

DATE: July 31, 2024

NL 12-1120
Supersedes: NL 09-0817
Index: Benefits

TO: All County Administrators and Medical Consultants for California Children's Services Program, Specialists at California Children's Services Communication Disorder Centers, and Integrated Systems of Care Division Staff

SUBJECT: Bone Conduction Hearing Devices

I. PURPOSE

This Numbered Letter (NL) establishes policy and procedures for the review and authorization of bone conduction hearing devices (BCHD). The California Children's Services (CCS) Program publishes this NL under the program's authority to authorize services that are medically necessary to treat CCS-eligible conditions.^{1, 2, 3}

II. BACKGROUND

BCHDs effectively transmit sound vibrations directly to the cochlea through the skull bones, thus bypassing any existing deficiencies in air conduction. Due to the associated loss in air conduction, children with hearing loss related to anatomic issues involving the external ear (such as microtia, aural atresia, and anotia), or having copious, chronic ear drainage, are unlikely to receive adequate benefit from traditional (air-conduction) hearing aids. BCHDs may also be used to treat unilateral or asymmetrical hearing loss.

BCHDs are considered prosthetic devices by the U.S. Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS). These devices can be categorized into two broad categories based on how the sound processor component is retained on the skull surface:

A. Bone conduction hearing devices that are surface-worn (BCHD-SW):

Devices under this category do not include any component which requires surgical implantation into the body. The sound processor remains on the surface

¹ [22 Cal. Code Regs. §41515.1](#)

² [22 Cal. Code Regs. §41700](#)

³ [22 Cal. Code Regs. §41740](#)

of the skull, secured (i.e., worn) using a head band or adhered to the surface of the skin behind the auricle.

Attachment 1 provides examples of FDA-approved BCHDs-SW.

B. Bone conduction hearing devices with surgically inserted components (BCHD-SI):

Devices under this category require a surgical implant to transmit sound by direct conduction through the skull bones (bone-conduction) to the inner ear. In doing so, the sound bypasses the external auditory canal (ear canal) and middle ear. Surgical solutions could include a small percutaneous abutment exposed outside the skin, or alternately, a transcutaneous magnetic coupling placed completely under the skin. The percutaneous abutment uses a snap coupling to attach the surface-worn sound processor while the transcutaneous solution retains the surface-worn sound processor through a magnetic coupling.

Attachment 2 provides examples of FDA-approved BCHDs-SI.

III. POLICY

A. Effective the date of this NL, the CCS Program will cover BCHDs and accessories if:

1. All professional services (including audiological services) are provided through a CCS-approved Communication Disorder Center (CDC).
2. BCHD(s), associated component(s), or related services, must be requested by a CCS-approved CDC, CCS-paneled audiologist, or CCS-paneled otolaryngologist.
3. Documentation is submitted by the requesting CCS-paneled provider which demonstrates that the request for BCHD(s) or associated components is clinically appropriate and medically necessary based on considerations including age, medical diagnosis, audiologic condition(s), and results of audiometric testing.

CCS considers the presence of one or more of the following conditions as evidence of clinical appropriateness for the use of BCHD (as opposed to an air conduction hearing aid):

- a. Congenital or acquired malformations of the external ear or middle ear, including those that are surgically-induced. Examples include microtia, tumors or malformations involving the external ear canal or middle ear.

- b. Severe and persistent (or chronic) infections involving external and/or internal ear (e.g., chronic otitis externa, chronic suppurative otitis media) that have not responded to medical treatment.
 - c. Inflammation or allergic reactions involving outer or middle ear that may be further exacerbated by use of a conventional hearing aid.
 - d. Ossicular disease that has caused conductive hearing loss but is not amenable to surgical correction.
 - e. Unilateral sensorineural hearing loss (single-sided deafness).
 - f. Significant air bone gap that cannot be overcome by traditional fitting with an air conduction hearing aid.
4. The provider's request for BCHD(s) or associated components includes a valid prescription for the device, written and signed by a CCS-paneled otolaryngology (ENT) specialist physician.
5. The provider's request for BCHD(s) or associated components includes audiological reports that provide details of the hearing loss which are in alignment with device-specific labeling (age and indications) approved by the FDA:
- a. Unilateral or bilateral conductive or mixed hearing loss.

The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 65 dB HL.

- b. Unilateral profound sensorineural hearing loss.
 - (1) Unilateral sensorineural profound hearing loss (greater than or equal to 90 dB HL) in one ear, with confirmed pure tone average air conduction thresholds better than or equal to 20 dB HL in the opposite ear.
 - (2) When child's age and developmental status allows for such testing, speech recognition score of greater than or equal to 60% using appropriate speech masking in the opposite ear.
- c. Requests for use of bilateral BCHDs must meet all of the following criteria:

- (1) Bilateral symmetrical conductive or mixed hearing loss with a pure-tone average bone conduction threshold better than or equal to 65 dB HL in both ears.
- (2) As optimal outcomes are achieved when bone conduction thresholds are roughly symmetrical, audiologist to provide justification for BCHD use when marked asymmetry in bone conduction thresholds are present.

d. Requests for BCHD-SI components must also fulfill the following criteria:

- (1) The request must be made by a CCS-paneled otolaryngologist (ENT) specialist physician, based on a thorough assessment, and documenting no contraindications for surgery and anesthesia.
- (2) For unilateral implantations, medical report(s) from the otolaryngologist should indicate on which ear surgery will be performed. This should also be annotated on Attachment 3.
- (3) Age and other characteristics must align with FDA-approved indications for use of the proposed device.
- (4) A history of documented compliance with the use of BCHD-SW.

B. If criteria described above are not met, the requesting provider may submit clinical documentation and/or scientific evidence relevant to their request, for consideration by the Integrated Systems of Care Division (ISCD) Medical Director or designee.

C. The CCS Program does not cover the following benefits:

1. Back-up device (BCHD including sound processor).
2. Repair of a back-up BCHD or accessories for its use.
3. Upgraded models of BCHD without specific medical need or when a well-functioning device is in use, when the current BCHD is less than 5 years old.

IV. POLICY IMPLEMENTATION

A. CCS-paneled providers may request coverage of initial BCHD(s) and associated components by submitting a Service Authorization Request (SAR) in the following manner:

1. The SAR must be accompanied by a completed "Prior Authorization Request Form for Bone Conduction Hearing Device(s)" (Attachment 3) and related documents that serve to validate that the proposed service(s) and/or device(s) is/are medically necessary for the CCS beneficiary.
2. CCS-paneled providers requesting BCHDs should utilize Attachment 4, "Coding and Coverage for Bone Conduction Hearing Devices(s), Related Equipment, and Accessories" when completing SARs.
3. Facility outpatient surgery services should be authorized with a Service Code Grouping (SCG) 01, and not with SCG51.⁴

B. Requests for coverage of BCHD replacement(s):

Coverage of all replacement BCHD(s) is subject to clinical re-evaluation and verification of compliance with device use. Based on the usual life expectancy of the sound processor, the CCS Program will ordinarily authorize replacements once every five years. However, if the request for replacement of BCHDs or related components is due to lost or broken equipment, due to circumstances that are beyond the beneficiary's control, the CCS Program will consider replacement coverage earlier than five years from the time of initial authorization. Situations involving repeated loss of equipment due to beneficiary negligence may jeopardize authorization of replacement. In such situations, the parent or caregiver may be required to sign a corrective action plan which includes specific plans to prevent future loss.

Requests for coverage of replacements must include all documents outlined in section IV A above, and must also include the following:

1. Current clinical records documenting continued need for device.
2. Report by a CCS-paneled audiologist indicating aided benefit, including (if appropriate) aided and unaided Speech Discrimination Scores (SDS).
3. Documentation of appropriate and regular use of the device.
4. Document(s) from the manufacturer(s) verifying that the currently used BCHD is not repairable or necessary repairs are not covered by the warranty.
5. If the surgical component will be placed by a physician other than the prescribing Otolaryngologist (i.e., a plastic surgeon), the surgeon performing the surgery will confirm that the surgical abutment is compatible with the existing sound processor, if applicable.

⁴ [Service Authorization Request Tools](#)

C. All requests for initial and replacement BCHDs and associated components should be directed as follows:

1. For non-Whole Child Model (WCM) CCS Program independent counties, all requests will be reviewed and authorized by county CCS Programs.
2. For non-WCM CCS Program dependent counties, all requests will be reviewed and authorized by ISCD Special Populations Unit at CCSDirectedReview@dhcs.ca.gov, or secure RightFax number, (916) 440-5768.
3. For children enrolled in the managed care plan (MCP) in a WCM county, all requests will be reviewed and authorized by the Managed Care Plan (MCP) and requests for authorization should be directed to the appropriate authorization county specific MCP authorization unit.

If you have any questions regarding this NL, please contact the ISCD Medical Director or designee, via email at ISCD-MedicalPolicy@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

Cortney Maslyn, Chief
Integrated Systems of Care Division
Department of Health Care Services

Attachments:

- Attachment 1: Examples of Bone Conduction Hearing Devices that are Surface-Worn (BCHD-SW)
- Attachment 2: Examples of Bone Conduction Hearing Devices that include Surgically-Inserted Component(s) (BCHD-SI)
- Attachment 3: Prior Authorization Request Form for Bone Conduction Hearing Device(s)
- Attachment 4: Coding and Coverage for Bone Conduction Hearing Devices(s), Related Equipment, and Accessories