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1.0 Description of the Procedure, Product, or Service

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 profound hearing impairment.

Refer to **Attachment A, Claims-Related Information**, for a detailed list of procedure codes and descriptions.

This policy does not address cochlear and auditory brainstem surgical implant coverage. For eligible recipients with profound hearing impairment requiring implantation, refer to Clinical Coverage Policy #1A-4, *Cochlear and Auditory Brainstem Implants*, (<http://www.ncdhhs.gov/dma/mp/mpindex.htm>).

2.0 Eligible Recipients

2.1 General Provisions

NC Medicaid (Medicaid) recipients shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) recipients, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and shall meet policy coverage criteria, unless otherwise specified.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

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 recipients 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 clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/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 recipient'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 recipient's right to a free choice of providers.

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

- a. that is unsafe, ineffective, or experimental/investigational.
- b. 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/or 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 recipient'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**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient 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 *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid and NC Health Choice Billing Guide:

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

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

2.3 Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Recipients ages 6 through 18 years of age

EPSDT does not apply to NCHC recipients. If a NCHC recipient does not meet the clinical coverage criteria within **Section 3.0** of the clinical coverage policy, the NCHC recipient shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC recipients.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

3.1 General Criteria

Procedures, products, and services related to this policy are covered when they are 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 recipient'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 recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Medicaid and NCHC cover cochlear and auditory brainstem implant external parts replacement and repair 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 #1A-4, *Cochlear and Auditory Brainstem Implant*.
- b. The implanted device is in continuous use and still meets the needs of the recipient.
- 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.

Refer to **Section 6.0, Providers Eligible to Bill for the Product or Service**, for specific criteria regarding eligible providers.

- 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.

Refer to **Subsection 5.5, Required Documentation**, for specific criteria regarding required documentation from the treating licensed audiologist.

- 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. Refer to **Subsection 5.4, Prior Approval for Replacement Speech Processors**, for specific information regarding additional criteria for replacement speech processors.

3.3 Speech Processor Upgrades

Upgrades of existing speech processors for next-generation speech processors are considered medically necessary only when:

- a. the recipient'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.

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

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

4.1 General Non-Covered Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily 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 Non-Covered Criteria

Cochlear and auditory brainstem implant external parts replacement and repair are not covered 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.

4.3 NCHC Non-Covered Criteria

Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Health Choice program shall be equivalent to coverage provided for dependents under the NC Medicaid Program except for the following:

- a. no services for long-term care;
- b. no non-emergency medical transportation;
- c. **no EPSDT**; and
- d. dental services shall be provided on a restricted basis.

4.4 Medicaid Non-Covered Criteria

No additional non-covered criteria.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

5.1 Prior Approval

Only speech processors that are not covered under warranty require prior approval.

5.2 Prior Approval Requirements

The provider(s) shall submit to DMA's designee the following:

- a. the prior approval request;
- b. all health records and any other records that support the recipient has met the specific criteria in **Subsection 3.2** of this policy; and
- c. if the Medicaid recipient is under 21 years of age, information supporting that all EPSDT criteria are met and evidence-based literature supporting the request, if available.

Refer to **Subsection 5.4, Prior Approval for Identical Speech Processors** and **Subsection 5.5, Required Documentation** for documentation requirements for prior approval requests for speech processors.

5.3 Replacing or Repairing Cochlear and Auditory Brainstem Implant External Parts under Warranty

Replacement and repair are handled under any warranty coverage that is applicable at the time of replacement. No charge to Medicaid or NCHC is allowed for replacement and repairs covered under warranty, pick-up or delivery of the item, or the assembly of Medicaid or NCHC reimbursed parts.

5.4 Prior Approval for Replacement Speech Processors

Prior approval is required for all replacement speech processors that are not covered under warranty. 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.).

5.4.1 Prior Approval for Identical Replacement Speech Processors—Under Warranty

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.

5.4.2 Prior Approval for Identical Replacement Speech Processor—Out of Warranty

When the requested replacement speech processor is identical to the existing speech processor and no longer covered under warranty, the provider shall obtain prior approval at <http://www.nctracks.nc.gov>. 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. Consideration will be given to the request and a decision will be returned to the provider. Recipients will be notified in writing if the request is denied.

Refer to **Subsection 5.5, Required Documentation**, for additional information regarding specific requirements.

5.4.3 Prior Approval for Replacement Speech Processor—Upgrade

When the requested replacement speech processor is an upgrade, the provider shall obtain prior approval. Documentation must be included with the electronic prior approval request that substantiates that the recipient'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. Documentation from the treating licensed audiologist, supporting the medical necessity for the upgrade, must accompany the electronic prior approval request. Consideration will be given to the request and a decision will be returned to the provider. Recipients will be notified in writing if the request is denied.

Refer to **Subsection 5.5, Required Documentation**, for additional information regarding specific requirements.

5.5 Required Documentation

For every cochlear and auditory brainstem external parts replacement and repair, the provider shall have the following on file from the treating licensed audiologist.

5.5.1 Physician's Medical Clearance

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.

5.5.2 Audiologist's Letter

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. Recipient's name and Medicaid or NCHC 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.

5.6 Delivery of Service

Providers shall dispense cochlear and auditory brainstem implant external parts replacement and repairs as quickly as possible due to the medical necessity identified for an item. However, providers who deliver an item requiring prior approval before approval has been received do so at their own risk.

Refer to **Subsection 5.4, Prior Approval for Replacement Speech Processors**, for specific information regarding prior authorization for payment.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet Medicaid or NCHC qualifications for participation;
- b. be currently Medicaid - enrolled; 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

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.

7.0 Additional Requirements

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

7.2 Medical Record Documentation

Providers shall keep the following documentation of their services:

- a. A copy of the physician's signed medical clearance with complete information regarding the cochlear or auditory brainstem implant system and surgery date(s).
- b. The signed letter documenting medical necessity from the treating licensed audiologist (refer to **Subsection 5.5, Required Documentation**, for specific requirements).
- c. A full description of all item(s) supplied to a recipient.
- d. The dates the items were supplied and to whom they were shipped.
- e. A full description of any services or repairs, including details of parts and applicable warranty information, and the date of the service or repair.

Note: All recipient information, including the recipient's Medicaid or NCHC status, must be kept confidential and may be shared only with those who are authorized to receive it.

7.3 Records Retention

Records and documentation relating to the delivery of cochlear and auditory brainstem implant external parts replacement and repair must be maintained through the life of the implant, and not less than six years.

Copies of records must be furnished upon request.

The Health Insurance Portability and Accountability Act (HIPAA) does not prohibit the release of records to Medicaid (45 CFR 164.502).

7.4 Disclosing Ownership Information

Providers shall disclose ownership and control information, and information about the owners or employees who have been convicted of criminal offenses against Medicare, Medicaid, and the Title XX services program (10A NCAC 22N.0202).

7.5 Seeking Other Sources of Payment

The provider shall take all reasonable measures to determine the legal liabilities of third parties, including Medicare and private insurance, to pay for services. If third-party liability is established, providers shall bill the third party before billing Medicaid.

Refer to **Attachment A: Claims-Related Information, I, Medicare Crossover Claims** for specific information regarding Medicare crossover claims.

Refer to the *Basic Medicaid and NC Health Choice Billing Guide* on DMA's Web site at <http://www.ncdhhs.gov/dma/medbillcaguide.htm> for additional information regarding third-party insurance.

7.6 Accepting Payment

Providers shall accept Medicaid payment according to the rules and regulations for reimbursement promulgated by the Secretary of the Department of Health and Human Services and the State of North Carolina, and established under the N.C. Medicaid program. This includes accepting Medicaid payment as payment in full (10A NCAC 22J.0106).

8.0 Policy Implementation/Revision Information

Original Effective Date: November 1, 2008

Revision Information:

Date	Section Revised	Change
07/01/2008	All sections and attachment(s)	Initial promulgation of current coverage.
01/01/2010	Header	Change clinical coverage policy references for the Cochlear and ABI Repair and Replacement policy to 13A.
07/01/2010	All sections and attachment(s)	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.
03/12/2012	All sections and attachment(s)	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 13-A under Session Law 2011-145, § 10.41.(b)
03/12/2012	All sections and attachment(s)	Technical changes to merge Medicaid and NCHC current coverage into one policy.
07/01/2013	All sections and attachment(s)	Changed "HP" to "CSC." Updated websites and contact information. Updated Prior Approval instructions to match CSC technology.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid or NCHC guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid and NCHC managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers shall bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Billing Code(s)

Providers are required to select the most specific billing code that accurately describes the service(s) provided.

HCPCS Code	Use When Billing For The Following Service(s)	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
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

Refer to **Attachment B, Instructions for Completing Claims**, for additional information regarding HCPCS code L7510.

D. Modifiers

Providers shall follow applicable modifier guidelines.

E. Billing Units

The provider shall report the appropriate procedure code(s) used which determines the billing unit(s).

Medicaid and NCHC pay for services in specific units that measure the amount of service provided to the recipient.

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.

Refer to **Attachment B, Instructions for Completing Claims**, for additional information regarding unit requirements.

F. Place of Service

Recipient's home.

G. Co-payments

Co-payment(s) may apply to covered services, procedures, prescription drugs and over-the-counter drugs.

Medicaid and NCHC recipients are exempt from co-payments for cochlear and auditory brainstem external parts replacement and repair.

H. Reimbursement

Providers shall bill their usual and customary charges.

For a schedule of rates, see: <http://www.ncdhhs.gov/dma/fee/>.

I. Medicare Crossover Claims

Effective with **date of service September 6, 2004**, claims filed to **Medicare cross over automatically** to Medicaid for payment if a Medicare Crossover Request form is on file with Medicaid for that provider and Medicare and Medicaid have matching data for the recipient. It is the provider's responsibility to check the Medicaid Remittance and Status Report to verify that the claim crosses over from Medicare. Providers may verify that their Medicare provider number is cross-referenced to their Medicaid provider number by contacting CSC Provider Services at 1-800-688-6696 or 919-851-8888. If the Medicare provider number is not cross-referenced to the Medicaid provider number, the provider shall complete the Medicare Crossover Request form (available from DMA's Web site at <http://www.ncdhhs.gov/dma/forms.html>) and submit it by fax or mail to the fax number or address listed on the form. Claims will be paid to the Medicaid provider number indicated on the claim filed to Medicare. If no Medicaid provider number is on the claim filed to Medicare, claims will be paid to the Medicaid provider number indicated on the Medicare Crossover Request form.

Note: When a provider has more than one Medicaid provider number, the provider number that is to receive payment must be indicated on the Medicare claim form. Refer to the August 2004 Special Bulletin V, *Medicare Part B Billing*, for details regarding crossover claims for recipients with both Medicaid and Medicare eligibility.

J. Payment Rates

Payment is calculated based on the lower of the provider's billed charge or the maximum amount allowed by Medicaid.

Attachment B: Instructions for Completing Claims

Refer to the following information for completing an electronic 857 or CMS-1500 claim form for DME/cochlear and auditory brainstem implant external parts replacement and repair.

A. Billing Instructions Specific to Cochlear and Auditory Brainstem Implant External Parts Replacement and Repair

There are several fields or lines for listing services. Each field or line is called a “detail.” When completing these blocks, observe the following conventions:

1. Use one line for each HCPCS code billed on a given date.
2. If more than one unit of the same item is provided on one day, include all the items on the same line. For example, for 60 batteries provided on May 1, include 60 on one line. Enter 60 units in 24G for that date of service.
3. If multiple miscellaneous items are provided on the same day, enter L7510 on one line, enter one unit, and enter the total invoice cost of all the items. Do not bill each miscellaneous item separately.
4. Claims for L7510 do not require prior approval but must include an invoice with the manufacturer’s item number for each miscellaneous item being billed.
5. Include only those dates of service on which the recipient is eligible for Medicaid or NCHC.

B. Instructions for Submitting Attachments Specific to Cochlear and Auditory Brainstem Implant

External Parts Replacement and Repair Claims

Required attachments for claims must be submitted in one of the following ways:

- Via the web at <http://www.nctracks.nc.gov>
- Fax to (919) 859-9703

Attachment C: Instructions for Prior Approval Request for Replacement Speech Processors

Prior approval requests for replacement speech processors must be submitted electronically and must include required documentation.

A. Electronic Submission of Prior Approval Requests for Replacement Speech Processors

Prior approval requests for replacement speech processors must be submitted electronically at <http://www.nctracks.nc.gov>.

B. Submission of Required Additional Documentation

Providers shall submit required documentation as attachments through either:

- The web, at <http://www.nctracks.nc.gov>
- Fax to (919) 233-6845, ATTN: AI Parts

Refer to **Subsection 5.4, Prior Approval for Replacement Speech Processors**, for specific information regarding required documentation.