Anthem

Clinical UM Guideline

Subject: Bone-Anchored and Bone Conduction Hearing Aids
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Description

This document addresses the use of bone-anchored and bone conduction hearing aids. These devices are proposed as an alternative to a conventional air conduction hearing aid in the treatment of moderate-to-severe hearing loss or to improve speech recognition in individuals with unilateral sensorineural hearing loss (also referred to as single-sided deafness). This document does not address audiology services, such as those relating to fitting and programming the bone-anchored (BAHA) device.

Note: Please see the following documents related to implants and hearing aids for the treatment of hearing loss:

- CG-DME-37 Air Conduction Hearing Aids
- CG-SURG-81 Cochlear Implants and Auditory Brainstem Implants
- SURG.00084 Implantable Middle Ear Hearing Aids

Note: Benefit language supersedes this document. Hearing aids are not a covered benefit under all member contracts/certificates. Please see the text in the footnote of this document regarding Federal and State mandates and contract language, as these requirements or documents may specifically address the topic of hearing aids.

Clinical Indications

Medically Necessary:

I. Bilateral Hearing Loss

The following devices are considered **medically necessary** *for the age groups specified* (criterion A) when the audiologic (criterion B) and medical condition (criterion C) criteria listed below have been met:

A. Devices:
   1. Fully- or partially-implantable bone conduction (bone-anchored) hearing aid, including as an alternative to an air conduction hearing aid for individuals 5 years of age or older*;* **or**
   2. A transcutaneously worn bone conduction hearing aid that is applied to the head with a headband or adhesive adapter, *regardless of age*;
      and

B. Audiologic criteria:
   1. For bilateral implants:
      Conductive or mixed (conductive and sensorineural) hearing loss with symmetric bone conduction threshold appropriate to the device used*; **or**
   2. For a unilateral implant:
      Conductive or mixed (conductive and sensorineural) hearing loss with pure tone average bone conduction threshold appropriate to the device used*;
      and

C. Medical condition criteria (must meet **at least one):**
   1. Congenital or surgically induced ear malformations of the external or middle ear canal (for example, atresia); **or**
   2. Severe chronic external otitis or otitis media; **or**
   3. Tumors of the external ear canal or tympanic cavity; **or**
   4. Dermatitis of the external ear canal, including reactions from ear molds used in air conduction hearing aids; **or**
   5. Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid.

*Please refer to the Discussion section of this document for a list of device-specific thresholds.

II. Unilateral Hearing Loss (Conductive, Mixed or Sensorineural)

A fully- or partially-implantable bone conduction (bone-anchored) hearing aid is considered **medically necessary** for individuals *5 years of age and older* with unilateral conductive, mixed or sensorineural hearing loss and normal hearing** in the other ear.

A transcutaneously worn hearing aid utilizing a headband or adhesive adapter is considered **medically necessary** *for individuals of any age* with unilateral conductive, mixed or sensorineural hearing loss and normal hearing** in the other ear.

**Normal hearing in the non-affected ear is defined as pure tone average air conduction threshold less than or equal to 20 decibels at 0.5, 1, 2, and 3 kilohertz.

III. Replacement Parts and Upgrades

Replacement parts or upgrades to existing bone conduction (bone-anchored) hearing aid components (for example, batteries, processor, headband or adhesive adapter) are considered **medically necessary** for individuals whose response to existing components is inadequate to the point of interfering with activities of daily living **or** when components are no longer functional and can't be repaired with return to normal function.

Not Medically Necessary:

The following are considered **not medically necessary** when the medically necessary criteria above have not been met:

A. Fully-implantable bone conduction (bone-anchored) hearing aids;
B. Partially-implantable bone conduction (bone-anchored) hearing aids;
C. Transcutaneously worn hearing aids applied to the head with a headband or adhesive adapter.

Replacement parts or upgrades to existing fully- or partially-implanted bone conduction (bone-anchored) or transcutaneously worn hearing aid components (for example, batteries, processor, headband, or adhesive adapter systems) are considered **not medically necessary** when:

A. The medically necessary criteria for replacement parts or upgrades specified above have not been met; **or**
B. When requested for convenience; **or**
C. To upgrade to newer technology when the current components remain functional.

An intraoral bone conduction hearing aid is considered **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Fully- or partially-implantable or transcutaneously worn bone conduction (bone-anchored) hearing aids:
When services may be Medically Necessary when criteria are met:

CPT

69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex

HCPCS

L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor; used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device, abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each
	For the following code **when specified as a bone conduction hearing aid using an adhesive adapter behind the ear**:
V5298	Hearing aid, not otherwise classified [when specified as a *bone conduction hearing aid using an adhesive adapter behind the ear*]

ICD-10 Procedure

09HD04Z-09HD44Z	Insertion of bone conduction hearing device into right inner ear [by approach; includes codes 09HD04Z, 09HD34Z, 09HD44Z]
09HE04Z-09HE44Z	Insertion of bone conduction hearing device into left inner ear [by approach; includes codes 09HE04Z, 09HE34Z, 09HE44Z]
09HD0SZ-09HD4SZ	Insertion of hearing device into right inner ear [by approach; includes codes 09HD0SZ, 09HD3SZ, 09HD4SZ]
09HE0SZ-09HE4SZ	Insertion of hearing device into left inner ear [by approach; includes codes 09HE0SZ, 09HE3SZ, 09HE4SZ]
0NH50SZ-0NH54SZ	Insertion of hearing device into right temporal bone [by approach; includes codes 0NH50SZ, 0NH53SZ, 0NH54SZ]
0NH60SZ-0NH64SZ	Insertion of hearing device into left temporal bone [by approach; includes codes 0NH60SZ, 0NH63SZ, 0NH64SZ]

ICD-10 Diagnosis

H60.311-H60.329	Diffuse/hemorrhagic otitis externa
H60.391-H60.93	Other infective otitis externa, cholesteatoma of external ear, noninfective otitis externa
H61.301-H61.399	Acquired stenosis of external ear canal
H65.20-H65.93	Chronic serous/mucoid/nonsuppurative otitis media
H66.10-H66.93	Chronic tubotympanic/atticoantral/other suppurative otitis media, otitis media unspecified
H71.00-H71.93	Cholesteatoma of middle ear
H72.00-H72.93	Perforation of tympanic membrane
H74.01- H74.93	Other disorders of middle ear mastoid
H90.0-H90.8	Conductive and sensorineural hearing loss
H90.A11-H90.A32	Conductive and sensorineural hearing loss with restricted hearing on the contralateral side
H91.01-H91.23	Ototoxic hearing loss, presbycusis, sudden idiopathic hearing loss
H91.8X1-H91.93	Other specified/unspecified hearing loss

Q16.0-Q16.9	Congenital malformations of ear causing impairment of hearing

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

Other bone conduction hearing aids:
When services are Not Medically Necessary:
When the code describes a procedure designated in the Clinical Indications section as not medically necessary.

HCPCS

	For the following code **when specified as an intraoral bone conduction hearing aid**:
V5298	Hearing aid, not otherwise classified [when specified as an*intraoral bone conduction hearing aid*]

ICD-10 Diagnosis

	All diagnoses

Discussion/General Information

Hearing loss is a common condition with effects that can range from minimal to profound functional impairment. The National Institute on Deafness and other Communication Disorders reported in 2020 that as many as 2 to 3 out of every 1000 children have loss of hearing in one or both ears detectable at birth. About 15% of American adults aged 18 or older report difficulty with hearing. The prevalence of hearing loss increases with age. Causes can be temporary such as infection or Eustachian tube blockage or permanent such as that caused by cochlear or auditory nerve damage. These causes are classified into three major groups: conductive, sensorineural, or mixed hearing loss.

Conductive hearing loss (CHL) is due to mechanical or physical blockage of sound transmission through the external and middle ear. This can occur as a result of excessive cerumen, ear infections, puncture of the eardrum, Eustachian tube dysfunction, tumors, exostoses, cholesteatoma, otosclerosis, or congenital defects, such as microtia (underdevelopment or absence of the outer ear) or atresia of the external auditory canal.

Damage to the auditory nerve is the basis of sensorineural or “nerve” hearing loss. This can result from prenatal exposure to viral infections such as CMV, hepatitis, HIV, rubella, syphilis, or toxoplasmosis. Auditory nerve damage can also be caused by trauma, exposure to loud noises, the use of certain drugs, fluid buildup in the middle ear, or tumors such as acoustic neuroma. Children with inherited sensorineural hearing loss often have normal-hearing parents with recessively-transmitted genes.

The term mixed hearing loss refers to conductive hearing loss coexisting with sensorineural hearing loss.

A person with normal hearing can perceive sounds in the 20 to 20,000 Hz frequency range. The range between 500 and 4000 Hz is most important for understanding speech. Hearing loss is objectively assessed by pure-tone audiometry. While in a sound-proof room, the subject is presented with a series of tones at different frequencies and at increasing decibel levels. Earphones are used to test air conduction hearing. A transducer is placed over bone to test bone conduction. The hearing threshold is defined as the lowest decibel level at which the subject perceives half of the presented tones. Thresholds typically differ at different frequencies. Thresholds lower than 20 dB indicate hearing in the normal range. Thresholds between 25 and 40 dB are considered to show moderate hearing loss.

Mechanical amplification using tapering tubes called ear trumpets has been used to assist people with hearing loss since the early 1800s. Invention of the telephone in the 1870s led to the development of electrically amplified hearing aids. Many improvements since then resulted in the current availability of a wide selection of available air conduction (AC) hearing aids.

For a variety of reasons, AC hearing aids are not suitable for many individuals. Such reasons include atresia of the ear canal, tumors or excessive bone growth occluding the ear canal or middle ear, chronic external or middle ear infections, or allergic responses to ear molds. Bone-conduction hearing aids may be an option for individuals with significant hearing loss who are unable to use an AC hearing aid.

Historically, bone conduction (BC) hearing aids needed to be closely applied to the temporal bone using a steel spring over the top of the head or a spring-loaded arm on a pair of eyeglasses. These hearing aids were often associated with pressure headaches or soreness. Implanted BC hearing aids, also known as bone-anchored hearing aids, avoid pressure-related problems while providing effective hearing assistance. Due to the thinness and expected rapid growth of the skull, bone-anchored hearing aids may not be appropriate for young children. Development of elastic headbands such as SoftBand and adhesive coupling systems such as ADHEAR has provided options for individuals who cannot use an AC hearing aid and for whom an implanted BC hearing aid is not appropriate.

The U.S. Food and Drug Administration (FDA) classifies bone-anchored hearing aids and bone conduction hearing aids as Class II devices: Hearing Aid, Bone Conduction with a Product Code of LXB and MAH. The FDA indicates that these hearing aids are substantially equivalent technology to AC hearing aids with digital sound processing. In December 2005, the Centers for Medicare and Medicaid Services (CMS) updated their benefit manual, clarifying coverage for specific hearing aid devices. CMS now considers bone-anchored hearing aids, referred to as osseointegrated implants, as prosthetic devices.

It is important to match the capabilities of the selected BC hearing aid to the audiologic thresholds characterizing the hearing loss to be addressed.

Manufacturer’s Recommended Hearing Loss Thresholds			
	Bilateral Use		Unilateral Use
Device	Between-ear difference max. @ 0.5, 1, 2, and 3 KHz	Between-ear difference max. @ individual frequency	Pure tone average BC threshold @ 1, 2, and 3 KHz
BAHA 4	10 dB	15 dB	≤ 45 dB
BAHA 5 Power	10 dB	15 dB	≤ 55 dB
BAHA Attract	10 dB	15 dB	≤ 45 dB
BAHA BP100	10 dB	15 dB	≤ 45 dB
BAHA Cordelle II	10 dB	15 dB	≤ 65 dB
BAHA Divino®	10 dB	15 dB	≤ 45 dB
BAHA Intenso™	10 dB	15 dB	≤ 55 dB

OBC	10 dB*	15 dB	≤ 45 dB
Ponto Plus Power	10 dB	15 dB	≤ 55 dB
Ponto Pro	10 dB*		
Ponto™ Plus	10 dB	15 dB	≤ 45 dB
Sophono® Alpha System	10 dB	15 dB	≤ 45 dB
	* also measured at 4 KHz		

In addition to assuring that the BC hearing aid is appropriate for the observed hearing loss thresholds, consideration should be given to the individual's psychological, physical, emotional and developmental capabilities for maintaining good hygiene of the skin adjacent to the implant abutment. For children and individuals with congenital malformations, sufficient bone volume and bone quality must be present for a successful fixture implantation.

Implantable Bone-Anchored Hearing Aid Systems

The BAHA® System

The BAHA (Cochlear Americas, Centennial, CO and Cochlear Limited Bone Anchored Solutions AB, Molnlycke, Sweden) is a bone-anchored, bone conduction hearing aid system cleared for use in children ages 5 years and older and in adults for the following indications:

- Individuals who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Individuals with bilaterally symmetric conductive or mixed hearing loss (may be implanted bilaterally);
- Individuals with sensorineural deafness in one ear and normal hearing in the other (single-sided deafness);
- Individuals who are candidates for an AC CROS (contralateral routing-of-signal) hearing aid but who cannot or will not wear an AC CROS hearing aid.

The BAHA processor is coupled to a titanium fixture (screw) protruding through the skin located in the upper mastoid region on the temporal bone where it has fused with the bone in a process called "osseointegration." The BAHA system bypasses the middle ear altogether, sending sound around the area, naturally stimulating the cochlea through bone conduction. The difference between the standard bone conduction hearing aid and the bone-anchored hearing aid is direct stimulation of the bone instead of stimulation through the skin.

Numerous BAHA sound processors have received FDA 510(k) clearance for use with the BAHA auditory osseointegrated implant system (K021837; K011438; K984162):

- BAHA Cordelle II (K080363)
- BAHA Divino (K042017)
- BAHA Intenso (K081606) (digital signal processing)
- BAHA BP100 (K090720)
- BAHA 4 (K132278) (upgrades from the BP100)
- BAHA 5 Power Sound Processor (K142907; K161123) (upgrade from the BP100).

BAHA for Moderate to Severe Conductive or Mixed Hearing Loss

The peer-reviewed medical literature contains numerous prospective and retrospective clinical trials that evaluate the safety and efficacy of the BAHA for moderate to severe conductive or mixed hearing loss. Participants in these studies usually received unilateral hearing aids (Granstrom, 1997 and 2001; Hakansson, 1990 and 1994, Snik, 1995 and 2001; Stenfelt, 2000; van der Pouw, 1998 and 1999; Dutt, 2002a; Dutt, 2002b; Dutt, 2002c; Dutt, 2002d; McDermott, 2002a; McDermott, 2002b; McLarnon, 2004). Results from each of the centers are reported in multiple articles with overlapping study populations. The authors suggest that the BAHA can provide significant improvements in functional gain, speech perception, and hearing ability in various listening situations. User satisfaction was also reported in self-assessed outcomes measurements including satisfaction with fit and comfort and with the quality and clarity of the sound. Follow-up in these studies varied widely, ranging from a few weeks or months to more than 20 years.

Kiringoda and colleagues (2013) performed a meta-analysis of 20 studies evaluating complications related to 2310 BAHA implants in 2134 adults and children. The quality of available studies was considered "poor" due to retrospective designs, lack of uniformity in methodology, and wide variation in sample sizes and duration of follow-up. Complications related to BAHA implants were mostly minor. Zero to 18% of implants failed osseointegration in adult and mixed population studies, while 0% to 14.3% failed osseointegration in pediatric population studies. Adult and mixed population studies reported revision surgery was required in 1.7% to 34.5% of cases, while pediatric population studies reported revision surgery was required in 0.0% to 44.4% of cases. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and from 0.0% to 25% in pediatric studies. The authors concluded the relative lack of large prospective studies limited a more thorough characterization of the complications and limitations associated with osseointegrated hearing aids.

Bilateral BAHA for Conductive Hearing Loss

The implantation of bilateral BAHA has been evaluated in several small studies (Dutt and colleagues, 2002b; Priwin and colleagues, 2004; Bosman and colleagues, 2003).

Priwin and colleagues (2007) evaluated whether fitting of bilateral BAHA in children with conductive bilateral hearing loss provided additional hearing benefits. The authors reported an additional BAHA in the children with bilateral hearing loss resulted in a tendency to have improved hearing in terms of better sound localization and speech recognition in noise.

Davids and colleagues (2007) retrospectively compared auditory and speech-language development in 20 children 5 years of age and younger fitted with the BAHA to a control group of older children (n=20). Traumatic fractures occurred more frequently in older children (control group) compared to younger children (five vs. two fractures, respectively). Three younger children required skin site revision. McDermott and colleagues (2008) reported on the role of the BAHA in 15 children (ages 2 to 15 years) with Down syndrome in a retrospective case analysis and postal survey of complication rates and quality of life outcomes. All of the children were using their BAHA after follow-up of 14 months. No fixtures were lost; skin problems were encountered in 3 children. All 15 children were reported as having improved social and physical functioning as a result of improved hearing.

The Health Technology Assessment Program (Colquitt, 2011) published a systematic review of 12 studies on the use of BAHAs for bilateral hearing impairment. No studies with control groups were identified for the review. Cohort pre-post studies and cross-sectional comparative studies demonstrated improvements in hearing with use of BAHAs over conventional bone conduction hearing aids or unaided hearing. Bilateral use of BAHAs improved hearing outcomes in some individuals over unilateral use, but the evidence was uncertain. Implant loss was noted to be between 6.1% and 19.4%. Improvements in hearing-specific quality of life with BAHAs were

found by a hearing-specific instrument, but not general quality of life measures. Overall, adverse events data was limited and the quality of the studies was low. The authors concluded, however, that based on the available evidence, BAHAs appear to be a reasonable treatment option for individuals with bilateral conductive or mixed nearing loss.

Janssen and colleagues (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent conductive hearing loss (CHL). Studies were included if subjects of any age had permanent bilateral CHL and bilateral implanted BAHAs. In most studies, comparisons between unilateral and bilateral BAHA were intra-subject. Subjects ranged in age from 5 to 83 years of age. Heterogeneity between studies precluded meta-analysis; therefore, the authors performed a qualitative review. Adverse events were not an outcome measure of any of the included studies. In general, bilateral BAHA was observed to provide additional objective and subjective benefit compared to unilateral BAHA in measures of improvement in tone thresholds associated with bilateral BAHA (range, 2 dB to 15 dB), improvement in speech recognition patterns (range, 4 dB to 5.4 dB), and improvement in word recognition scores (range, 1% to 8%).

Farnoosh and colleagues (2014) retrospectively compared BAHA placement with reconstruction of the external auditory canal for children and adolescents with congenital aural atresia or stenosis who were treated at a single institution from 1988 to 2011. A total of 68 children and adolescents were included, 49 who underwent external auditory canal reconstruction (EACR) and 19 who received a unilateral or bilateral BAHA. Groups differed significantly in terms of age, presence of bilateral atresia, and presence of an associated syndrome. Audiologic data were available for 41 participants. At short-term (< 6 months postsurgery) follow-up, the BAHA group had larger hearing gains on AC than the EACR group (44.3 dB vs. 20.0 dB; $p<0.001$); similarly, the BAHA group had larger hearing gains at long term (> 1 year postsurgery) follow-up (44.5 dB vs. 15.3 dB; $p<0.001$). Quality of life scores and requirements for revision surgery did not differ significantly between the groups.

Amonoo-Kuefi and colleagues (2015) reported outcomes from a single-center, prospectively maintained New Zealand database of 24 children (26 ears/26 implants) younger than 5 years of age implanted with a BAHA via a two-stage surgical approach. Most children (52%) were implanted for isolated microtia or Goldenhaar syndrome (16%). 13 children (54%, 14 implants) had grade 2 or grade 3 local reactions (that is, redness, moistness, and/or granulation tissue) and 7 children (29%, 8 implants) had grade 4 local reactions (extensive soft-tissue reactions), the latter group requiring removal of the abutment. Quality of life scores were reported by 18 caregivers using the Glasgow Children's Benefit Inventory (GCBI) (scoring range, -100 to 100), with a final mean score change of + 40 points. The average performance of the BAHA fell within the range of normal auditory perception in noisy and quiet environments.

Different surgical techniques for implanting BAHAs and specific BAHA designs have yielded improved safety outcomes across all age groups. Safety and adverse effects outcomes after BAHA placement are reported in observational cohort studies ranging in size from 47 to 974 participants (Calvo Bodnia, 2014; den Besten 2015; Larsson, 2015; Nelissen, 2014; Rebol, 2015). Across these studies, implant loss ranged from 4% to 18%.

BAHA for Unilateral Sensorineural Hearing Loss

The BAHA system was cleared by the FDA in 2002 for use in individuals with unilateral sensorineural hearing loss. The BAHA system is intended to improve speech recognition in these individuals with single-sided deafness (SSD) and normal hearing in the other ear. Baguley and colleagues (2006) reviewed the evidence for use of a BAHA in adults with acquired unilateral sensorineural hearing loss. None of the four controlled trials in this meta-analysis reported a significant improvement in auditory localization with the BAHA (Bosman, 2003; Hol, 2004; Niparko, 2003; Wazen, 2003). However, speech discrimination in noise and subjective measures improved with these aids; for these parameters, use of the BAHA resulted in greater improvement than that obtained with the CROS systems. Baguley and colleagues (2006) noted a number of limitations in these studies including bias in terms of participant selection (two studies); all four studies were underpowered, and there was double reporting of study participant outcomes.

Additional case series with sample sizes ranging from 9 to 145 participants have reported outcomes after BAHA implantation for unilateral sensorineural hearing loss (Lin, 2016; Morini, 2015; Pai, 2012). Overall, these studies report improvements in user-reported speech quality, speech perception in noise, and satisfaction with the device.

To date, the BAHA system has not received FDA 510(k) clearance for use in individuals with bilateral sensorineural hearing loss.

Transcutaneously Worn, Non-Surgical Application of an Implantable BAHA with Headband or Softband

The Softband (or headband) for BAHA received FDA 510(k) clearance in October 2000 as substantially equivalent to devices already on the market. The Softband is a transcutaneous, non-surgical application of the hearing aid part of a bone-anchored hearing aid. It is intended for use in individuals who meet criteria for moderate to severe mixed bone conductive hearing loss or SSD. The BAHA with Softband has been suggested as a temporary solution for use in younger children until the strength and thickness of the bone of the skull behind the ear allows for surgical implantation of the titanium abutment.

The Softband consists of an elastic band with a plastic disc-like snap connector sewn into the band. A BAHA sound processor is attached to the plastic connector. The band is then adjusted to the size of the individual's head and secured with a hook-and-loop fastener. The sound processor is held against the skin through pressure from the band.

The manufacturer of the BAHA system cautions against use of the Softband during the titanium implant/fixture healing process. The sound processor must not be placed on top of the abutment/implant as it may jeopardize osseointegration. In addition, the Softband contains natural rubber latex that may cause an allergic reaction in some individuals.

In May 2010, the Otomag Bone Conduction Hearing System (Sophono, Inc., Boulder, CO; now owned by Medtronic, Minneapolis, MN) received FDA 510(k) clearance (K100193) as a bone conduction hearing aid. The FDA determined the system was substantially equivalent to predicate devices that use a headband or Softband such as the Oticon Medical Ponto Pro Bone Anchored Sound Processor (K090996) and the BAHA BP100 Sound Processor (K090720). The Otomag System includes the Otomag Alpha 1 (S) Sound Processor (K102199) which is attached magnetically to a headband or Softband. The Otomag Alpha 1 (S) Sound Processor with headband or Softband is intended for use in individuals with conductive or mixed hearing losses, bilateral fitting, and SSD. The approval does not have a minimum age. For bilateral CHL, the BAHA with Softband has been suggested to provide an average of 40.5 dB functional gain across the speech spectrum.

A number of small retrospective case series, comparative studies, and review publications suggest that infants and children under 5 years of age with bilateral congenital aural atresia may benefit from an externally worn BAHA prior to BAHA implantation (Dun, 2010; Priwin, 2007; Zarowski, 2011; Hol, 2005; Verhagen, 2008). The studies have reported the improvements in the mean aided hearing threshold of the children with the BAHA with Softband compared to the reference group.

Ramakrishnan and colleagues (2011) used the Glasgow Benefit Inventory (GBI) and Listening Situation Questionnaire to report quality of life findings in a retrospective cross-sectional survey administered to parents of 22 children. Overall, parents reported short-term satisfaction in the mean GBI scores for the children after 3 months of implanted BAHA or externally worn BAHA with Softband use. Despite the heterogeneous etiology of children in the study population, the authors suggest that:

> The utility of BAHAs for children with syndromes and craniofacial anomalies is poorly recognized, resulting in delays in aid fitting and therefore in early hearing rehabilitation...In such cases, surgical reconstruction of the ear canal and middle-ear defects is not only technically challenging but also plagued by poor results (with a high rate of ear canal restenosis and limited functional hearing benefit). Hence, alternative treatment options such as Softband and BAHA may be of considerable benefit (Christensen, 2010).

Nicholson and colleagues (2011) retrospectively reviewed cases of 25 children, ages 6 months to 18 years with craniofacial disorders and bilateral CHL, who were consistent full-time, externally worn, unilateral BAHA with Softband users as a prerequisite to surgical implantation. The investigators concluded use of the BAHA with Softband provided audibility of the speech spectrum for infants and children with bilateral congenital CHL

In summary, while there are no published, randomized controlled trials comparing the efficacy of an externally worn BAHA with Softband to an implantable BAHA in measurements of directional hearing, sound localization, and speech recognition in noise, this device may be clinically appropriate for individuals under age 5 who are not yet considered appropriate candidates for a surgically implanted device, in particular infants and children with bilateral congenital aural atresia who cannot be fitted for standard acoustic hearing aids placed in the ear canal.

Other Bone-Anchored Hearing Systems

The FDA has provided 510(k) clearance for the following implants and BC sound processors:

- OBC Bone Anchored Hearing Aid System (Oticon Medical AB; Oticon Medical, LLC, USA, Somerset, NJ);
- OBC Ponto Bone Anchored Hearing Implant System (K112053) intended for use with the Ponto, Ponto Pro, or Ponto Pro Power sound processors;
- Ponto Plus and Ponto Plus Power (K132775) sound processor systems for use in mixed hearing loss, bilateral fitting, and SSD. The Ponto Pro, Ponto Plus, and Ponto Plus Power sound processor can be used with either the Ponto Implant System or with specific compatible BAHA (Cochlear Americas) abutments/implant systems.

Partially Implantable Magnetic Bone Conduction Hearing Aids

Partially implantable magnetic bone conduction hearing systems are available as an alternative to a bone-anchored hearing system that is connected percutaneously via an abutment. These systems use a magnet implanted into bone to connect across healed skin to a magnet attached to the sound processors. Devices in this category that have received 510(k) clearance from the FDA include:

- Otomag Bone Conduction/Magnetic Implant System (Otomag GmbH, Medtronic, Minneapolis, MN) (K102199);
- BAHA Attract System (Cochlear Americas, Centennial, CO) (K131240);
- Bonebridge™ (MED-EL, Innsbruck, Austria).

The body of evidence in the peer-reviewed published medical literature evaluating implantable magnetic bone conduction hearing aids for individuals with conductive or mixed hearing loss includes, but is not limited to, prospective studies evaluating different transcutaneous systems (Briggs, 2015; Denoyelle, 2015), nonrandomized comparative studies (Hol, 2013; Iseri, 2014; Iseri, 2015), a systematic review (Dimitriadis, 2016), and retrospective observational case series (Baker, 2015; Centric, 2014; Powell, 2015; Siegert, 2011; Siegert and Kanderske, 2013) involving small sample populations with short-term follow-up. Pertinent outcomes include evaluations of functional status, quality of life, and treatment-related morbidity. Most studies compare hearing thresholds with and without a partially implantable hearing system. These single-arm studies have shown improvements in hearing in the device-aided condition. Authors have noted that individuals unable to wear an external hearing aid may have few alternative treatments available to them.

The available evidence, along with the views of relevant medical specialists practicing in otolaryngology and neurotology, suggest that a partially implantable magnetic bone conduction hearing aid is associated with improvements in hearing similar to that of a fully implantable bone conduction (bone-anchored) hearing aid. Results have demonstrated clinical effectiveness in producing meaningful improvements in select individuals with conductive or mixed (conductive and sensorineural) hearing loss.

Intraoral Bone Conduction Hearing Aid

In January 2011, the SoundBite™ Hearing System (Sonitus Medical, Inc., San Mateo, CA), a non-surgically implanted intraoral bone conduction hearing aid, received FDA 510(k) clearance (K100649) for use in individuals 18 years or older who have moderately severe, severe, or profound sensorineural hearing loss in one ear and normal hearing in the other ear (that is, SSD). The system consists of two main components: a behind-the-ear device which contains the receiver, a wireless transmitter and microphone; and a removable, custom-fit in-the-mouth oral retainer-like hearing device. Accessories include a system charger and programming software. According to the manufacturer, the behind-the-ear device uses a digital signal processor to process the sound and a wireless chip to transmit the signals to the hearing device worn in the mouth. The in-the-mouth hearing device in turn creates imperceptible vibrations using a piezoelectric actuator that are sent via the teeth through the skull bones, and ultimately to the cochlea.

Evidence in the peer-reviewed medical literature is limited in comparisons of the SoundBite Hearing System to other currently available bone-anchored or bone conduction hearing aids (Murray, 2011a, 2011b; Gurgel and Shelton, 2013; Gurgel, 2015). Limitations in these studies include small sample sizes, short follow-up periods, and lack of appropriate control or comparator groups.

As of January 1, 2015, Sonitus Medical, Inc. informed consumers they had ceased operations and were no longer manufacturing the Soundbite Hearing System. To date, no new information is available concerning production of this oral hearing aid by another company.

Adhesive Bone Conduction Hearing Aid

On April 27, 2018 the FDA cleared the ADHEAR system (MED-EL, Durham, NC) through their 510K process. The ADHEAR system is a non-implantable bone conduction hearing device that is attached to the individual's head behind the ear with adhesive or with a headband. The ADHEAR system is intended to treat individuals of all ages with CHL or SSD via bone conduction.

In 2019, Dahm and colleagues reported results for a prospective, randomized cross-over trial that involved 13 subjects with CHL aged between 12 and 63 years. Subjects were assigned to use either a conventional bone conduction device or a non-invasive bone conduction device for a period of 2 weeks followed by a battery of tests. Subjects were then instructed to use the opposite device for an additional 2 weeks, followed by the same set of tests. The authors reported no statistically significant differences between groups with regard to sound field audiometry, Freiburg monosyllables word tests, or Oldenburg sentence tests. Ten subjects reported pain using the conventional device and two subjects reported skin irritations using the adhesive device.

A study by Favoreel and colleagues in 2020 evaluated the audiological benefit of the ADHEAR system in a group of children with

unilateral or bilateral CHL during a short-term exposure of 3 weeks compared to a conventional bone conduction hearing aid using a softband. The study used a prospective design with repeated measures in which each subject served as his or her own control. Ten children (4-17 y/o) were included in this study. Pure tone audiometry and speech audiometry in quiet, both unaided and aided, were performed initially with the ADHEAR system and a conventional bone conduction hearing aid with a softband, and after 3 weeks with the ADHEAR alone. Satisfaction and quality of life were assessed using the SSQ12 and the ADHEAR questionnaire. The mean unaided free field hearing threshold of 50 dB HL (with 95% CI between 41.7 and 57.5 dB HL) expressed in Bureau International d'Audiophonologie' (BIAP), improved significantly by 22 dB (13.0-29.9) with the ADHEAR and by 23 dB (13.6-32.9) with the conventional hearing aid ($p<0.001$). The mean unaided speech recognition threshold (SRT) in quiet improved significantly by 19 dB (10.3-28.1) with the ADHEAR and by 21 dB (12.6-29.4) with the conventional bone conduction hearing aid ($p<0.001$). For both audiological tests, there were no significant differences between groups, and after 3 weeks of use, the mean pure tone threshold of 28 dB HL (20.0-36.5) and the mean SRT of 47 dB SPL (41.9-51.5) with the ADHEAR system were comparable and not significantly different than the outcomes during the first visit. Speech understanding in noise and in multiple streams, sound localization and sound quality were rated significantly better with the ADHEAR, compared to the ratings without the ADHEAR system ($p<0.001$). None of the children reported skin irritations or pain. The authors concluded that the children included in this study had significantly improved hearing thresholds, speech perception in quiet and quality of life with the ADHEAR and that the device can be an effective treatment method and a valuable alternative to conventional bone conduction hearing aids for children with a CHL, although the subjective experience of each child has to be taken into account (Favoreel, 2020).

In 2019, Skarzynski and colleagues conducted a prospective comparative study of the ADHEAR system to that of a passive bone conduction implant and a bone conduction device using a softband in 3 situations: unaided, with conventional bone conduction hearing aids (passive implant or on softband), and with the ADHEAR. Ten subjects with CHL were evaluated with the ADHEAR, 5 of these were users of a passive bone conduction implant (Baha Attract with Baha4) and 5 received a Baha4 on a softband for test purposes at a tertiary referral center. Results showed that users of the passive bone conduction implant received comparable hearing benefit with the ADHEAR. The mean aided thresholds in sound field measurements and speech understanding in quiet and noise were similar, when subjects were evaluated either with the ADHEAR or the passive bone conduction implant. The audiological outcomes for the non-implanted group were also comparable between the ADHEAR and the bone conduction hearing device using the softband. The authors concluded that the ADHEAR system seemed to be a suitable alternative for individuals with CHL but who cannot or do not want to undergo surgery for a passive bone conduction implant (Skarzynski, 2019).

Neumann (2019) reported results of a small case series involving 10 subjects with unilateral or bilateral, permanent, stable, CHL aged between 0.7 and 9.7 years who used a conventional non-invasive bone conduction device integrated in softbands (BCDS) and the new non-surgical hearing system (ADHEAR) that consists of an audio processor connected to an adhesive adapter fixed behind the ear. They reported that functional gains in hearing frequencies between 0.5 and 4 kHz were statistically higher with the ADHEAR device than during use of conventional BCDS devices (35.6 dB ± 15.1 vs. 29.9 dB ± 14.6; $p=0.001$, $n=9$). Speech perception in quiet and noise improved similarly in the aided situation for both groups, and 8 children continued using the ADHEAR after the study; 1 received an active middle ear implant and 1 continued to use a BCDS.

Urik (2019) reported a first experience trial of the ADHEAR device involving 17 subjects aged between 3 months and 10 years with unilateral CHL (n=5), bilateral CHL (n=6) or unilateral sensorineural hearing loss (n=6). Subjects were tested at baseline and after 8 weeks of device use. The analysis showed the average value of hearing threshold in sound field in the group of children with CHL supported 20.23 (± 16.84) dB HL with the device and 33.52 (± 27.27) dB HL for those not using the ADHEAR device, which is a statistically significant gain ($p=0.008$). The average value of speech audiometry was 23.45 (± 14.45) dB HL with the ADHEAR device and 37.27 (± 26.65) dB HL without the device, which is a statistically significant gain ($p=0.012$). The average value of speech audiometry with bubble noise was 30.55 (± 10.03) dB HL with the ADHEAR device and 45.45 (± 18.41) dB HL without the device, which is a statistically significant gain ($p=0.008$). The authors concluded that children with sensorineural hearing loss were reported to be significantly improved with use of the ADHEAR device vs. when unaided ($p=0.027$). There were no reports of referred pain or irritation.

Additional small studies of audiological benefit and subjective satisfaction with the ADHEAR hearing system for children with unilateral CHL yielded favorable results especially for children who are not eligible for semi-implantable hearing systems or who do not accept hearing devices on a softband (Gawliczek, 2018; Hirth, 2020).

Adhesive bone conduction devices such as the ADHEAR system appear to achieve results comparable to results obtained with other bone conduction hearing aids for adults and children with CHL or SSD.

Other Considerations

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2016) issued a position statement on bone conduction hearing devices which was reiterated in 2021 as follows:

> The American Academy of Otolaryngology-Head and Neck Surgery considers bone conduction hearing devices (BCHD) as appropriate, and in some cases preferred, for the treatment of conductive and mixed hearing loss. BCHD may also be indicated in select patients with single-sided deafness. BCHD include semi-implantable bone conduction devices utilizing either a percutaneous or transcutaneous attachment, as well as bone conduction oral appliances and scalp-worn devices. The recommendation for BCHD should be determined by a qualified otolaryngology-head and neck surgeon. Use of these devices, which have been Food and Drug Administration (FDA) approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and other similar regulatory agencies in countries other than the United States.

The AAO-HNS statement does not cite any new evidence from the peer-reviewed medical literature in support of this recommendation.

Definitions

Asymmetric hearing loss (AHL): A condition in which hearing in the better ear is not normal but can be restored using a conventional hearing aid (pure-tone average [PTA] between 30 dB HL and 55–60 dB HL).

Conductive hearing loss (CHL): Hearing loss that occurs when sound is conducted inefficiently through the outer ear canal to the eardrum and the small bones (ossicles) of the middle ear; this disorder involves a reduction in sound level or the ability to hear faint sounds.

Congenital aural atresia (CAA): A rare spectrum of congenital deformities present at birth that involve some degree of failure of the development of the external auditory canal; it is commonly accompanied by abnormalities of both the middle ear bones in various degrees, as well as the external ear, including microtia (small ear) or incomplete development of the auricle (the outer projecting portion of the ear).

CROS (contralateral routing-of-signal [CROS]) hearing aid: A type of hearing aid used by individuals with single-sided deafness (SSD). A CROS hearing aid transmits sound presented to the ear with hearing loss to the contralateral ear in order to provide two-sided sound perception.

Decibel (dB): A unit of measurement indicating the loudness of sound. The intensity relates to how loud or soft a sound is. Sound scales are based on either sound pressure level (dB SPL) or hearing level (dB HL).

Degree of hearing loss: According to the American Speech-Language-Hearing Association (ASHA, 2018) (Clark, 1981), the degree of hearing loss refers to the severity of an individual's hearing loss range in decibels (dB):

Classification of Hearing Loss	**Hearing Threshold**
Normal hearing	0 to 20 dB
Mild	21 to 40 dB hearing loss
Moderate	41 to 55 dB hearing loss
Moderately-severe	56 to 70 dB hearing loss
Severe	71 to 90 dB hearing loss
Profound	91 dB or more hearing loss

Hearing in Noise Test (HINT): A commonly used speech recognition test consisting of 250 sentences (25 lists of 10 sentences per list) performed in the evaluation of an individual's ability to hear speech in quiet and in noise in the context of sentences.

Hearing loss: Any degree of impairment of the ability to detect and discriminate/apprehend sound.

Hertz (Hz): A unit of frequency equivalent to 1 cycle per second. Frequency of pitch is measured in Hz. Frequencies of 250-8000 Hz are typically used in audiometric testing because this range represents most of the speech spectrum.

Kilohertz (kHz): A measure of frequency equivalent to 1000 cycles per second.

Mixed hearing loss: Hearing loss that is both conductive and sensorineural, occurring in one or both ears. This term refers to a condition where conductive hearing loss coexists with sensorineural hearing loss.

Otitis externa: Inflammation or infection of the ear canal.

Pure-tone average (PTA): The average of hearing sensitivity (that is, the minimum volume that the person hears) calculated at multiple frequencies (perceived by pitch), typically within the range of 0.25 to 8 kHz (kilohertz).

Pure tone threshold audiometry: The measurement of an individual's hearing sensitivity for calibrated pure tones; includes manual air-conduction measurements at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz (125 Hz under some circumstances) plus bone-conduction measurements at intervals from 250 Hz to 4000 Hz and at 3000 Hz as needed (ASHA, 2005). Pure tone thresholds (PTTs) are the faintest tones or softest sound (lowest intensity) a person can hear at least 50% of the time; PTT is measured in dB.

Sensorineural hearing loss: A permanent hearing loss related to the sensory or neural structures responsible for hearing that involves a reduction in sound level or ability to hear faint sounds; this disorder affects speech understanding or the ability to hear clearly; the involved structures include, but are not limited to, the cochlea and the acoustic nerve.

Single-sided deafness (SSD): Significant or total hearing loss in one ear; this disorder is sometimes referred to as unilateral sensorineural hearing loss. SSD is defined as a unilateral severe-to-profound deafness (PTA ≥ 70 dB HL), with a contralateral ear that has better, normal or near-normal hearing (PTA ≤ 30 dB HL). SSD may be a result of a congenital unilateral hearing loss, a sudden sensorineural hearing loss, significant head trauma affecting the ear(s), and surgery to treat acoustic neuroma or other tumors of the eighth cranial nerve.

Speech reception threshold: The intensity at which speech is recognized as meaningful symbols; in speech audiometry, it is the dB level at which 50% of spondee words (a bisyllabic word with equivalent stress on each syllable) can be repeated correctly by the subject.

Temporal bone: A bone located on the side of the head that is part of the skull.

Transcutaneous: Refers to a device or medication applied directly to unbroken skin.

Tympanic membrane: The membrane in the ear that vibrates to sound; referred to as the eardrum.

Unilateral hearing loss (UHL): Is generally defined as a condition in which an individual has non-functioning hearing in one ear, receives little or no clinical benefit from amplification in that ear, and has normal or near normal audiometric function in the contralateral ear. UHL includes single-sided deafness (SSD) and asymmetric hearing loss (AHL).

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Websites for Additional Information

1. American Speech-Language-Hearing Association (ASHA). Available at: http://www.asha.org. Accessed on May 15, 2023.

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ADHEAR

BAHA 4
BAHA 5 Power
BAHA Attract
BAHA BP100
BAHA BP110 Power
BAHA Cordelle II
BAHA Divino
BAHA Intenso
BAHA Bone-Anchored Hearing System
Bonebridge

Cochlear™ Osia® System
OBC Ponto Bone Anchored Hearing Implant System
Osia System, Osia 2 System
Otomag Bone Conduction Hearing System
Ponto Pro
Ponto Pro Power
Ponto Plus
Ponto Plus Power
Semi-implantable bone conduction hearing aids
SoundBite Hearing System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Description section specifying audiology services for the BAHA are not addressed. Updated References section. Updated Coding section diagnosis ranges and removed NOC code 69799 no longer applicable.
	12/28/2022	Updated Coding section with 01/01/2023 CPT changes; added 69729, 69730, and revised descriptors for 69716, 69717, 69719.
Revised	05/12/2022	MPTAC review. The criteria for unilateral hearing loss have been clarified to include conductive, mixed and sensorineural hearing loss. The MN criteria for replacement parts and upgrades have been clarified. The Discussion, Definitions and References sections were updated.
	12/29/2021	Updated Coding section with 01/01/2022 CPT changes; added 69716, 69719 effective 01/01/2022, revised descriptors for 69714, 69717 and removed 69715, 69718 deleted 12/31/2021, also added 69799 NOC code.
Revised	08/12/2021	MPTAC review. The stance on the ADHEAR device (adhesive adapter systems) has been changed to MN when criteria are met. Updated Coding, Discussion, Definitions and References sections.
Revised	02/11/2021	MPTAC review. Reorganized MN section and clarified formatting. Reorganized and clarified bilateral hearing loss MN statements. Clarified MN statements for transcutaneously-worn bone conduction hearing aid for both bilateral and unilateral hearing loss. Revised audiologic pure tone average bone conduction threshold criteria for unilateral implant for bilateral hearing loss. Moved device-specific threshold information to the Discussion section. Clarified unilateral hearing loss MN statements regarding transcutaneously worn and fully- or partially-implantable bone conduction hearing aids. Added NMN statement for when MN criteria have not been met. Clarified NMN statement regarding replacement parts or upgrades. Added new NMN statement addressing bone conduction hearing aids using an adhesive adapter. Updated Discussion, References, Websites, and Index sections. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. Updated References, Websites, and Index sections.
Reviewed	06/06/2019	MPTAC) review. The Discussion, References and Index sections were updated.

New	07/26/2018	MPTAC review. Initial document development. Moved content of SURG.00020 Bone-Anchored and Bone Conduction Hearing Aids to a new clinical utilization management guideline document with the same title.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.