INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

Coverage Criteria Summary – PreferredOne

Radiofrequency Ablation (Neurotomy, Denervation, Rhiztomy) Cervical, Thoracic, Lumbosacral, Sacroiliac or Knee Pain #MC/F024 (i.e., Intracept™ Procedure)

PreferredOne issued a coverage policy for the Intracept™ Procedure effective **09/10/24**. 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:

Medical Necessity Criteria - Must satisfy the following:

☐ 1. Site of care - must satisfy **any** of the following:

a. The procedure will be done in an office of ambulatory surgery center setting; or
b. The procedure may be allowed in a facility-based (outpatient hospital) setting if thenearest office or ambulatory surgery center capable of providing the service is 60 miles driving distance or greater from the member's home; or
c. The procedure may be allowed in a facility-based (outpatient hospital) setting if documentation supports that the member is considered at high risk for complications that require a hospital setting, such as but not limited to, member's physical status is classified as ASA III – VI, per the American Society of Anesthesiologists Physical Status Classification System (see Attachment B); or
d. The procedure may be allowed in a facility-based (outpatient hospital) setting if the servicing provider does not hold privileges at an office or ambulatory surgery center within60 miles driving distance from the member's home

☐ 2. Initial request for intraosseous ablation (e.g., Intracept™ system) of the basivertebral nerve (BVN) for low back pain – must satisfy **all** of the following:

a. Member has chronic (at least 6 months) isolated low back pain suggestive of skeletal endplate inflammation (such as, but not limited to, presence of pain that is aggravated by extension, rotation, or lateral bending of spine, and is not typically associated with any neurological deficits) as evidenced by documentation in the medical record on history and physical exam; and
b. MRI shows Type 1 or Type 2 Modic changes of the vertebral endplates at 3 or less contiguous levels, L3-S1; and

(continued on the next page)

c. Member has failed at least 3 months of conservative therapy (such as, but not limited to, activity modification, pharmacotherapies [analgesics, NSAIDs, and muscle relaxants], spinal manipulation, steroid injections, physical therapy [including muscle reconditioning], a structured home exercise program, and weight loss [if indicated]), or a chronic back program.

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.preferredone.com/getting-care/medical-policy/viewpdf.aspx?dc=MC_F024

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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.