Clinical Policy: Invasive Electrical Bone Growth Stimulation

Reference Number: WNC.CP.198 Coding Implications
Last Review Date: 11/2023 Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1]

Electrical bone growth stimulation is a medical technique to promote bone growth in difficult to heal fractures by applying a low electrical current to the fracture site.
Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed.

Policy/Criteria[1]

I. WellCare of North Carolina® shall cover invasive electrical bone growth stimulation for a beneficiary who is 18 years of age or older or demonstrated proof of skeletal maturity for **ONE** of the following:
- A. When used as an adjunct to surgical treatment of non-union of a long bone fracture documented radiographically;
- B. When medically necessary for spinal fusion surgery in a beneficiary at high risk for pseudarthrosis with **one or more** of the following risk factors for fusion failure:
  1. One or more previously failed spinal fusion(s);
  2. Grade III or worse spondylolisthesis;
  3. Fusion to be performed at more than one level;
  4. History of tobacco use or alcohol;
  5. Diabetes, renal disease, or other metabolic diseases where bone healing is likely to be compromised or growth is poor;
  6. Nutritional deficiency;
  7. Obese individuals with a Body Mass Index (BMI) greater than 30 or who are at greater than 50% over their ideal body weight (IBW)
  8. Severe anemia; **or**
  9. Steroid therapy;
- C. When medically necessary as an adjunct to lumbar spinal fusion surgery in patients at high risk for fusion failure, when **one** of the following criteria is met:
  1. One or more previous failed spinal fusion(s);
  2. Grade III or worse Spondylolisthesis;

3. Fusion to be performed at more than one level;
4. current tobacco use, diabetes, renal disease, alcoholism, steroid use, **OR**

D. As an adjunct to spinal fusion surgery for beneficiaries at high risk of pseudarthrosis due to previously failed fusion surgery or for those undergoing fusion at more than one level.

II. WellCare of North Carolina® shall **not cover** invasive electrical bone growth stimulation for the following contraindications:

A. Fracture gap greater than one centimeter or greater than half the diameter of the bone;
B. Avascular or necrotic (dead) bone at the fracture site;
C. Pathologic long bone fractures due to malignant tumors;
D. Synovial pseudarthrosis;
E. Osteomyelitis or infection (for invasive devices);
F. Interposition of soft tissue or sequestrum between fragments;
G. Significant motion at the fracture site;
H. Post-reduction displacement greater than 50 percent or post-reduction angulation or malalignment;
I. Beneficiary not expected to comply with treatment regimen (immobilization, proper use of devices);
J. Decelerated fracture healing process as identified by x-ray;
K. Skeletal immaturity;
L. Fresh fractures;
M. Pregnancy;
N. Presence of pacemaker or implantable defibrillator;
O. Presence of magnetic metal fixation device(s) in the area of nonunion; **or**
P. Concurrent use of ultrasound stimulation.

III. WellCare of North Carolina® shall **not cover** Semi-electrical bone growth stimulation.

Background[1]

1. Definitions:

A. **Nonunion** is defined as when characteristic changes are observed radiographically and clinically which suggest that fracture healing has ceased and additional intervention is necessary as the standard for treatment. Nonunion can be identified by fibrocartilage which remains in the fracture gap, impeding vascularization and subsequent calcification, and can present on radiographs as sclerotic bone ends around a fracture gap with a visible fracture line.

Fracture nonunion is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two

sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

B. **Delayed union** is defined as a decelerating healing process as determined by serial x-rays, together with a lack of clinical and radiologic evidence of union, bony continuity or bone reaction at the fracture site.
C. **Delayed healing** is when healing has not advanced at the "average" rate for the location and type of fracture. Delayed union is often characterized by slow radiographic progress and continued mobility and pain at the fracture site. Delayed union differs from nonunion in that in the former, there are no indications that union will fail, while in the latter, there are no longer any visible signs that union will occur.
D. **Skeletally mature** defined as a system of fused skeletal bones, which occurs when bone growth ceases after puberty; for females, this generally occurs around age 16, and for males, around age 18.
E. **Long bone** is defined as a bone that has a shaft and two ends and is longer than it is wide. Long bones have a thick outside layer of compact bone and an inner medullary cavity containing bone marrow. Long bones are the clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpals, metatarsals, and phalanges.
F. **Failed spinal fusion** is defined as a spinal fusion which has not healed at a minimum of 6 months after the original surgery, as evidenced by serial X-rays over a course of 3 months.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS ®* Codes	Description
A4559	Coupling gel or paste, for use with ultrasound device, per oz
E0747	Osteogenesis stimulator; electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator; electrical, noninvasive, spinal applications
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	04/21	06/21
Reviewed CPT and HCPCS codes.	01/22	02/22
Annual Review. I.B.2 changed Grade II to Grade III	02/23	02/23
NCHC verbiage removed from NC Guidance Verbiage	04/23	04/23
Annual Review. Removed CPT 20974 & 20979, HCPCS E0749, and ICD-10-CM table.	11/23	11/23

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 1A-6 Invasive Electrical Bone Growth Stimulation. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published August 15, 2023. Accessed September 6, 2023.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:
   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
   EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.
   Unlisted Procedure or Service
   CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
   HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service
d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.