Clinical Policy: Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair

Reference Number: WNC.CP.119
Last Review Date: 05/24

Coding Implications
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]

Replacement and repair of external components of a cochlear or auditory brainstem implant device that are necessary to maintain the device's ability to analyze and code sound, therefore providing an awareness and identification of sounds and facilitating communication for individuals with severe to profound hearing loss.

Policy/Criteria[1]

I. It is the policy of WellCare of North Carolina® that Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair is **medically necessary** when **all** of the following conditions are met:

A. The implanted device being repaired is FDA approved and meets all Medicaid standards of coverage under Clinical Coverage Policy **WNC.CP.112** *Cochlear and Auditory Brainstem Implants*.
B. The implanted device is in continuous use and still meets the needs of the member.
C. Replacement or repair is necessary to allow the implanted device to be functional.
D. The treating licensed audiologist has obtained a physician's medical clearance with complete information regarding the implant system and surgery date(s) and submitted it to the provider.
E. The treating licensed audiologist has documentation that substantiates the need for the replacement or repair of external part(s) and submitted it to the provider.
F. The component or service is furnished at a safe, efficacious, and cost-effective level.
G. Additionally, all replacement speech processors, except those covered under warranty, require prior approval.
H. Speech Processor Upgrades
   1. Upgrades of existing speech processors for next-generation speech processors are considered medically necessary **only** when:
      a. the member's response to the existing speech processor is inadequate to the point of interfering with the activities of daily living; **or**
      b. the speech processor is no longer functional and cannot be replaced with the same model.

Note: Upgrades to existing, functioning, replaceable speech processors to achieve aesthetic improvement are not medically necessary and will not be covered.

II. It is the policy of WellCare of North Carolina® that Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair is **not medically necessary** when:
A. The component or service is for a resident of a nursing facility **or**
B. The component or service is covered by another agency.

Background[1]
This policy does not address cochlear and auditory brainstem surgical implant coverage. For eligible Members with severe to profound hearing loss requiring implantation, refer to Clinical Coverage Policy **WNC.CP.112** *Cochlear and Auditory Brainstem Implants*.

I. Prior Approval for Replacement Speech Processors

A. Under Warranty

1. When the requested replacement speech processor is identical to the existing speech processor and the existing speech processor is under warranty, prior approval is **not** required.

B. Out of Warranty

1. Prior approval is required for **all** replacement speech processors that are not covered under warranty.
2. Each prior approval request for a replacement speech processor **must** include the reason for replacement (loss, theft, damaged beyond repair, original discontinued, inadequate performance, etc.).
3. When the requested replacement speech processor is identical to the existing speech processor and no longer covered under warranty, the provider shall submit an electronic prior approval request with a copy of the prescribing physician's original medical clearance and a letter of medical necessity from the treating licensed audiologist.
4. Consideration will be given to the request and a decision will be returned to the provider. Members will be notified in writing if the request is denied.

C. Upgrade

1. When the requested replacement speech processor is an upgrade, the provider shall obtain prior approval.
2. Documentation must be included with the electronic prior approval request that substantiates that the member's response to the existing speech processor is inadequate to the point of interfering with the activities of daily living, or that the speech processor is no longer functional and cannot be replaced with the same model.
3. Documentation from the treating licensed audiologist, supporting the medical necessity for the upgrade, must accompany the electronic prior approval request.
4. Consideration will be given to the request and a decision will be returned to the provider. Members will be notified in writing if the request is denied.

II. Required Documentation

A. Physician's Medical Clearance

1. A physician's signed medical clearance with complete information regarding the cochlear implant system and surgery date(s) must be kept on file with the provider.

B. Audiologist's Letter

1. A letter signed by the treating licensed audiologist must be kept on file with the provider. This letter **must** include the following:
   a. Audiologist's name, business name, address, and telephone number.
   b. Member's name and Medicaid identification number.
   c. Original surgery date(s).
   d. Verification that the device is FDA approved and currently being used in a functional manner by the patient.
   e. Specific information regarding the repair and/or replacement parts, and quantity of parts, that are medically necessary for the patient.

III. Provider Qualifications and Occupational Licensing Entity Regulations

A. Only cochlear and auditory brainstem implant manufacturers who meet Medicaid's qualifications for participation and are currently enrolled with the Medicaid program are eligible to bill for cochlear and auditory brainstem implant external parts replacement and repair.

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 2024, 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.

HCPCS ®* Codes	Description	Lifetime Expectancy
L8615	Replacement cochlear implant device headset or headpiece	Once every 3 years
L8616	Replacement cochlear implant device microphone	Once annually
L8617	Replacement cochlear implant device transmitting coil	Once annually
L8618	Replacement cochlear implant device transmitter cable	8 times each year

HCPCS ®* Codes	Description	Lifetime Expectancy
L8619	Replacement cochlear implant external speech processor	Once every 5 years
L8621	Replacement cochlear implant device zinc air battery, each	N/A
L8622	Replacement cochlear implant device alkaline battery, each	N/A
L8623	Replacement cochlear implant device speech processor (not ear level) lithium-ion battery, each	1 set of 3 each year
L8624	Replacement cochlear implant device speech processor (ear level) lithium-ion battery, each	1 set of 4 each year
L7510	Repair or replace minor parts of prosthetic device	As necessary; requires invoice

Note: Billing units
For cochlear and auditory brainstem implant external parts replacement and repair, the units of service are as follows: 1. Purchased Equipment: The unit of service is 1 for each item provided. 2. Service and Repair: The unit of service is 1 for each service or repair.

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	03/21	05/21
Reviewed HCPCS codes.	08/21	11/21
Description changed to read '… individuals with severe to profound hearing loss.' Reviewed HCPCS codes. References updated.	08/22	08/22
Annual Review. NCHC verbiage removed from NC Guidance Verbiage. Note: Billing units For cochlear and auditory brainstem implant external parts replacement and repair, the units of service are as follows: 1. Purchased Equipment: The unit of service is 1 for each item provided. 2. Service and Repair: The unit of service is 1 for each service or repair."	05/23	05/23
Annual Review. HCPCS codes reviewed. ICD-10-CMS & CPT tables removed.	05/24	05/24

References
State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 13A Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov) April 1, 2023. Accessed January 3, 2024.

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.