Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/24**
(See policy history boxes for previous effective dates)

Title: Spinal Surgery: Percutaneous Disc Decompression Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

Description/Background

Laser energy (laser discectomy) and radiofrequency (RF) coblation (nucleoplasty) have been 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. These minimally invasive procedures are being evaluated for the treatment of discogenic back pain.

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. Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

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 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.

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.

Regulatory Status

A number of laser devices have received U.S. Food and Drug Administration (FDA) 510(k) clearance for incision, excision, resection, ablation, vaporization, and coagulation of tissue. Intended uses described in FDA summaries include a wide variety of procedures, including percutaneous discectomy. Trimedyne Inc. received 510(k) clearance in 2002 for the Trimedyne® Holmium Laser System Ho1mium:Yttrium Aluminum Garnet (Ho1mium:YAG), 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 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.

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.

Medical Policy Statement

Decompression of the intervertebral disc using laser energy (laser discectomy) and radiofrequency coblation (nucleoplasty) are experimental/investigational as techniques for disc decompression for the treatment of associated low back pain. These procedures have not been shown to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

S2348 62287

Rationale

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

Clinical Context and Therapy Purpose

The purpose of decompression of the intervertebral disc using laser discectomy for individuals with discogenic back pain or radiculopathy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant populations of interest are individuals with discogenic back pain or radiculopathy.

Interventions

The therapy being considered is laser discectomy. Laser discectomy is performed by an orthopedist or spine specialist in an outpatient clinical setting.

Comparators

The following therapies are currently being used to make decisions about laser discectomy. Conservative management such as physical therapy and medication, epidural steroid injection, and the potential for conventional discectomy or surgical decompression in severe cases. Patients with discogenic back pain or radiculopathy are managed by orthopedists or spine specialists.

The optimal comparators are conservative therapy with a sham control, epidural steroid injection, or conventional discectomy.

Outcomes

The general outcomes of interest are *s*ymptoms, functional outcomes, and treatment-related morbidity.

Laser discectomy has a fairly extensive literature describing different techniques using different lasers. Follow-up would ideally be ≥ 1 year.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

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. 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 a period of 18.5 years, reporting an overall success rate, according to 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 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 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

Clinical Context and Therapy Purpose

The purpose of decompression of the intervertebral disc using radiofrequency coblation for individuals with discogenic back pain or radiculopathy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant populations of interest are individuals with discogenic back pain or radiculopathy.

Interventions
The therapy being considered is disc nucleoplasty with radiofrequency coblation. Disc nucleoplasty with radiofrequency coblation is performed by an orthopedist or spine specialist in an outpatient clinical setting.

Comparators
The following therapies are currently being used to make decisions about disc nucleoplasty with radiofrequency coblation. Conservative management such as physical therapy and medication, epidural steroid injection, and the potential for conventional discectomy or surgical decompression in severe cases. Patients with discogenic back pain or radiculopathy are managed by orthopedists or spine specialists.

The optimal comparators are conservative therapy with a sham control, epidural steroid injection, or conventional discectomy.

Outcomes
The general outcomes of interest are *s*ymptoms, functional outcomes, and treatment-related morbidity. Follow-up would ideally be ≥ 1 year.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

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; the authors concluded that the evidence was limited to fair.[7]

Randomized Controlled Trials
Included in the systematic review was an industry sponsored RCT by Gerszten et al (2010) unblinded multicenter 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 by Chitragran et al from Asia compared nucleoplasty with conservative treatment in 64 patients.[9] 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.

De Rooij et al (2020) compared the effects of percutaneous cervical nuceloplasty and anterior cervical discectomy in 48 patients with cervical radicular pain due to a single-level contained soft-disc herniation.[10,] Tables 1 and 2 summarize the key characteristics and results of this trial. The primary outcome measure was arm pain intensity as measured by a visual analog scale. Overall, a statistically significant interaction between the groups on arm pain intensity and the secondary outcome of SF-36 item pain, in favor of anterior cervical discectomy, was noted at 3 months. There was also a trend for more improvement of arm pain in favor of anterior cervical discectomy at 12 months, with no statistical interactions on the secondary outcomes observed. Of note, the trial was discontinued before reaching the required sample size as enrollment into the trial was low. Tables 3 and 4 discuss study relevance and design/conduct limitations.

Table 1. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
de Rooij et al (2020)[10,]	The Netherlands	5	2012-2018	48	Percutaneous cervical nucleoplasty (n=24)	Anterior cervical discectomy (n=24)

RCT: randomized controlled trial.

Table 2. Summary of Key RCT Results

Study	Arm Pain Intensity (measured with VAS)	Neck Pain Intensity (measured with VAS)	Satisfaction after Treatment (measured by GPE questionnaire)	Disability due to Neck Pain (measured by Neck Disability Index)
de Rooij et al (2020)[10,]	*ITT analysis*	*ITT analysis*	*ITT analysis*	*ITT analysis*
Percutaneous cervical nucleoplasty (mean; 95% CI)	Baseline: 53.1 (43.8-62.4) 1 week: 38.4 (26.3-50.5) 3 months: 35.7 (24.1-47.2)	Baseline: 60.1 (50.8-69.4) 1 week: 46.7 (35.5-57.9) 3 months: 37.1 (26.3-49.3)	1 week: 2.95 (2.37-3.55) 3 months: 2.60 (1.92 to 3.28) 12 months: 3 (2.36-3.64)	Baseline: 61.88 (56.17 to 67.59) 3 months: 49.09 (40.4-57.76) 12 months: 46.13 (37.35-54.91)

	12 months: 31 (19.9-42.1)	12 months: 35.0 (24.1-45.9)		
Anterior cervical discectomy (mean; 95% CI)	Baseline: 58.9 (49.7-68.3) 1 week: 41.9 (29.6-54.3) 3 months: 24.3 (12.7-35.9) 12 months: 21.3 (10-32.6)	Baseline: 59.9 (50.1-69.9) 1 week: 48.9 (50.5-70.4) 3 months: 26.0 (13.9-38.0) 12 months: 24.7 (13.5-35.8)	1 week: 2.46 (1.83 to 3.06) 3 months: 1.97 (1.26 to 2.67) 12 months: 2.27 (1.62 to 2.92)	Baseline: 67.7 (61.99-73.41) 3 months: 49.79 (41.12-58.48) 12 months: 46.35 (37.57-55.13)

CI: confidence interval: GPE: global perceived effect; ITT: intention-to-treat; RCT: randomized controlled trial; VAS: visual analog scale.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
de Rooij et al (2020)[10,]	4. Inclusion by participating hospitals was limited as several patients preferred to be treated in their local hospital, resulting in the majority of patients coming from 2 sites			6. At 12 months, no significant interaction on any outcomes was seen, presumed due to trial being underpowered	

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
de Rooij et al (2020)[10,]		1. Patients and interventionists were not blinded to treatment, increased risk of performance bias		2. Change in study intended to physiotherapy treatment arm. Withdrawn due to refusal of patients with prior unsuccessful physiotherapy	3. Trial did not accrue required sample size	

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

Chen et al (2022) conducted an open-label, case-control, single-center study in China in individuals with cervical herniated intervertebral disc and cervical radiculopathy treated with nucleoplasty (n=71) compared to conventional treatment (n=21).[11] The nucleoplasty group demonstrated significantly greater changes from baseline in pain scores measured by the visual analog scaleat 1-month post-operation (p<.001), 3 months post-operation (p<.001), and 6 months post-operation (p<.01) compared to conventional therapy. At 1 month post-operation, the nucleoplasty group also exhibited improved Oswestry Disability Index scores (p<.05) and Neck Disability Index scores (p<.05) compared to conventional therapy, but there was no difference between groups at 6 months follow-up. These results are limited by the small sample size, lack of randomization, and loss to follow-up of some participants at the 6-month point.

Bokov et al reported a nonrandomized cohort study comparing nucleoplasty and microdiscectomy in 2010.[12] 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.[13] 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.

Cuellar et al (2010) reported accelerated degeneration after failed nucleoplasty.[14] 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: 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 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 versus microdiscectomy are needed to evaluate efficacy and time for 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 radiofrequency 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05601791	Efficacy of Percutaneous Laser Disc Decompression Versus Epidural Steroid and Local Anesthetic Injection by Transforaminal Approach in the Treatment of Lumbar Radicular Pain	116	Jul 2024

NCT: national clinical trial

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute For Health and Care Excellence

The National Institute for Health and Care Excellence guidance on laser lumbar discectomy for the treatment of sciatica was updated in December 2016. The guidance states that current evidence "is inadequate in quantity and quality," and that this procedure should only be used in the context of research.[15]

NICE's guidance on percutaneous disc decompression using coblation for lower back pain 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.[16]

American Society of Interventional Pain Physicians

Practice guidelines were published in 2009 and updated in 2013 by the American Society of Interventional Pain Physicians.[17,18] The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty.[2,7]

In 2020, ASIPP guidelines for comprehensive evidence based guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain do not mention percutaneous laser disc decompression or nucleoplasty.[18]

North American Spine Society
In 2012, the North American Spine Society (NASS) released clinical practice guidelines on the diagnosis and treatment of lumbar disc herniation with radiculopathy.[19] NASS stated, "there is insufficient evidence to make a recommendation for or against the use of plasma disc decompression/nucleoplasty in the treatment of patients with lumbar disc herniation with radiculopathy."

Government Regulations

National:

National Coverage Determination. 150.11. publication number 100-3. Effective on 9/29/2008. 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.[20, 21]

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.”

Local:

There is no local coverage determination (LCD) on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Spinal Surgery: Automated Percutaneous Discectomy
- Spinal Surgery: Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Thermocoagulation

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
8/9/02	8/9/02	8/9/02	Joint medical policy established
7/20/04	7/20/04	7/21/04	Routine maintenance
9/23/04	N/A	N/A	S code received – S2348. Effective date 1/01/2005
9/1/06	7/11/06	7/6/06	Routine maintenance
9/1/07	7/3/07	6/1/07	Routine maintenance
3/1/09	12/9/08	12/21/08	Routine maintenance. Effective 3/1/12, this policy is consolidated into another policy, "Spinal Surgery-Percutaneous, Endoscopic, Laser and/or Radiofrequency Decompression"
5/1/15	2/17/15	3/2/15	Joint policy re-established as a separate policy.
7/1/16	4/19/16	4/19/16	Routine policy maintenance.
7/1/17	4/18/17	4/18/17	Routine maintenance. Updated rationale and references. Policy status unchanged. Altered title to mirror BCBSA title of same name.
7/1/18	4/17/18	4/17/18	Routine maintenance. No change in policy status.
7/1/19	4/16/19		Routine policy maintenance. No change in policy status.
7/1/20	4/14/20		Routine policy maintenance. No change in policy status.
7/1/21	4/20/21		Routine policy maintenance. No change in policy status.
7/1/22	4/19/22		Routine policy maintenance, added reference #10, removed reference 15 and 16. No change in policy status.
7/1/23	4/18/23		Routine policy maintenance, no change in policy status. Vendor managed: Turning Point, OR-1039. (ds)
7/1/24	4/16/24		Updated rationale, added references 11 & 19. No change in policy status.

			Vendor managed: Turning Point, OR-1039 (ds)

Next Review Date: 2nd Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 5/8/01	Revised: N/A
BCBSM: 10/11/00	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SPINAL SURGERY: PERCUTANEOUS DISC DECOMPRESSION USING LASER ENERGY (LASER DISCECTOMY) OR RADIOFREQUENCY ABLATION (DISC NUCLEOPLASTY™)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.