To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

Table of Contents

Related Clinical Coverage Policies

Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below:

5A *Durable Medical Equipment and Supplies* (for non-invasive electrical osteogenesis stimulator).

1.0 Description of the Procedure, Product, or Service

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

1.1 Definitions

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. Nonunions 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.

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.

Delayed healing delayed 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.

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.

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.

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.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid policies*)

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.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. Medicaid
None Apply.

2.2 Special Provisions

2.2.1 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.

b. **EPSDT and Prior Approval Requirements**

a. 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.

b. **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/

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by Medicaid

Medicaid 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 as defined in **Subsection 1.1** 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) (**Note:** See Definition section for calculation of 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.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by Medicaid

Medicaid 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.

Medicaid shall not cover invasive electrical bone growth stimulation for any conditions or criteria other than those cited in **Subsection 3.2.1** above.

Medicaid shall not cover Semi-electrical bone growth stimulation.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid shall require prior approval for invasive electrical bone growth stimulation.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

a. the prior approval request; and
b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

In addition to **Subsection 5.2.1** requirements, the provider shall submit the following medical documentation:

a. The date of the injury or re-injury;
b. The nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs, separated by a minimum of three months or more, each including multiple views of the fracture site with a written interpretation by a physician stating that there has been no evidence of fracture healing between the two sets of radiographs;
c. Radiological documentation of a failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery;
d. Medical evidence of congenital pseudarthrosis; and
e. There must be medical evidence that the beneficiary does not have any of the contraindications listed in **Subsection 4.2**.

5.3 Additional Limitations or Requirements

a. Stimulators require monthly inspection by the orthopedic surgeon.
b. The physician Evaluation and Management visit for the monthly inspection counts toward the annual visit limit for Medicaid.

6.0 Providers 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 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).

The provider shall comply with the safety and effectiveness of invasive electrical bone growth stimulation devices that have been established. The provider(s) shall use FDA-approved invasive electrical bone growth stimulation devices when used within the scope of the FDA indications for use.

8.0 Policy Implementation/Revision Information

Original Effective Date: April 1, 1982

Revision Information:

Date	Section Revised	Change
9/1/05	Section 2.0	A special provision related to EPSDT was added.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2 through 5	A special provision related to EPSDT was added.
5/1/07	Sections 2 through 5	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age
7/1/10	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
3/12/12	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
08/01/2015	All Sections and Attachments	Updated policy template language.
08/01/2015	All Sections and Attachments	Policy name changed from Electrical Osteogenic Stimulators to Invasive Electrical Bone Growth Stimulation
08/01/2015	Section 1.0	Rewrote section to more accurately describe the Procedure, Product, or Service
08/01/2015	Subsection 3.2	Expanded and clarified specific criteria covered by both Medicaid and NCHC
08/01/2015	Subsection 4.2	Expanded and clarified specific criteria not covered by Medicaid and NCHC
08/01/2015	Subsection 5.2	Reworded to clarify with no change in scope or coverage
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
05/15/2018	All Sections and Attachments	Corrected spelling and grammar as needed.
05/15/2018	Attachment A	Removed ICD 10 codes from policy.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.

12/04/2019	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
12/04/2019	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
8/15/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid. Policy posted 8/15/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks 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

Professional (CMS-1500/837P 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

CPT Code(s)
20975

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

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Inpatient, Outpatient, Office.

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

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