INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

Coverage Criteria Summary – PEHP
Back Pain – Invasive Procedures
Intracept™ System – Intraosseous Basivertebral Nerve Ablation

PEHP issued a coverage policy for the Intracept™ Procedure effective **05/22/23**. 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. It is the provider's responsibility to ensure the most current version of the coverage policy is reviewed and followed.

Policy Statement:

PEHP considers any of the following injections or procedures medically necessary for the treatment of back pain; provided, however, that only 1 invasive modality or procedure will be considered medically necessary at a time.

The Intracept™ System (intraosseous basivertebral nerve ablation) is considered medically necessary when the following criteria are met:

☐ 1. The member is >17 years of age and skeletally mature

☐ 2. The member has experienced chronic low back pain for at least six months

☐ 3. Low back pain fails to improve after trial of **all the following**:
   a. NSAIDs or Acetaminophen for at least six months
   b. Activity modification for at least six weeks
   c. Physical Therapy (minimum of four visits over eight weeks)

☐ 4. The provider documents Type I or Type II Modic changes of the L3-S1 vertebral level endplates as noted by MRI.
   a. Type I Modic changes refer to fibrovascular replacement which includes MRI findings of inflammation, edema, disruption and fissuring of the endplate, vascularized fibrous tissue within the adjacent marrow, or hypointensive signals.
   b. Type II Modic changes refer to fatty marrow replacement and hyperintensive signals on MRI.

☐ 5. Minimum ODI (Oswestry Low Back Disability Questionnaire) of 30 points (100-point scale)

☐ 6. Minimum VAS of 4cm (10cm scale)

☐ 7. Intraosseous basivertebral nerve ablation is recommended by two physicians, one of which must be a preferred pain specialist.

The Intracept Procedure is not covered for members with a history of:

- Osteoporosis
- Beck Depression Inventory score >24
- Those exhibiting three or more Waddell's signs of organic behavior
- Those with spondylolisthesis if grade or higher at a segment intended to be accessed during basivertebral nerve ablation
- Lumbar region central canal stenosis with neurogenic claudication
- Those with anatomy, hardware, or other obstructions that negatively affects access to perform the procedure

Coding:

Intracept System (intra-osseous basivertebral nerve ablation):	
CPT codes covered for indications listed in the policy:	
64628	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum
64629	Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure)
ICD-10 codes covered for indications listed in the policy:	
M54.5	Low back pain [chronic]

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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.