Medica

UTILIZATION MANAGEMENT POLICY

TITLE: NON-INVASIVE ELECTRICAL BONE GROWTH STIMULATION OF THE SPINE – MAYO MEDICAL PLAN ONLY

EFFECTIVE DATE: May 01, 2024

THIS POLICY APPLIES TO MAYO MEDICAL PLAN (MMP) MEMBERS.

NOTE: Medica is using clinical criteria developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering medical necessity criteria.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY
These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

PURPOSE
To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND
I. Definitions
   A. **Delayed union** is when the healing process continues, but the fracture takes longer than usual to heal. The fact that a bone is delayed in its union does not mean that it will become a non-union. Reasons for delayed union may include inadequate reduction, inadequate immobilization, poor calcium and vitamin D3 intake, and impaired blood supply.
   B. **Electrical bone growth stimulators (aka, osteogenesis stimulators)** use electromagnetic current to promote bone healing in spinal fusion through delivery of electrical current to the fusion site. Noninvasive devices are worn externally, beginning at any time from the date of surgery until up to six months after surgery.
   C. **Multiple level spinal fusion** involves fusion of three or more vertebrae (e.g., L3-L5, L4-S1).

BENEFIT CONSIDERATIONS
1. Prior authorization **is required** for non-invasive electrical bone growth stimulation of the spine.
2. Coverage is limited to devices that have FDA approval for use on the involved bone.
3. Coverage may vary according to the terms of the member's plan document.
4. Concurrent use of electrical and ultrasound stimulation devices is not eligible for coverage.
5. Non-invasive electrical bone growth stimulation of the spine *is investigative and therefore not covered* for all indications not specifically mentioned in the Medical Necessity Criteria section, including but not limited to:
   a. Treatment of spondylolysis or pars interarticularis defect
   b. Semi-invasive electrical bone growth stimulation for any indication
   c. As an adjunct for primary bone healing of a spinal fracture

d. As a nonsurgical treatment of an established pseudoarthrosis.

6. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
7. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica administrative handbook.

MEDICAL NECESSITY CRITERIA

I. Non-invasive electrical bone growth stimulation of the spine to augment **thoracic or lumbar** fusion in individuals at high risk for pseudoarthrosis is considered medically necessary when documentation in the medical records indicates that **one of the following** are met:
   A. Fusion revision (e.g., repeat surgery due to prior unhealed fusion attempt) when **all of the following** criteria are met:
      1. At least six months have passed since the original surgery, and
      2. Imaging studies confirm that healing has not progressed in the preceding three months

   <or>

   B. Fusion was performed at two (2) or more adjacent levels*

      *Defined as 2 or more motion segments (3 vertebrae); alternatively, one level includes the upper and lower vertebral segment and the intervening disc space, e.g., L4-L5 is one level.

   <or>

   C. Presence of **at least one** of the following risk factors:
      1. Active nicotine use
      2. Diabetes
      3. History of long-term use of corticosteroids
      4. Immunocompromised
      5. Metabolic bone disease (including osteoporosis, osteopenia, and bone disease secondary to renal disease, nutritional deficiency, or conditions in which bone healing is likely to be compromised
      6. Systemic vascular disease.

II. Non-invasive electrical bone growth stimulation of the spine to augment **cervical fusion** in individuals at high risk for pseudoarthrosis is considered medically necessary when documentation in the medical records indicates that **one of the following** are met:
   A. Fusion revision (e.g., repeat surgery due to prior unhealed fusion attempt) when at least 6 months has passed since the original surgery and imaging studies confirm that healing has not progressed in the preceding 3 months

   <or>

   B. Fusion performed at three (3) or more adjacent levels* for cervical fusion when ANY of the following risk factors are present:
      1. Diabetes
      2. Osteoporosis
      3. Active nicotine use

      *Defined as 3 or more motion segments (4 vertebrae)

DOCUMENT HISTORY

Original Effective Date	May 01, 2024
Administrative Updates	