INTRACEPT™
Vertebrogenic Pain Relief

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Coverage Criteria Summary – Noridian Medicare
Intraosseous Basivertebral Nerve Ablation DL #39642

Noridian Medicare issued a local coverage determination (LCD) for the Intracept™ Procedure **effective 01/28/2024**. The policy outlines specific details regarding criteria and limitations to meet medical necessity. Please review the policy in its entirety. The requirements should be adhered to closely and documented accordingly in the patient chart to ensure the patient meets medical necessity. Please review the entire LCD and Local Coding Article.

Coverage Criteria & Documentation Requirements:

Thermal ablation of the intraosseous Basivertebral Nerve (BVN) is considered medically reasonable and necessary for the treatment of Chronic Low Back Pain (CLBP) in patients who meet **ALL** the following criteria for coverage and reimbursement:

☐ 1. Individual is skeletally mature and has had CLBP for at least 6 months, with lower back pain as the dominant symptom.

☐ 2. Has failed to adequately improve despite documented non-surgical management, to include **at least 3 or more** of the following modalities:
   a. Avoidance of activities that aggravate pain
   b. Course of physical therapy or professionally directed therapeutic exercise program
   c. Chiropractic manipulation
   d. Cognitive therapy
   e. Pharmacotherapy, including narcotic and non-narcotic analgesics, muscle relaxants, neuroleptics, and anti-inflammatories
   f. Injection therapy of epidural or facet joint implicated pain sources in the region of concern

☐ 3. Type 1 or Type 2 Modic changes on MRI: Endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1) involving the endplates between L3 and S1.

☐ 4. Absence of additional vertebral pathology by physical, history, radiologic or clinical assessment including, but not limited to fracture, tumor, infection, deformity, trauma, or post-surgical change which could cause the patient's symptoms or complicate the procedure and outcome.

☐ 5. Physical and psychological assessment of patient’s ability to tolerate and benefit from BVN ablation.

Limitations:

- No previous history of BVN ablation at the planned level of treatment
- No more than one to two (1-2) vertebral bodies may be treated at a single session
- Treatment of no more than 4 vertebral bodies per patient lifetime
- Treatment is within the confines of L3-S1 vertebral bodies
- Retreatment of a single vertebral body with BVN ablation within the patient's lifetime is not considered reasonable and necessary
- Local anesthesia is considered appropriate for the region treated. Mild sedation may be administered by the performing physician or staff under his direction but should not be coded separately. Additional anesthesia services may not be billed separately without documentation of medical necessity

Contraindications: Medical Necessity & Noncoverage

The following conditions are considered relative contraindications to BVN ablation as suboptimal outcome and adverse exacerbation of symptoms may occur, precluding expected benefit from the procedure.

Documentation in the patient's medical record must explain the precautionary provisions taken for the individual patient to preclude anticipated or potential adverse events secondary to treatment. In the absence of documentation to support the procedure in individuals with the following concomitant conditions, medical necessity cannot be established.

These conditions represent contraindication to treatment and render the service not medically appropriate, reasonable and necessary, or eligible for Medicare Coverage and Reimbursement.

- Skeletal immaturity (<18 years of age)
- Evidence on imaging (MRI, flexion/extension radiographs, CT) of another etiology for LBP symptoms, including, but not limited to, lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, facet arthropathy or effusion with clinically suspected facet joint pain
- Metabolic bone disease (e.g., osteoporosis with T score <-2.5), treatment of spine fragility fracture, trauma/compression fracture, or spinal primary or metastatic tumor
- Active Spine or Systemic Infection
- Neurogenic claudication, lumbar radiculopathy, radicular pain, nerve impingement or compression (e.g., NHP, stenosis), as primary symptoms
- Patients with severe cardiac or pulmonary compromise, systemic vulnerability to bleeding, or concern for further compromise of existing disease

- Patients with implantable pulse generators (e.g., pacemakers, defibrillators, or neurostimulator) and other electronic implants, unless type specific precautions are taken to maintain patient safety
- Ongoing use or abuse of addictive medications without evidence of potential weaning or decreased use with treatment

References:

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39642

https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59466&ver=6

Coding:

CPT Code	Description
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first two vertebral bodies lumbar or sacral
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral

Group 1 (3 Codes)

Group 1 Paragraph

Note: level of vertebral body treated should be recorded with diagnosis code (and procedure code- see above)

Group 1 Codes

Code	Description
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M54.51	Vertebrogenic low back pain

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KX Modifier Requirements:

Identification of a vertebral body with Modic 1 or Modic 2 changes eligible for treatment by BVN ablation, and the absence of previous BVN ablation, is denoted by affixing the -KX modifier to the procedure code, signifying the requirements for treatment have been met.

Documentation Requirements:

- No more than two vertebral levels may be treated at one session and may not be combined with any other paravertebral injection or intervention (facet or epidural)
- Documentation of the indication requirements must be reported for each vertebral level separately
- The use of local anesthesia is considered included within the procedure code
- The use of medicament or biological materials into the vertebral body or into the surrounding paravertebral tissue is considered contraindicated and will render the claim for BVN ablation non-payable

The patient's medical record should include but is not limited to:

- The assessment of the patient (complete history and physical exam) by the performing provider as it relates to the complaint of the patient
- Relevant medical history including concomitant disease diagnoses, prior operative procedures, allergies, prescription and non-prescription medications in use at the time of the procedure and preceding 6 months
- Results of pertinent tests/procedures including date and professional interpretation of results
- All aspects of the treatment provided, including medications, equipment utilized, energy levels at treatment, medication administered during treatment sessions, and imaging (films or interpretation) utilized for treatment as required by the local coverage determination (LCD)
- Signed and dated office visit records and operative report (Please note that all services ordered or rendered to Medicare beneficiaries must be signed.)
- Documentation of other requirements listed in LCD, if applicable

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Indications for Use: 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 six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change). Contraindications - Use of the Intracept Intraosseous Nerve Ablation System is contraindicated in: Patients with severe cardiac or pulmonary compromise, patients with active implantable pulse generators (e.g. pacemakers, defibrillators), patients where the targeted ablation zone is < 10 mm away from a sensitive structure not intended to be ablated, including the vertebral foramen (spinal canal), patients with active systemic infection or local infection in the area to be treated, patients who are pregnant, and/or skeletally immature patients (generally ≤ 18 years of age). Refer to the Instructions for Use provided with the Intracept Procedure or www.relievant.com/intracept/ for potential adverse effects, warnings, and precautions prior to using this product.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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