INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
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Coverage Criteria Summary – Blue Cross and Blue Shield of Minnesota

Intraosseous Basivertebral Nerve Ablation for Chronic Low Back Pain – IV-111-006

Blue Cross and Blue Shield of Minnesota issued a coverage policy for the Intracept™ Procedure **effective 04/07/2025.** 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:

Intraosseous basivertebral nerve ablation (i.e., Intracept Procedure) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

☐ 1. Diagnosis of vertebrogenic pain including **ALL** of the following:
   a. Modic Type 1 or Type 2 changes in at least one vertebral endplate at one or more levels from L3-S1; **AND**
   b. Absence of non-vertebrogenic pathology, including but not limited to fracture, tumor, infection, significant deformity, trauma, or post-surgical change; **AND**

☐ 2. Skeletally mature; **AND**

☐ 3. Chronic low back pain (CLBP) present for at least 6 months that causes functional deficit measured by an Oswestry DIsability Index (ODI) score ≥ 30; **AND**

☐ 4. At least 6 months of continuous, professionally directed non-surgical medical management, including 3 or more of the following:
   a. Avoidance of activities that aggravate pain;
   b. Chiropractic manipulation;
   c. Course of physical therapy or professionally directed therapeutic exercise program;
   d. Injection therapy (e.g., epidural, facet);
   e. Pharmacotherapy (e.g., non-narcotic analgesics, anti-inflammatories, muscle relaxants, neuroleptics, and narcotics); **AND**

5. Radiographic evidence shows absence of another etiology for the individual's symptoms (e.g., lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, facet arthropathy or effusion with clinically suspected facet joint pain); **AND**

(criteria continued on next page)

☐ 6. Treatment is limited to 4 vertebral levels per patient lifetime; **AND NONE** of the following:
   a. Disc extrusion or protrusion > 5 mm; **OR**
   b. Spondylolisthesis > 2 mm at any level; **OR**
   c. Metabolic bone disease (e.g., osteoporosis), spine fragility fracture, trauma/compression fracture, or spinal cancer; **OR**
   d. Spine infection or active systemic infection; **OR**
   e. Previous lumbar/lumbosacral spine surgery at the intended treatment level; **OR**
   f. Presence of active implantable pulse generators (e.g., pacemakers, defibrillators); **OR**
   g. Neurogenic claudication, lumbar radiculopathy or radicular pain due to neurocompression as primary symptoms; **OR**
   h. Severe cardiac or pulmonary compromise, systemic vulnerability to bleeding, or concern for further compromise of existing disease.

Intraosseous basivertebral nerve ablation (i.e., Intracept Procedure) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Clinical notes documenting **ALL** of the following:
   a. Diagnosis and clinical features of the diagnosis, including Modic changes and absence of non-vertebrogenic pathology;
   b. History of chronic low back pain of at least 6 months duration;
   c. Documentation of current and previous non-surgical medical management;
   d. Documentation of the absence of another etiology for the patient's symptoms, and all other exclusions noted in the criteria.

2. Imaging confirms Modic Type 1 or 2 changes of the vertebral endplates at one or more levels from L3-S1.

3. Imaging confirms absence of another etiology for the individual's symptoms (e.g., lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, facet arthropathy or effusion with clinically suspected facet joint pain).

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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.bluecrossmn.com/sites/default/files/DAM/2024-03/upcoming-policies-effective-may-6-2024.pdf

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Indications for Use: The IntraceptTM 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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