CareSource

MEDICAL POLICY STATEMENT
Marketplace

Policy Name & Number	Date Effective
Intraosseous Basivertebral Nerve Ablation-MP-MM-1376	GA, IN, KY, WV: 04/01/2023-08/31/2023 OH: 05/01/2023-08/31/2023
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

This policy applies to the following Marketplace(s):				
☒ **Georgia**	☒ **Indiana**	☒ **Kentucky**	☒ **Ohio**	☒ **West Virginia**

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A. Subject

Intraosseous Basivertebral Nerve Ablation

B. Background

Interventional procedures for management of acute and chronic pain are part of a comprehensive pain management care plan that incorporates conservative treatment in a multimodality approach. Multidisciplinary treatments include promoting patient self-management and aim to reduce the impact of pain on a patient's daily life, even if the pain cannot be relieved completely. Interventional procedures for the management of pain unresponsive to conservative treatment should be provided only by physicians qualified to deliver these health services.

Chronic low back pain (CLBP) is a common disabling condition, estimated to afflict 80% of adults at some point. Degenerative disc disease (DDD) is an important cause of CLBP. While discs are avascular with limited nerve distribution, vertebral endplates have the potential to trigger a cascade of degenerative events if there is a loss of integrity. Vertebral endplates are a thin interface between bone marrow and discs and contain neural elements. Breakdown of the endplate is believed to cause vertebrogenic chronic low back pain, a type of chronic low back pain. Endplate degeneration can be observed on MRI through Modic changes (MC).

Histologically, in MC type I (MC I) lesions, the endplate is disrupted as fibrous tissue replaces bone marrow, causing the disc-bone interface to be filled with vascularized granulation tissue. MC I represents bone marrow edema and inflammation. In MC type II (MC II) lesions, there is demonstration of fatty marrow replacement in addition to MC type I findings. MC II represents conversion of hematopoietic marrow into fatty, yellow bone marrow. MC type III (MC III) lesions are related to subchondral bone sclerosis. Analysis of Modic lesions shows that MC I is characterized by high bone turnover, MC II is characterized by decreased bone turnover, and MC III are stable.

Radiofrequency ablation is a minimally invasive, percutaneous treatment which uses heat to ablate the nerve pathway that conducts the pain signal. The goal of RFA is to interrupt the pain pathway without causing excessive sensory loss, motor dysfunction, or other complications. Intracept is an RFA system designed to ablate the basivertebral nerve of the vertebral endplate.

C. Definitions

- **Chronic Low Back Pain** – Persistent pain in the lumbar region lasting for more than 12 weeks.
- **Conservative Therapy** – A multimodality plan of care. Multimodality care plans include both active and inactive conservative therapies.
  - **Active Conservative Therapies** – Include physical therapy, occupational therapy, a physician supervised home exercise program (HEP), and/or chiropractic care.
  - **Inactive Conservative Therapies** – Include rest, ice, heat, medical devices, TENS unit, and/or prescription medications.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

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- **Modic Changes** – Vertebral bone marrow signal intensity changes that are observable on MRI and are commonly associated with degenerative disc disease.
  - **Modic Change Type I** – Characterized by hypo- and hyper-intense signal intensities on T1- and T2-weighted spin-echo (T1W1 and T2W1), respectively.
  - **Modic Change Type II** – Characterized by hyper-intense signal intensities on both T1W1 and T2W1.
  - **Modic Change Type III** – Characterized by hypo-intense signal intensities on both T1W1 and T2W1.
- **Radiofrequency Ablation (RFA)** – Minimally invasive treatment modality that percutaneously introduces an electrode under fluoroscopic guidance to thermocoagulate medial or lateral branches of the dorsal spinal nerves.
- **Transcutaneous Electrical Nerve Stimulator (TENS Unit)** – A durable medical equipment device dispensed by prescription.

D. Policy

I. CareSource considers intraosseous basivertebral nerve ablation medically necessary when **ALL** the following clinical criteria is met:

A. The member has a diagnosis and documentation of chronic low back pain of at least 6 months duration;

B. The member has undergone and failed a minimum 6 weeks of conservative therapy, including **ALL** the following:

1. ACTIVE conservative therapy as part of a multimodality comprehensive approach and is addressed in the patient's care plan with documentation in the medical record that includes **ONE** of the following:

a. The patient has received ACTIVE conservative therapy lasting 6 weeks or more within the past 6 months including **at least ONE** of the following:

01. Physical therapy
02. Occupational therapy
03. A physician supervised home exercise program (HEP), including the following two requirements:

(1). An exercise prescription and/or plan documented in the medical record;

(2). A follow-up documented in the medical record regarding completion of an HEP (after suitable 6-week period), or inability to complete a HEP due to a state physical reason (i.e., increased pain, inability to physically perform exercises) (patient inconvenience or noncompliance without explanation does not constitute "inability to complete");

b. The medical record documents **at least ONE** of the following exceptions to the 6 weeks active conservative therapy requirement in the past 6 months:

01. Moderate pain with significant functional loss at work or home;
02. Severe pain unresponsive to outpatient medical management;
03. Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s);

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2. INACTIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record lasting for 6 weeks or more within the past 6 months, including **at least ONE** of the following:
   a. Rest;
   b. Ice;
   c. Heat;
   d. Medical devices;
   e. Pain medications (prescription or over the counter) (e.g., non-steroidal anti-inflammatory drugs [NSAIDS], acetaminophen). Opioid narcotics are not required, necessary, or recommended to meet pain medication criteria;
   f. TENS unit;
      01. If a TENS unit is part of the care plan, the frequency of use, and duration of use with dates must be documented in the medical record. General statements in the medical record such as "patient has a TENS unit" do not document use and will not suffice to meet this policy criterion;

C. MRI has been performed and demonstrates Type 1 or Type 2 Modic changes at one or more vertebral endplates from level L3 to S1, as demonstrated by:
   - Hypointense T1-weighted signal and hyperintense T2-weighted signal (i.e., bone marrow edema and inflammation); or
   - Hyperintense T1-weighted signal and hyperintense T2-weighted signal (i.e., bone marrow ischemia);

D. The device is FDA-approved (e.g., Intracept System);

E. Member does not have any of the following contraindications:
   1. Severe cardiac or pulmonary compromise;
   2. Member has a targeted ablation zone less than 10mm from a sensitive structure not intended to be ablated (including vertebral foramen);
   3. Active systemic infection or localized infection in the area to be treated;
   4. Member is currently pregnant;
   5. Skeletal immaturity;
   6. Implantable pulse generator (e.g., pacemaker, defibrillator) or other electronic implant;
   7. Scoliosis;
   8. Spinal instability.

II. Repeat or additional intraosseous basivertebral nerve ablation is not considered medically necessary, as it has not been adequately studied in the peer-reviewed medical literature.

III. Monitored anesthesia and conscious sedation during intraosseous basivertebral nerve ablation are considered not medically necessary and will therefore not be reimbursed.

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IV. Coverage is limited to the above criteria. Intraosseous basivertebral nerve ablation is considered not medically necessary for all other indications.

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	01/04/2023	New policy
Date Revised		
Date Effective	GA, IN, KY, WV: 04/01/2023 OH: 05/01/2023	
Date Archived	GA, IN, KY, WV: 08/31/2023 OH: 08/31/2023	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

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2. Becker S, Hadjipavlou A, Heggeness MH. Ablation of the basivertebral nerve for treatment of back pain: a clinical study. Spine J. 2017 Feb;17(2):218-223.
3. Evolving Evidence Review. (2021 July 30). Intracept intraosseous nerve ablation system (Relievant Medsystems Inc.) for Treatment of Adults with Low Back Pain. Hayes. Retrieved March 30, 2022 from www.evidence.hayesinc.com.
4. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. Int J Spine Surg. 2019 Apr 30;13(2):110- 119.
5. Lorio M, Clerk-Lamalice O, Beall DP, Julien T. (2019 December). ISASS guideline – intraosseous ablation of the basivertebral nerve for the relief of chronic low back pain. Retrieved March 8, 2022 from www.isass.org.
6. North American Spine Society (NASS). Clinical guidelines. Evidence based clinical guidelines for multidisciplinary spine care. Diagnosis and treatment of low back pain. Copyright ©2020. North American Spine Society. Retrieved February 17, 2022 from www.spine.org.
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8. U.S. Food and Drug Administration. Intracept Intraosseous Nerve Ablation System (component Intracept RF Probe). 510(K) approval K180369. 2018. Retrieved

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9. U.S. Food and Drug Administration. Intracept Intraosseous Nerve Ablation System (RF Probe), Intracept Intraosseous Nerve Ablation System (Access Instruments), Relievant RF Generator. 510(K) approval K190504. 2019. Retrieved February 17, 2022 from www.accessdata.fda.gov.
10. Viswanathan VK, Shetty AP, Rajasekaran S. Modic changes – an evidence-based, narrative review on its pathophysiology, clinical significance and role in chronic low back pain. J Clin Orthop Trauma. 2020 Sep-Oct;11(5):761-769. doi:10.1016/j.jcot.2020.06.025.

A. State-Specific Information
   A. Georgia
      1. Effective: 04/01/2023
   B. Indiana
      1. Effective: 04/01/2023
   C. Kentucky
      1. Effective: 04/01/2023
   D. Ohio
      1. Effective: 05/01/2023
   E. West Virginia
      1. Effective: 04/01/2023

Independent medical review – 2022

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