INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
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Coverage Criteria Summary – BCBS Michigan

Radiofrequency Ablation of Basivertebral Nerve for Low Back Pain (i.e., Intracept™ Procedure)

BCBS Michigan issued a coverage policy for the Intracept™ Procedure effective **January 1, 2025**. The policy outlines specific details regarding criteria and limitations to meet medical necessity. The requirements should be adhered to closely and documented accordingly in the patient chart to ensure the patient meets medical necessity.

Coverage Criteria & Documentation Requirements:

The safety and effectiveness of radiofrequency ablation of the basivertebral nerve has been established. It may be considered a useful therapeutic option when selection criteria are met.

Basivertebral nerve ablation, with an FDA cleared device, for one or more levels of L3 through S1 when **ALL** of the following are met:

☐ 1. Individual is skeletally mature (≥ 18 years of age)

☐ 2. Moderate to severe chronic low back pain that is primarily axial* in nature.
***Note:** Pain that is localized (e.g., lower back) and is **not** accompanied by motor or sensory dysfunction in the associated extremities (e.g. legs)*

☐ 3. Pain is refractory to at least 6 months of non-operative treatment* within the past year, including at least 6 weeks of detailed professional directed exercise program (i.e. Physical Therapy).
***Note:** Pharmacological therapy (e.g., analgesics, anti-inflammatory drugs, muscle relaxants), exercise, spinal manipulation, acupuncture, cognitive-behavioral therapy, and physical therapy*

☐ 4. Type 1 or Type 2 Modic changes are noted at the vertebral body(ies) to be treated, on an MRI between L3 and S1.
   a. **Type 1** – inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypo-intensive signals
   b. **Type 2** – changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyper-intensive signals

***Note:** When performing ablations for members with implanted electric devices (spinal cord stimulator, pacemaker/defibrillator, etc.), manufacturer guidelines should be followed regarding turning off or monitoring the device during the ablation procedure.*

Exclusions:

- Imaging suggests other etiologies for pain including:
  - Active or recurrent facet symptoms
  - Disc extrusion or protrusion (>5 mm)
  - Spondylolisthesis (>2 mm at any level)
  - Spondylolysis at any level
  - Lumbar scoliosis (> 10 degrees)
  - Modic changes at any level above L3-L4
- History of spine fragility/fracture
- Osteoporosis (T-score < -2.5)
- Trauma/compression fracture
- Spinal cancer
- Imaging-confirmed spinal stenosis with neurogenic claudication (pain, numbness, and/or weakness into the buttocks, thighs, and/or calves, often brought on by standing or walking and relieved by flexion or sitting)
- Active or recurrent radicular pain (pain that travels along a dermatomal distribution into the lower extremity, which can be associated with numbness, weakness, and/or tingling)
- Any prior lumbar spine surgery, other than laminectomy or discectomy > 6 months prior with resolution of radiculopathy
- Bed bound or other condition that prevent early mobility
- BMI > 40
- Active, untreated substance/drug use disorder
- Uncontrolled moderate to severe depression, evaluated by psychiatric examination or by a validated depression screening test (e.g., Beck Depression Inventory, PHQ-9, etc.)
- Presence of severe cardiac or pulmonary compromise
- Pregnancy less than 12 months postpartum or current breast-feeding
- Active systemic infection, spine infection or bleeding diathesis
- Any current litigation related to back pain or injury
- Planned in conjunction with any other procedures, or within 6 weeks of any prior procedure
- Repeat basivertebral ablation at the same level as a previous BVN ablation
- Above criteria are not met

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

References:

https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/2143173.pdf

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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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