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MEDICAL POLICY – 7.01.547

Implantable Bone-Conduction and Bone-Anchored Hearing Aids

BCBSA Ref. Policy:	7.01.03
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Last Revised:	April 8, 2024
Replaces:	7.01.03

RELATED MEDICAL POLICIES:

1.01.528	Hearing Aids (Excludes Implantable Devices)
7.01.83	Auditory Brainstem Implant
7.01.84	Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
7.01.586	Cochlear Implant

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

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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

Subject	Medical Necessity
Unilateral conductive or mixed hearing loss	**A unilateral, fully or partially implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction hearing aid in individuals 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 (e.g., 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 less than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device) or 65 dB (Cordele II device). (See **Table 1** for more information)
Bilateral conductive or mixed hearing loss	**Bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in individuals 5 years of age and older when all of the** above **criteria are met as well as 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) (See **Table 1** for more information)

Subject	Medical Necessity
	OR ○ Less than 15 dB at individual frequencies
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 an air-conduction contralateral routing of signal (CROS) hearing aid when the following criteria are met:** • The individual is 5 years of age or older • The individual has single-sided sensorineural deafness • The individual has normal hearing in the other ear. • The pure tone average air-conduction threshold of the normal ear should be less than or equal to 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 (transcutaneous) 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 as an alternative to an air conduction hearing aid in children under 5 years of age when the conductive or mixed hearing loss criteria (see above) are met. 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.** **The ADHEAR non-invasive bone conduction hearing device worn with a headband or adhesive adapter is considered medically necessary as an alternative to an air conduction hearing aid in children under 5 years of age with unilateral or bilateral conductive hearing loss, or single-sided sensorineural deafness when the following criteria are met:** • The pure tone average bone-conduction hearing threshold is less than 25 dB measured at 0.5, 1, 2, and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz) for unilateral or bilateral conductive hearing loss **OR** • The individual has single-sided sensorineural deafness with normal hearing in the other ear and the pure tone average air-conduction hearing threshold of the normal ear should be less than or equal to 20 dB measured at 0.5, 1, 2, and 3 kHz (same as 500, 1,000, 2,000, and 3,000 Hz).

Replacement Parts	Medical Necessity
Replacements parts and upgrades	**Replacement parts or upgrades to existing bone-conduction (bone-anchored) or transcutaneously worn hearing aid components (e.g., batteries, processor, headband, or adhesive adapter) are considered medically necessary for individuals whose response is inadequate or when components are no longer functional and can't be repaired.** **Replacement parts or upgrades to existing bone-conduction (bone-anchored) or transcutaneously hearing aid components (e.g., batteries, processor, headband, or adhesive adapter) are considered NOT medically necessary when:** • The above medically necessary criteria have not been met • The parts or upgrades are requested for the convenience of the individual • The request is for an upgrade to a newer technology when the current components remain functional **Note**: See **Reasonable Useful Life Expectancy for BAHA Parts** below

Subject	Investigational
Other uses of implanted bone-conduction/bone-anchored hearing aids	**Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in individuals with bilateral sensorineural hearing loss, are considered investigational.**

Reasonable Useful Life Expectancy for BAHA Parts

Replacement Parts	Life Expectancy
Batteries	72 per 6 months
Headband	1 per year
Processor	1 per 5 years

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 member who is 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**)

Coding

Code	Description
CPT	
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
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
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	

Code	Description
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, replacement
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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Conductive hearing loss occurs when sound is not conducted effectively through the outer ear canal and the small bones of the middle ear to the inner ear. This condition makes it hard to hear soft sounds. This type of hearing loss can generally be corrected medically or surgically.

Contralateral Routing-of-Signals (CROS) hearing aids capture sound from the ear with hearing loss and transmits it to the ear with better hearing. CROS hearing aids are used in individuals with single sided deafness to replicate the experience of natural hearing in both ears.

Decibel (dB) is a unit used to measure the intensity or loudness of a sound. (The degree of hearing loss is based on how loud sounds need to be for an individual to hear them. dB HL describes an individual's hearing loss in decibels).

Mixed hearing loss occurs when conductive hearing loss occurs in combination with a sensorineural hearing loss indicating there is damage in the outer or middle ear and in the inner ear (cochlea) or auditory nerve.

Pure-tone average (PTA) is the average of an individual's hearing level in each ear calculated at various frequencies (the pitch of the sound).

Sensorineural hearing loss occurs when there is damage to the sensitive hair cells inside the inner ear (cochlea), or to the auditory nerve. This type of hearing loss cannot be medically or surgically corrected and is the most common type of permanent hearing loss.

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

Table 1. 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

	Bilateral Use		Unilateral Use
Sophono Alpha System	10 dB	15 dB	≤ 45 dB

Note: * also measured at 4 KHz

Individual Characteristics

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

Bone-anchored hearing solutions may also be known as osseointegrated hearing implants. Assessing individuals 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, individuals (or caregivers) must be trained to properly clean the implanted and external components to prevent 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 (e.g., congenital malformation of the external ear canal, pinna, and middle ear structures) may require the use of a non-implantable bone conduction hearing aid when the use of an air-conduction hearing aid is not possible. These non-implantable bone-conduction or bone-anchored hearing aids are not surgically implanted; rather the sound processor is attached to the surface of the skull with a headband or softband and the amplified vibrational sound is transmitted transcutaneous to the bones of the skull for transmission to the cochlea. Children under 5 years of age may use this method until their temporal bone is mature enough for surgical implantation of a bone-anchored hearing aid.

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 prosthetic device used to produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve and therefore, treats a medical condition. The device and implantation surgery should be reimbursed under the medical benefit as these devices do not meet the definition of hearing aids that are excluded from coverage; this also includes the transcutaneous application of the BAHA processor using a headband or softband or the ADHEAR bone-conduction hearing device using a headband or adhesive adapter for use in children under the age of 5 years.

These hearing devices are referred to as Hearing Aid, Bone Conduction in US Food and Drug Administration (FDA) approval documentation. FDA review also indicates that these devices have substantially equivalent technology as air-conduction hearing aids with digital sound processing. In 2005, the Centers for Medicare & Medicaid Services began to consider these devices as prosthetics; however, in 2014, the Centers 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.

Evidence Review

Description

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction or bone-conduction external hearing aids. Air-conduction hearing aids may not be suitable for individuals 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 individuals with conductive or mixed hearing loss or for individuals 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 detects sound at or below 20 decibels (dB). The American Speech-Language Hearing Association has defined the degree of hearing loss based on pure-tone average detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (≥ 80 dB). Pure-tone average is calculated by averaging hearing sensitivities (i.e., the minimum volume that an individual hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25-8 kHz.

Sound amplification using an air-conduction (AC) hearing aid can provide benefit to individuals 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.

Treatment

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 applied close to the temporal bone, with either a steel spring over the top of the head or 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 three to six 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 aids. Implantable bone-conduction hearing systems are primarily indicated for people with conductive or mixed sensorineural or conductive hearing loss. These 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 until their temporal bone is mature enough for surgical implantation of a bone-anchored hearing aid.

Partially implantable magnetic bone-conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to bone-conduction hearing systems that connect to bone percutaneously via an abutment. With this technique, acoustic transmission occurs transcutaneously via magnetic coupling of the external sound processor and the 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. Because 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 have reported pre-post differences in hearing parameters after treatment with BAHAs. The 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 an 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 a randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. The relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 180 individuals, have generally reported improvements in individual-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of the signal. However, a well-conducted systematic review of studies comparing bone-anchored devices with hearing aids using 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 individuals and, therefore, does not provide definitive evidence. Quality RCTs on BAHA for unilateral sensorineural hearing loss are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in **Table 2** below.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05615649[a]	Expanded Indications in the Pediatric BONEBRIDGE Population	36	Jun 2025
NCT04427033[a]	The BCI 602 BONEBRIDGE Post-Market Clinical Follow-up Study	51	Dec 2024

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.

2016 Clinical Input

In response to requests, input was received from two specialty societies and three academic medical centers (one of which provided four responses and one of which provided three 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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology Head and Neck Surgery

In 2021, the American Academy of Otolaryngology Head and Neck Surgery updated its position statement on the use of implantable hearing devices.[77] It states that the Academy "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. These devices are approved by the Food and Drug Administration (FDA) for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and the respective regulatory agencies in countries other than the United States."

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.[78] 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."[79]

Regulatory Status

Several implantable bone-conduction hearing systems have been approved by the US Food and Drug Administration (FDA) for marketing through the 510(k) process (see **Table 3**).

Product codes: MAH, LXB

Table 3. Implantable Bone-Conduction Hearing Systems Approved by the US Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.
Baha 6 System	Cochlear Americas	Sept 2021	K212136
BA310 Abutment, BIA310 Implant/Abutment	Cochlear Americas	Dec 2018	K182116

Device	Manufacturer	Date Cleared	510(k) No.
Baha 5 Power Sound Processor	Cochlear Americas	May 2016	K161123
Baha 5 Super Power Sound Processor	Cochlear Americas	Mar 2016	K153245
Baha Divino	Cochlear Americas	Aug 2004	K042017
Baha Intenso (digital signal processing)	Cochlear Americas	Aug 2008	K081606
Baha 4 (upgraded from the BP100)	Cochlear Americas	Sep 2013	K132278
Baha 5 Sound Processor	Cochlear Americas	Mar 2015	K142907
Baha Attract System	Cochlear Americas	Nov 2013	K131240
Baha Cordelle II	Cochlear Americas	Jul 2015 Apr 2008	K150751 K080363
Cochlear Osia2 System	Cochlear Americas	Dec 2019	K191921
OBC Bone-Anchored Hearing Aid System	Oticon Medical	Nov 2011	K112053
Ponto Bone-Anchored Hearing System	Oticon Medical	Sep 2012	K121228
Ponto 5 SuperPower	Oticon Medical	Dec 2021	K213733
Ponto 4	Oticon Medical	May 2019	K190540
Ponto 3, Ponto 3 Power and Ponto 3 SuperPower	Oticon Medical	Sep 2016	K161671

The FDA cleared the majority of these systems for use in children ages 5 years and older and 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 (i.e., single-sided deafness);
- Patients who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS device.

Baha sound processors can be used with the Baha Softband. 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 the FDA for use in children younger than 5 years (K002913).

The most recently cleared Osia2 system may be used by adults and children 12 years of age and older with conductive hearing loss, mixed hearing loss, and single-sided sensorineural deafness.

The ADHEAR system received FDA premarket clearance (K172460) in 2018 as substantially equivalent to a predicate device. It is intended to treat individuals of all ages with conductive hearing loss or single-sided deafness via bone conduction. This system is a non-invasive bone conduction hearing device placed on the head with the use of an elastic headband or adhesive adapter that is placed behind the ear.

The FDA also cleared three partially implantable magnetic bone-conduction devices for marketing through the 510(k) process (see **Table 4**).

Table 4. Partially Implantable Magnetic Bone-Conduction Devices Approved by the US Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.
Bonebridge	MED-EL	Mar 2019	K183373
Otomag Bone-Conduction Hearing System	Medtronic (Formerly Sophono)	Nov 2013	K132189
Cochlear Baha 4 Sound Processor	Cochlear Americas	Oct 2012	K121317

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. In 2011, it was cleared for marketing by the FDA through the 510(k) process for indications similar to the Baha. However, the manufacturer, Sonitus Medical, closed in 2015. (See **Related Policies** 1.01.528 Hearing Aids (Excludes Implantable Devices)

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

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Appendix

Figure 1.

Implanted used of BAHA

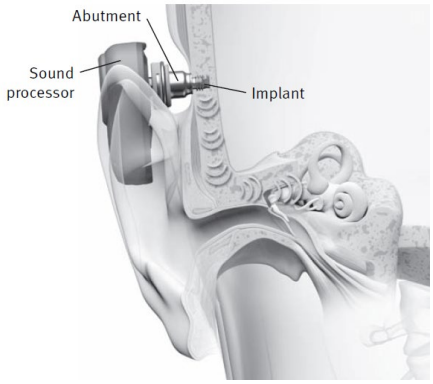

Figure 1 source: **http://emedicine.medscape.com/article/1604065-overview** Accessed Accessed March 13, 2024

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** (retired)

Figure 3.

ADHEAR Adhesive Bone Conduction System

Figure 3 source: **https://www.medel.com/en-us/hearing-solutions/bone-conduction-system** Accessed Accessed March 13, 2024.

History

Date	Comments
10/09/12	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.
03/08/13	Replace policy. Updated with literature review and references renumbered. Policy statements unchanged.
03/25/14	Replace policy. Added "magnetic" and "BAHA Attract" 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.
03/10/15	Annual Review. Policy updated with literature review through January, 2015. References 3-5, 19, 36-43, 46-55, 57, 59 added. Rationale section reorganized. Policy statements unchanged.
06/01/16	Annual Review, changes approved May 10, 2016. Policy updated with literature review, references added. Policy statements unchanged. Added code L8695.
05/01/17	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

Date	Comments
	USA.
10/24/17	Policy moved to new format; no change to policy statements.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through December 2017; no references added. Added HCPCS code L8694. Policy statement unchanged.
09/01/18	Minor update. Re-added Consideration of Age information; it was inadvertently removed in a previous update.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through December 2018; references 35 and 46 added. Minor edits for clarity; otherwise policy statements unchanged. Removed HCPCS code L8695. Added HCPCS code L8625.
05/01/20	Delete policy, approved April 14, 2020, effective May 1, 2020. This policy is replaced with 7.01.03. Removing criteria for transcutaneous BAHA with Softband and removing HCPCS Code L8692 in the new policy 7.01.03; this is effectively a policy renumber.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through January 10, 2021; references added. Policy statements unchanged.
01/01/22	Coding update, added new CPT codes 69716 & 69719.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through November 15, 2021; no references added. Policy statements unchanged.
02/01/23	Policy renumbered, approved January 10, 2023 from 7.01.03 to 7.01.547 and criteria re-instated for transcutaneous BAHA with Softband. References added. Added medical necessity criteria for the ADHEAR non-invasive bone conduction hearing device. Added medical necessity criteria for replacement parts and upgrades. Minor edits to policy statement language for greater clarity and ease of understanding; policy intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Removed terminated CPT codes 69715 & 69718. Updated description for CPT codes 69716, 69717, & 69719. Added new CPT code 69729 & 69730 and HCPCS L8692.
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through December 9, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
06/15/23	Updated Related Policies. 7.01.05 is replaced with 7.01.586 Cochlear Implant.
05/01/24	Annual Review, approved April 8, 2024. Policy updated with literature review through December 22, 2023; no references added. Policy statements unchanged.

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Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

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PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው: 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.

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