INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

Intracept™ Procedure: Documentation Best Practices

DISCLAIMER: Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Mental health statement or psychological screening (not performed by a mental health professional):

- Are there any alcohol or substance abuse issues? If yes, explain.
- Is there anything from a psychological perspective that would preclude the patient from benefiting from the Intracept Procedure?
- From your perspective, will the patient benefit, from a psychologically perspective, from receiving the Intracept Procedure?

Mental health statement of psychological screening (performed as part of a multidisciplinary team approach); their should be comments addressing:

- The presence/absence of drug or alcohol abuse and if there are mental health issues that would preclude of interfere with a positive outcome following the Intracept Procedure.

Modic Type I or Type II changes:

- MRI report states specific Modic Type I or Type II or Modic descriptors (active Schmorl's node, endplate changes, edema, inflammation, disruption and/or fissuring at the endplates, fibrovascular bone marrow changes or fatty bone marrow changes) per FDA clearance (May 2019) and the affected vertebral bodies; **and**
- Documentation of Modic changes by the treating provider should be corroborated by the radiologists report.

Visual Analog Scale (VAS) and functional score:

- If the Medical Policy requires a VAS and/or functional score, clinic note should follow the requirements to include:
  - Clinic note includes VAS 1-10 score; **or**
  - Clinic note includes functional capacity score, such as Oswestry Disability Index (ODI).
  - Consider the Intracept Procedure Intake Form to capture these.

Rule out other sources of low back pain that are present clinically or radiographically:

- Address any conditions identified in the MRI report and whether they are pertinent to the patient's complaints or physical exam.
- If applicable, document that the patient's primary source of pain is coming from their vertebrogenic low back pain based on radiology report, physical exam and patient complaints.
- Address prior treatments that were used to treat or rule out other conditions.

Previous treatment and results:

- Clinic notes should do more than list past treatments. Documentation should include all tried/failed treatment for low back pain along with timeframes of the treatments and results.
- If applicable, summarize that the Intracept Procedure is the most appropriate treatment for vertebrogenic low back pain.

Exclusions or limitations:

If the below conditions have been listed as an exclusion or limitation in the payer policy, we cannot make recommendations, as we did not study these in our clinical trials. You should use your clinical judgment as to why the Intracept Procedure is the most appropriate.

- BMI > 40
- Osteoporosis
- Spondylolysis (pars defect)
- > Grade I Spondylolisthesis

Past spinal surgeries:

In the INTRACEPT trial, 10% of patients had prior lumbar spine surgery (laminectomy/discectomy) as long as the surgery was completed >6 months prior to the Intracept Procedure. If the patient is 6 months or more post op, consider referencing this data. Some policies have a broad statement that prior surgery precludes proceeding with the Intracept Procedure. This does not follow the science of the clinical studies.

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.