INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

Coverage Criteria Summary – Paramount

Thermal Destruction of Intraosseous Basivertebral Nerve (BVN) for Vertebrogenic Lower Back Pain #PG0512 (i.e., Intracept™ Procedure)

Paramount issued a coverage policy for the Intracept™ Procedure **effective 11/01/22.** 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:

- ☐ 1. Skeletally mature patients, Age > 18 years old, **AND**
- ☐ 2. Chronic lumbar back pain of ≥6 months duration suggestive of skeletal endplate inflammation (such as, but not limited to, presence of pain that is aggravated by flexion, extension, rotation, or lateral bending of spine, and is not typically associated with any neurological deficits) that causes functional deficit measured on a pain or disability scale*, **AND**
- ☐ 3. Documented failure to respond to ≥6 months of non-surgical management**, **AND**
- ☐ 4. Absence of untreated radiculopathy or neurogenic claudication, **AND**
- ☐ 5. 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**
- ☐ 6. MRI shows Type 1 or Type 2 Modic changes, such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypotensive 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 one or vertebrae from L1-S1. [***Please note:*** *while Paramount's coverage criteria requires the presence of Modic changes in one or more vertebrae from L1-S1, the Intracept Procedure is only indicated for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain, and* ***Boston Scientific does not promote off-label usage.***]

(continued on next page)

*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; when members coverage benefit allows
- Trial of Physical Therapy, including muscle reconditioning
- Cognitive support and recovery reassurance
- Steroid injection therapy – epidural and/or facet
- Spinal manipulation and 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)
- Weight loss, if indicated

Limitations:

Thermal destruction of the intraosseous BVN is contraindicated in the following:

- Severe cardiac or pulmonary compromise;
- Active systemic infection or local infection at the intended treatment level;
- Bleeding diathesis;
- Currently pregnant;
- Radicular pain into the lower extremities (defined as nerve pain following a dermatomal distribution and that correlates with nerve compression on imaging);
- 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);
- Symptomatic lumbar or lumbosacral spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging);
- Diagnosed osteoporosis (T-score of -2.5 or less), spine fragility fracture history, trauma/compression fracture at the intended treatment level, or spinal cancer;
- Radiographic evidence of:
    - Lumbar/lumbosacral disc extrusion or protrusion >5mm at levels L1-S1;
    - Lumbar/lumbosacral spondylolisthesis > Grade 2 at any level;
    - Lumbar/lumbosacral spondylolysis at levels L1-S1;
    - Lumbar/lumbosacral facet arthrosis/effusion correlated with facet-mediated pain at levels L1-S1
- Skeletally immature patients (generally ≤ 18 years of age)

- Advanced generalized systemic disease that limits quality-of-life (QOL) improvements would require a statement of the objective of treatment in such cases.

There are two types of Modic changes found on Magnetic Resonance Imaging (MRI):

- Type 1 – Vascular development in the vertebral body, inflammation and edema, vertebral endplate changes, vascularized fibrous tissues within the adjacent marrow, hypointensive signals.
- Type 2 – Changes in the vertebral body's bone marrow including replacement of normal bone marrow by fat, and hyperintensive signals.

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

Disclaimer: Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. Boston Scientific does not promote the use of its products outside their FDA-approved label.

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.