INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
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Coverage Criteria Summary – GEHA

Intraosseous Radiofrequency Ablation of the Basivertebral Nerve for Chronic Low Back Pain #III.237

GEHA issued an updated coverage policy for the Intracept™ Procedure **effective 01/01/2024**. 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. The Intracept Procedure is currently the only procedure specifically cleared for the treatment of basivertebral nerve pain.

Coverage Criteria & Documentation Requirements:

Thermal destruction of the intraosseous BVN 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 > 6 months duration that causes function deficit measured on a pain or disability scale*, **AND**

☐ 2. Documented failure to respond to > 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, 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 1 or more vertebrae from L3-S1.

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.

*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 *(continued on next page):*

- 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)

Limitations:

Thermal destruction of the intraosseous basivertebral is considered not medically necessary or unproven for the following:

a) Skeletally immature patients (<18 years old);
b) Severe cardiac or pulmonary compromise;
c) Active systemic infection or local infection at the intended treatment level;
d) Bleeding diathesis;
e) Pregnancy;
f) Primary radicular pain into the lower extremities (defined as nerve pain following a dermatomal distribution and that correlates with nerve compression on imaging);
g) 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);
h) Primary symptomatic lumbar or lumbosacral spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging);
i) Diagnosed osteoporosis (T-score of -2.5 or less), spine fragility fracture history, trauma/compression fracture at the intended treatment level or spinal cancer;
j) Radiographic evidence of any of the following that correlates with predominant physical complaints:
    a. Lumbar/lumbosacral disc extrusion or protrusion >5mm 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-medicated pain at levels L3-S1.
k) BMI > 40;
l) Advanced generalized systemic disease that limits quality-of-life (QOL) improvements would require a statement of the objective of treatment in such cases;
m) Active, untreated substance abuse disorder.

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CPT 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.geha.com/~/media93/Project/GEHA/GEHA/documents-files/coverage-policies/geha-coverage-policy-intraosseous-radiofrequency-ablation-of-the-basivertebral-nerve.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.

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

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