Clinical Policy: Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement and Repair

Reference Number: WNC.CP.113 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]

Replacement and repair of components of soft band and implantable bone conduction hearing aids 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.

Policy/Criteria[1]

I. It is the policy of WellCare of North Carolina® that Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement and Repair is **medically necessary** for the following indications:

A. New Soft Band Bone Conduction Hearing Aid

1. The osseointegrated device, external sound processor, used without osseointegration (soft band device without surgically implanted components) is covered when the Member is a candidate for bone conduction hearing aid implant surgery and has not reached the age of 5 years or is under 21 years of age **AND** is not an appropriate surgical candidate, whose moderate to severe, bilateral, conductive or mixed hearing loss cannot be effectively restored by conventional air conduction hearing aids or a conventional bone conduction hearing aid.
2. The Member shall meet at least one of the following conditions as stated in the Clinical Coverage Policy **WNC.CP.111**, *Implantable Bone Conduction Hearing Aids (BAHA)*:
   a. One or more congenital or acquired abnormalities of the middle or external ear canal that precludes the wearing of a conventional air conduction hearing aid;
   b. One or more tumors of the external canal or tympanic cavity;
   c. Dermatitis of the external ear canal; **OR**
   d. Chronic external otitis or otitis media with persistent discharge.

AND the Member shall meet **ALL** of the following criteria:

e. The Member has a bone conduction pure-tone average of 40–50 decibels or better, with no single frequency poorer than 50 decibels (at 1000 and 2000 Hz); **AND**
f. The Member has speech discrimination of the indicated ear of 60% or more at elevated sound pressure levels (SPL) during speech discrimination testing using consonant–nucleus–consonant [CNC] words (conventional testing) except when the Member is too young to perform the speech discrimination testing;

AND ALL of the following conditions are met:

g. The soft band bone conduction hearing aid being requested is approved by the Food and Drug Administration (FDA);
h. The treating audiologist has obtained medical clearance from an otolaryngologist regarding the soft band bone conduction hearing aid and submits it to the provider;
i. The treating audiologist has documentation that substantiates the need for a soft band bone conduction hearing aid and submits it to the provider; and refer to the additional information below regarding required documentation from the treating audiologist for new soft band bone conduction hearing aids.
j. The component or service is furnished at a safe, efficacious, and cost effective level. Refer to the additional information below regarding prior approval for new soft band bone conduction hearing aids.

B. External Parts Replacement and Repair for Soft Band and Implantable Bone Conduction Hearing Aids – Out of Warranty

1. Soft band and implantable bone conduction hearing aid external parts replacement and repair that are not covered under warranty are covered when all of the following conditions are met:
   a. The Member is approved for and is currently wearing a soft band bone conduction hearing aid prior to turning 21 years of age or is 5 years of age or older and implanted;
   b. The soft band bone conduction hearing aid being repaired is approved by the FDA or the implantable bone conduction hearing aid being repaired is approved by the FDA and meets all standards of coverage under Clinical Coverage Policy **WNC.CP.111**, *Implantable Bone Conduction Hearing Aids (BAHA)*;
   c. The device is in continuous use and still meets the needs of the Member;
   d. Replacement or repair is necessary to allow the device to be functional;
   e. The treating audiologist has obtained medical clearance from an otolaryngologist regarding the soft band bone conduction hearing aid and submitted it to the provider or has obtained a physician's prescription with complete information regarding the implant system and surgery date(s) and submitted it to the provider;
   f. The treating audiologist has documentation that substantiates the need for the replacement or repair of part(s) and submitted it to the provider; refer to

the additional information below regarding required documentation from the treating audiologist.

g. The component or service is furnished at a safe, efficacious, and cost effective level; **AND**
h. Additionally, all replacement sound processors, except for those covered under warranty, require prior approval. Refer to the additional information below regarding prior approval criteria for replacement sound processors.

C. Sound Processor Upgrades for Soft Band and Implantable Bone Conduction Hearing Aids

1. Upgrades of existing sound processors for next-generation sound processors require prior approval and are considered medically necessary only when
   a. The Member's response to the existing sound processor is inadequate to the point of interfering with the activities of daily living; **OR**
   b. The sound processor is no longer functional and cannot be replaced with the same model.

AND are covered only when **ALL** of the following criteria are met:

c. The Member is approved for and is currently wearing a soft band bone conduction hearing aid prior to turning 21 years of age or is 5 years of age or older and implanted;
d. The soft band bone conduction hearing aid sound processor upgrade is approved by the FDA or the implantable bone conduction hearing aid sound processor upgrade is approved by the FDA and meets all standards of coverage under Clinical Coverage Policy **WNC.CP.111**, *Implantable Bone Conduction Hearing Aids (BAHA)*;
e. The device is in continuous use and still meets the needs of the Member;
f. The treating audiologist has obtained medical clearance from an otolaryngologist regarding the soft band bone conduction hearing aid and submitted it to the provider or has obtained a physician's prescription with complete information regarding the implant system and surgery date(s) and submitted it to the provider;
g. The treating audiologist has documentation that substantiates the medical necessity for the sound processor upgrade and submits it to the provider; and refers to the additional information below regarding required documentation from the treating audiologist for sound processor upgrades.
h. The component or service is furnished at a safe, efficacious, and cost effective level. Refer to the additional information below for additional information regarding criteria for replacement sound processors.

II. It is the policy of WellCare of North Carolina® that Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement and Repair is **not medically necessary** for the following indications:

A. Soft band and implantable bone conduction hearing aid external parts replacement and repair are not covered under this policy when:

1. The request for a sound processor, battery replacement, or repair is for spare or back-up equipment for use in emergencies;
2. The request for a soft band bone conduction hearing aid is for unilateral sensorineural hearing loss (single sided deafness);
3. The component or service is for a resident of a nursing facility; **OR**
4. The component or service is covered by another agency.

Background[1]

I. It is the policy of WellCare of North Carolina® that documentation of medical necessity includes the following:

A. For every **new soft band bone conduction hearing aid**, the provider shall keep the following on file from the treating audiologist:

1. Audiologist's Letter: The provider shall keep on file a letter signed by the treating audiologist and shall ensure that this letter includes the following:
   a. Audiologist's name, business name, address, and telephone number;
   b. Member's name and Medicaid identification number;
   c. Verification that the soft band bone conduction hearing aid is FDA approved and currently being used in a functional manner by the Member; **AND**
   d. Specific information regarding the medical necessity for the Member
2. Additional Documentation: The provider shall keep on file the following additional documentation obtained from the treating audiologist:
   a. Medical clearance from an otolaryngologist;
   b. Audiology report to include audiogram, sound field audiogram, speech perception test, sound awareness test, speech awareness test, and history of hearing aid use;
   c. Documentation that includes information regarding future bone conduction hearing aid surgery or inappropriateness of candidate for surgical implant; **AND**
   d. Documentation that supports that hearing loss cannot be effectively restored by conventional air conduction or bone conduction hearing aids.

B. For every soft band or implantable bone conduction hearing aid **external parts replacement and repair that is no longer covered under warranty**, the provider shall keep the following documentation on file:

1. Audiologist's Letter: The provider shall keep on file a letter signed by the treating audiologist and shall ensure that this letter includes 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) if device is implanted;
   d. Verification that the soft band or implantable bone conduction hearing aid is FDA approved and currently being used in a functional manner by the Member; **AND**

e. Specific information regarding the repair or replacement external parts, and quantity of external parts, that are medically necessary for the Member.

2. Physician's Medical Clearance or Prescription

a. For soft band bone conduction hearing aids, a copy of the medical clearance from the otolaryngologists **OR** for implantable bone conduction hearing aid systems, a copy of the physician's signed prescription with complete information regarding the implanted system and surgery date(s) shall be kept on file with the provider.

C. Documentation of Medical Necessity for Replacement Sound Processor – Upgrade

1. Audiologist's Letter: The provider shall keep on file a letter signed by the treating audiologist and shall ensure that this letter includes 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) if device is implanted;
   d. Verification that the soft band or implantable bone conduction hearing aid is FDA approved and currently being used in a functional manner by the Member; **AND**
   e. Specific information regarding the medial necessity of the upgrade, such as the current sound processor is no longer functional and cannot be replaced with the same model.
2. Physician's Medical Clearance or Prescription
   a. For soft band bone conduction hearing aids, a copy of the medical clearance from the otolaryngologists **or** for implantable bone conduction hearing aid systems, a copy of the physician's signed prescription with complete information regarding the implanted system and surgery date(s) shall be kept on file with the provider.
3. Additional Documentation for Sound Processor Upgrade
   a. If the current sound processor is functional or can be replaced with the same model, the provider shall provide the following additional documentation that substantiates that the Member's response to the existing sound processor is inadequate to the point of interfering with the activities of daily living:
      i. sound field audiogram, aided
      ii. speech perception test, aided
      iii. sound awareness test, aided
      iv. speech awareness test, aided

D. Replacing or Repairing External Parts - Under Warranty

1. Replacement and repair are handled under any warranty coverage an item may have. No charge to the plan is allowed for replacement and repairs covered under warranty, pick-up or delivery of the item, or the assembly of Medicaid-reimbursed parts.

E. Delivery of Service

1. Providers shall dispense soft band and implantable bone conduction hearing aid external parts replacement and repairs as quickly as possible due to the medical necessity identified for an item.

NOTE: Providers who deliver an item requiring prior approval before approval has been received do so at their own risk. Refer to the additional information below regarding prior approval for services.

F. Medical Record Documentation

1. Depending upon the service being provided, the providers shall maintain some or all of the following documentation of their services:
   a. A copy of the medical clearance from an otolaryngologist regarding the soft band bone conduction hearing aid or a copy of the physician's signed prescription with complete information regarding the bone conduction implant system and surgery date(s);
   b. The signed letter documenting medical necessity from the treating audiologist;
   c. All tests, evaluations, and documentation submitted by the treating audiologist;
   d. A full description of all item(s) supplied to a Member;
   e. The dates the items were supplied and to whom they were shipped; **AND**
   f. A full description of any services or repairs, including details of external parts and labor, applicable warranty information, and the date of the service or repair.
2. The provider shall maintain all records and documentation through the life of the implant **OR** for five years, whichever is greater and ten years for soft band bone conduction hearing aids.
3. The provider shall furnish records and documentation upon request.

Note: The provider shall keep all Member information, confidential including the Member's Medicaid status, and share only with those who are authorized to receive it.

G. Prior Approval

1. Providers shall obtain prior approval for all new soft band bone conduction hearing aids and replacement and repair for all sound processors that are not covered under warranty.
2. New Soft Band Bone Conduction Hearing Aid
   a. When the request is for a new soft band bone conduction hearing aid, the provider shall obtain prior approval. The provider shall submit a copy of the medical clearance from an otolaryngologist, a letter of medical necessity

from the treating audiologist, an audiology report to include audiogram, evaluation, speech and sound tests, history of hearing aid use, future surgery information, and documentation substantiating that hearing loss cannot be effectively restored by conventional air conduction or conventional bone conduction hearing aids.

3. Identical Replacement Sound Processor—Out of Warranty
   a. When the requested replacement sound processor is identical to the existing sound processor, the provider shall obtain prior approval. The provider shall submit a copy of the medical clearance from the otolaryngologist regarding the soft band bone conduction hearing aid or a copy of the prescribing physician's original prescription with surgery for the implanted device, and a letter of medical necessity from the treating audiologist.
4. Replacement Sound Processor—Upgrade
   a. When the requested replacement sound processor is an upgrade, the provider shall obtain prior approval. The provider shall submit documentation that the sound processor is no longer functional and cannot be replaced with the same model or documentation which substantiates that the Member's response to the existing sound processor is inadequate to the point of interfering with the activities of daily living. The provider shall include a copy of the medical clearance from the otolaryngologist regarding the soft band bone conduction hearing aid or a copy of the prescribing physician's original prescription with surgery information for implanted device, a letter of medical necessity from the treating audiologist, and the treating audiologist's documentation supporting the medical necessity for the upgrade with the prior approval request.
5. Identical Replacement Sound Processors—Under Warranty
   a. When the requested replacement sound processor is identical to the existing sound processor and the existing sound processor is under warranty, prior approval is not required.

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
L7510	Repair or replacement of minor prosthetic device parts	As necessary; requires invoice

HCPCS ®* Codes	Description	Lifetime Expectancy
L8691	Replacement external sound processor for auditory osseointegrated device	Once every 5 years
L8692	Replacement body worn (headband or other means of external attachment) external sound processor for auditory osseointegrated device used without osseointegration	Once every 5 years
L8621	Replacement zinc air battery for use with cochlear implant device, each	N/A

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	01/21	06/21
Reviewed HCPCS codes.	08/21	11/21
Annual Review. Reviewed HCPCS codes, Added Column Lifetime expectancy; Reviewed references.	08/22	08/22
NCHC verbiage removed from NC Guidance Verbiage.	03/23	03/23
Annual Review. Reviewed HCPCS codes.	08/23	08/23
Annual Review. Changed 'beneficiary' to 'member.' Removed ICD-10 and CPT code tables. 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:13B Soft Band and Implantable Bone Conduction Hearing Aid External Parts Replacement and Repair. 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.

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.