Anthem Blue Cross Blue Shield Coverage Policy Q+A

Percutaneous Vertebral Disc and Vertebral Endplate Procedures

Policy #: SURG.00052

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When is the policy effective and what are the coverage criteria?

Anthem Blue Cross Blue Shield, representing over 36 million covered lives, published an Intracept™ Procedure coverage policy, effective **September 27, 2023**. A link to the coverage policy can be found ***here***.

Are there coverage criteria that should be closely reviewed and adhered to?

All criteria within the policy must be adhered to and can be found in the policy using the link above. Please refer to the criteria listed below and the checklist resource for a complete list of the criteria. Payers require providers document these criteria to demonstrate the patient meets medical necessity.

Intraosseous basivertebral nerve ablation (BVNA) is considered **medically necessary** when all of the following criteria are met:

1. Individual is skeletally mature; **and**
2. Chronic unremitting low back pain of at least 6 months duration is present; **and**
3. Has failed to respond to at least 6 months of supervised conservative medicalmanagement (for example, exercise, nonsteroidal and/or steroidal medication [unlesscontraindicated], physical therapy, including passive and active treatment modalities,and activity/lifestyle modification); **and**
4. Diagnosis of vertebrogenic pain meeting the following criteria:
   a. Documented by history and physical examination; **and**
   b. Magnetic resonance imaging (MRI)-demonstrated Modic Type 1 or 2 changes inat least one vertebral endplate, at one or more levels from L3 to S1, includingthe following:
      i. Fibrovascular bone marrow changes are present (hypointense MRI signalfor Modic Type 1); **or**
      ii. Fatty bone marrow changes are present (hyperintense MRI signal forModic Type 2); **and**
5. Qualifying Modic changes are exhibited at each level to be treated; **and**
6. Documentation that other causes of low back pain have been excluded (including, butnot limited to: chronic lumbar strain, lumbar stenosis, degenerative scoliosis, facetarthroplasty and disc disease).

Should Anthem patients continue being put into the Intracept Procedure prior authorization portal?

Yes, as you identify appropriate Intracept patients who have Anthem insurance, put the patients into the portal. Please review the coverage policy and submit all clinical information that demonstrates the patient meets medical necessity. Should the case be denied, our patient access team can begin the appeal process. Atier a period of time, we will transition Anthem cases out of the portal and will provide additional communication at that time.

What about Anthem patients that are currently going through the prior authorization process in the portal?

Relievant is currently reviewing the in-process cases to determine if additional information is needed to support gaining prior authorization or submiting an appeal based on the new coverage policy. If so, we will contact you. Otherwise, communication will be sent if all parties if there is any change to the process.

INTRACEPT™
Vertebrogenic Pain Relief

What resources are available to me?

- Customer Q+A document (this document)
- Policy Criteria Checklist
- Reimbursement Business Manager (RBM). Reach out to your local Relievant TerritoryManager who can put you in contact with the RBM in your area.

What influence does this policy have on other payers, including other Blue Cross Blue Shield plans?

It is significant when a large payer establishes positive coverage, however, each payer will establish their own coverage criteria. The Relievant reimbursement and health policy team will continue to partner with physicians and societies to work with payers to establish positive coverage.

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.

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