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Medical Policy

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

Related Policies:	▪ *Automated Percutaneous and Percutaneous Endoscopic Discectomy* ▪ *Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation*

Professional / Institutional
Original Effective Date: October 18, 2004 / July 1, 2005
Latest Review Date: June 13, 2023
Current Effective Date: February 8, 2010

Archived Date: June 13, 2023

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Populations	Interventions	Comparators	Outcomes
Patients/individuals with: • With discogenic back pain or radiculopathy	Interventions of interest are: • Laser discectomy	Comparators of interest are: • Conservative management • Epidural steroid injection • Discectomy	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related morbidity
Individuals: • With discogenic back pain or radiculopathy	Interventions of interest are: • Disc nucleoplasty with radiofrequency coblation	Comparators of interest are: • Conservative management • Epidural steroid injection • Discectomy	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related morbidity

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.

OBJECTIVE

The objective of this evidence review is to evaluate whether laser discectomy or disc nucleoplasty with radiofrequency coblation improve the net health outcome in patients who have discogenic back pain.

BACKGROUND

Discogenic Low Back Pain

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptom findings, in conjunction with radiologically confirmed degenerative disc disease.

Treatment

Typical treatment includes conservative therapy with physical therapy and medication management, with the 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

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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 BCBSKS medical policy *Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation*.

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 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.

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

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POLICY

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

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

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

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 1 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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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 review.

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

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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 to include. Due to the lack of RCTs, a 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 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 through 2001 by 6 surgeons) with 500 patients treated using percutaneous laser disc decompression (2002 through 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 to 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

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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 review.

Populations

The relevant populations of interest is 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

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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 the coblation nucleoplasty arm and 44 to the epidural steroid injections arm). The intention-to-treat analysis was defined on the basis of 85 patients (45 in the nucleoplasty group and 40 in the 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 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 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

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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 to 62.4) 1 week: 38.4 (26.3 to 50.5) 3 months: 35.7 (24.1 to 47.2) 12 months: 31 (19.9 to 42.1)	Baseline: 60.1 (50.8 to 69.4) 1 week: 46.7 (35.5 to 57.9) 3 months: 37.1 (26.3 to 49.3) 12 months: 35.0 (24.1 to 45.9)	1 week: 2.95 (2.37 to 3.55) 3 months: 2.60 (1.92 to 3.28) 12 months: 3 (2.36 to 3.64)	Baseline: 61.88 (56.17 to 67.59) 3 months: 49.09 (40.4 to 57.76) 12 months: 46.13 (37.35 to 54.91)
Anterior cervical discectomy (mean; 95% CI)	Baseline: 58.9 (49.7 to 68.3) 1 week: 41.9 (29.6 to 54.3) 3 months: 24.3 (12.7 to 35.9) 12 months: 21.3 (10 to 32.6)	Baseline: 59.9 (50.1 to 69.9) 1 week: 48.9 (50.5 to 70.4) 3 months: 26.0 (13.9 to 38.0) 12 months: 24.7 (13.5 to 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 to 73.41) 3 months: 49.79 (41.12 to 58.48) 12 months: 46.35 (37.57 to 55.13)

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

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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.

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[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 outcome 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 to 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 the 6-month follow-up, scores for pain and functional status were superior in 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, the 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.

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SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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, 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 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."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

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

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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.

No review or update is scheduled on this Medical Policy. Blue Cross and Blue Shield of Kansas will continue to monitor published literature for any updated information. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, or your professional / institutional relations representative.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
77002	Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

REVISIONS	
02-08-2010	The Decompression of the Intervertebral Disc Using Laser or Radiofrequency medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
09-20-2011	Modified Title from: "Decompression of the Intervertebral Disc Using Laser (Laser Discectomy) or Radiofrequency (DISC Nucleoplasty TM) Energy" to: "Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)"
	Description section updated
	In Policy section ▪ Revised wording from: "Laser discectomy and DISC nucleoplasty are considered experimental / investigational as techniques of disc decompression and treatment of associated pain." to: "Laser discectomy and radiofrequency coblation (disc nucleoplasty) are considered experimental / investigational as techniques of disc decompression and treatment of associated pain." ▪ No change in policy intent was made.
	Rationale section updated

No review or update is scheduled on this Medical Policy. Blue Cross and Blue Shield of Kansas will continue to monitor published literature for any updated information. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, or your professional / institutional relations representative.

REVISIONS	
	In Coding section: ▪ Updated nomenclature for CPT code 77002.
	Referenced updated.
01-01-2012	In Coding section: ▪ Revised CPT code nomenclature: 62287
11-06-2012	Revision section updated
	In Coding section: ▪ Removed all reference to specific diagnoses codes and replaced with the wording, "Experimental / Investigations for all diagnoses related to this policy."
	References updated
10-13-2015	Description section updated
	Rationale section updated
	References updated
01-01-2017	In Coding section: ▪ Revised CPT Codes: 62287, 77002
05-23-2018	Description section updated
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated
09-11-2019	Description section updated
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated
08-21-2020	Description section updated
	Rationale section updated
	References updated
06-03-2021	Description section updated
	Rationale section updated
	References updated
06-01-2022	Updated Description Section
	Updated Rationale Section
	Updated References Section
06-13-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Diagnoses box
	Updated References Section
06-13-2023	Archived

No review or update is scheduled on this Medical Policy. Blue Cross and Blue Shield of Kansas will continue to monitor published literature for any updated information. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, or your professional / institutional relations representative.

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