Clinical Policy: Cochlear and Auditory Brainstem Implants

Reference Number: WNC.CP.112 Coding Implications
Last Review Date: 08/24 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]

A cochlear implant is an electronic medical device designed to restore some ability to perceive sounds and understand speech by individuals with severe to profound hearing loss. A cochlear implant bypasses damaged hair cells in the cochlea and stimulates the remaining nerve fibers directly through the application of electrical current. Cochlear implants have external parts and internal (surgically implanted) parts that work together to allow the user to perceive sound.
An auditory brainstem implant (ABI) is a modification of the cochlear implant in which the stimulating electrode is placed directly into the brain.
After surgery, these two devices require activation, fitting of essential external components, programming, and rehabilitation for proper function and benefit.

Policy/Criteria[1]

I. It is the policy of WellCare of North Carolina® that Cochlear and Auditory Brainstem Implants are **medically necessary** for the following indications:

A. Cochlear Implant and Aural Rehabilitation

1. Covered for ages 9 months of age and older when **ALL** of the following requirements are met and are documented in the health record:
   a. The device must be used according to the U.S. Food and Drug Administration (FDA) labeled indications.
   b. There are no contraindications for the surgery.
   c. The personal physician or otolaryngologist documents that the Member has realistic expectations of the performance of the device and is able to participate in a program of aural rehabilitation.
   d. The Member has a confirmed diagnosis of severe to profound (greater than or equal to 70 dB HL) sensorineural hearing loss in the ear to be implanted.

Note: An exception to the degree of hearing loss provision of severe to profound sensorineural hearing loss (greater than or equal to 70 dB HL) is the confirmed and documented case of auditory neuropathy spectrum disorder wherein hearing thresholds may be better than this level but word recognition is poor.

e. The Member is free of middle ear infection, has an accessible cochlear lumen that is structurally sound for implantation, and is free of lesions in the auditory nerve and acoustic areas of the central nervous system.

2. The Member age 9 months to 20 years has limited benefit from at least a three-consecutive month trial of appropriately fitted hearing aids. When radiological evidence of cochlear ossification on computerized tomography (CT) scan or obstruction exists, the trial requirement may be waived.

   Note: Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the ear to be implanted using an age-appropriate test of speech recognition.

3. The Member age 21 years of age and older has an appropriate hearing aid evaluation completed with an appropriate hearing aid fitting trialed by a licensed audiologist.

B. Auditory Brainstem Implants

1. Covered for ages 12 years through 20 years of age when **ALL** of the following criteria are met:
   a. The Member has been diagnosed with neurofibromatosis type 2;
   b. The Member:
      i. is undergoing bilateral removal of tumors of the auditory nerves, **and** the Member is expected to become completely deaf as a result of the surgery;
      or
      ii. has had bilateral auditory nerve tumors removed and is now bilaterally deaf;
   c. The FDA approved device must comply with the FDA indications for use.
   d. There are no contraindications for the surgery

C. Upgrades and Maintenance

1. WellCare of North Carolina® shall cover the replacement of an existing traditional cochlear implant as medically necessary when **ANY** of the following criteria is met:
   a. The currently used component is no longer functional and cannot be repaired and there is no evidence to suggest that the device has been abused or neglected;
   b. The currently used component renders the implanted Member unable to adequately or safely perform age-appropriate activities of daily living; **or**
   c. The current technology has been made obsolete by the manufacturer.

Note: For information on requirements and limitations for external components, refer to Clinical Coverage Policy **WNC.CP.119** *Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair*.

D. Contralateral Cochlear Implant

1. WellCare of North Carolina® shall consider coverage of contralateral cochlear implant after the successful placement of the **original** implant on a **case-by-case** basis for Members ages 9 months of age and older with documentation of medical necessity and when **ALL** the following are met:
   a. Demonstrated successful usage of the device;
   b. Active participation in an appropriate auditory-based intervention program;
   c. Active participation in an appropriate educational program;
   d. Radiographic evidence that contralateral cochlea and nerves are present;
   e. Demonstration by the Member or family of the ability to care for the equipment needs of two devices;
   f. No evidence of severe physical, psychomotor, or cognitive delays; **AND**
   g. When at least ONE of the following applies:
      i. continued usage of a hearing aid has been unsuccessful if residual hearing is present;
      ii. the first side device is non-functional for medical or surgical reasons and replacement surgery is not an option;
      iii. the first side is suspected of having a device failure but still provides some beneficial auditory input; **or**
      iv. the Member develops significant delayed-onset visual impairment.
   h. the date of the initial placement of a cochlear implant must be documented

E. Simultaneous Bilateral Cochlear Implants

1. WellCare of North Carolina® shall cover simultaneous bilateral cochlear implants **ONLY** when there is:
   a. Clear evidence of ongoing bilateral cochlear ossification or fibrosis from previous meningitis or cochlear inflammation **or**
   b. Significant bilateral visual impairment present or expected to develop, such as in Usher's syndrome.

F. Diagnostic Analysis and Programming

1. After the postoperative period, WellCare of North Carolina® shall cover activation, evaluation, and programming of:
   a. Cochlear implants as separate procedures for Members 9 months of age and older; **and**
   b. Auditory brainstem implants as separate procedures for Members ages 12 years through 20 years of age.
   c. Health record documentation must contain the date of the surgery and status of the analysis and programming procedures.

II. It is the policy of WellCare of North Carolina® that Cochlear and Auditory Brainstem Implants is **not medically necessary** for the following:

A. Indications include:

1. Deafness due to lesions of the central auditory pathway, lesions of the eighth cranial (acoustic) nerve or brain stem;
2. Active or chronic infections of the external or middle ear and mastoid cavity, or tympanic membrane perforation;
3. Cochlear ossification that prevents electrode insertion; **or**
4. Absence of cochlear development as demonstrated by imaging.

B. **WellCare of North Carolina® shall not cover bilateral cochlear implants** during the same or subsequent operative session except when the criteria outlined above is met.

C. **Upgrades to existing**, functioning external systems to achieve aesthetic improvement, such as substituting smaller-profile components or switching from a body-worn external sound processor to a behind-the-ear model, are not medically necessary and are not covered.

Background[1]

I. Prior Approval

A. Cochlear Implant

1. Prior approval **is required** for a routine, unilateral cochlear implant that meets the criteria above.

B. **Auditory Brainstem Implant**

1. Prior approval **is required** for an auditory brainstem implant. Health record documentation must be submitted with the prior approval request indicating that the Member:
   a. is 12 years through 20 years of age; and
   b. has been diagnosed with neurofibromatosis type 2; **and**
   c. is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the Member will become completely deaf as a result of the surgery; **or**
   d. has had bilateral auditory nerve tumors removed and is now bilaterally deaf.

C. **Upgrades and Maintenance**

1. Prior approval **is required** for the upgrade and maintenance of internal components. Health record documentation must be submitted with the prior approval request indicating that:
   a. the Member's response to the existing component(s) is inadequate to the point of interfering with the activities of daily living; **or**
   b. the component(s) are no longer functional **or**
   c. the device has been made obsolete by the manufacturer.

D. Contralateral Cochlear Implant

1. Prior approval **is required** for a contralateral cochlear implant. The prior approval request must contain the following documentation:
   a. the date of the initial placement of a cochlear implant; **and**
   b. the successful aural rehabilitation and use of the current implant; **and**
   c. the reason a contralateral implant is medically necessary, as outlined above.

E. Simultaneous Bilateral Cochlear Implants

1. Prior approval **is required** for simultaneous bilateral cochlear implants. Health record documentation must be submitted with the prior approval request indicating that the requirements above have been met.

F. Aural Rehabilitation

1. Prior approval **is not required**.

G. Diagnostic Analysis and Programming

1. Prior authorization **is not required** for the postoperative diagnostic analysis and programming of the cochlear and auditory brainstem implants. Health record documentation must contain the date of the surgery and status of the analysis and programming procedures.

H. Replacement Parts and Repairs

1. Coverage requirements and limitations for replacement parts and repairs to cochlear and auditory brainstem implants are documented in Clinical Coverage Policy **WNC.CP.119** *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.

CPT®* Codes	Description
69930	Cochlear device implantation, with or without mastoidectomy
69949	Unlisted procedure, inner ear
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming

CPT®* Codes	Description
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS®* Codes	Description
S2235	Implantation of auditory brain stem implant

Hospital Revenue ®* Codes	Description
RC 278	Medical/Surgical Supplies: Other implants

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side
H90.3	Sensorineural hearing loss, bilateral
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
Q85.02	Neurofibromatosis, type 2

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	01/21	05/21
Reviewed CPT, HCPCS and ICD-10-CM codes.	08/21	11/21
Annual Review. CPT, HCPCS and ICD-10-CM codes reviewed.	08/22	08/22
NCHC verbiage removed from NC Guidance Verbiage.	03/23	03/23
Annual Review. Reviewed CPT, HCPCS and ICD-10-CM codes.	08/23	08/23

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Annual Review. Changed 'beneficiary' to 'member.' Removed the 'Medicaid and health choice' verbiage from the References.	08/24	08/24

References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 1A-4 Cochlear and Auditory Brainstem Implants. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published April 1, 2023. Accessed June 5, 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.

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