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

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TO: ALL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS) ADMINISTRATORS, MEDICAL CONSULTANTS AND SYSTEMS OF CARE DIVISION (SCD) STAFF

SUBJECT: BONE ANCHORED HEARING AIDS (BAHA)

I. PURPOSE

The purpose of this Numbered Letter (N.L.) is to provide policy for both the CCS Dependent and Independent County programs, and all SCD Staff on how to review and authorize requests for BAHA softband or implant surgery.

II. BACKGROUND

The Food and Drug Administration (FDA) has approved BAHA devices since 1996 for patients with bilateral conductive or mixed hearing losses in cases where traditional hearing aids have not been medically appropriate. The BAHA device consists of two parts, an external sound processor and a surgically implanted screw in the mastoid process to which the sound processor is attached with either a screw or magnet abutment.

Historically, BAHA implants were approved for children with special ear conditions such as aural atresia or continuous ear drainage, who could not be fit with traditional hearing instruments. The BAHA sound processor can also be placed on younger children with the use of a soft headband and without a surgical procedure. Used in either capacity, the BAHA device transmits sound to the cochlea, bypassing any conductive component that may be hindering the sound process. Bone conduction (BC) transmits sound to the better cochlea, regardless of where the BC is placed and if there is a difference in hearing between the two ears, then sound lateralizes to the better cochlea. Sound quality and clarity improves with the surgical implantation of the device.

In December 2005, the Centers for Medicare and Medicaid Services (CMS) changed the definition of hearing aids to exclude the BAHA and auditory implants. This allowed payment for the BAHA in the Medicare system as a prosthetic device. CMS and the FDA have approved surgical implantation of BAHA for children over the age of five where hearing aids cannot be used due to congenital malformations, chronic disease, and profound unilateral sensorineural hearing loss (SNHL).

III. POLICY

A. Effective the date of this letter, the requests for BAHA softbands and implants will be reviewed and authorized as an Early and Periodic Screening, Diagnosis, and Treatment Supplemental Services (EPSDT-SS) benefit to full-scope, no share of cost Medi-Cal recipients, or as a CCS Program benefit for the CCS Program-only, and other Medi-Cal beneficiaries.

B. Requests for the BAHA softband should be considered appropriate for children of any age who have conditions that are eligible for a BAHA implant or who have chronic draining otitis media, which has been documented to be unmanageable or poorly responsive to treatment.

C. BAHA implantation for children <u>over 5 years of age</u> should be considered in those who have any of the following diagnoses or qualifying ear conditions:

1. Congenital malformation of the outer/middle ear that cannot be fit with air conduction (AC) hearing aids such as microtia, aural atresia, and/or anotia. Having at least a moderate (or worse) conductive or mixed hearing loss with confirmed BC. Having BC thresholds no worse than 40 dB (decibel) in one of the ears, unless the device is FDA approved for BC thresholds of greater severity (i.e. 65 dB Hearing Level (HL)) and documentation of failed reconstructive surgery or no plans for full reconstructive surgery that would restore hearing to normal.

2. Stenosis of the external auditory canal, verified by the otolaryngology report, and for which an ear mold cannot be made due to anatomical deformities.

3. Ossicular discontinuity or erosion that cannot be repaired by surgery and for which a traditional hearing aid cannot be fit.

4. Profound SNHL/mixed HL (hearing thresholds must be at least 95 dB or worse across the range of frequencies from 500 Hz to 8 KHz) in one ear, with no usable speech discrimination (0%) in the dead ear and unable to be fit with a CROS/Bi-CROS aid or FM system.

D. Additional criteria for BAHA implantation include the following:

1. BAHA implantation must be recommended/requested by a CCS Program approved Otolaryngologist (ENT).

2. Implantation is in conformance with current FDA standards for the device used.

3. No contraindications to anesthesia or surgery.

4. Appropriate expectations regarding the care and prognosis of the implant.

5. ENT and audiology reports must accompany the request and must specify which ear will be implanted and which BAHA device will be implanted.

6. BAHA implantation for young children must document good compliance with the use of a BAHA softband system. Objective evidence of compliance with BAHA use may be required (e.g. – download of data logging). A history of non-compliance with BAHA use or repeated loss of hearing aids may preclude BAHA implantation.

7. BAHA implantation for children ages 15 and older does not necessarily require prior use of BAHA softband device. However, if such a device was used, good compliance must be documented prior to consideration of implantation.

8. If a current external BAHA sound processor is under 5 years old and still functional, the internal device to be implanted must be compatible with the current external BAHA sound processor.

9. Requests to replace all components of an existing BAHA system requires medical justification.

Note: Currently, there are three BAHA device manufacturers: Cochlear Americas, Oticon Medical and Sophono. BAHA sound processors are not interchangeable with the internal components from a different manufacturer. Implantation of devices that are not compatible with the patient's retained equipment will not be authorized.

E. All BAHA devices and requests for surgical implantation require prior authorization. Retro-authorization for provision of BAHA devices or for surgical implantation will not be given.

F. Requests for BAHA component replacements require documentation of continuation of the condition for which the BAHA was originally authorized and a medical necessity.

G. The following are not benefits of the CCS Program:

1. Back-up BAHA;

2. Repair of a back-up BAHA or BAHA accessories;

3. Upgraded models of a well-functioning BAHA without specific medical need.

IV. IMPLEMENTATION

A. The CCS Program will review the request and documentation, which must include:

1. The BAHA Request Form (see enclosure), completed by the provider fitting the BAHA. Specify which ear will be implanted.

2. An ear-specific, pure-tone audiogram, or audiometric data from evoked potential testing (with "estimated hearing level"), to include both AC & BC thresholds in dB HL. Speech discrimination score (or word recognition score) is required if the child is verbal and can be tested.

3. Medical documentation to support the request from both the audiologist & the otolaryngologist is required. These reports should include current devices in use or tried.

4. If the child has private insurance coverage, a copy of the exclusion letter confirming that a BAHA device is not a covered benefit. Denials for lack of medical justification or medical necessity or for an out-of-network provider will require that the parents pursue the appeal process of the private insurer.

Note: Thresholds estimated from the auditory brainstem response (ABR) are typically higher by as much as 20-30 dB higher, depending on the frequency, when compared to behavioral thresholds. Therefore, a correction is applied to the ABR threshold estimates to better predict the behavioral threshold. ABR thresholds estimates used in the BAHA fitting report for young infants or children with impaired cognition who cannot be evaluated through behavioral audiometry must include estimated hearing level (eHL) and **not** in normalized hearing level (nHL).

B. If the request is determined to be medically appropriate, authorizations for full scope Medi-Cal, no share of cost beneficiaries should be processed as an EPSDT-SS and should be done as follows:

   1. The BAHA device should be authorized using the HCPCS procedure code L8690-3, for either the surgical implant or the softband.

   2. The surgery for the implanted device should be authorized using CPT Code 69714 (with procedure type K).

   3. Facility outpatient surgery services should be authorized with Service Code Group (SCG) 01, not SCG 51.

C. The authorization for the CCS Program-only and other Medi-Cal beneficiaries should be processed as a CCS Program benefit utilizing the national codes above. The EPSDT-SS field should remain unchecked on the SAR.

D. The authorization for a BAHA should include in the Special Instructions area:

   1. The name of the hearing device manufacturer (e.g. “Cochlear”).

   2. The type and model of the hearing device (e.g. “BAHA BP 5” sound processor).

   3. An instruction to the provider stating that a copy of the specific invoice for the hearing device provided to the patient must be submitted with the provider’s claim for reimbursement.

   4. The surgeon is responsible for choosing internal BAHA components compatible with existing external sound processors.

E. Other SAR instructions**:**

   1. External BAHA sound processor: 1 unit for each ear.

   2. Surgical BAHA (Implanted device): 1 unit for each ear.

   3. Softband or headband replacement: Limited to 2 units per year.

   4. National Codes for BAHA: (Local codes Z5946 will <u>no longer</u> be used.)

      a. L8690 – Auditory osseointegrated device includes all internal and external components.

b. L8691 – Auditory osseointegrated device, external sound processor, replacement.

c. L8692 – Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment.

d. L8693 – Auditory osseointegrated device abutment, any length, replacement only.

e. 69714-K – Implantation without mastoidectomy, 6 units.

5. For implantation: The exact device name, manufacturer and the implanted ear.

6. For hearing aid fittings: The first 6 fittings are included in the initial authorization. Subsequent to this, aural rehabilitation codes for education may be authorized.

7. Functional gain testing: May be authorized as requested.

F. Replacements: Unlike other hearing aids, BAHA replacement every 4 years is NOT a benefit because the life expectancy of BAHA equipment is at least 5 years. BAHA devices require regular cleaning and a lifelong commitment to care of the area around the surgical abutment. All replacements are subject to medical re-evaluation and verification of compliance with device use.

1. Required documentation:

a. Current medical records documenting continued need.

b. Print out of data logging of device use.

c. Aided and unaided speech discrimination scores (SDS) and parent report of benefit.

d. Manufacturer verification that a BAHA is not repairable and out of warranty.

2. Lost BAHA equipment: If lost due to circumstances beyond the beneficiary's control, replacement may be authorized, subject to medical review, with submission of a written explanation for the loss by the parent or caregiver.

3. Stolen devices: Require submission of a formal police report (per Medi-Cal regulation, Title 22, Section 51319).

Note: Medi-Cal regulations mandate that beneficiaries are responsible for the appropriate use and care of devices purchased on their behalf. Repeated loss due to negligence may jeopardize replacement and require submission of a corrective action plan signed by the parent or caregiver acknowledging this, their understanding of this regulation and plans to prevent future loss.

G. If, upon review, the child does not appear to meet the criteria for the BAHA softband or implantation, a Notice of Action should be generated by the local county CCS program office or Regional Office medical consultant.

The SCD will continue to monitor developments in the hearing health care industry and will update criteria for the authorization of BAHA technology and services as appropriate.

If you have any questions regarding the authorization of cochlear implant services, please contact the Audiology Consultant via e-mail at audconsult@dhcs.ca.gov (preferred) or call the CCS Program at 916-327-1400.

Sincerely,

ORIGINIALLY SIGNED BY AMY KRAWIEC, M.D.

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Attachment