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

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Coverage

Laser discectomy and radiofrequency coblation (disc nucleoplasty) **are considered experimental, investigational and/or unproven** as techniques of disc decompression and treatment of associated pain.

Policy Guidelines

None.

Description

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. 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.

Treatment

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

A variety of minimally invasive techniques have been investigated as treatment of low back pain related to disc disease. Techniques can be broadly divided into those designed to remove or ablate disc material, and thus decompress the disc, and those designed to alter the biomechanics of the disc annulus. The former category includes chymopapain injection, automated percutaneous lumbar discectomy, laser discectomy, and, most recently, disc decompression using radiofrequency energy, referred to as a disc nucleoplasty.

Techniques that alter the biomechanics of the disc (disc annulus) include a variety of intradiscal electrothermal procedures discussed in medical policy SUR712.023.

A variety of different lasers have been investigated for laser discectomy, including YAG (yttrium aluminum garnet), KTP (potassium titanyl phosphate), 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.

Radiofrequency 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 a radiofrequency 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 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 the FDA summaries include a wide variety of procedures, including percutaneous discectomy. Trimedyne received 510(k) clearance in 2002 for the Trimedyne® Holmium Laser System Holmium: Yttrium, Aluminum Garnet (Holmium:YAG), in 2007 RevoLix Duo™ Laser System, and in 2009 Quanta System LITHO Laser System. All were cleared, based on equivalence with predicate devices for percutaneous laser disc decompression/discectomy, including foraminoplasty, percutaneous cervical disc decompression/discectomy, and percutaneous thoracic disc decompression/discectomy. The summary for the Trimedyne® system states that indications for cervical and thoracic decompression/discectomy include uncomplicated ruptured or herniated discs, sensory changes, imaging consistent with findings, and symptoms unresponsive to 12 weeks of conservative treatment. Indications for treatment of cervical discs also include positive nerve conduction studies. FDA product code: GEX.

In 2001, the Perc-D SpineWand™ (ArthroCare) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to predicate devices. It is used in conjunction with the ArthroCare Coblation® System 2000 for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs. Smith & Nephew acquired ArthroCare in 2014; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website. FDA product code: GEI.

Rationale

This medical policy has been updated regularly with searches of the PubMed database. The most recent update was performed through February 14, 2023.

Medical policies 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.

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 PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with discogenic back pain or radiculopathy.

Interventions

The therapy being considered is laser discectomy.

Comparators

The following therapies are currently being used to make decisions about discogenic back pain or radiculopathy: conservative management such as physical therapy and medication, epidural steroid injection, and the potential for conventional discectomy or surgical decompression in severe cases.

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

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and treatment-related morbidity. Laser discectomy has 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.

Review of Evidence

Systematic Reviews

Singh et al. (2013) updated their systematic review of current evidence on percutaneous laser disc decompression. (1, 2) The authors selected 17 observational studies. Due to the lack of RCTs, meta-analysis could not be conducted, and evidence was considered limited, as rated using U.S. Preventive Services Task Force criteria. A Cochrane review (2007) of surgical interventions for lumbar disc prolapse included 2 comparative studies on laser discectomy that were reported in as proceedings and abstracts. (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 who had discogenic pain and herniated discs treated using microdiscectomy (1997-2001 by 6 surgeons) with 500 patients treated using percutaneous laser disc decompression (2002-2004 by a single surgeon). (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 shorter or had lower rates in the laser group than in the microdiscectomy group. No statistical comparisons were provided. The percentage of patients with overall good/excellent outcomes (Macnab criteria measuring pain and function) 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. Choy (2004) published the largest series, which included 1,275 patients treated with 2,400 procedures (including cervical, thoracic, lumbar discs) over 18.5 years, with an overall success rate using the Macnab criteria 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 scores for pain decreased from 8.5 preoperatively to 2.3 at the 3-year follow-up but increased to 3.4 at the 5-year follow-up. There was a correlation between fair/poor results and subannular extrusion; 40% of these cases were treated with microsurgery after 1 to 3 months.

Section Summary: Laser Discectomy

Evidence on decompression of the intervertebral disc using laser energy consists of observational studies. Given the variable natural history of back pain and the possibility of placebo effects with this treatment, observational studies are insufficient to permit conclusions concerning the effect of this technology on health outcomes.

Disc Nucleoplasty with Radiofrequency Coblation

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 PICO was used to select literature to inform this policy.

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.

Comparators
The following therapies are currently being used to make decisions about discogenic back pain or radiculopathy: conservative management such as physical therapy and medication, epidural steroid injection, and the potential for conventional discectomy or surgical decompression in severe cases.

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

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and treatment-related morbidity.

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.

Review of Evidence
Systematic Reviews
Manchikanti et al. (2013) identified an RCT (described below) and 14 observational studies on disc nucleoplasty (radiofrequency coblation) that met inclusion criteria for their systematic review; the authors concluded that the evidence was limited to fair. (7)

Randomized Controlled Trials

Gerszten et al. (2010), conducted an industry-sponsored, unblinded, multicenter RCT, included in the above systematic review, that compared coblation nucleoplasty with 2 epidural steroid injections. (8) Ninety patients were initially randomized (46 to coblation nucleoplasty arm and 44 to epidural steroid injections arm). The intention-to-treat analysis was defined on the basis of 85 patients (45 in nucleoplasty group and 40 in epidural steroid injections group) who ultimately underwent the assigned intervention. All patients had previously had an epidural steroid injection at 3 weeks to 6 months with no relief, temporary relief, or partial relief of pain. The primary outcome was pain reduction assessed by visual analog scale score. At the 6-month follow-up, the mean improvement in visual analog scale scores for leg pain, back pain, Oswestry Disability Index 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, Oswestry Disability Index, and 36-Item Short-Form Health Survey (SF-36) scores. The proportion of patients in each group with unresolved symptoms requiring a secondary procedure during the first 6 months of the trial did not differ between groups (27% for nucleoplasty vs. 20% for epidural steroid). At 1-year follow-up, secondary procedure rates increased to 42% of the nucleoplasty group and to 68% of the steroid group. All patients who requested a secondary procedure were cared for as considered appropriate by the study investigator. For the epidural steroid injections and coblation nucleoplasty groups, respectively, secondary procedures that were pursued included additional epidural steroid injections (5 and 13 patients), other radiofrequency ablation (2 and 2), coblation nucleoplasty (20 and 0), microdiscectomy (2 and 4), and lumbar interbody fusion (0 and 1).

Chitragran et al. (2012) published results of an unblinded RCT conducted in Asia that compared nucleoplasty with conservative treatment in 64 patients. (9) Visual analog scale scores at 15 days after treatment were reduced by 4 points from baseline (9 to 5). The nucleoplasty group was reported to have a reduction in pain and medication use compared with conservatively treated controls at 1-, 3-, 6-, and 12-months posttreatment, although the data were not presented. Comparison of magnetic resonance images at baseline and after treatment showed a decrease in disc bulging from 5.09 mm to 1.81 mm at 3 months after nucleoplasty.

De Rooij et al. (2020) compared the effects of percutaneous cervical nucleoplasty 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) 12 months: 31 (19.9-42.1)	Baseline: 60.1 (50.8-69.4) 1 week: 46.7 (35.5-57.9) 3 months: 37.1 (26.3-49.3) 12 months: 35.0 (24.1-45.9)	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)
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 (1.83-3.06) 3 months: 1.97 (1.26-2.67) 12 months: 2.27 (1.62-2.92)	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.

Tables 3 and 4 display notable limitations identified in each study.

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 literature 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 literature 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 scale at 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. (2010) reported a nonrandomized cohort study comparing nucleoplasty with microdiscectomy. (12) 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 visual analog scale and Oswestry Disability Index scores. A satisfactory result was defined as a 50% decrease in visual analog scale score and a 40% decrease in Oswestry Disability Index score. For patients with a disc protrusion treated with nucleoplasty, satisfactory results were obtained in 36 (78%) patients. For patients with a disc protrusion treated with microdiscectomy, a satisfactory result was observed in 61 (94%) patients. For patients with a disc extrusion, nucleoplasty had a significantly higher rate of unsatisfactory results; clinically significant improvements were observed in 12 (44%) cases, and 9 (33%) patients with disc extrusion treated with nucleoplasty subsequently underwent microdiscectomy for exacerbation of pain.

Birnbaum (2009) compared outcomes from a series of 26 patients who had cervical disc herniation treated using disc nucleoplasty with a group of 30 patients who received conservative treatment using bupivacaine and prednisolone acetate. (13) Baseline visual analog scale score was 8.4 in the control group and 8.8 in the nucleoplasty group. At 1 week, scores

were 7.3 and 3.4, respectively, and at 24 months, 5.1 and 2.3, respectively. No other outcomes data were provided.

Cuellar et al. (2010) reported on an observational study evaluating accelerated degeneration after failed nucleoplasty. (14) Of 54 patients referred for persistent pain after nucleoplasty, 28 patients were evaluated by magnetic resonance imaging to determine the source of their symptoms. Visual analog scale score for pain in this cohort was 7.3. At a mean follow-up of 24 weeks (range, 6-52 weeks) after nucleoplasty, no change was observed between baseline and postoperative magnetic resonance imaging results for increased signal hydration, disc space height improvement, or shrinkage of the preoperative disc bulge. Of 17 cervical levels treated in 12 patients, 5 (42%) patients appeared to show progressive degeneration at treated levels. Of 17 lumbar procedures in 16 patients, 4 (15%) patients showed progressive degeneration. Overall, 32% of the patients in this series showed progressive degeneration at the treatment level less than 1 year after nucleoplasty. The proportion of discs showing progressive degeneration of the total nucleoplasty procedures performed cannot be determined from this study. It is also unknown whether any morphologic changes occurring after nucleoplasties were considered successful. Additional study of this potential adverse event of nucleoplasty is needed.

Section Summary: Disc Nucleoplasty With Radiofrequency Coblation

Three unblinded RCTs have assessed nucleoplasty. One was from Asia and compared nucleoplasty with conservative therapy. Another RCT was an industry-sponsored comparison of coblation nucleoplasty with 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 trial (2-year follow-up), 50% of patients in the epidural steroid group crossed over to nucleoplasty. The manner in which alternative interventions were offered in the observational phase is uncertain. Overall, interpretation of these study results is limited. In the third unblinded, prospective RCT, nucleoplasty was compared to anterior cervical discectomy in patients with cervical radicular pain. Overall, no significant differences between the groups were observed at 1 year. Additionally, the RCT was terminated early as the enrollment rate was low, resulting in the study being underpowered. Results from a case-control study demonstrated that nucleoplasty may be more effective than conservative therapy but results from a cohort study support the conclusion that nucleoplasty is not as effective as microdiscectomy for disc extrusion. Further prospective controlled trials comparing nucleoplasty with microdiscectomy are needed to evaluate efficacy and time to recovery in patients with disc protrusion. Notably, a case series reported accelerated degeneration after nucleoplasty. Adequate follow-up with magnetic resonance imaging is needed to determine if nucleoplasty accelerates disc degeneration.

Summary of Evidence

For individuals who have discogenic back pain or radiculopathy who receive laser discectomy, the evidence includes systematic reviews of observational studies. Relevant outcomes are

symptoms, functional outcomes, and treatment-related morbidity. While numerous case series and uncontrolled studies have reported improvements in pain levels and functioning following laser discectomy, the lack of well-designed and -conducted controlled trials limits interpretation of reported data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, and prospective and retrospective nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 3 RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in one, and inadequate data reporting in the second, and low enrollment with early study termination in the third. 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 that the technology results in an improvement in the net health outcomes.

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

In 2009, updated in 2013, the American Society of Interventional Pain Physicians issued practice guidelines on lumbar disc compression and chronic spinal pain. (15, 16) The systematic reviews informing the 2013 guidelines found limited evidence for percutaneous laser disc decompression and limited to fair evidence for nucleoplasty. (2, 7)

National Institute for Health and Care Excellence

In 2016, the National Institute for Health and Care Excellence (NICE) updated its guidance on laser lumbar discectomy for the treatment of sciatica. (17) The guidance stated that current evidence “is inadequate in quantity and quality.”

Also in 2016, NICE also updated its guidance on percutaneous disc decompression using coblation for lower back pain and sciatica. (18) NICE stated: “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.” The guidance also noted that the patient should be informed of the range of treatment options available.

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."

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy 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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	62287, 77002
HCPCS Codes	S2348

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Reviewed. No changes.
12/15/2023	Document updated with literature review. Coverage unchanged. Reference 11 & 19 added.
10/15/2022	Document updated with literature review. Coverage unchanged. Reference 10 added.
08/01/2021	Reviewed. No changes.
08/01/2020	Document updated with literature review. Coverage unchanged. No new references added.
08/01/2019	Reviewed. No changes.
11/15/2018	Document updated with literature review. Coverage unchanged. References 13 and 14 were added, several references were removed.
06/01/2017	Reviewed. No changes.
09/15/2016	Document updated with literature review. Coverage unchanged.
10/01/2015	Reviewed. No changes.
08/01/2014	New medical document originating from SUR712.004 Intervertebral Techniques to Treat Chronic Discogenic Back Pain. Experimental, investigational and/or unproven coverage position for laser discectomy and radiofrequency coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated pain remains unchanged.