INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

Coverage Criteria Summary – BCBS of Massachusetts

Intraosseous Basivertebral Nerve Ablation Policy: 485

Intraosseous radiofrequency nerve ablation of the basivertebral nerve (i.e., Intracept™ Procedure)

BCBS of Massachusetts issued a revised coverage policy for the Intracept™ Procedure effective **05/01/25**. 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:

Basivertebral nerve ablation from L3 through S1 may be considered medically necessary in individuals 18 and over when **ALL** of the following criteria have been met:*

- ☐ 1. Chronic lower back pain > 6 months; **AND**
- ☐ 2. Refractory to optimal nonsurgical medical management including but not limited to physical therapy and chiropractic therapy, epidural or facet injection therapy, lumbar exercise and low impact exercise programs, home use of heat/cold therapies, pharmacotherapy, cognitive support and recovery assurance; **AND**
- ☐ 3. Modic type I or II changes on MRI, endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1) involving in the endplates between L3 and S1 as evidenced by inflammation, edema, disruption, and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, and changes to the vertebral body marrow including replacement of normal bone marrow by fat; **AND**
- ☐ 4. No previous history of BVN ablation at the planned level of treatment; **AND**
- ☐ 5. No more than one to two (1-2) vertebral bodies treated during a single session; **AND**
- ☐ 6. Treatment of no more than 4 vertebral bodies per patient lifetime.

*Retreatment of a single vertebral body with BVN ablation is considered **NOT MEDICALLY NECESSARY**.

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Intraosseus radiofrequency ablation of the basivertebral nerve (e.g., Intracept™ System) for the treatment of vertebrogenic back pain is considered **INVESTIGATIONAL** when any of the following are present:

- Treatment of three (3) or more vertebral bodies during a single session; **OR**
- Evidence on imaging (MRI, flexion/extension radiographs, etc.) indicating that pain may be due to another condition including but not limited to lumbar stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, or facet arthropathy or effusion with clinically suspected facet joint pain; **OR**
- Metabolic bone diseases (e.g. osteoporosis) treatment of spine fragility fracture, trauma/compression fracture; **OR**
- History of active spinal cancer; **OR**
- Spine infection or active systemic infection; **OR**
- Bleeding diathesis; **OR**
- Neurogenic claudication, lumbar radiculopathy or radicular pain due to neurocompression (e.g., HNP, stenosis), as primary symptoms; **OR**
- Radiographic evidence of:
    - Lumbar/lumbosacral disc extrusion or protrusion > 5mm at levels L3-S1;
    - Lumbar/lumbosacral spondylolisthesis > Grade 2 at any level;
    - Lumbar/lumbosacral spondylolisthesis at levels L3-S1;
    - Lumbar/lumbosacral facet arthrosis/effusion correlated with facet-mediated pain at levels L3-S1; **OR**
- Patients with severe cardiac or pulmonary compromise; **OR**
- Patients with active implantable pulse generators (eg. pacemakers, defibrillators) or other electronic implants; **OR**
- Pregnancy; **OR**
- BMI > 40

Prior Authorization:

Inpatient – For services described in this policy, precertification/preauthorization is required for all products if the procedure is performed inpatient.

Outpatient – For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient:

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is required
Commercial PPO and Indemnity	Prior authorization is required
Medicare HMO Blue	Prior authorization is required
Medicare PPO Blue	Prior authorization is required

****Please use this form to assist in the Prior Authorization process.****

Coding:

CPT codes:	Code Description
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; ***first 2 vertebral bodies***, lumbar or sacral

The following CPT code is considered investigational:

CPT codes:	Code Description
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; ***each additional vertebral body***, lumbar or sacral (List separately in addition to code for primary procedure)

References:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/485%20Intraosseous%20Basivertebral%20Nerve%20Ablation.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.