KAISER PERMANENTE® Mid-Atlantic States	**Osteogenic Stimulator** **Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- Please refer to CMS guidelines or National Coverage Determination (NCD) for Medicare members
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Procedure: **Osteogenic Stimulators (Ultrasonic and Electrical)**

II. Specialties: Orthopedic, DME, Physical Therapy, Podiatry

III. Electrical Osteogenic Stimulator

A. Electrical Osteogenic Stimulator (non-invasive or invasive)

Clinical Indications

Electrical or electromagnetic osteogenic stimulator is medically necessary when used for **any** of the following:

1. Grade II or greater spondylolisthesis; or
2. Congenital pseudarthroses; or
3. Fusion surgery as indicated by any of the following:
   a. Multi-level fusion surgery; or
   b. Previously failed lumbar spinal fusion(s) where a minimum of 6 months has elapsed since the most recent operation; or
   c. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site; or
   d. As adjunct to lumbar spinal fusion surgery for patients who are high risk for subsequent failed fusion due to non-union predisposing factors:
      i. Location of the bone in the body that receives poor blood supply; or
      ii. Presence of risk factors for fusion failure as indicated by 1 or more of the following
         1) Steroid use; or
         2) Current tobacco use; or
         3) Alcoholism; or
      iii. Comorbid condition associated with compromised bone healing (such as obesity, diabetes, renal disease, osteoporosis)

4. Non-union of a long bone fracture or failed arthrodesis as indicated by **ALL** of the following;
   a. Absence of clinically significant bone healing 3 or more months since the date of fracture or surgery, confirmed by 2 sets of multiple view serial radiographs of the site taken separately between a minimum of 90 days showing that healing has ceased prior to treatment with osteogenic stimulator; and
   b. Fracture gap of 10 mm or less; and
   c. Reduced and immobilized fracture; and
   d. There is no sign of osteomyelitis; and
   e. The fracture is not tumor related.

B. Exclusions for Electrical Osteogenic Stimulator (invasive and non-invasive)

1. Electrical osteogenic stimulator is considered **experimental, investigational, or unproven** for the following:
   a. Treatment of fresh fractures
   b. Avascular necrosis of the hip
   c. Charcot arthropathy
   d. Charcot foot
   e. Comminuted toe fracture
   f. Fractures of the scapula or pelvis
   g. Loosened hip prosthesis
   h. Loosened knee prosthesis
   i. Lunate fractures
   j. Odontoid fractures
   k. Pre-operative use for fractures that require surgical intervention or internal or external fixation
   l. Sacroiliac fusion
   m. Spondylolysis/Spondylolisthesis

IV. Ultrasonic Osteogenic Stimulator

A. Clinical Indications

Ultrasonic osteogenic stimulator is medically necessary when ALL criteria are met.

1. For treatment of non-union fractures prior to surgical intervention, confirmed by **all** of the following:
   a. 2 sets of multiple view serial radiographs of the fracture site, separated by a minimum of 90 days prior to treatment with ultrasonic osteogenic stimulator; and
   b. Written interpretation by a physician of no clinically significant evidence of fracture healing between the 2 sets of serial radiographs.
2. Fracture is not of the skull or vertebrae; and

3. Fracture is not tumor related.

B. Inclusions for Ultrasonic Osteogenic Stimulators for patients who have undergone an Osteotomy. This is for treatment of non-union after osteotomy surgery prior to repeat surgical intervention confirmed by all of the following:

1. Surgery performed more than 6 months ago; and
2. 2 sets of multiple view serial radiographs of the fracture site, separated by a minimum of 90 days prior to treatment with ultrasonic osteogenic stimulator; and
3. Written interpretation by a physician of no clinically significant evidence of fracture healing between the 2 sets of serial radiographs; and
4. Fracture is not of the skull or vertebrae; and
5. Fracture is not tumor related; and .
6. Normal ESR, CRP, Vitamin D and Serum Calcium levels; and
7. No radiographic evidence of fixation loosening or loss of deformity correction.

C. Exclusions for Ultrasonic Osteogenic stimulators

1. Ultrasonic osteogenic stimulator should not be used for the following:
   a. Concurrently with other non-invasive osteogenic devices; or
   b. Treatment of fresh fractures or delayed unions

2. Ultrasonic osteogenic stimulator is considered **experimental and investigational** for the following:
   a. Iliac apophysitis;
   b. Stress fractures;
   c. Pathological fractures due to malignancy (unless the neoplasm is in remission);
   d. Pre-operative use for fractures that require surgical intervention or internal or external fixation;
   e. Talar dome lesion following osteochondral autograft transfer system (OATS);
   f. Avascular necrosis of the femoral head;
   g. Calcaneal apophysitis (Sever disease);
   h. Charcot arthropathy; and
   i. Fractures with post-reduction displacement of more than 50% (such as fractures in which the opposing broken bone ends are out of alignment by more than one half of the width of the bone)

V. Additional requirements for approval of both Ultrasonic and Electrical/Electromagnetic Osteogenic Stimulators

A. Normal Serum Vitamin D levels **AND**

B. Normal Serum Calcium levels

VI. Contraindications and Exclusions both Ultrasonic and Electrical/electromagnetic Osteogenic Stimulators

A. All Osteogenic stimulators are not to be used for any of the following:
1. Pregnant women; or
2. Patients with implanted electronic devices such as defibrillator or pacemaker unless there is clearance with their cardiologist; or
3. Patients with growth disorder or skeletal immaturity; or
4. Bone is stabilized with magnetic materials; or
5. For treatment of fresh fractures and delayed unions; or
6. Fracture gap is greater than 50% of the diameter of the bone; or
7. Non-union fractures of the skull and vertebrae;
8. Tumor-related fractures; or
9. Pseudarthrosis or "false joint"

VII. Definitions

Ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound waves at the fracture site to stimulate fracture healing. The leads of the device are applied to the surface of the skin at the fracture site via conductive coupling gel, connected to the inserted cathodes with opposing pads wired to a power supply that is externally placed over the cast creating an electromagnetic field between the pads at the fracture site.

Electrical osteogenic stimulator is a non-invasive or invasive device that provides electrical stimulation directly at the fracture site by implanting the power pack into the soft tissue near the fracture site through percutaneously placed cathodes or by implantation of a coiled cathode wire directly into the fracture site, creating a self-contained system with no external components.

Non-union of long bone fracture is defined as a fracture that ceases to heal 3 or more months from the time of injury, as confirmed by 2 sets of serial radiographs taken at least 90 days apart. Non-union is considered established

- when the fracture site shows no visibly progressive signs of healing after at least 3 months have passed since the date of the fracture, AND
- Serial radiographs have confirmed that no progressive signs of healing have occurred, AND
- The fracture gap is 1cm or less, AND

- The patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.
- Long bone is defined as the clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal or metatarsal bone

Failed spinal fusion is a non-healing spinal fusion at a minimum of 6 months after original surgery, confirmed by 2 sets of serial radiographs taken at least 90 days apart.

Fresh fracture is a fracture that occurs within 7 days from the time of injury.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
06/26/2023	06/26/2023
05/23/2024	05/23/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.