OSTEOGENESIS STIMULATORS

REQUIRED DOCUMENTATION

All Claims

- ☐ **Standard Written Order/Written Order Prior to Delivery**
  - ○ Beneficiary's name or Medicare Beneficiary Identifier (MBI)
  - ○ Order Date
  - ○ General description of the item
    - ☐ The description can be either a general description (e.g., osteogenesis stimulator), a HCPCS code, a HCPCS code narrative, or a brand name/model number
    - ☐ For equipment – In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately).
    - ☐ For supplies – In addition to the description of the base item, the DMEPOS order/ prescription may include all concurrently ordered supplies that are separately billed (List each separately).
  - ○ Quantity to be dispensed, if applicable
  - ○ Treating Practitioner Name or NPI
  - ○ Treating Practitioner's signature
    - ☐ Practitioner's signature on the written order meets **CMS Signature Requirements** 100-08 Program Integrity Manual (PIM), Chapter 3, Section 3.3.2.4
  - ○ Standard Witten Order was obtained prior to submitting the claim to Medicare.
  - ○ Any changes or corrections have been initialed/signed and dated by the ordering practitioner.
- ☐ Effective April 13, 2022 the E0748 - Osteogenesis Stimulator, Electrical, Non-Invasive, Spinal Applications must have a required Face-to-Face Encounter and Written Order Prior to Delivery (WOPD)
- ☐ Effective August 12, 2024 the E0747 - Osteogenesis Stimulator, Electrical, Non-Invasive, Other Than Spinal Applications and E0760 - Osteogenesis Stimulator, Low Intensity Ultrasound, Non-Invasive must have a required Face-to-Face Encounter and Written Order Prior to Delivery (WOPD)
- ☐ **Refill Request**

DOCUMENTATION CHECKLIST

OSTEOGENESIS STIMULATORS

For dates of service prior to January 1, 2024

Items Were Obtained In Person at a Retail Store	Written Refill Request Received from the Beneficiary	Telephone Conversation Between Supplier and Beneficiary
☐ Signed Delivery Slip ○ Beneficiary's name ○ Date ○ List of items purchased ○ Quantity received ○ Signature of person receiving the items **OR** ☐ Itemized Sales Receipt ○ Beneficiary's name ○ Date ○ Detailed list of items purchased ○ Quantity received	☐ Name of beneficiary or authorized rep (indicate relationship) ☐ Description of each item being requested ☐ Date of request ☐ Quantity of each item beneficiary still has remaining ☐ Request was not received any sooner than 14 calendar days prior to the delivery/shipping date ☐ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product	☐ Beneficiary's name ☐ Name of person contacted (if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Description of each item being requested ☐ Date of contact ☐ Quantity of each item beneficiary still has remaining ☐ Contact was not made any sooner than 14 calendar days prior to the delivery/shipping date ☐ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product

For dates of service on and after January 1, 2024

Items Were Obtained In Person at a Retail Store	Delivered Refill Communications
☐ Signed delivery slip or copy of itemized sales receipt ☐ Delivery slip/receipt should indicate items were picked up at store front	☐ Beneficiary name and/or authorized representative (Suggested: if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Date of Request ☐ Description of each item requested ☐ Documentation of affirmative response indicating a need for the refill ☐ Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply ☐ Shipment/delivery occur no sooner than 10 calendar days prior to expected end of current supply

☐ **Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
☐ Beneficiary's name ☐ Delivery address ☐ Quantity delivered ☐ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ☐ Signature of person accepting delivery ☐ Relationship to beneficiary ☐ Delivery date	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ☐ Tracking slip ○ References each individual package ○ Delivery address ○ Package I.D. #number ○ Date shipped ○ Date delivered ☐ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ○ Date shipped ○ Signature of person accepting delivery ○ Relationship to beneficiary ○ Delivery date

NOTE: If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim

☐ **Medical Record Documentation**

- ○ Medical records from the treating practitioner which verify the beneficiary meets the coverage criteria for one of the following Osteogenesis Stimulators: non-spinal electrical osteogenesis stimulator, spinal electrical osteogenesis stimulator, or ultrasonic osteogenesis stimulator
- ○ Signatures on medical records meet CMS Signature Requirements 100-08 Program Integrity Manual (PIM), Chapter 3, Section 3.3.2.4

☐ **Non-Spinal Electrical Osteogenesis Stimulator (E0747)**

- ○ Nonunion of a long bone fracture defined as radiographic evidence that fracture healing has ceased for **three or more months** prior to starting treatment with the osteogenesis stimulator. Nonunion of a long bone fracture must be documented by:
  - ☐ Minimum of two sets of radiographs must be separated by a minimum of 90 days
  - ☐ Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a treating practitioner stating there has been no clinically significant evidence of fracture healing between the two sets of radiographs; **or**
- ○ Failed fusion of a joint other than in the spine where a minimum of **nine months** has elapsed since the last surgery; **or**
- ○ Congenital pseudarthrosis

☐ **Spinal Electrical Osteogenesis Stimulator (E0748)**

- ○ Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, **or**
- ○ Following a multilevel spinal fusion surgery, **or**
- ○ Following a spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site

Effective April 13, 2022, for the E0748 and effective August 12, 2024, for the E0747 and E0760

- ○ The treating practitioner must have a face-to-face encounter with a beneficiary within the six (6) months prior to prescribing the item
- ○ The face-to-face encounter must support payment for the item(s) ordered/prescribed and be documented in the pertinent portion of the medical record.
- ○ The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.
- ○ If the encounter is performed via telehealth, the requirements for telehealth services and payment for telehealth services must be met.
- ○ A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

☐ **Ultrasonic Electrical Osteogenesis Stimulator (E0760)**

- ○ Nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator
  - ☐ Radiographs must be separated by a minimum of 90 days
  - ☐ Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a treating practitioner stating there has been no clinically significant evidence of fracture healing between the two sets of radiographs; **and**

- ○ The fracture is not of the skull or vertebrae; **and**
- ○ The fracture is not tumor related

☐ **Continued Medical Need for the equipment/accessories/supplies within 12 months of the date of service is verified by:**

- ○ A recent order/prescription by the treating practitioner for refills of supplies;
- ○ A recent order/prescription by the treating practitioner for repairs;
- ○ A recent change in an order/prescription;
- ○ Timely documentation in the beneficiary's medical record showing usage of the item. Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

☐ **Continued Use** (within 12 months of the date of service)

- ○ Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies
- ○ Supplier records documenting the request for refill/replacement of supplies
- ○ Compliance with refill documentation requirements
- ○ Supplier records documenting beneficiary confirmation of continued use of a rental item, dated within 12 months of the date of service under review

REMINDERS

- Items with no physician or other licensed health care provider order must be submitted with an "EY' modifier added to each affected HCPCS code
- E0747, E0748 and E0760 are Class III devices which must be submitted with a "KF" modifier on every claim submitted. Suppliers should contact the Pricing, Data, Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.
- Osteogenesis Stimulator(s) are in the inexpensive or routinely purchased (IRP) payment category. The NU, UE or RR modifier must be added to the stimulator on every claim submitted.
- Ultrasound conductive coupling gel (A4559) is covered and separately payable if an ultrasonic osteogenesis stimulator (E0760) is covered.
- Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.
- An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.
- Effective April 13, 2022 the E0748 and effective August 12, 2024 the E0747 and E0760 must have a required Face-to-Face Encounter and Written Order Prior to Delivery (WOPD)
- For dates of service on or after 07/02/23 claim lines billed with codes without a KX, GA, GY or GZ modifier will be rejected as missing information.

ONLINE RESOURCES

- **DME MAC Supplier Manual**
  - **JB:** https://www.cgsmedicare.com/jb/pubs/supman/index.html
  - **JC:** https://www.cgsmedicare.com/jc/pubs/supman/index.html
- **Local Coverage Determinations (LCDs) and Policy Articles**
  - **JB:** https://www.cgsmedicare.com/jb/coverage/lcdinfo.html
  - **JC:** https://www.cgsmedicare.com/jc/coverage/LCDinfo.html

NOTE: It is expected that the beneficiary's medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

DISCLAIMER

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the *DME MAC Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.