Bone Growth Stimulators
Clinical Coverage Criteria

Overview

A bone growth stimulator, also referred to as an osteogenesis stimulator, is an adjunct intervention used to stimulate the body's natural bone healing process which may be impaired in some at-risk patients.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)

☒ MassHealth ACO

☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)

☒ NaviCare SCO (MassHealth-only)

☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

☒ Community Care (Commercial/Exchange)

Prior authorization is required for bone growth stimulators.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care and MassHealth ACO members. For Medicare members, follow Medicare coverage criteria described in the Medicare Variation section below.

A noninvasive non-spinal electrical bone growth stimulator (HCPCS code E0747) is covered for the following indications:

- Nonunion of long bone fractures in skeletally mature patients without serious systemic disease who are not taking steroids or other immunosuppressants, or
- Congenital pseudoarthrosis.

A non-spinal electrical bone growth stimulator will be denied as not medically necessary if neither of the criteria above are met.

A noninvasive spinal electrical bone growth stimulator (HCPCS code E0748) is covered for the following indications:

- Failed spinal fusion, where a minimum of 6 months has elapsed since the last surgery and serial radiographs confirm there is no evidence of progression of healing for 3 months prior to starting treatment with the bone growth stimulator, or
- As an adjunct to spinal fusion for patients at high-risk for pseudoarthrosis.*

A spinal electrical bone growth stimulator will be denied as not medically necessary if none of the criteria above are met.

An invasive electrical bone growth stimulator (CPT code 20975 is used to report the implantation of an electric bone growth stimulator and HCPCS code E0749 is used to report the device) is covered for the following indications:

- Nonunion of a long bone fractures, or

- As an adjunct to spinal fusion in patients at high risk for pseudoarthrosis* due to previously failed fusion at the same site, or for patients undergoing multiple-level spinal fusion involving 3 or more vertebrae, or
- As an adjunct to primary ankle or foot fusion in patients at high risk for pseudoarthrosis.*

The following criteria must also be met for noninvasive and invasive electrical bone growth stimulators:
- The patient is 20 years of age or older or demonstrates proof of skeletal maturity, and
- The fracture gap is < 1 centimeter, and
- For nonunion of long bone fractures, serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the bone growth stimulator, as demonstrated by a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

* Patient factors play a significant role with regards to pseudoarthrosis risk. High risk for pseudoarthrosis exists when:
- Previously failed fusion at the same site, OR
- Grade III or worse spondylolisthesis, OR
- Undergoing a multiple-level spinal fusion involving 3 or more vertebrae: e.g., L3-L5, L4-S1,
- etc.), OR
- Body mass index (BMI) of > 30 or who are greater than 50% over their ideal body weight, OR
- Diabetes, renal disease, or other metabolic diseases where bone healing is likely to be
- compromised or growth is poor, OR
- Nutritional deficiency/malnutrition, OR
- Severe anemia, OR
- Steroid therapy, OR
- Smoking, OR
- Alcohol consumption

An ultrasound bone growth stimulator (HCPCS code E0760) is covered for the treatment of established nonunions when all of the following criteria are met:
- The patient is 20 years of age or older or demonstrates proof of skeletal maturity, and
- The fracture is not of the skull or vertebrae, and
- The fracture is not tumor related, and
- The fracture is stable and well-aligned with a gap < 1 centimeter, and
- Serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the bone growth stimulator, as demonstrated by a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days, and
- The patient has failed at least one surgical or medical intervention for the treatment of the fracture.

An ultrasound bone growth stimulator will be denied as not medically necessary if any of the criteria above are not met.

Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for bone growth stimulators, also referred to as an osteogenesis stimulators. Medicare has an NCD for Osteogenic Stimulators (150.2), Version Number 2, Effective Date of this Version 04/27/2005. Noridian Healthcare Solutions, LLC, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in our service area has an LCD for Osteogenesis Stimulators (L33796), Revision

Effective Date: For Services Performed on or after 01/01/2024 (Medicare Coverage Database search 05/26/2025).

Link: NCD Osteogenic Stimulators
Link: LCD Noridian Healthcare Solutions, LLC LCD Osteogenesis Stimulators (L33796)

Coverage criteria for bone growth stimulators are fully established by Medicare, therefore, the Plan's coverage criteria are not applicable.

MassHealth Variation

MassHealth does not have Guidelines for Medical Necessity Determination for bone growth stimulators (MassHealth website search 05/26/2025), therefore Fallon Health Clinical Coverage Criteria are applicable.

Exclusions

- Any use of bone growth stimulators other than outlined in this policy.
- Concurrent use of electrical (invasive or noninvasive) and ultrasound bone growth stimulators is not covered.

Evidence Summary

Bone healing is a complex process dependent on a variety of factors. The rate of bone repair and composition of tissue varies depending on type of bone fractured, the extent of the bone and soft tissue damage, the adequacy of the blood supply, and the degree of separation between bone ends. The individual's general health and nutritional status also play a significant role in bone healing. The presence of infection may adversely affect healing. Diminished blood flow to the fracture site will often suppress the healing response; factors that can cause diminished blood flow include heavy smoking, malnutrition, diabetes, alcoholism, peripheral vascular disease, increasing age, and the use of some medications such as steroids. Other characteristics such as high-grade trauma, high grade and open fractures, comminution of the fracture, vertical or oblique fracture pattern, and fracture displacement may also contribute to poor healing of bone. (Schoelles et al., 2005).

Two types of bone growth stimulators currently exist: electrical and ultrasound.

Three forms of electrical bone growth stimulation devices are currently used: direct current electrical stimulation, capacitive coupling and pulsed electromagnetic fields (PEMF). Indications for use are based upon U.S. Food and Drug Administration (FDA) labeling for specific devices and evidence in the peer-reviewed published scientific literature.

Direct current electrical stimulation consists of cathodes connected to a power supply which also serves as an anode. These devices are surgically implanted with the cathode placed at the fusion site and the anode in the soft tissue. Direct current devices may or may not be removed following achievement of a solid fusion.

Clinical evidence to support the use of electrical stimulators for bone healing has been inconclusive. Systematic reviews of electrical stimulation have been limited by narrow scope, poor methodologic quality, and a focus on radiographic healing over patient-important outcomes. A Cochrane review published in 2011 reported non-significant differences for electrical stimulation in improving union rates in four trials involving 125 patients (Griffin et al., 2011). Park et al., 2014 conducted a systematic review of randomized controlled trials comparing the electrical stimulation to no stimulation on fusion rates after lumbar spinal fusion for degenerative disease. Six RCTs met the inclusion criteria. Marked heterogeneity in study populations, characteristics, and design prevented a meta-analysis. Cumulative incidences of fusion varied widely across the RCTs, ranging from 35.4 to 90.6% in the intervention groups and from 33.3 to 81.9% in the control groups across 9 to 24 months of follow-up. The authors are unable to conclude that electrical

stimulation results in better fusion outcomes compared with no stimulation. The overall strength of evidence for the conclusions is low.

Aleem et al., 2016, conducted a meta-analysis of randomized sham-controlled trials to determine the effect of electrical stimulation on bone healing, focusing on patient-important outcomes. A total of 15 trials that were reported in 16 manuscripts, with a total of 1247 patients were included. Mean age of study participants was 45 years in the experimental and control arm. The proportion of male patients in the experimental and control arm was 58.3% and 56.3%, respectively. Mean follow-up was 8.2 (SD 3.4) months for radiographic outcomes and 8.6 (SD 3.7) months for pain and function. Four trials included patients undergoing a spinal fusion, five trials evaluated fresh fracture treatment, five trials examined treatment of delayed or nonunions and one study included patients undergoing surgical osteotomy. Trials of the appendicular skeleton assessed patients with tibial or femoral fractures, femoral neck, scaphoid fractures, and other long-bone fractures. Radiographic nonunion was compared across 15 trials with 1247 patients. Moderate quality evidence from 4 trials found that stimulation produced a significant improvement in pain (mean difference (MD) on 100-millimeter visual analogue scale=−7.7mm; 95% CI −13.92 to −1.43; p=0.02). Two trials found no difference in functional outcome (MD=−0.88; 95% CI −6.63 to 4.87; p=0.76). Moderate quality evidence from 15 trials found that stimulation reduced radiographic nonunion rates by 35% (95% CI 19% to 47%; number needed to treat=7; p<0.01). This systematic review and meta-analysis found that patients treated with electrical stimulation as an adjunct for bone healing have significantly less pain and experience lower rates of radiographic nonunion or persistent nonunion. No difference was seen with regards to functional outcomes in a limited number of trials. Future trials focusing on functional outcomes to identify appropriate indications and ideal patient selection are warranted.

In contrast, capacitive coupling and PEMF are non-invasive techniques. Capacitive coupling consists of two electrodes placed on the skin over the fusion site and connected to an external generator. Patients are encouraged to use the stimulator as much as possible, up to 24 hours per day. PEMF consists of a treatment coil that is incorporated into a cast or placed directly on the skin over the fracture site. The coil produces a time varying magnetic field around the area of the desired fusion. Patients are generally instructed to wear PEMF devices for 3 to 8 hours per day (Resnick et al., 2005, Kaiser et al., 2014).

An ultrasound bone growth stimulator provides low-intensity pulsed ultrasound to the skin surface above fracture site. Exogen (Bioventus, LLC) is the only FDA-approved ultrasound bone healing device. Exogen (PMA P900009) is approved for the non-invasive treatment of established nonunions excluding skull and vertebra, and for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing. On December 19, 2019, Exogen received FDA approval for expanded indications for use to include adjunctive use in patients with internal or external fracture fixation hardware present, patients undergoing treatment for infection at the fracture site, and patients believed to have diminished bone quality.

A 2013 technology assessment on the use of Exogen for long bone fractures with nonunion or delayed union conducted by the National Institute for Health and Care Excellence (NICE) concluded that despite the absence of direct evidence on avoiding surgery, there was "some radiologic evidence of improved healing," the adoption of Exogen in the treatment of long bone fractures with nonunion was supported by the evidence. NICE concluded that the use of Exogen in the treatment of long bone fractures with delayed healing was not supported by the evidence.

Regarding the use of Exogen for the treatment of fresh fractures, a 2014 Cochrane review (Griffin et al., 2014) concluded that while a potential benefit of ultrasound for the treatment of acute fractures in adults cannot be ruled out, the currently available evidence is insufficient to support the routine use in clinical practice. The publication of the TRUST trial (NCT00667849), a

multicenter trial randomized sham-controlled trial of 501 patients with fresh tibial fractures cast doubt on the effectiveness of LIPUS for the treatment of fresh fractures (Busse et al., 2016). Busse et al. concluded that postoperative use of LIPUS after tibial fracture fixation does not accelerate radiographic healing and fails to improve functional recovery. To best inform evidence based patient care, it is desirable to compare competing therapies. There have been no comparative studies evaluating electrical stimulation versus ultrasound bone growth stimulators (Ebrahim et al., 2014).

Hanneman et al., 2011 performed a systematic review of randomized controlled trials comparing the effects of low-intensity pulsed ultrasound (LIPUS) or pulsed electromagnetic fields (PEMF) with placebo specifically in acute fractures. Pooled results from 13 trials (N=737) reporting the proportion of nonunion showed no significant difference between PEMF or LIPUS and control. Current evidence from randomized trials is insufficient to conclude a benefit of PEMF or LIPUS bone growth stimulation in reducing the incidence of nonunions when used for treatment in acute fractures.

Analysis of Evidence (Rationale for Determination)

Despite the widespread acceptance of bone growth stimulators for management of bone healing, the literature supporting the use of bone growth stimulators is not strong. Multiple randomized controlled trials exist, however, there is heterogeneity among the trials, making critical evaluation and assessment difficult. Large, randomized, placebo-controlled trials are lacking and most of the data available for review consists of case series and comparative studies.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

CPT code 20975 should be used to report the implantation of an electric bone growth stimulator (physician services) and HCPCS code E0749 should be used to report the implanted device.

CPT code 20974 and 20979 should be used to report noninvasive electric or ultrasound stimulation treatment performed by a physician to aid bone healing. It is not appropriate to report these codes for demonstration, measuring, and/or education related to an electric or ultrasound bone growth stimulation device.

Bone growth stimulators, also known as osteogenic stimulators (E0747, E0748, E0749 and E0760) are considered durable medical equipment.

Osteogenic stimulators E0747, E0748 and E0760 are classified by Medicare as “inexpensive or routinely purchased” items. This means they must be offered as either a rental or purchase option to a Medicare member, i.e., the decision whether to rent or purchase the item of equipment generally resides with the member (Medicare Benefit Manual, Chapter 15, Section 110 – Durable Medical Equipment).

Osteogenic stimulator E0749 is classified as a capped rental item.

Ultrasound conductive coupling gel (A4559) is covered for Medicare and Community Care members and separately payable if an ultrasonic osteogenesis stimulator is covered. HCPCS A4559 is not covered for MassHealth ACO members (MassHealth Durable Medical Equipment Manual Subchapter 6; DME-47).

Code	Description
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive,

	(nonoperative)
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenic stimulator, low intensity ultrasound, non-invasive

References

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Policy history

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Review/Approval(s):	Utilization Management Committee: 06/2003 Technology Assessment Committee: 11/2000, 01/21/2001, 11/05/2003, 11/15/2012, 08/28/2014 (updated references, template, coverage criteria), 03/25/2015 (added smoking to list of high risk factors of pseudoarthritis, added references), 03/23/2016 (updated references), 03/22/2017 (updated references), 03/28/2018 (updated references), 02/27/2019 (updated references), 07/22/2020 (removed coverage for ultrasound bone growth stimulator for the treatment of fresh fractures, updated references); 06/22/2021 (annual review, no changes; 6/15/2021: Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 05/28/2024 (annual review, updated Medicare information in Policy section, removed Medicare coverage criteria under Fallon Health Clinical Coverage Criteria, added Evidence Summary and Analysis of Evidence, updated References), 05/27/2025 (annual review; updated to include new sections for Medicare and MassHealth Variation; no changes to coverage criteria). Utilization Management Committee: 06/17/2025: (annual review; approved).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.