

**EFFECTIVE DATE:** 02 | 01 | 2024

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## OVERVIEW

This policy addresses a variety of minimally invasive techniques that have been investigated over the years as treatment of low back pain related to disc disease. Surgical management of herniated intervertebral discs most commonly involves discectomy or microdiscectomy, performed manually through an open incision. Automated percutaneous discectomy involves placement of a probe within the intervertebral disc under image guidance with aspiration of disc material using a suction cutting device. 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. 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.

## MEDICAL CRITERIA

### Medicare Advantage Plans

Thermal destruction of the intraosseous basivertebral nerve (e.g., Intracept® system) will be considered medically reasonable and necessary for the treatment of chronic low back pain in patients who meet ALL the following criteria:

1. Chronic lumbar back pain of  $\geq 6$  months duration that causes functional deficit measured on a pain or disability scale\*, AND
2. Documented failure to respond to  $\geq 6$  months of non-surgical management\*\*, AND
3. Absence of non-vertebrogenic pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity, AND
4. Evidence of Type 1 or Type 2 Modic changes on MRI, such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointense signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hypertensive signals (Type 2 Modic change), in 1 or more vertebrae from L3-S1.

\* Pain assessment and a disability scale must be obtained at baseline to be used for functional assessment.

\*\* Non-surgical management may include but is not limited to:

- Avoidance of activities that aggravate pain;
- Trial of Chiropractic manipulation
- Trial of Physical Therapy;
- Cognitive support and recovery reassurance;
- Injection therapy – epidural and/or facet;
- Spine biomechanics education;

- Specific lumbar exercise program;
- Home use of heat/cold modalities;
- Low impact aerobic exercise as tolerated;
- Pharmacotherapy (e.g., non-narcotic analgesics, NSAIDs, muscle relaxants, neuroleptics, and narcotics).

5. Individuals must have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to thermal destruction of the intraosseous BVN (such screening must include psychological, as well as, physical evaluation). Documentation of the history and careful screening must be available in the patient chart if requested.

**NOTE:** Thermal destruction of the intraosseous BVN must only be performed once per vertebral body from L3-S1 per lifetime. Up to 4 vertebral bodies may be treated during 1 procedure.

Thermal destruction of the intraosseous basivertebral nerve (e.g., Intracept® system) is not covered in the following:

1. Skeletally immature patients ( $\leq 18$  years old);
2. Severe cardiac or pulmonary compromise;
3. Active systemic infection or local infection at the intended treatment level;
4. Bleeding diathesis;
5. Pregnancy;
6. Primary radicular pain into the lower extremities (defined as nerve pain following a dermatomal distribution and that correlates with nerve compression on imaging);
7. Previous lumbar/lumbosacral spine surgery at the intended treatment level (with the exception of discectomy/laminectomy if performed  $> 6$  months prior to BVN nerve ablation and radicular pain resolved);
8. Primary symptomatic lumbar or lumbosacral spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging);
9. Diagnosed osteoporosis (T-score of  $-2.5$  or less), spine fragility fracture history, trauma/compression fracture at the intended treatment level, or spinal cancer;
10. Radiographic evidence of any of the following that correlates with predominant physical complaints:
  - a. Lumbar/lumbosacral disc extrusion or protrusion  $> 5$ mm at levels L3-S1;
  - b. Lumbar/lumbosacral spondylolisthesis  $> 2$ mm at any level;
  - c. Lumbar/lumbosacral spondylolysis at levels L3-S1;
  - d. Lumbar/lumbosacral facet arthrosis/effusion correlated with facet-mediated pain at levels L3-S1.
11. BMI  $> 40$ ;
12. Advanced generalized systemic disease that limits quality-of-life (QOL) improvements would require a statement of the objective of treatment in such cases;
13. Active, untreated substance abuse disorder.

### **PRIOR AUTHORIZATION**

Prior authorization is required for Medicare Advantage for thermal destruction of the intraosseous basivertebral nerve (e.g., Intracept® system).

### **POLICY STATEMENT**

#### **Medicare Advantage Plans**

Thermal destruction of the intraosseous basivertebral nerve (e.g., Intracept® system) will be considered medically necessary when the criteria above have been met.

#### **Commercial Products**

The following service is not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain

## Medicare Advantage Plans and Commercial Products

The following services are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain
- Laser discectomy and radiofrequency coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated pain.
- Automated percutaneous discectomy as a technique of intervertebral disc decompression in individuals with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

### COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

### BACKGROUND

Medicare Advantage Plans

Percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter(s)/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.

The scope of the Centers for Medicare and Medicaid Services national coverage determination on TIPs includes percutaneous intradiscal techniques that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of a contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probe(s)/catheter(s), which utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction, or the annulus.

Although not intended to be an all-inclusive list, TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Each technique or device has its own protocol for application of the therapy.

The Centers for Medicare and Medicaid Services has determined that TIPs are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs, 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. Therefore, these services are not covered for Medicare Advantage Plans.

Low back pain (LBP) is the most expensive occupational disorder in the United States and the leading cause of disability worldwide. Chronic low back pain (cLBP) is defined as persistent pain in the lumbar region lasting for >12 weeks. cLBP has many different etiologies. Research shows evidence that one etiology is associated with degeneration of the vertebral body or vertebral body endplates, resulting in inflammation. The inflammatory response is perceived by the basivertebral nerve (BVN), a sensory nerve that enters the

posterior vertebral body and branches out to the superior and inferior endplates. The pain signals are then transmitted to the central nervous system, causing what is known as vertebrogenic pain.

Clinically, vertebrogenic pain is generally described as a midline, deep, aching, burning pain that is progressive. Also, it is often associated with an intermittent electrical shock sensation. Vertebrogenic pain is also characterized by absence of radicular expression, lower extremity weakness, or sensory deficits, and the neural tension sign and pain is generally worse with spinal flexion, sitting, standing and general physical activity, when compared to extension.

Diagnosis of vertebrogenic cLBP focuses on the chronic inflammatory response caused by endplate damage, which is visible on MRI. These signal changes, known as Modic changes (MC), are found in the vertebral body bone marrow that is adjacent to the degenerative endplates. Modic 1 changes indicate inflammation and edema, and Modic 2 changes occur in the setting of marrow ischemia when the red hematopoietic bone marrow has converted into yellow fatty marrow.

Thermal destruction (i.e., ablation) of the intraosseous BVN (Intracept® Procedure) is a therapeutic, interventional surgical procedure used to treat cLBP of vertebrogenic origin. The procedure is performed using fluoroscopic imaging under moderate/conscious sedation or general anesthesia. Radiofrequency energy is applied for 15 minutes at 85 degrees Celsius to produce a lesion to destroy the BVN within the vertebral body. At a minimum, the BVN is ablated in at least 1 vertebral body.

The International Society for the Advancement of Spine Surgery (ISASS) 2020 guideline – Intraosseous Ablation of the Basivertebral Nerve for the Relief of Chronic Low Back Pain concluded that “The procedure is supported by level 1 evidence including 2 RCTs demonstrating a statistically significant decrease in pain and an improvement in function with outcomes sustained to at least 24 months in a limited number of studies.” BVN ablation may be indicated as a treatment option for cLBP for patients that fail nonsurgical treatment and their cLBP is diagnosed using well-established clinical and MRI findings.

The American Society of Pain and Neuroscience (ASPN) identified evidence-based guidelines from the available literature for the proper identification and selection of patients with vertebrogenic low back pain for BVN ablation. The systematic review was conducted using United States Preventive Services Task Force Criteria Modified for Interventional Spine Procedures and assigned a Grade A rating of the quality of evidence for BVN ablation indicating a high certainty that the net benefit is substantial in appropriately selected individuals.

#### Commercial Products

For individuals who have vertebrogenic back pain who receive intraosseous 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 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. The INTRACEPT trial 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### Medicare Advantage Plans and Commercial Products

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.

For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on the net health outcome. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain or radiculopathy who receive laser discectomy, the evidence includes systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. While numerous case series and uncontrolled studies have reported improvements in pain levels and functioning following laser discectomy, the lack of well-designed and conducted controlled trials limits the interpretation of reported data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain or radiculopathy who receive disc nucleoplasty with radiofrequency coblation, the evidence includes randomized controlled trials (RCTs), systematic reviews, and prospective and retrospective nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 3 RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in 1, inadequate data reporting in the second, and low enrollment with early study termination in the third. The available evidence is insufficient to permit conclusions concerning the effect of these procedures on health outcomes due to multiple confounding factors that may bias results. High-quality randomized trials with adequate follow-up (at least 1 year), which control for selection bias, the placebo effect, and variability in the natural history of low back pain, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **CODING**

### **Medicare Advantage Plans and Commercial Products**

The following CPT code(s) are covered for Medicare Advantage Plans when medical criteria above have been met and are not medically necessary for Commercial Products.

- 64628** Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
- 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)

The following CPT code(s) are not covered for Medicare Advantage Plans, when identified as Percutaneous Thermal Intradiscal Procedures (TIPs), and not medically necessary for Commercial Products:

- 22526** Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
- 22527** Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels (List separately in addition to code for primary procedure)

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 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
- S2348** Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

#### **PUBLISHED**

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