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

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Replaces N/A

Policy

Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered investigational as techniques of disc decompression and treatment of associated pain.

Related Policies

7.01.18 Automated Percutaneous and Endoscopic Discectomy
7.01.72 Percutaneous Intradiscal Electrothermal Annuloplasty, Percutaneous Intradiscal Radiofrequency Annuloplasty and Biacuplasty
7.01.126 Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis
7.01.551 Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy

Policy Guidelines

Coding

<table>
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<th>Description</th>
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<td>62287</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy)</td>
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<tr>
<td>S2348</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar</td>
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Laser energy (laser discectomy) and radiofrequency (RF) 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.

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 randomized controlled trials (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.

Background
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 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 RF 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 three of these procedures use radiofrequency (RF) energy—DISC nucleoplasty, IDET, and PIRFT—but apply the energy in distinctly different ways such that the procedures are unique.

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.

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.

Regulatory Status
A number of laser devices have been cleared for marketing by the U.S. Food and Drug Administration (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/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.

Arthrocare’s Perc-D SpineWand™ received 510(k) clearance in 2001 based on equivalence to predicate devices. It is used in conjunction with the Arthrocare Coblation® System 2000 for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs. Smith and Nephew acquired ArthroCare in 2014. FDA product code: GEI.

Scope
Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application
N/A

Rationale
This policy was created in 2003 and updated periodically using the MEDLINE database. The most recent update was performed through November 7, 2016.

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 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.(1, 2) 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 as proceedings and abstracts.3 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).(4) 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 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%.5 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 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
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
A 2013 systematic review by Manchikanti et al identified 1 RCT (described below) and 14 observational studies on disc nucleoplasty (radiofrequency coblation) that met inclusion criteria; they concluded that the evidence was limited to fair.(7)

Randomized Controlled Trials
An industry-sponsored RCT from 2010 was an unblinded multi-center comparison of coblation nucleoplasty versus 2 epidural steroid injections.(8) 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 mean improvement in VAS for leg pain, back pain, the Oswestry Disability Index (ODI), and 36-Item Short -Form Health Survey (SF-36) subscores were significantly greater in the nucleoplasty group. A greater percentage of patients in the nucleoplasty group also had a minimum clinically important change for leg pain, back pain, ODI, and SF-36 scores. A similar percentage of patients (27% of the nucleoplasty group, 20% of the epidural steroid group) had unresolved symptoms and received a secondary procedure during the first 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 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.

**Controlled Cohort Studies**

Bokov et al. 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 by MRI to determine the source of their symptoms. VAS for pain in this cohort was 7.3. At a mean follow-up of 24 weeks (range, 6-52) after nucleoplasty, no change was observed between the baseline and postoperative MRI for increased signal hydration, disc space height improvement, or shrinkage of the preoperative disc bulge. Of 17 cervical levels treated in 12 patients, 5 (42% of patients) appeared to show progressive degeneration at treated levels. Of 17 lumbar procedures in 16 patients, 4 (15% of patients) showed progressive degeneration. Overall, a total of 26% of the patients in this series showed progressive degeneration at the treated level less than 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 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 and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

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<td>NCT01797172</td>
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<td>in Patients With Contained Cervical Disc Herniation; a Double-blind</td>
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<td></td>
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<td>NCT00940810</td>
<td>A Prospective, Randomized, Controlled, Multi Center, Clinical</td>
<td>46</td>
<td>Nov 2011 (completed)</td>
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<td></td>
<td>Study With Plasma Disc Decompression Versus Conservative Care</td>
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<td>NCT00124774</td>
<td>Nucleoplasty for Contained Herniated Lumbar Discs: A Randomised,</td>
<td>50</td>
<td>Apr 2006 (completed)</td>
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<tr>
<td></td>
<td>Double Blind, Prospective Comparison With Sham Treatment</td>
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NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

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.

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Practice Guidelines and Position Statements

**National Institute for Clinical Excellence (NICE)**
The National Institute for Health and Care Excellence (NICE) 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” and that this procedure should only be used in the context of research. (13)

NICE’s 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. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent, and audit.” The guidance also notes that the patient should be informed of the range of treatment options available. (14)

**American Pain Society (APA)**
A 2009 APA 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.(15,16)

**American Society of Interventional Pain Physicians (ASIPP)**
Practice Guidelines were published in 2009 and updated in 2013 by the ASIPP.(17,18) The 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty, as described in the 2013 systematic reviews by Singh et al., and Manchikanti et al.(2,7).

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
The Centers for Medicare and Medicaid Services (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 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.(19)

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 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 Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.”(20)

**References**


Appendix

N/A

History

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<td>Replace Policy - Policy updated; references added. Policy statement originally limited to treatment of low back pain; this has been revised to remove this limitation such that treatment at all disc levels is considered investigational.</td>
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<td>Replace Policy - Policy updated with literature search; reference numbers 6, 7, and 22 added. No change has been made to the policy statement; the title reflects a slight change in wording from, “Decompression of the Intervertebral Disc Using Laser (Laser Discectomy) or Radiofrequency Energy (DISC Nucleoplasty™)” to “Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency-Coblation (Nucleoplasty)”</td>
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Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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