study has an estimated enrollment of 46 patients with completion noted July 2012.
- An industry-sponsored sham-controlled randomized trial on nucleoplasty is listed as completed as of March 2008 (NCT00124774).

Summary

While numerous case series and uncontrolled studies report improvements in pain and functioning following laser discectomy and nucleoplasty, the lack of well-designed and conducted controlled trials limits interpretation of reported data. Questions remain about the safety and efficacy of these treatments. Reconsideration of the policy position awaits randomized trials with adequate follow-up (at least 1 year) that control for selection bias, the placebo effect, and variability in the natural history of low back pain. These procedures are considered investigational.



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Coding

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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-9 Diagnosis	722.0 thru 722.9
ICD-9 Procedure	80.59

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.

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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.
Next Scheduled Review Date:	04/2015

*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:
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