MEDICAL POLICY – 7.01.547

Implantable Bone Conduction and Bone-Anchored Hearing Aids

BCBSA Ref. Policy: 7.01.03

Effective Date: May 1, 2018
Last Revised: Sept. 1, 2018
Replaces: 7.01.03

RELATED MEDICAL POLICIES:
1.01.528 Hearing Aids (Excludes Implantable Devices)
7.01.05 Cochlear Implant
7.01.84 Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | APPENDIX | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

A typical hearing aid amplifies or increases sounds. If there are problems with the outer or middle ear, those problems could interfere with the sound waves traveling to the inner ear. A bone anchored hearing aid bypasses the outer and middle ear. A sound processor is worn near the ear and connects to a small implant. The implant is connected to the skull bone. The sound processor gathers sounds in the air and converts them into vibrations. The vibrations are sent through the implant into the skull bone. The skull bone naturally sends the vibrations to the inner ear. The inner ear is able to switch the vibrations into nerve signals, which the brain interprets as sound. This policy describes when bone anchored hearing aids may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| **Unilateral conductive or mixed hearing loss** | A unilateral implantable bone conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older with a conductive or mixed hearing loss when ONE of the following medical criteria is present:  
  - Congenital or surgically induced malformations (eg, atresia) of the external ear canal or middle ear  
  OR  
  - Chronic external otitis or otitis media  
  OR  
  - Tumors of the external canal and/or tympanic cavity  
  OR  
  - Dermatitis of the external canal  

  **AND the following audiologic criterion is met:**  
  - A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz) of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso™ device) or 65 dB (Cordele II™ device). |
| **Bilateral conductive or mixed hearing loss** | Bilateral implantable bone conduction (bone-anchored) hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older when the following criteria are met:  
  - A symmetrically conductive or mixed hearing loss is present as defined by:  
    - A difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz) (4 kHz for OBC and Ponto™ Pro devices)  
    OR  
    - Less than 15 dB at individual frequencies;  

  **AND the following audiologic criterion is met:**  
  - A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz) of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso™ device) or 65 dB (Cordele II™ device). |
<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Single-sided sensorineural deafness and normal hearing in the other ear | **An implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to a contralateral routing of sound (CROS) air-conduction hearing aid when the following criteria are met:**  
  • The patient is 5 years of age or older  
  • The patient has single-sided sensorineural deafness  
  • The patient has normal hearing in the other ear.  
    o The pure tone average air-conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2, and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz). |
| Use of non-implanted bone-conduction (bone-anchored) hearing aids      | **A bone conduction hearing aid sound processor held against the skull with a softband or headband may be considered medically necessary in children under 5 years of age when the conductive or mixed hearing loss criteria (see above) is met, as an alternative to an air conduction hearing aid. The non-implanted use of the bone conduction sound processor may be used as a pre-surgical trial in children under 5 years of age. (See Benefit Application).** |

<table>
<thead>
<tr>
<th>Subject</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other uses of implanted bone-conduction/bone-anchored hearing aids</td>
<td>The use of implantable bone-conduction (bone-anchored) hearing aids is considered investigational when the criteria above are not met, including use in patients with bilateral sensorineural hearing loss.</td>
</tr>
</tbody>
</table>

**Patient Characteristics**

**Implanted bone-conduction (bone-anchored) hearing aid(s)**

Bone-anchored hearing solutions may also be known as osseointegrated hearing implants. Assessing patients prior to surgery for skull bone quality and thickness adequacy will help to ensure stability of the implanted abutment in the bone behind the ear. Additionally, patients (or caregivers) must be trained to properly clean the implanted and external components to prevent
Patient Characteristics

Infection and safeguard the skin integrity at the site where the sound processor attaches to the skull. Surgical implantation of the bone anchored hearing aid (BAHA®) device is not FDA approved for children younger than 5 years of age.

**Non-implanted use of a bone-conduction (bone-anchored) hearing aid(s)**

Unique clinical circumstances may justify individual consideration for wearing the bone-conduction sound processor on the surface of the skull with a headband or softband before 5 years of age. Consideration for each request for a non-implanted bone conduction device should be based on a clinical review of applicable medical records to verify the medical necessity criteria listed in this policy are met. (See Benefit Application).

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**Reasonable Useful Life Expectancy for BAHA Parts**

<table>
<thead>
<tr>
<th>Replacement Parts</th>
<th>Life Expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batteries</td>
<td>72 per 6 months</td>
</tr>
<tr>
<td>Headband</td>
<td>1 per year</td>
</tr>
<tr>
<td>Processor</td>
<td>1 per 5 years</td>
</tr>
</tbody>
</table>

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**Documentation Requirements**

The medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- The type of hearing loss for members who are 5 years old or older
- Any inner or outer ear conditions that prevent use of a conventional air-conductive hearing aid
- Result of audiologic test (hearing test) showing the level of hearing loss

**Note:** Cochlear implants, used for the treatment of severe to profound deafness are addressed in a separate medical policy. (See Related Policies)
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing in temporal bone</td>
</tr>
<tr>
<td>69714</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69715</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
<tr>
<td>69717</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69718</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
</tr>
<tr>
<td>L8691</td>
<td>Auditory osseointegrated device, external sound processor, replacement</td>
</tr>
</tbody>
</table>
| L8692  | Auditory osseointegrated device, external sound processor; used without osseointegration, body worn, includes headband or other means of external attachment  
Note: this code describes the non-implanted use of the bone conduction sound processor. |
| L8693  | Auditory osseointegrated device abutment, any length, replacement only                                                                                                                                       |
| L8694  | Auditory osseointegrated device, transducer/actuator, replacement only, each                                                                                                                                   |
| L8695  | External recharging system for battery (external) for use with implantable neurostimulator, replacement only                                                                                                  |

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Consideration of Age

The age stated in this policy for which implantable bone conduction hearing aids may be considered medically necessary is 5 years and older. This is based on the FDA approval. Surgical implantation of the BAHA® device is not FDA approved for children younger than 5 years of age. The age stated in this policy for which a sound processor worn on the skull may be considered medically necessary is age 5 and younger. This is based on the nonsurgical/transcutaneous application of the BAHA® processor using a headband or softband which received FDA approval for use in children under the age of 5 years.

Benefit Application

A bone-conduction (bone-anchored) hearing aid is a surgically implantable device used to treat a medical condition. The device and implantation surgery should be reimbursed under the medical benefit.

Benefit limitations regarding hearing aids may apply to these devices, specifically when the Implantable Bone-Conduction and Bone-Anchored Hearing Aid (BAHA®) device is used transcutaneously (on the surface of the skin of the head) held in place by a headband or softband and not implanted.

Evidence Review

Description

Sensorineural, conductive and mixed hearing loss may be treated with various devices, including conventional air-conduction (AC) or bone-conduction external hearing aids. AC hearing aids may not be suitable for patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. Bone-conduction hearing aids may be useful for individuals with conductive hearing loss, or (if used with contralateral routing of signal), for unilateral sensorineural hearing loss. Implantable, bone-anchored hearing aids (BAHAs) that use a percutaneous or transcutaneous connection to a sound processor have been investigated as alternatives to conventional bone-conduction hearing aids for patients with conductive or mixed hearing loss or for patient with unilateral single-sided sensorineural hearing loss.
In children under 5 years of age the transcutaneous use of the BAHA® has shown positive outcomes in small studies. The bone conduction-type hearing aid is held against the skin behind the ear, or at another bony location of the skull using a strap, headband or softband. The headband is soft plastic while the softband is soft elastic with a plastic disc-like snap connector either modeled or sewn into the band. A BAHA® sound processor is attached to the plastic connector and the band/headband is adjusted to the size of the individual's head and is secured with a Velcro® fastener (Velcro USA Inc., Manchester, NH) (see Appendix).

**Background**

**Hearing Loss**

Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB (decibel). The American Speech Language Hearing Association (ASLHA) has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (equal to or greater than 80 dB). PTA is calculated by averaging the hearing sensitivities (ie, the minimum volume that the patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25-8 kHz.

Sound amplification through the use of an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an AC hearing aid on the normal or less affected side.

**Bone-Conduction Hearing Devices**

External bone-conduction hearing devices function by transmitting sound waves through the bone to the ossicles of the middle ear. The external devices must be closely applied to the temporal bone, with either a steel spring over the top of the head or with the use of a spring-loaded arm on a pair of spectacles. These devices may be associated with either pressure headaches or soreness.

A bone-anchored implant system combines a vibrational transducer coupled directly to the skull via a percutaneous abutment that permanently protrudes through the skin from a small titanium implant anchored in the temporal bone. The system is based on osseointegration through which living tissue integrates with titanium in the implant over 3 to 6 months, conducting amplified
and processed sound via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing devices. Implantable bone-conduction hearing systems are primarily indicated for people with conductive or mixed sensorineural and conductive hearing loss. They may also be used with CROS as an alternative to an AC hearing aid for individuals with unilateral sensorineural hearing loss.

A bone conduction processor can also be used with a softband or headband. The sound processor is pressed against the head, usually behind the ear. With this application, there is no titanium peg implantation surgery. The amplified sound is transmitted transcutaneously to the cochlea using the skull bones, bypassing the outer and middle ear. In children under 5 years of age, this non-implanted use of the processor may be part of the trial period before surgery.

Partially implantable magnetic bone-conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to the bone-conduction hearing systems connected percutaneously via an abutment. With this technique, acoustic transmission occurs via magnetic coupling of the external sound processor and internally implanted device components. The bone-conduction hearing processor contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment to physically connect the external and internal components. To facilitate greater transmission of acoustics between magnets, skin thickness must be reduced to 4-5 mm over the implant when it is surgically placed.

**Summary of Evidence**

For individuals who have conductive or mixed hearing loss who receive an implantable bone-anchored hearing aid (BAHA) with a percutaneous abutment or a partially implantable BAHA with transcutaneous coupling to the sound processor, the evidence includes observational studies that report pre-post differences in hearing parameters after treatment with BAHAs. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified. Observational studies reporting on within-subjects changes in hearing have generally reported hearing improvements with the devices. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement can be attributed to the device. Studies of partially implantable BAHAs have similarly demonstrated within-subjects improvements in hearing. The single-arm studies have shown improvements in hearing in the device-aided state. No direct
comparisons other than within-individual comparisons with external hearing aids were identified, but, for individuals unable to wear an external hearing aid, there may be few alternative treatments. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable BAHA with the contralateral routing of signal, the evidence includes one randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 180 patients, generally have reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of signal. However, a well-conducted systematic review of studies comparing bone-anchored devices to hearing aids with contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT included in the systematic review was a pilot study enrolling only 10 patients and, therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1 below.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01858246</td>
<td>A Randomised Controlled Trial Comparing Bone Anchored Hearing Aid With Bonebridge</td>
<td>60</td>
<td>December 2017 ongoing</td>
</tr>
<tr>
<td>NCT02022085a</td>
<td>Post-market Clinical Follow-up of a Magnetic Bone Conduction Implant (Cochlear BAHA Attract System)</td>
<td>54</td>
<td>August 2017 ongoing</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

a Denotes industry-sponsored or cosponsored trial
Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty societies and 3 academic medical centers (one of which provided 4 responses and one of which provided 3 responses) while this policy was under review in 2016. Input focused on the categorization of partially implantable bone-anchored devices relative to fully implantable devices. There was a strong consensus that partially implantable devices are considered an evolution of earlier devices, and that direct trials comparing the two are not necessary.

Practice Guidelines and Position Statements

American Academy of Otolaryngology-Head and Neck Surgery

In 2016, The American Academy of Otolaryngology-Head and Neck Surgery updated its position statement on the use of implantable hearing devices. It states that the Academy "considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngologist-head and neck surgeon".

Medicare National Coverage

There is no national coverage determination. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage, including air-conduction and bone-conduction devices. However, devices producing the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be used. Along with cochlear and auditory brainstem implants, the benefits manual specifically refers to osseointegrated implants as prosthetic
devices. In 2014, Medicare clarified its hearing aid coverage to state that “certain auditory implants, including cochlear implants, brain stem implants, and osseointegrated implants, do not meet the definition of hearing aids that are excluded from coverage.”

**Regulatory Status**

There are 6 BAHA ® sound processors manufactured by Cochlear Americas (Englewood, CO), that have received 510(k) clearance for marketing from the U.S. Food and Drug Administration (FDA):

- BAHA 5
- BAHA® Cordelle II™
- BAHA® Divino™
- BAHA® Intenso™ (digital signal processing)
- BAHA® BP 100™
- BAHA® 4 (upgraded from the BP 100™)

The FDA cleared the BAHA® system for use in children aged 5 years and older and in adults for the following indications:

- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification
- Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally
- Patients with sensorineural deafness in 1 ear and normal hearing in the other (ie single-sided deafness, SSD)
- Patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who cannot or will not wear an AC CROS device

BAHA® sound processors can also be used with the BAHA® Softband™ without surgery. With this application, there is no implantation surgery. The sound processor is attached to the head using a hard or soft headband. The amplified sound is transmitted transcutaneously to the cochlea via the bones of the skull. In 2002, the Baha® Softband™ was cleared for marketing by FDA for use in children younger than 5 years.
Other implantable bone-conduction hearing systems that rely on an abutment and have similar indications as the Cochlear Americas’ BAHA devices include:

- **OBC Bone Anchored Hearing Aid System (Oticon Medical, Askim, Sweden).** Cleared in November 2008
- **The Ponto Bone Anchored Hearing System (Oticon Medical).** Cleared in September 2012
- **A next-generation Ponto Pro device can be used with either Oticon or BAHA implants**

The 2 partially implantable magnetic bone-conduction devices cleared by the FDA through the 510(k) process are:

- **Otomag® Bone Conduction Hearing System (Sophono, Inc., Boulder, CO, now owned by Medtronic, Minneapolis, MN)**
- **Cochlear BAHA® 4 Attract System (Cochlear Americas, Centennial, CO)**

The BoneBridge™ (MedEl, Innsbruck, Austria) is a partially-implantable bone-conduction implant that is considered an active transcutaneous device. It is cleared for marketing in Europe but is not FDA approved for use in the U.S.

In 2011, The SoundBite™ Hearing System (Sonitus Medical, San Mateo, CA) is an intraoral bone-conducting hearing prosthesis that consists of a behind-the-ear microphone and an in-the-mouth hearing device was cleared through the FDA’s 510(k) clearance process for similar indications as the BAHA. Since this system has no implanted components, it is not addressed in the current policy. As of January 2015, Sonitus Medical closed.

FDA product code (for bone-anchored hearing aid): LXB

FDA product code (for implanted bone-conduction hearing aid): MAH

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**References**


Appendix
Figure 1. Implant used of BAHA

Figure 1 source: http://emedicine.medscape.com/article/1604065-overview  Accessed April 2018

Figure 2. Transcutaneous use of BAHA with Softband

Figure 2 source: http://www.cochlear.com/wps/wcm/connect/uk/home/support/baha-system/connections/softband  Accessed April 2018

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/09/12</td>
<td>New policy. Policy includes statement about medical necessity criteria for use of BAHA with headband or softband for children less than 5 years of age; that was not addressed in the BC policy. A table of frequency of BAHA replacement parts is included in the benefit application section. This policy replaces 7.01.03.</td>
</tr>
<tr>
<td>03/08/13</td>
<td>Replace policy. Updated with literature review and references renumbered. Policy statements unchanged.</td>
</tr>
<tr>
<td>03/25/14</td>
<td>Replace policy. Added &quot;magnetic&quot; and &quot;BAHA Attract&quot; to last investigational policy statement. Clarified Benefit Application statement. Rationale updated with literature review through February 2014. Simplified Medicare National Coverage statement. References 3, 25, 34 added; others renumbered/removed. In appendix, revised figures 1-2, added source hyperlinks. Policy statement changed as noted. ICD-9 and ICD-10 codes removed from the policy; these are not utilized in adjudication and were informational only.</td>
</tr>
<tr>
<td>05/01/17</td>
<td>Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 23, 37, 53, 57, 59-61, and 69 added. Investigational statement for partially implantable devices is removed. Evaluating the BoneBridge implant as it is not currently cleared for marketing in the</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>USA.</td>
<td>USA.</td>
</tr>
<tr>
<td>10/24/17</td>
<td>Policy moved to new format; no change to policy statements.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through December 2017; no references added. Added HCPCS code L8694. Policy statement unchanged.</td>
</tr>
<tr>
<td>09/01/18</td>
<td>Minor update. Re-added Consideration of Age information; it was inadvertently removed in a previous update.</td>
</tr>
</tbody>
</table>

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  - 200 Independence Avenue SW, Room S909, HHH Building

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