Medical Policy

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Title: Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation

Related Policies	• *Automated Percutaneous and Percutaneous Endoscopic Discectomy* • *Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency-Coblation (Nucleoplasty)*

Professional
Original Effective Date: October 18, 2004
Revision Date(s): September 7, 2005; February 21, 2006; May 6, 2006; July 27, 2006; September 14, 2006; October 31, 2006; January 1, 2007; November 18, 2009; February 8, 2010; December 1, 2011; January 1, 2012; November 6, 2012; October 13, 2015; February 15, 2017; March 1, 2018; July 17, 2019; August 21, 2020; June 16, 2021; December 18, 2021; January 3, 2022
Current Effective Date: December 18, 2021

Institutional
Original Effective Date: July 1, 2005
Revision Date(s): September 7, 2005; February 21, 2006; May 6, 2006; July 27, 2006; September 14, 2006; October 31, 2006; January 1, 2007; November 18, 2009; February 8, 2010; December 1, 2011; January 1, 2012; November 6, 2012; October 13, 2015; February 15, 2017; March 1, 2018; July 17, 2019; August 21, 2020; June 16, 2021; December 18, 2021; January 3, 2022
Current Effective Date: December 18, 2021

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Populations	Interventions	Comparators	Outcomes
Individuals: • With discogenic back pain	**Interventions of interest are:** • Intradiscal electrothermal annuloplasty	**Comparators of interest are:** • Conservative management • Surgical spinal decompression	**Relevant outcomes include:** • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With discogenic back pain	**Interventions of interest are:** • Intradiscal radiofrequency annuloplasty	**Comparators of interest are:** • Conservative management • Surgical spinal decompression	**Relevant outcomes include:** • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With discogenic back pain	**Interventions of interest are:** • Intradiscal biacuplasty	**Comparators of interest are:** • Conservative management • Surgical spinal decompression	**Relevant outcomes include:** • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With vertebrogenic back pain	**Interventions of interest are:** • Intraosseous Basivertebral nerve ablation	**Comparators of interest are:** • Conservative management • Surgical spinal decompression	**Relevant outcomes include:** • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are designed

to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening annular tissue.

OBJECTIVE

The objective of this evidence review is to evaluate whether intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, intradiscal biacuplasty, and intraosseous basivertebral nerve ablation improve net health outcomes in patients with discogenic or vertebrogenic 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 potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency energy into the disc. It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures. Pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

With the intradiscal electrothermal annuloplasty procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterior laterally into the disc annulus or nucleus. Using indirect radiofrequency energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90°C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of radiofrequency energy with intradiscal electrothermal annuloplasty include precise temperature feedback and control, and the ability to provide electro thermocoagulation to a broader tissue segment than would be allowed with a direct radiofrequency needle. Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

Percutaneous intradiscal radiofrequency thermocoagulation uses direct application of radiofrequency energy. With percutaneous intradiscal radiofrequency thermocoagulation, the radiofrequency probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70°C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics Radiofrequency Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty uses 2 cooled radiofrequency electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that, by cooling the probes, a larger area may be treated than could occur with a regular needle probe.

Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the basivertebral nerve, has been purported to occur with endplate damage or degeneration.

REGULATORY STATUS

A variety of radiofrequency coagulation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA), some of which are designed for disc nucleotomy. In 2002, the Oratec Nucleotomy Catheter (ORATEC Interventions, Menlo Park, CA, acquired by Smith & Nephew in 2002) was cleared for marketing by FDA through the 510(k) process. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. The Radionics (a division of Tyco Healthcare group) Radiofrequency Disc Catheter System received marketing clearance by FDA through the 510(k) process in 2000. FDA product code: GEI.

In 2005, the Baylis Pain Management Cooled Probe was also cleared for marketing by FDA through the 510(k) process. It is intended for use "in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue." FDA product code: GXI.

The Intracept Intraosseous Nerve Ablation System "is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least 6 months of conservative care". FDA reviewed the device and issued a substantially equivalent designation in August 2017 (K170827). FDA product code: GXI.

Note: This evidence review does not address disc nucleoplasty, a technique based on the bipolar radiofrequency device (Coblation®; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar radiofrequency device is used to provide lower energy treatment to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. Disc nucleoplasty is closer in concept to a laser discectomy in that tissue is removed or ablated to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered in BCBSKS medical policy *Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency-Coblation (Nucleoplasty)*

POLICY

A. Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **experimental/ investigational.**

B. Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain is considered **experimental/ investigational**.

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 September 5, 2021.

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. Randomized controlled trials 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.

INTRADISCAL ELECTROTHERMAL ANNULOPLASTY

Clinical Context and Therapy Purpose

The purpose of percutaneous intradiscal electrothermal annuloplasty in patients who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does intradiscal electrothermal annuloplasty improve the net health outcome in patients with discogenic back pain?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with discogenic back pain.

Interventions
The therapy being considered is percutaneous intradiscal electrothermal annuloplasty.

Comparators
Relevant comparators are conservative management and surgical spinal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

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

Randomized Controlled Trials
Pauza et al (2004)[1], published the results of a RCT evaluating intradiscal electrothermal annuloplasty (referred to as intradiscal electrothermal therapy in Pauza) in patients with discogenic low back pain. The trial included 64 patients with low back pain of more than 6 months in duration who were randomized to intradiscal electrothermal annuloplasty or a sham procedure. Visual analog scale scores for pain were reduced by an average of 2.4 cm in the intradiscal electrothermal annuloplasty group compared with 1.1 cm in the sham group, a statistically significant difference between groups (p=.045). The mean change in the Oswestry Disability Index score was also significantly greater for the intradiscal electrothermal annuloplasty group than for the sham group. Improvements in the 36-Item Short Form Health Survey (SF-36) bodily pain subscale score were slightly higher for the intradiscal electrothermal annuloplasty group. The trial also reported a percent change in visual analog scale scores more than 2.0 cm, which is greater than the minimal clinically significant improvement of 1.8 to 1.9. When the visual analog scale score was dichotomized in this way, a relative risk of 1.5 was observed with a 95% confidence interval (CI) of 0.82 to 2.74. While this single-center trial was well-designed with respect to randomization, clear description of the intervention, and use of valid and reliable outcomes measures, it does not permit conclusions about the relative effects of intradiscal electrothermal annuloplasty and placebo, and it is unclear whether intradiscal

electrothermal annuloplasty achieves clinically and statistically significant improvements in measures of pain, disability, or QOL.

Freeman et al (2005) reported on an industry-sponsored, double-blind, sham-controlled randomized trial evaluating intradiscal electrothermal annuloplasty (referred to as intradiscal electrothermal therapy in this report) in patients with chronic discogenic low back pain, marked functional disability, magnetic resonance imaging evidence of degenerative disc disease, and failure of conservative management. [2,] Both the active intradiscal electrothermal annuloplasty and sham groups had an intradiscal catheter that was navigated to cover at least 75% of the posterior annulus. Planned enrollment based on power analysis was for 75 patients; however, the trial was stopped early due to slower than expected recruitment after 57 patients (38 intradiscal electrothermal annuloplasty, 19 placebo) had been enrolled. Follow-up was for 6 months, and the outcome measure was successful treatment response, as defined by all of the following: (1) no neurologic deficit; (2) an increase on the Low Back Outcome Score of at least 7 points; and (3) improvements in the SF-36 physical functioning and bodily pain subscale scores of at least 1 standard deviation. No subject in either group achieved a successful treatment response. Outcomes were similar between the intradiscal electrothermal therapy and sham groups on the Low Back Outcome Score (38.31 vs.. 37.45), Oswestry Disability Index score (39.77 vs. 41.58), SF-36 subscale scores (35.10 vs. 30.40), Zung Depression Index score (41.39 vs. 40.82), and the Modified Somatic Perception Questionnaire score (8.67 vs. 8.6), respectively. None of the subgroup analyses showed statistically or clinically significant differences in study outcomes. No serious adverse events were reported in either group.

Section Summary: Intradiscal Electrothermal Annuloplasty
Two RCTs on intradiscal electrothermal annuloplasty have reported conflicting results, with 1 finding a benefit for intradiscal electrothermal annuloplasty and the other no benefit. The most recent RCT identified was from 2005. No recent literature on intradiscal electrothermal annuloplasty has been identified.

PERCUTANEOUS INTRADISCAL RADIOFREQUENCY ANNULOPLASTY

Clinical Context and Therapy Purpose
The purpose of percutaneous intradiscal radiofrequency annuloplasty in patients who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does percutaneous intradiscal radiofrequency annuloplasty improve the net health outcome in patients with discogenic back pain?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with discogenic back pain.

Interventions
The therapy being considered is percutaneous intradiscal radiofrequency annuloplasty.

Comparators

Relevant comparators are conservative management and surgical spinal decompression.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

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

Randomized Controlled Trials

There is relatively little published data on percutaneous intradiscal radiofrequency thermocoagulation. Barendse et al (2001) reported on a double-blind trial that randomized 28 patients with chronic low back pain to percutaneous intradiscal radiofrequency thermocoagulation or a sham-control group.[3,] The primary outcome was the percentage of success at 8 weeks, as measured by changes in pain level, impairment, Oswestry Disability Index scores, and analgesics taken. At the end of 8 weeks, there were 2 treatment successes in the sham group and 1 in the treatment group. Trialists concluded that percutaneous intradiscal radiofrequency thermocoagulation was no better than placebo in reducing pain and disability.

Kvarstein et al (2009) published a 12-month follow-up from an RCT of intra-annular radiofrequency thermal disc therapy using the discTRODE probe. [4,] Recruitment was discontinued when blinded interim analysis of the first 20 patients showed no trend toward overall effect or difference in pain intensity between active and sham treatment at 6 months. At 12 months, there was a reduction from baseline pain, but no significant difference between the groups. Two patients from each group reported an increase in pain.

Section Summary: Percutaneous Intradiscal Radiofrequency Annuloplasty

Two sham-controlled randomized trials showed no evidence of a benefit with percutaneous intradiscal radiofrequency thermocoagulation. One found that only 1 of 14 patients was considered a treatment success. The other was terminated after a blinded interim analysis showed no trend to benefit compared with sham.

INTRADISCAL RADIOFREQUENCY BIACUPLASTY

Clinical Context and Therapy Purpose

The purpose of intradiscal radiofrequency biacuplasty in patients who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does intradiscal radiofrequency biacuplasty improve the net health outcome in patients with discogenic back pain?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with discogenic back pain.

Interventions
The therapy being considered is intradiscal radiofrequency biacuplasty.

Comparators
Relevant comparators are conservative management and surgical spinal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

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

Randomized Controlled Trials
Kapural et al (2013), Desai et al (2016), and colleagues have published studies on the use of trans discal radiofrequency annuloplasty using 2 trans discal probes (biacuplasty) in patients with discogenic lower back pain, including a 2013 industry-sponsored, phase 1, double-blind RCT and a 2016 RCT. [5,6,7,8,]

Kapural et al (2013) conducted the phase 1 RCT. [5,] Of the 1894 patients screened, 1771 (94%) did not meet inclusion criteria. Sixty-four subjects consented and were enrolled. Outcome measures were the SF-36 physical functioning subscale (0-100), a numeric rating scale for pain (0-10), and the Oswestry Disability Index (0-100). There were no significant differences between the groups at 1 month or 3 months. At 6 months, the biacuplasty group showed a significantly greater change from baseline for the SF-36 (15.0 vs. 2.63), numeric rating scale (-2.19 vs. -0.64), and Oswestry Disability Index (-7.43 vs. 0.53) scores. Mean SF-36 and numeric rating scale scores were considered to be clinically significant, but mean Oswestry Disability Index scores did not achieve the minimally important difference of 10 points. With clinical success defined post hoc as a 15-point increase in physical function together with a greater than 2-point

decrease in pain, 30% of biacuplasty patients and 3% of sham-treated patients were considered successful. There was no significant difference in opioid use between groups.

Kapural et al (2015) reported on the unblinded 12-month follow-up from this phase 1 trial.[6] Improvements continued through 12 months, with a change from baseline to posttreatment of 47.0 to 68.9 (of 100) on the SF-36 physical functioning subscale (p<.01) and 7.1 to 4.4 (of 10) on the numeric rating scale (p<.01). Although the change in numeric rating scale score was statistically significant, the magnitude of the decrease was modest, and a final numeric rating scale score (4.4) remained high. The change in Oswestry Disability Index score (from 40.37 at baseline to 32.44 at 12 months) was also modest (p=.05). Opioid usage did not decrease significantly (53.47 mg at baseline to 34.07 mg at follow-up, p=.23).

Desai et al (2016) randomized 63 patients with lumbar discogenic pain diagnosed by provocation discography to intradiscal biacuplasty plus conservative medical management (n=29) or medical management alone (n=34).[7] Another 234 patients were scheduled for diagnostic discography but did not meet inclusion criteria. The primary outcome (the mean reduction in visual analog scale score for pain at 6 months) was significantly greater in the biacuplasty group (-2.4) than in the medical management group (-0.56; p=.02). The secondary outcomes were not statistically significant, which included the proportion of responders, defined as a 2-point or 30% decrease in visual analog scale scores, which was achieved in 50% of the biacuplasty group compared to 18% of controls (p=.073). Investigators did not report whether the trial was adequately powered. Other limitations of this industry-sponsored trial were the lack of a sham-control and patient blinding, which could contribute to a placebo effect in the subjective pain outcomes.

Of the 29 patients originally randomized to intradiscal biacuplasty, 22 (76%) were available for 12-month follow-up. [8] Mean 12-month change in visual analog scale score was -2.2 (from 6.7 at baseline to 4.4 at 12 months; p=.001). After 6 months, patients randomized to medical management were allowed to receive intradiscal biacuplasty and were followed for another 6 months; 25 of 34 patients crossed over. The visual analog scale scores improved from 7.0 to 4.7 (p<.001) in the crossover group, and 55% were considered to be responders.

Section Summary: Intradiscal Radiofrequency Biacuplasty
Two industry-sponsored RCTs have assessed use of biacuplasty to treat chronic low back pain. In one, only 6% of subjects screened met the strict inclusion and exclusion criteria for the study. Significant differences in outcomes were observed at 6 months, but not at 1 month or 3 months, and the definition of successful treatment appears to have been post hoc. In the second multicenter RCT, 63 patients met inclusion criteria, which included a positive result on provocation discography. There was a significant treatment effect for the primary outcome measure, but not the secondary outcome measures. This trial was not sham-controlled, and it was not reported whether it was adequately powered. Additional sham-controlled trials in a broader population of patients are needed to determine the effect of this treatment with greater certainty.

INTRAOSSEOUS BASIVERTEBRAL NERVE ABLATION

Clinical Context and Therapy Purpose

The purpose of intraosseous basivertebral nerve ablation in patients who have vertebrogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does intraosseous basivertebral nerve ablation improve the net health outcome in patients with vertebrogenic back pain?

The following PICO was used to select literature to inform this review.

Population
The relevant population of interest is patients with vertebrogenic back pain.

Interventions
The therapy being considered is intraosseous basivertebral nerve ablation.

Comparators
Relevant comparators are conservative management and surgical spinal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

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

Randomized Controlled Trials
Fischgrund and colleagues conducted a randomized, double-blind, sham controlled study (SMART trial) of basivertebral nerve ablation using the Intracept system in 225 participants from the U.S. and Europe.[9,] Patients had chronic isolated lumbar pain that had not responded to at least 6 months of nonoperative management. Additional study inclusion criteria were a minimum Oswestry Disability Index of 30 points (on a 100 point scale), a minimum visual analog scale of 4, and Modic type 1 or 2 changes at the vertebral endplates of the levels targeted for treatment. Treatment was limited to a minimum of 2 and a maximum of 3 consecutive vertebral levels from L3 to S1. The active treatment group (n=147) received radiofrequency and the sham group (n=78) underwent the same protocol for the same overall duration as the treatment group; however, the radiofrequency treatment was simulated. Patients were blinded to the group assignment for 1 year, at which time those in the sham arm were allowed to cross over, 57 (73%) of whom elected to do so, and receive the Intracept treatment. The primary endpoint of

the original study was comparative change in Oswestry Disability Index from baseline to 3 months, and in the intent-to-treat analysis there was no statistically significant difference in this outcome between groups at this time point. There was a difference between groups in the 3-month per protocol analysis (mean Oswestry Disability Index improved 20.5 and 15.2 points in the treatment and sham arms, respectively; p=.019). However, at the 12 month per protocol analysis, the difference in mean Oswestry Disability Index between groups was no longer statistically significant. Pain severity, measured by visual analog scale, was not significantly different between groups at 3 months (p=.083) but there was significantly greater improvement in the treatment group at 6 and 12 months.

The 24 month follow-up results were reported for the active treatment group from the SMART trial.[10] Of the per protocol population treated with ablation (treatment arm), 106 (83%) completed a 24-month follow-up visit. A durable Oswestry Disability Index mean improvement was observed (23.4 points). Data for Oswestry Disability Index outcomes were not available for the sham group because of the high crossover rate. Therefore, long-term comparative outcomes are not available.

Five year results were reported for the 100 U.S. patients from the treatment arm from the original SMART trial who were available for follow-up.[11] Mean Oswestry Disability Index scores improved from 42.8 to 16.9 at 5 years, a reduction of 25.9 points. Mean reduction in visual analog scale score was 4.4 points (baseline 6.7, p<.001).

The INTRACEPT trial was an open-label RCT conducted at 20 U.S. sites.[12] A total of 140 patients with lower back pain of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, were randomized to undergo radiofrequency ablation of the basivertebral nerve or continue standard care. Standard care consisted of pain medications, physical therapy, exercise, chiropractic treatment, acupuncture, and spinal injections; the specific treatment(s) administered were determined by the treating investigator in conjunction with the patient. Treatment of up to 4 vertebrae in non-consecutive levels from L3 to S1 was allowed. The primary study endpoint was change in Oswestry Disability Index at 3 months. A pre-planned interim analysis was undertaken when 60% of participants reached the 3 month follow-up (n=51 in the treatment group and n=53 in the standard care group), and reported statistically significant differences between groups on all patient-reported outcome measures, favoring the treatment group. The study was halted and the individuals were allowed to cross over to the treatment arm. Study limitations include short term follow-up, lack of a sham group, and allowance of crossover at 3 months.

Twelve month follow-up results were reported from the INTRACEPT trial; after a median of 175 days post randomization, 92% of patients initially randomized to the standard care arm elected to receive early treatment with basivertebral nerve ablation.[13] Six month results for the Oswestry Disability Index were significantly improved with basivertebral nerve ablation (n=66) compared to standard care (n=74) (least squares mean difference between groups, -24.5; 95% CI, -29.4 to -19.6; p=.0001). Improvements in the Oswestry Disability index and mean visual analog scale that were reported among patients initially treated with basivertebral nerve ablation were maintained throughout the 12-month study period, with reported reductions of -25.7±18.5 points, and -3.8±2.6 cm, respectively (p<.001 for both comparisons to baseline). However, comparative data were not available beyond 6 months due to the high rate of crossover.

Details of the SMART and INTRACEPT trials can be found below in Table 1 and Table 2.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Fischgrund et al (2018)[9]; SMART	US, Germany	15	2011-2014	Skeletally mature patients with ≥6 months of isolated lumbar pain unresponsive to ≥6 months nonoperative management	BVN ablation (n=147)	Sham control (n=78)
Khalil et al (2019)[12]; INTRACEPT	US	20	2017-2019	Skeletally mature patients with ≥6 months of isolated lumbar pain unresponsive to ≥6 months nonoperative management	BVN ablation (n=51)	Standard care (n=53)

BVN: basivertebral nerve; RCT: randomized controlled trial.

Table 2. Summary of Key RCT Results[a]

Study		Oswestry Disability Index, LS mean change from baseline	Visual Analog Scale score, LS mean change from baseline	SF-36 PCS score, LS mean change from baseline
Fischgrund et al (2018)[9]	n			
BVN ablation	147	-19.0	-2.76 cm[b]	9.17[b]
Sham control	78	-15.4	-2.16 cm[b]	7.63[b]
p value		.107	.038[b]	NS[b]
Khalil et al (2019)[12]; INTRACEPT				
BVN ablation	51	-25.3	-3.46	14.021
Standard care	53	-4.4	-1.02	2.114
Difference between arms, (95% CI)		-20.9 (-27.0 to -14.7)	-2.44 (-3.36 to -1.53)	11.907 (9.035 to 14.780)
p value		<.001	<.001	<.001

BVN: basivertebral nerve; CI: confidence interval; LS: least squares; NS: not significant; PCS: physical component summary; SF-36: 36-item short form health survey.
[a] Results displayed are for the intent-to-treat population at 3 months unless otherwise specified.
[b] Results are for the per protocol population at 12 months.

Limitations of the SMART and INTRACEPT trials are described in Table 3 and 4 below.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Fischgrund et al (2018)[9,]					
Khalil et al (2019)[12,]			1. Not clearly defined		2. Outcomes reported at 3 months

The study 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]
Fischgrund et al (2018)[9,]				3. High number of crossovers 6. Per protocol analysis of secondary outcomes		
Khalil et al (2019)[12,]		1,2. Open-label design				

The study 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.

Section Summary: Basivertebral Nerve Ablation

Two RCTs have been conducted to assess the efficacy of basivertebral nerve ablation for treatment of vertebrogenic back pain. One RCT did not find a difference in the Oswestry Disability Index between patients treated with basivertebral nerve ablation or sham control at 3 months using an intent-to-treat analysis. Although the per protocol analysis showed a significant difference; results for the per protocol population at 12 months were not significantly different. Additionally, 73% of patients in this trial crossed over to the active treatment group at 12 months and therefore, long-term comparative data are not available. A second RCT found a significant difference in the Oswestry Disability Index and other pain scores between patients treated with basivertebral nerve ablation and standard care at 3 months. Comparative data at 6 months post randomization showed similar results. However, 92% of patients initially assigned to standard care elected to cross over to receive early basivertebral nerve ablation, thus, long-term comparative data beyond 6 months are not available. Additional limitations to this RCT include lack of a sham control.

Summary of Evidence

For individuals who have discogenic back pain who receive intradiscal electrothermal annuloplasty, the evidence includes a small number of RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty reported conflicting results, with 1 reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. Further study in a sham-controlled trial with a representative population of patients is needed. 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 who receive intradiscal radiofrequency annuloplasty, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Neither RCT found evidence of benefit with the treatment. More sham-controlled trials are needed. 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 who receive intradiscal biacuplasty, the evidence includes 2 industry-sponsored RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. One trial reported significant improvements at 6 months post-treatment, but not at 1 and 3 months. The other trial also showed a significant reduction in visual analog scale scores at 6 months that appeared to continue to the 12 month follow-up; however, it is unclear whether this trial was sufficiently powered. More sham-controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have vertebrogenic back pain who receive ablation of basivertebral nerves, the evidence includes 2 RCTs (the SMART and INTRACEPT trials). Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The SMART trial was unable to show a significant improvement in the Oswestry Disability Index with basivertebral nerve ablation compared to sham control at 3 months post randomization in the intent-to-treat population. The INTRACEPT trial showed a significant improvement in the Oswestry Disability Index with basivertebral nerve ablation compared to standard care at 3- and 6-months post randomization; however, the trial is limited by its lack of sham control. Both trials are further limited by the fact that the majority of patients assigned to control crossed over to receive active

treatment, thus, long-term comparative data are not available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

A 2013 systematic review informing American Society of Interventional Pain Physicians guidelines found limited-to-fair evidence for intradiscal electrothermal therapy (IDET; another term for intradiscal electrothermal annuloplasty) and biacuplasty and limited evidence for percutaneous intradiscal radiofrequency thermocoagulation.[14] These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET.[15] Complications included catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage. The evidence for percutaneous intradiscal radiofrequency thermocoagulation was limited, with complications similar to IDET.[15]

International Society for the Advancement of Spine Surgery

In 2020, the International Society for the Advancement of Spine Surgery published guidelines on intraosseous ablation of the basivertebral nerve for relief of chronic low back pain.[16] The guidelines suggest that basivertebral nerve ablation is an appropriate treatment for chronic low back pain in select patients who meet the following additional criteria:

- "CLBP (chronic low back pain) of at least 6 months duration,
- Failure to respond to at least 6 months of nonsurgical management, and
- MRI (magnetic resonance imaging)-demonstrated MC1 or MC2 in at least 1 vertebral endplate at 1 or more levels from L3 to S1."

National Institute for Health and Care Excellence

A 2016 guidance update by the National Institute for Health and Care Excellence (NICE) indicated that the evidence on safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for low back pain was "limited" and should only be used by "special arrangement".[17]

In 2016, NICE guidance on electrothermal annuloplasty was also updated.[18] NICE considered evidence on the efficacy of percutaneous intradiscal radiofrequency thermocoagulation for low back pain to be inconsistent and of poor quality, although no major safety concerns were identified. NICE recommended percutaneous intradiscal radiofrequency thermocoagulation only with special arrangements for clinical governance, consent, and audit or research.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in September 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

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

22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)
22899	Unlisted procedure code, spine (used for the Intercept procedure)
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral (Effective 01-01-2022)
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure) (Effective 01-01-2022)
72285	Discography, cervical or thoracic, radiological supervision and interpretation
72295	Discography, lumbar, radiological supervision and interpretation
62290	Injection procedure for discography, each level; lumbar
62291	Injection procedure for discography, each level; cervical or thoracic

ICD-10 DIAGNOSIS

	Experimental / Investigational for all diagnoses related to this policy.

REVISIONS	
02-08-2010	The Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty 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.
12-01-2011	Description section updated
	Rationale section updated
	References updated

REVISIONS	
01-01-2012	In Coding section: ▪ Revised CPT code nomenclature: 62310, 62311
11-06-2012	Rational section updated
	In Coding section: Revised CPT code nomenclature: 62292
	References updated
10-13-2015	Description section updated
	Rationale section updated
	In Coding section: ▪ Removed CPT Codes: 62292, 62310, 62311, 64640, 64999
	References updated
02-15-2017	Title revised to "Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty" from "Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty, and Percutaneous Intradiscal Radiofrequency Annuloplasty"
	Description section updated
	In Policy section: ▪ Removed "percutaneous" and "thermocoagulation" and added "annuloplasty" to read "Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered experimental / investigational."
	Rationale section updated
	References updated
03-01-2018	Description section updated
	Rationale section updated
	References updated
07-17-2019	Description section updated
	Rationale section updated
	References updated
08-21-2020	Description section updated
	Rationale section updated
	References updated
06-16-2021	Description section updated
	Rationale section updated
	References updated
12-18-2021	Updated Policy Title ▪ Changed to: Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation
	Updated Description Section
	Updated Policy section • Added policy section B to state: " Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain is considered experimental/ investigational.
	Updated Rationale Section
	In coding Section • Added CPT codes 64628(eff 1/1/2022) , 64629 (eff 1/1/2022) • Added HCPCS codes C9752, C9753
	Updated References Section
01-03-2022	In Coding Section

REVISIONS	
	Removed C9752, C9753 terminated codes (effective 01-01-2022)

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