



BlueCross BlueShield  
of Alabama

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**Name of Blue Advantage Policy:**

**Implantable Bone Conduction and Bone-Anchored Hearing Aids  
(BAHA)**

Policy #: 145

Latest Review Date: February 2025

Category: Surgery

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**BACKGROUND:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational\*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
  - *Furnished in a setting appropriate to the patient's medical needs and condition;*
  - *Ordered and furnished by qualified personnel;*
  - *One that meets, but does not exceed, the patient's medical need; and*
  - *At least as beneficial as an existing and available medically appropriate alternative.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## **POLICY:**

**Blue Advantage** will treat **unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s)** as a **covered benefit** as an alternative to an air-conduction hearing aid in patients **five years of age and older** with a **conductive or mixed hearing loss** who also meet **at least one** of the following medical criteria:

- A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device), or 65 dB (Cordele II device); and **one of the following**:
  - 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.

For **bilateral implantation**, patients should **meet the above audiologic criteria and have a symmetrically conductive or mixed hearing loss** 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 (4 kHz for OBC and Ponto Pro), or less than 15 dB at individual frequencies.

**Blue Advantage** will treat an **implantable bone-conduction (bone-anchored) hearing aid** as a **covered benefit** as an **alternative to an air-conduction contralateral routing of signal hearing aid** in patients **5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear**. The pure tone average air conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2, and 3 kHz.

**Blue Advantage** will treat **other uses of implantable bone-conduction (bone-anchored) hearing aids**, including use in patients with bilateral sensorineural hearing loss, as a **non-covered benefit** and as **investigational**.

Non-osseointegrated hearing devices (e.g., BAHA Soft Band, SoundBite, Med-El Adhear) are not addressed in this medical policy since they are not osseointegrated. Please check benefit plan descriptions for hearing aid coverage.

Replacements for **lost** sound processors are non-covered. Members should contact the manufacturer for replacement under warranty or the manufacturer's replacement policy.

**Replacement or upgrade** of existing properly functioning durable medical equipment (including prosthetics), even if the warranty has expired is a **contract exclusion**.\*

\*Always check benefits for self-funded groups as it relates to contract exclusions.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue*

*Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## **DESCRIPTION OF PROCEDURE OR SERVICE:**

Sensorineural, conductive, and mixed hearing loss may be treated with a variety of devices, including conventional air-conduction (AC) 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 (BAHA) 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.

### **Hearing Loss**

Hearing loss is described as conductive, sensorineural, or mixed and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB (decibel). The American Speech-Language-Hearing Association 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 the hearing sensitivities (i.e., the minimum volume that the patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 to 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 air-conduction hearing aid on the normal or less affected side.

### **Treatment**

External bone-conduction hearing aids 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 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 the process of osseointegration through which living tissue integrates with titanium in the implant over 3 to 6 months, conducting amplified and processed sound via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing 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 with CROS for individuals with unilateral sensorineural hearing loss.

Partially implantable magnetic bone-conduction hearing system, 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 may be reduced to 4 to 5 mm over the implant when it is surgically placed.

## **KEY POINTS:**

The most recent literature update was performed through December 16, 2024.

### **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. 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. 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 patient-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.

**Practice Guidelines and Position Statements**

**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. 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.”

**U.S. Preventative Services Task Force Recommendations**

Not applicable.

**KEY WORDS:**

Bone conduction hearing aid, bone-anchored hearing aid (BAHA), implantable bone conduction hearing aid, air conduction hearing aid, single-sided deafness, and hearing aid, Otomag Sophono, partially implantable hearing aid, BAHA 4 Attract, BoneBridge™, BA310 Abutment, BIA 310 Implant/Abutment, Bonebridge, Baha 5 Super Power Sound Processor, Ponto 3, Ponto 4, OSIA bone conduction hearing system, Cochlear Osia, Cochlear™ Osia® 2 System, Osia OSI200 Implant, Baha 6

**APPROVED BY GOVERNING BODIES:**

Several implantable bone-conduction hearing systems have been approved by the US Food and Drug Administration for marketing through the 510(k) process (Table 1).

**Table 1. Implantable Bone-Conduction Hearing Systems Approved by the U.S Food and Drug Administration**

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

Baha 5 Power Sound Processor		May 2016	K161123
Baha 5 Super Power Sound Processor		Mar 2016	K153245
Baha® 5 Sound Processor		Mar 2015	K142907
Baha® Attract System		Nov 2013	K131240
Baha® Cordelle II		Jul 2015 Apr 2008	K150751 K080363
Baha Divino®		Aug 2004	K042017
Baha Intenso® (digital signal processing)		Aug 2008	K081606
Baha® 4 (upgraded from the BP100)		Sep 2013	K132278
Cochlear™ Osia™2 System		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		May 2019	K190540
Ponto 3, Ponto 3 Power and Ponto 3 SuperPower		Sep 2016	K161671

The FDA cleared these systems for use in children age 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 FDA for use in children younger than 5 years. Because this application has no implanted components, it is not addressed in this evidence review.

The FDA also cleared 3 partially implantable magnetic bone-conduction devices for marketing through the 510(k) process (Table 2) .

**Table 2. Partially Implantable Magnetic Bone-Conduction Devices Approved by the U.S Food and Drug Administration**

<b>Device</b>	<b>Manufacturer</b>	<b>Date Cleared</b>	<b>510(k) No.</b>
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 FDA through the 510(k) process for indications similar to the Baha. However, the manufacturer, Sonitus Medical, closed in 2015.

**BENEFIT APPLICATION:**

Coverage is subject to member’s specific benefits. Group-specific policy will supersede this policy when applicable.

**CURRENT CODING:**

**CPT codes:**

69710	Implantation or replacement of electromagnetic bone-conduction hearing device in temporal bone
69711	Removal or repair 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
69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, entire 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
69728	Removal, osseointegrated implant, skull; with attachment to external speech processor, outside the mastoid
69729	Implantation, osseointegrated implant, skull; with attachment to external speech processor, outside of the mastoid
69730	Replacement osseointegrated implant, skull; with attachment to external speech processor, outside the mastoid
92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes
92623	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure)
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour
92627	Each additional 15 minutes (list separately in addition to code for primary procedure)



**HCPCS Codes:**

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, excludes transducer/actuator, replacement only, each
L8693	Auditory osseointegrated device abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each

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## **POLICY HISTORY:**

Adopted for Blue Advantage, March 2005  
 Available for comment May 1-June 14, 2005  
 Medical Policy Group, April 2006

Available for comment May 5-June 20, 2006  
Medical Policy Group, August 2007  
Available for comment September 4-October 18, 2007  
Medical Policy Group, December 2007  
Available for comment January 1-February 15, 2008  
Medical Policy Group, April 2008  
Medical Policy Group, January 2010  
Medical Policy Group, December 2010  
Medical Policy Group, June 2012  
Available for comment June 26 through August 9, 2012  
Medical Policy Group, March 2013  
Medical Policy Group, August 2013  
Available for comment August 22 through October 5, 2013  
Medical Policy Group, May 2014  
Available for comment May 30 through July 13, 2014  
Medical Policy Group, June 2014  
Medical Policy Group, January 2015  
Medical Policy Group, March 2016  
Medical Policy Group, August 2016  
Medical Policy Group, September 2016  
Medical Policy Group, February 2017  
Medical Policy Group, December 2017  
Medical Policy Group, March 2018  
Medical Policy Group, March 2019  
Medical Policy Group, December 2019: Annual Coding Update  
Medical Policy Group, March 2020  
Medical Policy Group, March 2021  
Medical Policy Group, June 2021  
Medical Policy Group, December 2021: 2022 Annual Coding Update. Added CPT codes 69716 and 69719 to the Current coding section. Created Previous Coding section to include codes 69715 and 69718 which will be deleted as of 12/31/21. Revised CPT codes 69714 and 69717 to state: For 69714 “temporal bone” replaced with “skull”. “Cochlear stimulator” and “without mastoidectomy” also removed. For 69717 in addition to the changes to 69714, added that 69717 could be used for a revision in addition to a replacement.  
Medical Policy Group, February 2022  
Medical Policy Group, October 2022  
Medical Policy Group, November 2022: 2023 Annual Coding Update. Added CPT codes 69728, 69729, 69730 to Current Coding section. Revised CPT codes 69716, 69717, 69719, 69726, 69727.  
Medical Policy Group, February 2023  
Medical Policy Group, November 2023: 2024 Annual Coding Update. Added codes 92622 and 92623 to the Current Coding section.  
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.  
Medical Policy Group, March 2024

UM Committee, March 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.  
Medical Policy Group, February 2025

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*