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Related Clinical Coverage Policies

Refer to <http://www.ncdhhs.gov/dma/mp/> for the related coverage policies listed below:
13A, *Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair*
10A, *Outpatient Specialized Therapies*

1.0 Description of the Procedure, Product, or Service

A cochlear implant device is an electronic instrument, part of which is implanted surgically into the cochlea to stimulate auditory nerve fibers and part of which is capable of detecting and codifying sound for neural stimulation and is worn or carried by the individual. The goal of implantation is to enable an awareness of sound, identification of sounds, and facilitation of auditory/oral communication for individuals with severe to profound sensorineural hearing loss.

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.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC 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.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.
- b. **NCHC**
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

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: <http://www.ncdhhs.gov/dma/epsdt/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

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 and NCHC 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 both Medicaid and NCHC

3.2.2 Cochlear Implant

Cochlear implants and aural rehabilitation are covered for Medicaid beneficiaries ages 12 months through 20 years of age and for NCHC beneficiaries ages 6 through 18 when **all** of the following criteria are documented in the medical record.

- a. The beneficiary

1. has the confirmed diagnosis of bilateral profound (>90 dB HL) sensorineural hearing loss.
2. has limited benefit from at least a 3-month hearing aid trial. When radiological evidence of on-going cochlear ossification or obstruction exists, the trial requirement can be waived.

Note: For older children, limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on age appropriate tests of open-set speech perception.

3. is free of middle ear infection, has an accessible cochlear lumen that is structurally sound for implantation, and is free of lesions of the central auditory pathway from the brainstem and higher.
- b. The device must be approved by the Food and Drug Administration (FDA), and must be used in accordance with FDA labeling.
 - c. There are no contraindications for the surgery.
 - d. The personal physician or otolaryngologist documents that the beneficiary has realistic expectations of the performance of the device and is able to participate in the required postoperative therapy, training, and rehabilitation.

3.2.3 Auditory Brainstem Implants

ABIs are covered when **all** of the following criteria are met. Refer to **Subsection 5.1.2** for prior approval requirements.

- a. The Medicaid beneficiary is age 12 months through 20 years of age and NCHC beneficiary age 6 through 18.
- b. The beneficiary has been diagnosed with neurofibromatosis type 2.
- c. The beneficiary:
 1. is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the beneficiary will become completely deaf as a result of the surgery; **or**
 2. has had bilateral auditory nerve tumors removed and is now bilaterally deaf.
- d. The device must be approved by the FDA, and must be used in accordance with FDA labeling.
- e. There are no contraindications for the surgery.

3.2.4 Upgrades and Maintenance

Refer to **Subsection 5.1.3** for prior approval requirements.

Medically necessary maintenance and upgrades of existing internal components for next-generation devices are covered for Medicaid beneficiaries ages 12 months through 20 years of age and NCHC beneficiaries ages 6 through 18 when:

- a. the beneficiary's response to existing components is inadequate to the point of interfering with the activities of daily living; **or**
- b. the components are no longer functional.

Note: 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 will not be covered.

For information on requirements and limitations for external components, refer to Clinical Coverage Policy 13A, *Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair* on DMA's Web site at <http://www.ncdhhs.gov/dma/mp/>

3.2.5 Contralateral Cochlear Implant

Coverage of contralateral cochlear implant after the successful placement of the original implant is considered on a case-by-case basis for Medicaid beneficiaries ages 12 months through 20 years of age and Health Choice beneficiaries ages 6 through 18 and must be supported by documentation of medical necessity. Refer to **Subsection 5.1.4** for information on prior approval for contralateral implants.

Contralateral implants are covered, after the implantation of the **first side** device, when **all of** the following are met:

- a. demonstrated successful usage of the device **and**
- b. active participation in an appropriate auditory-based intervention program **and**
- c. active participation in an appropriate educational program **and**
- d. radiographic evidence that contralateral cochlea and nerves are normal **and**
- e. demonstration by the patient or family of an ability to care for the equipment needs of 2 devices **and**
- f. no evidence of severe physical, psychomotor, or cognitive delays **and**
- g. when at least **one** of the following applies:
 1. continued usage of a hearing aid has been unsuccessful, if residual hearing is present or
 2. the first side device is non-functional for medical/surgical reasons and replacement surgery is not an option or
 3. the first side is suspected of having a device failure but still provides some beneficial auditory input or
 4. the beneficiary develops significant delayed-onset visual impairment

3.2.6 Simultaneous Bilateral Cochlear Implants

Refer to **Subsection 5.1.5** for prior approval requirements.

Simultaneous bilateral cochlear implants are covered 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.

3.2.7 Diagnostic Analysis and Programming

Activation, evaluation, and programming of the cochlear and auditory brainstem implants are covered as separate procedures for Medicaid beneficiaries ages 12 months through 20 years of age and Health NCHC beneficiaries ages 6 through 18 after the postoperative period. Refer to **Subsection 5.2** for additional information on diagnostic analysis and programming.

3.2.8 Medicaid Additional Criteria Covered

None Apply.

3.2.9 NCHC 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 and NCHC 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 both Medicaid and NCHC

- a. A cochlear implant is contraindicated for the following conditions:
 1. Deafness due to lesions of the central auditory pathway.
 2. Otitis media or other active, unresolved ear problems.
 3. Radiographic evidence of absent cochlear development.
- b. Medicaid does not cover bilateral cochlear implants during the same or subsequent operative session except when the criteria outlined in **Subsection 3.2.6** are met.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

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

5.1.1 Cochlear Implant

Prior approval is not required for routine, unilateral cochlear implantation that meets the criteria in **Subsection 3.2.2**

5.1.2 Auditory Brainstem Implant

Prior approval is required. Medical record documentation must be submitted with the prior approval request indicating that the beneficiary:

- 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 beneficiary will become completely deaf as a result of the surgery; **or**
- d. has had bilateral auditory nerve tumors removed and is now bilaterally deaf.

5.1.3 Upgrades and Maintenance

Prior approval is required for the upgrade and maintenance of internal components. Medical record documentation must be submitted with the prior approval request indicating that:

- a. the beneficiary'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.

5.1.4 Contralateral Cochlear Implant

Prior approval is required for a contralateral cochlear implant. The prior approval request must include 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 in **Subsection 3.2.5**

5.1.5 Simultaneous Bilateral Cochlear Implants

Prior approval is required. Medical record documentation must be submitted with the prior approval request indicating that the requirements of **Subsection 3.2.6** have been met.

5.1.6 Aural Rehabilitation

Prior approval is required. Refer to clinical coverage policy 10A, *Outpatient Specialized Therapies*, on DMA's Web site at <http://www.ncdhhs.gov/dma/mp/> for additional information.

5.2 Diagnostic Analysis and Programming

Postoperative diagnostic analysis and programming of the cochlear and auditory brainstem implants do not require prior approval. Medical record documentation should include the date of the surgery and status of the analysis and programming procedures.

5.3 Replacement Parts and Repairs

Coverage requirements and limitations for replacement parts and repairs to cochlear and auditory brainstem implants are documented in clinical coverage policy 13A, *Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair*, on DMA's Web site at <http://www.ncdhhs.gov/dma/mp/>.

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 or NCHC 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 DMA'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).

8.0 Policy Implementation/Revision Information

Original Effective Date: November 1, 2008

Revision Information:

Date	Section Revised	Change
7/1/08	Throughout	Initial promulgation of current coverage.
1/1/10	Header	Change clinical coverage policy references for the Cochlear and ABI Repair and Replacement policy to 13A.
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	To be equivalent where applicable to NC DMA’s Clinical Coverage Policy # 1A-4 under Session Law 2011-145, § 10.41.(b)
3/12/12	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
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.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. International Classification of Diseases, 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.

ICD-10 Code(s)
H90.5
H90.3
Q85.02

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.

Physicians	
CPT Code(s)	
69930	92602
S2235	92603
69949	92604
92601	92640
Aural rehabilitation is billed according to the guidelines listed in clinical coverage policy 0A, <i>Outpatient Specialized Therapies</i> .	

Hospitals
Revenue Code(s)
RC 278

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.
Simultaneous bilateral cochlear implants are billed with 69930 and modifier 50.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s). The procedure codes documented in Section C are billed with one unit, except for CPT code 92640, which is billed as 1 unit = 1 hour.

F. Place of Service

Inpatient, Outpatient.

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at <http://www.ncdhhs.gov/dma/plan/sp.pdf>.

For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html.

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: <http://www.ncdhhs.gov/dma/fee/>