Intracept™ Procedure

Documenting Medical Necessity and Medical Reasonableness

Clinical documentation demonstrates that care is justified as reasonable, necessary, and/or appropriate, based on evidence-based clinical standards of care (per indications for use and/or payer medical policy).

To document medical necessity, a concise clinical note should contain at a minimum the elements listed below. Form or templated letters should be avoided as they are quickly recognized by an insurer and discounted.

1. Duration of problem (must be minimum of 6 months) – include actual length of pain
2. Discuss other conditions that have been addressed and eliminated as a major cause of LBP
3. Failed conservative care (i.e. list all)
   a. Injections (specific types and number)
   b. Medications (including narcotics)
   c. Manual therapies
   d. Other
4. Pain/Function – ODI or VAS
5. Physician documentation of MRI findings of degenerative endplate changes consistent with Modic Type 1 or Type 2 and the specific vertebral bodies
6. Documentation of the specific vertebral bodies to be treated

Documentation is key to authorization for treatment.

Indications for Use: The Intracept™ Intraosseous Nerve Ablation System is indicated for patients who have had chronic low back pain for at least six months, who have tried conservative care for at least six months, and whose MRI shows features consistent with Modic changes – indicating damage at the vertebral endplates has led to inflammation. Not every patient who meets these criteria is a candidate for the Intracept Procedure, however – in fact, there are specific characteristics indicating a patient should not be considered for the procedure. Contraindications include being pregnant, having weakened cardiac or pulmonary function, having an active implanted electronic medical device in the body (such as a pacemaker or defibrillator), being diagnosed with a systemic or local infection, or having an anatomy that could be damaged unintentionally while ablating the basivertebral nerve (based on your physicians' clinical review). The Intracept Procedure is also contraindicated in patients who are skeletally immature – which generally means individuals under the age of 18 are not candidates. There are also certain risks and precautions regarding the procedure which you should be aware of before proceeding. Talk with your doctor about what indicates, and contraindicates, certain patients for the Intracept Procedure – as well as the risks and precautions for the procedure. For complete indications for use, contraindications, warnings, precautions, and side effects visit www.relievant.com/intracept/.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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