

Electric and Electromagnetic and Ultrasonic Bone Growth Stimulation

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<u>Version</u>	4

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Electric and Electromagnetic and Ultrasonic Bone Growth Stimulation.

Description & Definitions:

Bone Growth Stimulators is a therapy to accelerate healing of fractured bones, fusions, or delayed unions.

Electrical bone growth stimulator is a noninvasive device applied to the skin at the site of fracture which provides electrical stimulation for bone repair.

Criteria:

Bone growth stimulators are considered medically necessary for indications of **1 or more of the following**:

- Spinal Electrical or Ultrasonic Bone Growth Stimulation is considered medically necessary with **1 or more of the following**:
 - When used as an adjunct to spinal fusion surgery for individuals at risk for pseudoarthritis with **1 or more of the following**:
 - One or more previously failed spinal fusion(s)
 - Grade II or worse spondylolisthesis
 - Fusion to be performed at 2 levels or more
 - Current smoking habit
 - Diabetes or other metabolic diseases where bone growth is poor
 - Renal disease
 - Alcoholism

- Obese individuals with BMI greater than 30
 - When used during single level spinal fusion and **2 or more of the following**:
 - Active smoker or habitual smoker within the prior 6 months
 - Diabetes mellitus
 - Immunosuppressed individuals whose immunosuppression cannot be corrected
 - Individuals who cannot discontinue non-steroidal anti-inflammatory medications
 - Severe osteoporosis
 - Prior spinal fusion being extended by one level or more
 - Stable internal fixation of the fusion cannot be achieved
 - Active metabolic bone disease that cannot be corrected
 - Failed spinal fusion that has not healed within a minimum of 6 months after the original surgery
 - Spondylolysis (also known as pars inter-articularis fracture) when **1 or more** of the following occur:
 - Delay or non-union after 42 days
 - Failure of bracing treatment
- Non-Spinal Electrical or Ultrasonic Bone Growth Stimulators may be considered medically necessary with **1 or more of the following**:
 - Non-union fractures with **ALL of the following**:
 - The date of the fracture or surgical treatment has been at least 42 days prior
 - Individual has a minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days
 - Failed joint fusions with **ALL of the following**:
 - The date of the fracture or surgical treatment has been at least 42 days prior
 - Individual has a minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days
 - Failed arthrodesis with **ALL of the following**:
 - The date of the fracture or surgical treatment has been at least 42 days prior
 - Individual has a minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days
 - Congenital pseudoarthroses of the appendicular system with **ALL of the following**:
 - The date of the fracture or surgical treatment has been at least 42 days prior
 - Individual has a minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days
 - For the treatment of joint fusion secondary to failed surgical arthrodesis (e.g. knee, ankle, subtalar, foot fusion) when performed immediately following revision surgery with **1 or more of the following**:
 - Active smoker or habitual smoker within the prior 6 months
 - Diabetes mellitus
 - Immunosuppressed individuals whose immunosuppression cannot be corrected
 - Individuals who cannot discontinue non-steroidal anti-inflammatory medications
 - Severe osteoporosis
 - Stable internal fixation of the fusion cannot be achieved
 - Active metabolic bone disease that cannot be corrected
- Electromagnetic or Ultrasonic bone growth stimulators are considered medically necessary with **ALL of the following**:
 - Bone growth stimulator is being used as adjunctive treatment to cervical, thoracic, lumbar, sacral spine fusion.
 - Risk factors for fusion failure are present, as indicated by **1 or more of the following**:
 - Comorbid condition associated with compromised bone healing (eg, diabetes, obesity, osteoporosis, current tobacco use)
 - Multilevel fusion
 - Previous failed fusion

- Spondylolisthesis grade II or greater

The following **Non-spinal electrical or Ultrasonic Bone Growth Stimulators** do not meet the definition of medical necessity, to include but not limited to:

- Fresh fractures
- Patellar Tendinopathy
- Pathological fractures due to tumor/malignancy
- Stress fractures
- Synovial pseudoarthroses
- Toe fracture
- Whole Body Vibration for the promotion of bone growth as it is not shown to improve health outcomes upon technology review.

Coding:

Medically necessary with criteria:

Coding	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically impla
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

Considered Not Medically Necessary:

Coding	Description
	None

Document History:

Revised Dates:

- 2023: June
- 2022: June (Unarchived)
- 2021: November (Archived)
- 2019: October
- 2016: May
- 2014: May, July
- 2012: May
- 2011: May, November
- 2010: May

- 2009: May
- 2002: July
- 2000: May, November

Reviewed Dates:

- 2019: December
- 2018: July
- 2017: November
- 2016: June, December
- 2015: May
- 2013: May
- 2010: June
- 2008: January, May
- 2007: April
- 2005: February, November
- 2004: October
- 2002: June
- 1998: November
- 1994: February

Effective Date:

- February 1991

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

DME Manual - Appendix B. (2023, Jan). Retrieved Apr 20, 2023, from DMAS DME:

<https://www.dmas.virginia.gov/media/5542/appendix-b-bed-pans-urinals-incontinence-catheters-and-irrigation-equip-and-supplies-january-2023.pdf>

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to “correct or ameliorate” (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; • Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

Keywords:

SHP Electric, Electromagnetic and Ultrasound Bone Growth Stimulation, SHP Durable Medical Equipment 09, Spinal Electrical Bone Growth Stimulation, non-spinal Electrical Bone Growth Stimulation Non-union fractures, arthrodesis, joint fusions, Congenital pseudoarthroses, acute fractures, Closed Radial fracture posteriorly displaced, Colles', Tibial diaphyseal fractures, Grade I open, Jones fracture, Radial shortening osteotomy, scaphoid fracture, tibial osteotomy for distraction osteogenesis, tibial shaft fracture, Ulnar shortening osteotomy, delayed fracture, osteotomy healing, bone loss, lumbar, electrical bone growth stimulation devices (EBGS), ultrasonic osteogenesis stimulator, direct current electrical bone-growth stimulators, non-spinal electrical bone growth stimulator (non-invasive or invasive), invasive or noninvasive spinal electrical bone growth stimulator, Non-invasive, low-intensity pulsed ultrasound, Osteogenic Stimulators