INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
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Coverage Criteria Summary – Harvard Pilgrim and Tufts Health

Harvard Pilgrim and Tufts Health have issued a coverage policy for the Intracept™ Procedure effective **01/01/25**. 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.

Applies to:

Commercial Products

- Harvard Pilgrim Health Care Commercial products; 800-232-0816
- Tufts Health Plan Commercial products; 617-972-9409
  CareLink℠ – Refer to CareLink Procedures, Services and Item Requiring Prior Authorization

Public Plans Products

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
- Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

For Tuft's Health One Care Plan members, the following criteria is used: LCD - Intraosseous Basivertebral Nerve Ablation (L39642)

Policy:

The plan considers basivertebral nerve ablation as reasonable and medically necessary when **ALL** the following criteria are met:

☐ 1. Member is at least 18 years of age with documented skeletal maturity by the treating spine specialist; **and**

☐ 2. Member has vertebrogenic lower back pain between L3 to S1 that has lasted for more than 6 months; **and**

☐ 3. Member has documentation from the interpreting radiologist and treating spine specialist noted in the MRI report showing Modic type 1 (Modic Type 1 is defined as findings of inflammation and edema while there are no trabecular damage or marrow changes) or Modic Type 2 (Modic Type 2 is defined as changes in bone marrow and that marrow is substituted with fat) changes at one or more of the vertebral endplates at one or more level(s) between L3 to S1; **and**

☐ 4. Member has tried and failed at least 6 months of other conventional treatment options to treat their vertebrogenic pain, such as but not limited to, physical therapy, pharmaceuticals, and/or injections.

Note: Only 4 levels are covered per lifetime.

Limitations:

The Plan will not cover basivertebral nerve ablation in any of the following conditions:

1. Member is pregnant.
2. Unless all other low back/spinal conditions (i.e. symptomatic lumbar stenosis, osteoporosis, spinal infection, active/past spinal tumors, pain arising from lumbar radiculopathy, disc extrusion/ herniation or stenosis) that could impact the vertebrae at the treatment level that is being requested have been ruled out;
3. Member has previously received basivertebral nerve ablation for the spinal level of treatment that is being requested.
4. Member has a BMI>40 unless the member has documentation that their weight is not the main contributing factor for the members chronic low back pain.
5. Member has an active spinal cord stimulator.
6. Member is seeking basivertebral nerve ablation on any level outside of L3 to S1.
7. Member has a severe cardiac or pulmonary compromise.
8. Member has Modic type 3 (sclerotic change and endplate thickening) changes shown on MRI imaging.
9. Member has an active systemic infection or a local infection in the area that is to be treated at the time of the procedure.
10. Member has radiograph evidence of:
    a. Facet arthrosis or facet effusion at any lumbar level that correlates with clinical evidence of facet mediated low back pain
    b. a disc extrusion or disc protrusion more the 5mm at any level
    c. spondylolisthesis 2mm or great at any level
    d. Spondylolysis at any level unless statement by treating physician that this is not a cause of pain
11. Member has had previous lumber spine surgery at the level intended to be treated.

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.point32health.org/provider/wp-content/uploads/sites/2/2024/12/Basivertebral-Nerve-Ablation-MNG.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.

Boston Scientific Corporation | 7201 Metro Blvd #300 | Edina, MN 55439
P 650-368-1000

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