



State of California—Health and Human Services Agency
Department of Health Care Services



GAVIN NEWSOM
GOVERNOR

DATE: November 19, 2020

N.L.: 12-1120

Supersedes: N.L.: 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 (N.L.) establishes policy and procedures for the review and authorization of bone conduction hearing devices (BCHD).

The California Children's Services (CCS) Program publishes this N.L. 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 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 N.L., 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 has 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 ADMINISTRATION

- 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 client.
 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 client'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 client 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.

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 N.L., please contact the ISCD Medical Director or designee, via email at ISCD-MedicalPolicy@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

Roy Schutzengel
Medical Director
Integrated Systems of Care Division

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

¹ 22 Cal. Code Regs. § 41515.1 et. seq. Determination of Medical Eligibility
<https://govt.westlaw.com/calregs/Document/I28E30090D4B811DE8879F88E8B0DAAAE?viewType=FullText&originContext=documenttoc&transitionType=CategoryPageItem&contextData=%28sc.Default%29>

² 22 Cal. Code Regs. § 41700 Availability
[https://govt.westlaw.com/calregs/Document/I2F1A7E70D4B811DE8879F88E8B0DAAAE?viewType=FullText&originContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)&bhcp=1&ignorebhwarn=lgoreWarns](https://govt.westlaw.com/calregs/Document/I2F1A7E70D4B811DE8879F88E8B0DAAAE?viewType=FullText&originContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)&bhcp=1&ignorebhwarn=lgoreWarns)

³ 22 Cal. Code Regs. § 41740 Eligibility for Treatment Services
<https://govt.westlaw.com/calregs/Document/I2FDD8050D4B811DE8879F88E8B0DAAAE?viewType=FullText&originContext=documenttoc&transitionType=StatuteNavigator&contextData=%28sc.Default%29>

⁴ Service Authorization Request Tools
<https://www.dhcs.ca.gov/services/ccs/cmsnet/Pages/SARTools.aspx#service>

Examples of Bone Conduction Hearing Devices that are Surface-Worn (BCHD-SW)

Sound Processor Name	Baha 5, 5 Power, 5 Super Power	ADHEAR System	Ponto 3, 3 Power, 3 Super Power, Pro Power	Ponto 4
Manufacturer	Cochlear	MED-EL	Oticon Medical	Oticon Medical
Associated code(s)	K142907 ¹ K161123 ² K153245 ³ K171088 ⁴	K172460 ⁵	K161671 ⁶	K190540 ⁷
Age for approved use	Birth on	Birth on	Birth on	Birth on
Retention Mechanism(s)	Baha SoundArc Softband Headband	ADHEAR Adhesive adapter	Softband Headband	Softband Headband
Related accessories	Cochlear Mini Mic 2+ Cochlear Phone Clip Cochlear TV connector	Sleeve, Adhesive sticker, DAI cable	Oticon Medical Streamer	Oticon Connect Clip

¹ 510(k) Premarket Notification Summary

https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142907.pdf

² 510(k) Premarket Notification Summary

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161123.pdf

³ 510(k) Premarket Notification Summary

https://www.accessdata.fda.gov/cdrh_docs/pdf15/K153245.pdf

⁴ 510(k) Premarket Notification Summary

https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171088.pdf

⁵ 510(k) Premarket Notification Summary

https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172460.pdf

⁶ 510(k) Premarket Notification Summary

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161671.pdf

⁷ 510(k) Premarket Notification Summary

https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190540.pdf

Examples of Bone Conduction Hearing Devices that include Surgically-Inserted Component(s) (BCHD-SI)

Sound Processor Name	Baha 5, BAHA 5 Power, BAHA 5 Super Power	Baha 5, BAHA 5 Power, BAHA 5 Super Power	BoneBridge	OSIA 2	Ponto 4, Ponto 3, 3 Power, 3 Super Power, 3 Pro Power
Manufacturer	Cochlear	Cochlear	MED-EL	Cochlear	Oticon Medical
Associated code(s)	K142907 ¹ K161123 ² K153245 ³	K142907 ¹ K161123 ² K153245 ³	K191457 ⁴	K191921 ⁵ K100360 ⁵	K161671 ⁶ K190540 ⁷
Age for approved use (in years)	≥5	≥5	≥12	≥12*	≥5
Attachment mechanism	BAHA Attract Magnet and SoftWear pad	BAHA Connect System, Dermalock Connect	BoneBridge Bone Conduction Implant (BCI) 601, 602	Cochlear OSI200 and BI300 implant	BHX Implant
Related accessories	Cochlear Mini Mic 2+, Cochlear Phone Clip, Cochlear TV connector	Cochlear Mini Mic 2+, Cochlear Phone Clip, Cochlear TV connector	Charger	Cochlear Mini Mic 2+, Cochlear Phone Clip, Cochlear TV connector, Water wear	Oticon Connect Clip

¹ 510(k) Premarket Notification Summary
https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142907.pdf

² 510(k) Premarket Notification Summary
https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161123.pdf

³ 510(k) Premarket Notification Summary
https://www.accessdata.fda.gov/cdrh_docs/pdf15/K153245.pdf

⁴ 510(k) Premarket Notification Summary
https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191457.pdf

⁵ 510(k) Premarket Notification Summary
https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191921.pdf

⁶ 510(k) Premarket Notification Summary
https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161671.pdf

⁷ 510(k) Premarket Notification Summary
https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190540.pdf

Prior Authorization Request Form for Bone Conduction Hearing Device(s)

General Instructions:

1. The CCS Program requires prior authorization of the SAR for the types of devices and supplies associated with this NL. Prior authorization of SAR(s) is not a guarantee for claim payments.
2. The SAR must be submitted by completing the Prior Authorization Request Form and documentation that serves to validate Medical Necessity of the requested item(s) and service(s).
3. If surgical implantation is involved, submitted documentation must also specify medical clearance for anesthesia and surgery.
4. Prior Authorization requests accompanied by incomplete or inadequate documentation may be denied by CCS Program.

Document Checklist for SAR Prior Authorization

Type of Document	(Mark all that apply)
Completed "Prior Authorization Request Form for Bone Conduction Hearing Device(s)" (pages 2-3 of this attachment)	<input type="checkbox"/>
Report(s) from CCS-paneled Audiologist	<input type="checkbox"/>
Reports containing results of audiometric testing, including Bone Conduction thresholds in both ears	<input type="checkbox"/>
Reports containing results of audiometric testing, including Air Conduction threshold in affected ear(s)	<input type="checkbox"/>
Prescription for device signed by CCS-paneled ENT Specialist Physician	<input type="checkbox"/>
Report(s) from CCS-paneled ENT Specialist Physician	<input type="checkbox"/>
Other relevant reports (e.g., written explanation for device loss)	<input type="checkbox"/>
Catalog page listing price of the device or component(s) (if available)	<input type="checkbox"/>

Prior Authorization Request Form for Bone Conduction Hearing Device(s)

CCS Client Information	
CCS Client's Name (First, Last):	Date of Birth:
CCS Number:	CCS County:
Date of Request:	
CCS-Paneled Provider Information	
Name of Audiologist (First, Last):	NPI Number:
Practice Address:	Phone Number:
Name of ENT Specialist (First, Last):	NPI Number:
Practice Address:	Phone Number:

Prior Authorization Request Form for Bone Conduction Hearing Device(s)

Request for

- New device(s) Replacement device(s)

Side (if requesting devices for bilateral use, please mark both sides)

- Left side Right side

Device (please include details, including manufacturer and specific model)

- Bone Conduction Hearing Device, surface-worn (BCHD-SW)
- Bone Conduction Hearing Device used in conjunction with surgically-inserted component(s) (BCHD-SI)

Surgical Procedure(s)

- Surgical insertion of BCHD-SI component(s) - please include HCPCS® or CPT® code(s)

Additional Notes: (describe rationale for device use or replacement)

Coding and Coverage for Bone Conduction Hearing Devices(s), Related Equipment, and Accessories

HCPCS® Level II or National Code⁵	Description	Applicable Limits
L8690	Auditory osseointegrated device, includes all internal and external components ⁶	Sound Processor- 1 unit for each ear/side
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment ⁷	Sound Processor- 1 unit for each ear/side
L8691	Auditory osseointegrated device, external sound processor, replacement	With adequate justification, one replacement of external component every 5 years
L8693	Auditory osseointegrated device abutment, any length, replacement only ⁸	With adequate justification, one replacement of external component every 5 years
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each	With adequate justification, one replacement every 5 years
L8618	Transmitter cable for use with cochlear implant or auditory osseointegrated device, replacement	Up to 8 in each 12-month period, for each device
L 8621	Zinc Air battery for use with auditory osseointegrated sound processors	Up to 96 in each 12-month period, for each device
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each	Up to 2 replacements for each device, in each 12-month period
L8625	External recharging system for Li ion battery for use with cochlear implant or auditory osseointegrated device speech processor, replacement only, each	1 replacement for each device or side in each 12-month period
L9900	Orthotic and prosthetic supply, accessory, and/or service component of another L Code.	2 replacement Headbands or Softbands in each 12-month period; 110 adhesive stickers in each 12-month

Coding and Coverage for Bone Conduction Hearing Devices(s), Related Equipment, and Accessories

		period for each ADHEAR device
L7510	Repair of prosthetic device, repair or replace minor parts	
V5267	Hearing aid or assistive listening device/supplies/accessories, not otherwise specified	Accessories, including FM system

⁵ Current Procedural Terminology (CPT®), developed by the American Medical Association, is part of the Healthcare Common Procedure Coding System (HCPCS). HCPCS is a standardized coding system which enables use of a code to denote a specific healthcare-related procedure, service, or supply. All requests to the CCS Program must be submitted using HCPCS Level II (National) codes; HCPCS Level III codes (i.e., Local or "Z" codes) should not be used.

⁶ Denotes initial device implantation, not replacement. For reimbursement purposes, codes denoting surgical procedures associated with device implantation are to be reported separately.

⁷ Denotes device or systems which do not include surgically implanted components.

⁸ Denotes initial surgical implantation of the abutment (mechanical or magnetic component). Codes denoting surgical procedures for device implantation are to be reported separately for reimbursement purposes.