CareSource

MEDICAL POLICY STATEMENT
Ohio MyCare

Policy Name & Number	Date Effective
Intraosseous Basivertebral Nerve Ablation-MyCare OH FIDE-MM-1827	04/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements 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 or Certificate of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other plan policies and procedures.

Medical Policy Statements do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage or Certificate of Coverage) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract, then the plan contract 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.

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A. Subject

Intraosseous Basivertebral Nerve Ablation

B. Background

Interventional procedures for the 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 (RFA) 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 more than 12 weeks.
- **Conservative Therapy** – A multimodality plan of care including both active and inactive conservative therapies.
  - **Active Conservative Therapies** – Actions or activities that strengthen muscle groups and target key spinal structures, including physical therapy, occupational

therapy, physician supervised home exercise program (HEP), and/or chiropractic care.
    - **HEP** – A 6-week program requiring an exercise prescription and/or plan and a follow-up documented in the medical record after completion, or documentation of the inability to complete the HEP due to a stated physical reason (ie, increased pain, inability to physically perform exercises). Patient inconvenience or noncompliance without explanation does not constitute an inability to complete.
  - **Inactive Conservative Therapies** – Passive activities by the patient that aid in treating symptoms associated with pain, including rest, ice, heat, medical devices, TENS use, and/or pharmacotherapy (prescription or over the counter [eg, non-steroidal anti-inflammatory drugs, acetaminophen]).
    - **Transcutaneous Electrical Nerve Stimulator (TENS)** – A device that utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins. Its use, frequency, duration, and start dates must be documented in the medical record to be considered part of conservative therapy during the period of prior authorization request.
- **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.

D. Policy
  I. Intraosseous basivertebral nerve ablation is considered medically necessary when **ALL** the following clinical criteria are met:
    A. Member has a diagnosis and documentation of chronic low back pain of at least 6 months duration that causes functional deficit measured on a pain or disability scale.
    B. Failure of conservative therapy, as evidenced by **ALL** the following:
      1. documentation in the medical record of at least 6 weeks of active conservative therapy (see definition above) within the past 6 months OR inability to complete active conservative therapy due to contraindication, increased pain, or intolerance
      2. documentation in the medical record of at least 6 weeks of inactive conservative therapy (see definition above) within the past 6 months

C. MRI demonstrates Type I or Type II modic changes at one or more vertebral endplates from level L3 to S1, as demonstrated by
   1. hypointense T1-weighted signal and hyperintense T2-weighted signal (ie, bone marrow edema and inflammation), or
   2. hyperintense T1-weighted signal and hyperintense T2-weighted signal (ie, bone marrow ischemia)
D. Device is FDA-approved (eg, Intracept System).
E. Member does not have any of the following contraindications:
   1. severe cardiac or pulmonary compromise
   2. 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. current pregnancy
   5. skeletal immaturity
   6. implantable pulse generator (eg, 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 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.

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

E. Summary of Evidence

Fischgrund et al (2018) conducted a prospective randomized double-blind sham-controlled Food and Drug Administration (FDA) Investigational Device Exemption (IDE) clinical trial to evaluate the safety and efficacy of radiofrequency ablation (RFA) of the basivertebral nerve (BVN) for the treatment of chronic low back pain. The trial involved 225 patients diagnosed with chronic low back pain at 18 sites across the United States and Europe. Patients were skeletally mature, experienced chronic, isolated lumbar pain, had failed at least 6 months of conservative management, and demonstrated Type 1 or Type 2 Modic changes at 3 or fewer contiguous levels between L3 and S1 on MRI. At the start of the clinical trial, patients had a minimum Oswestry Disability Index (ODI) of 30 points (100-point scale) and a minimum visual analog scale (VAS) of 4cm (10cm scale). The primary endpoint was the comparative change in ODI from baseline to 3 months. At 3 months, the average ODI in the treatment arm decreased 20.5 points, compared to a 15.2 decrease in the sham control arm. Responder analysis demonstrated that 75.6% of patients in the treatment arm compared to 55.3% in the

sham control arm exhibited a clinically meaningful improvement at 3 months. Out of the 147 participants treated with RFA of the BVN, the procedure was deemed successful by imaging in 129 of 145 patients (89%) and in 300 of 317 treated vertebral bodies (94.6%).

Fischgrund et al (2019) reported on the 2-year follow up from the SMART Trial. Following the 1-year mark, participants in the sham arm were allowed to cross over; 57 (73%) chose to receive the Intracept intervention. Intra-patient comparison of patient-reported measures from baseline to each follow-up visit were used to evaluated long-term efficacy and treatment durability in RFA arm participants with 24-month data. 106 patients completed a 24-month follow-up visit. Patients exhibited a durable ODI mean improvement of 23.4 points at 24 months compared to the mean improvements observed during the first year of follow up (20.3, 20.8, and 19.8 points at 3, 6, and 12 months, respectively). Using a 10-point improvement in ODI as a commonly accepted minimum clinically important difference in the treatment of chronic low back pain, 75.6% of treated patients existed a successful response at 3 months, which was sustained at 24 months (76.4% of treated patients). VAS improvement was also maintained at 24 months, starting with a baseline of 6.73 cm and improving by 2.76 and 3.59 cm at 12 and 24-months follow-up, respectively. No device or procedure-related patient deaths, unanticipated adverse device effects, or device related serious adverse events were reported.

Fischgrund et al (2020) reported on the 5-year outcome for patients in the SMART Trial. Primary outcome was mean change in ODI. 100 patients of the original 117 US participants were available for review at a minimum of 5-years post BVN ablation. Mean ODI score improved from 42.81 to 16.86 at 5-year follow-up, a reduction of 25.95 points. Mean reduction of VAS pain score was 4.38 points. 66% of patients reported more than a 50% reduction in pain, 47% reported more than 75% reduction in pain, and 34% of patients reported complete pain resolution. 5-year results indicate a sustained improvement in patients treated with RFA of the BVN for chronic low back pain.

Khalil et al (2019) reported on the INTRACEPT Trial, a prospective, randomized, multicenter study at 20 US cites which compared the effectiveness of intraosseous basivertebral nerve ablation to standard of care for the treatment of chronic low back pain. The trial involved 140 patients experiencing chronic low back pain for at least 6 months, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, who had failed to respond to conservative therapy. Similar to the SMART Trial, patients were skeletally mature, with a minimum ODI of 30 points and a minimum VAS of 4cm. Patients had a baseline average ODI of 46.1 and VAS of 6.67. Comparing the RFA arm to the standard of care arm, the mean changes in ODI at 3 months were -25.3 points versus -4.4 points, respectively, resulting in an adjusted difference of 20.9 points ($p<0.001$). 74.5% of RFA patients achieved a ≥10-point improvement in ODI, compared with 32.7% in the standard care arm ($p<0.001$). The study demonstrated that RFA of the BVN led to significant improvement of pain and function at 3 months in patients with chronic vertebrogenic related low back pain.

The International Society for the Advancement of Spine Surgery released a guideline in 2020 addressing intraosseous ablation of the basivertebral nerve to treat chronic low back pain. The guideline states that RFA of the BVN from L3 through S1 vertebrae may be medically necessary for individuals with chronic low back pain when pain lasted for at least 6 months duration, the individual failed to respond to at least 6 months of nonsurgical management, and MRI demonstrated MC1 or MC2 in at least 1 vertebral endplate at 1 or more levels from L3 to S1.

F. Conditions of Coverage
NA

G. Related Policies/Rules
NA

H. Review/Revision History

	DATE	ACTION
Date Issued	06/18/2025	New market. Approved at Committee.
Date Revised	12/17/2025	Revised: updated references. Approved at Committee.
Date Effective	04/01/2026	
Date Archived		

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Independent medical review – March 2022

Approved by ODM 01/20/2026