February 15, 2007

N.L.: 03-0207
Index: Benefits

TO: ALL COUNTY CALIFORNIA CHILDREN’S SERVICES (CCS)
ADMINISTRATORS, MEDICAL CONSULTANTS AND STATE
CHILDREN’S MEDICAL SERVICES (CMS) BRANCH AND REGIONAL
OFFICE STAFF

SUBJECT: BONE ANCHORED HEARING AIDS (BAHA)

I. PURPOSE

The purpose of this N.L. is to provide policy for the CCS Independent County programs, CMS Regional Offices, and CCS Dependent County programs to review and authorize requests for BAHA softband or implant surgery.

II. BACKGROUND

BAHA have been approved by the Food and Drug Administration (FDA) since 1996, for patients with bilateral conductive or mixed hearing losses in cases where traditional hearing aids have not been medically appropriate. The BAHA is anchored behind the ear on the mastoid process with a surgically implanted screw and abutment added after osteointegration of the implant. The removable bone conduction device is adhered to the abutment as necessary. Historically, BAHA implants have been approved for older children and adults with congenital aural atresia, draining mastoid cavities, and severe cases of otitis externa. The BAHA device can also be placed on younger children with the use of a soft headband, and it is not a surgical procedure. Used in either capacity, the BAHA transmits sound to the cochlea, bypassing any conductive component that may be hindering the sound process. 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.
CMMS 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. Because bone conduction transmits sound to the better cochlea, regardless of where the bone conductor is placed, patients with profound unilateral hearing losses are finding benefit in speech discrimination and sound localization. Further research indicates a significant benefit of the BAHA over the Contralateral Routing of Signal (CROS) hearing aids in speech discrimination, patient use, and patient satisfaction. The BAHA has become the standard of practice for the chronic or permanent conductive hearing loss patients and those with profound unilateral hearing losses.

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 benefit for CCS-only, Healthy Families (HF), 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 is unresponsive to treatment.

C. Requests for BAHA surgery should be considered appropriate for children over the age of five with one of the following diagnoses:

- Congenital malformation of the external auditory canal or middle ear (atresia and/or microtia), moderate to severe conductive or mixed hearing loss with confirmed bone conduction results in the normal to mild hearing range (better than 40 dB HL) and documentation of failed reconstructive surgery and/or no plans for full reconstructive surgery that would restore hearing to normal.

- Acquired stenosis of the external auditory canal.

- Ossicular discontinuity or erosion that cannot be repaired by surgery.

- Confirmed profound hearing loss (greater than 90 dB HL) in one ear with confirmed bone conduction thresholds in the opposite ear of 40 dB HL or better.
D. Additional qualifying criteria for the BAHA implant should include:

- Implantation is in conformance with current FDA standards for the device used.
- No contraindications to anesthesia or surgery.
- Appropriate expectations regarding the care and prognosis of the implant.
- A minimum 30 day trial period with the BAHA softband or other bone conduction hearing aid.
- Recommendation by a CCS approved otolaryngologist.

IV. IMPLEMENTATION

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

- The “Bone Anchored Hearing Aid (BAHA) Request Form”, (see enclosure), completed by the provider fitting the BAHA.
- An ear specific pure-tone audiogram, or audiometric data from evoked potential testing, to include bone conduction results.
- Significant medical documentation to support the request, which may include, but is not limited to, reports and notes from audiologists, otolaryngologists, and radiologists.
- The presence of a denial letter from other health coverage stating that BAHA is not a benefit of the child’s coverage.

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 as provided for in N.L. 05-0896, and should be done as follows:

- The BAHA device should be authorized using the HCPCS procedure code Z5946, for either the surgical implant or the softband.
• The surgery for the implanted device should be authorized using CPT Code 69714 with the appropriate modifier.

• Facility outpatient surgery services should be authorized with Service Code Group (SCG) 01.

C. The authorization for CCS-only, HF, and other Medi-Cal beneficiaries should be processed as a CCS benefit in accordance with N.L. 05-0896 utilizing the codes listed above. The EPSDT-SS field should remain unchecked on the SAR.

D. The authorization for a BAHA should include in the Special Instructions area:
   • The name of the hearing device manufacturer,
   • The type and model of the hearing device, and
   • 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.

E. 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 CCS county office or Regional Office medical consultant.

For detailed instructions on the authorization and billing of BAHA services, please refer to N.L. 05-0896, and the Medi-Cal Provider Manuals.

The CMS Branch 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 Lisa Satterfield, Audiology Consultant, at (916) 323-8100.

Original signed by Harvey Fry for Marian Dalsey, M.D., M.P.H.

Marian Dalsey, M.D., M.P.H., Chief
Children’s Medical Services Branch
BONE ANCHORED HEARING AID (BAHA) REQUEST FORM

Child’s Name _____________________________________ Date of Birth ____________________

CCS Number ___________________________ Date of Request _____________________________

Provider________________________________Phone__________________E-mail________________

Please indicate:

<table>
<thead>
<tr>
<th>□ BAHA softband</th>
<th>□ BAHA surgery  □ Right Ear  □ Left Ear</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Chronic draining otitis media which is unresponsive to treatment</td>
<td>o Congenital malformation of the external auditory canal or middle ear (atresia and/or microtia), moderate to severe conductive or mixed hearing loss with confirmed bone conduction results in the normal to mild hearing range (better than 40 dBHL).</td>
</tr>
<tr>
<td>o Congenital malformation of the external auditory canal or middle ear (atresia and/or microtia), moderate to severe conductive or mixed hearing loss with confirmed bone conduction results in the normal to mild hearing range (better than 40 dBHL).</td>
<td></td>
</tr>
<tr>
<td>o Acquired stenosis of the external auditory canal.</td>
<td>o Acquired stenosis of the external auditory canal.</td>
</tr>
<tr>
<td>o Ossicular discontinuity or erosion that cannot be repaired by surgery.</td>
<td>o Ossicular discontinuity or erosion that cannot be repaired by surgery.</td>
</tr>
<tr>
<td>o Confirmed profound hearing loss (greater than 90 dB HL) in one ear with confirmed bone conduction thresholds in the opposite ear of 40 dB HL or better.</td>
<td>o Confirmed profound hearing loss (greater than 90 dB HL) in one ear with confirmed bone conduction thresholds in the opposite ear of 40 dB HL or better.</td>
</tr>
</tbody>
</table>

Air Conduction Threshold results:

| RE: _______ LE: _______ | RE: _______ LE: _______ |

Bone Conduction Threshold results:

| RE: _______ LE: _______ | RE: _______ LE: _______ |

Please include the following with this request form:

- The SAR request form
- An audiogram or audiometric report, indicating air conduction and bone conduction results
- A physician’s report, indicating diagnosis and medical necessity of treatment
- Other relevant reports for justification of medical necessity
- Catalog page listing prices of the BAHA device and requested accessories