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Medicare Advantage Policy Manual **Policy ID:** M-DME83.12

Bone Growth Stimulators (Osteogenic Stimulation)

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

"An electrical osteogenesis stimulator is a device that provides electrical stimulation to augment bone repair. A noninvasive electrical stimulator is characterized by an external power source which is attached to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site." *(Noridian Local Coverage Article, A52513)* Invasive electrical osteogenic stimulators are also available.

"An ultrasonic osteogenesis stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound conductive coupling gel in order to stimulate fracture healing." *(Article A52513)*

MEDICARE ADVANTAGE POLICY CRITERIA

Notes:

- ***Electrical*** osteogenic stimulators for the **spine** [HCPCS codes E0748 or E0749] are **not** addressed by this medical policy. They are currently reviewed by the vendor, eviCore healthcare (eviCore), under the physical medicine program.
- CPT codes 20974 and 20975 are also not addressed by this medical policy and are not subject to routine medical necessity review. These codes may be considered medically necessary unless reported with a device HCPCS code that has been reviewed and determined to not meet Medicare's medical necessity criteria.

CMS Coverage Manuals*	None	
National Coverage Determinations (NCDs)*	***Osteogenic Stimulators***	NCD 150.2
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	***Osteogenesis Stimulators***	LCD L33796
	Osteogenesis Stimulators - Policy Article	Article A52513
	**Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.	

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

*For additional assistance regarding required documentation for osteogenic stimulators, see the Noridian Article for *Standard Documentation Requirements for All Claims Submitted to DME MACs* (A55426) and the Documentation Checklist for Osteogenesis Stimulators and Standard Documentation Requirements for All Claims -Article A55426

- Medicare Certificate of Medical Necessity (CMN) (CMS form 847; **Note**: CMS removed the requirement for CMNs effective 1/1/2023, stating that the information on the CMN is available elsewhere. The relevant information continues to be required and will be accepted by the plan with or without a CMN.);
- All chart notes and medical records pertinent to the request, including history and physical documenting the condition being treated and symptoms experienced. Documentation must also include:
  - Location of the treatment.
  - Radiographs with written interpretation.
  - Cause of fracture, if applicable (e.g., is fracture tumor related).
- Type of stimulation (ultrasonic or electrical), including device name.

- Osteogenic stimulators are classified as “inexpensive or routinely purchased” items. This means they must be offered as either a rental or purchase option to the member.

REGULATORY STATUS

In 1994, the Sonic Accelerated Fracture Healing System (SAFHS®; renamed Exogen 2000® and since 2006, Exogen 4000+; Bioventus) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for treatment of fresh, closed, posteriorly displaced distal radius (Colles) 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. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull and vertebra.

The following table is current as of the date it the policy is reviewed and published. As a reminder, not all osteogenic stimulators are under the scope of this medical policy.

HCPCS CODE	DEVICE	MANUFACTURER
E0760	Sonic Accelerated Fracture Healing System (SAFHS®) *This device has been renamed Exogen 2000® and since 2006, Exogen 4000+; Bioventus. It may also be known as the SAFHS Model 2000 or the Exogen Pulsed Low-Intensity Ultrasound Bone Healing System Model 2000*	Exogen
E0747	OrthoPak 2	EBI Medical, Inc
E0747	EBI Bone Healing System Model 2001	EBI Medical, Inc
E0747	OL1000	dj Orthopedics, LLC
E0747	Physio-Stim	Orthofix

Of note, the fact a service or procedure has been FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Electrical Stimulation and Electromagnetic Therapy Devices, DME, Policy No. M-83

REFERENCES

1. Medicare Claims Processing Manual, Pub. No. 100-04, Chapter 32 - Billing Requirements for Special Services, §110 – Coverage and Billing for Ultrasound Stimulation for Nonunion and §110.1 – Coverage Requirements

CODING

NOTE: Stimulation devices and procedures which require prior authorization are found on our "*Medicare Pre-authorization List*" web page. Specific codes not listed on the prior authorization website do not require prior approval, while others may be reviewed by a vendor, and thus, are outside the scope of this policy. In addition, there may be more stimulation codes that are not included in any Medicare Advantage medical policy. However, providers are always expected to follow Medicare's medical necessity requirements when rendering treatment to beneficiaries whether or not a medical policy exists.

Codes	Number	Description
CPT	20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
HCPCS	E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
	E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*