Policy Number	**SUR712.023**
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Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

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Related Policies (if applicable)
SUR702.020: Intraosseous Radiofrequency Nerve Ablation of the Basivertebral Nerve for the Treatment of Low Back Pain
SUR712.037: Decompression of the Intervertebral Disc using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

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 and/or unproven**.

Policy Guidelines

None.

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.

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 posterolaterally 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 electrothermocoagulation 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.

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.

Note: This medical policy 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 medical policy SUR712.037.

Rationale

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 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 individuals who have discogenic back pain 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.

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:

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

Randomized Controlled Trials
Pauza et al. (2004) (1) published the results of an 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 individuals who have discogenic back pain 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.

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:

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

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 individuals who have discogenic back pain 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.

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:

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

Randomized Controlled Trials

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

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.

Summary of Evidence

For individuals who have discogenic back pain who receive intradiscal electrothermal annuloplasty, the evidence includes a small number of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life (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.

Practice Guidelines and Position Statements

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. (9) These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET. (10) 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.

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”. (11)

In 2016, NICE guidance on electrothermal annuloplasty was also updated. (12) 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.

Medicare National Coverage

The Centers for Medicare & Medicaid Services has determined that thermal intradiscal procedures, including IDET and percutaneous intradiscal radiofrequency thermocoagulation, “are not reasonable and necessary for the treatment of low back pain. Therefore, TIPS [thermal intradiscal procedures], which include procedures that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered.” (13)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2025 did not identify any ongoing or unpublished trials that would likely influence this policy.

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	22526, 22527
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 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**
11/15/2025	Document updated. Coverage unchanged. No new references added.
09/15/2024	Document updated with literature review. Coverage unchanged. No new references added.
01/01/2024	Reviewed. No changes.
10/01/2022	Document updated with literature review. Coverage unchanged. No new references added.
08/01/2021	Reviewed. No changes.
01/01/2021	Document updated with literature review. Coverage unchanged. No new references added.
08/01/2019	Reviewed. No changes.
05/01/2019	Document updated with literature review. Coverage unchanged, terminology noted in Coverage section clarified to: intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty. Title changed from: Percutaneous Intradiscal Electrothermal Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty. References 9-10, 13-14 added. Several references removed.
06/01/2017	Reviewed. No changes.
07/15/2016	Document updated with literature review. Coverage unchanged. Title changed from Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty.
08/15/2015	Reviewed. No changes.
08/01/2014	Restored medical document. Document updated with literature review. Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered experimental investigational and/or unproven. Coverage is unchanged. (This topic was previously addressed on SUR712.004 Intervertebral Techniques to Treat Chronic Discogenic Back Pain).