| MEDICAL POLICY STATEMENT North Carolina Marketplace | |
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| Policy Name & Number | Date Effective |
| Intraosseous Basivertebral Nerve Ablation-NC MP-MM-1377 | 05/01/2024 |
| 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.

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 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 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.

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

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. CareSource considers intraosseous basivertebral nerve ablation 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
 - 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



- 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: