INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

MRI Addendum Request Sample Language

Date:
Dear Dr. _____

Would you please review the MRI for _____, Date of Birth _____,
Medical Record # _____, that was performed on _____.

In particular, I am requesting that you comment specifically on the presence and location of Modic Changes.

This patient is an appropriate candidate for the Intracept™ Procedure (ablation of the basivertebral nerve) which is performed to address chronic low back pain that is identified by Modic Type 1 or 2 changes from L3 – S1; in patients that have had low back pain for >6 months; and have not responded to conservative treatment.

This addendum will support the medical necessity of the procedure for my patient. Rather than dictating an addendum, you can simply check the appropriate boxes below and return the signed form by fax. A response within 24 hours would be greatly appreciated.

Regards,
{{Physician's Signature}}

Please check the type of Modic seen and the location in the vertebral body:

Modic changes L3	☐ Type 1 ☐ superior endplate	☐ Type II ☐ inferior endplate
Modic changes L4	□ Type 1 □ superior endplate	□ Type II □ inferior endplate
Modic changes L5	□ Type 1 □ superior endplate	□ Type II □ inferior endplate
Modic changes S1	□ Type 1 □ superior endplate	□ Type II □ inferior endplate

#MRIs that demonstrate:

- Endplate changes, inflammation, edema, disruption and/or fissuring
- Fibrovascular bone marrow changes (hypointense signal for Modic type 1)
- Fatty bone marrow changes (hyperintense signal for Modic type 2)

INTRACEPT™
Vertebrogenic Pain Relief

Boston Scientific
Advancing science for life™

Indications: not intended to be included in copied text

Indications for Use: The IntraceptTM 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

NM-2137406-AA BVN