

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

<b>CLINICAL BENEFIT</b>	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
<b>Effective date:</b>	<b>7/1/2026</b>

### POLICY

Unilateral or 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 with a conductive or mixed hearing loss who also meet at least **one** of the following medical criteria:

- 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** meet the following audiologic 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).

For bilateral implantation, individuals 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.

An implantable bone-conduction (bone-anchored) hearing aid may be considered **medically necessary** as an alternative to an air-conduction contralateral routing of signal hearing aid in individuals 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.

Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in members with bilateral sensorineural hearing loss, are considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

### POLICY GUIDELINES

In patients being considered for implantable bone-conduction (bone-anchored) hearing aid(s), skull bone quality and thickness should be assessed for adequacy to ensure implant stability. Additionally, individuals (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.

Degree of hearing loss per the American Speech-Language-Hearing Association (ASHA, 2018), the degree of hearing loss refers to the severity of an individual's hearing loss range in decibels (dB) seen in Table 1:

**Table 1**

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

### **Cross-References:**

**MP 1.023 Cochlear Implants**

**MP 1.130 Semi-Implantable and Fully Implantable Middle Ear Hearing Aid**

### PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

**FEP PPO** - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: [fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies](http://fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies).

### DESCRIPTION/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 degree of hearing loss based on pure-tone average detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (greater than or equal to 80 dB). Pure-tone average is calculated by averaging hearing sensitivities (i.e., the minimum volume that a patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 to 8 kHz.

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

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

### 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 pressure headaches or soreness.

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

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 may be reduced to 4 to 5 mm over the implant when it is surgically placed.

### REGULATORY STATUS

Several implantable bone-conduction hearing systems have been approved by the U.S. Food and Drug Administration for marketing through the 510(k) process (Table 2).

Product codes: MAH, LXB

**Table 2. Implantable Bone-Conduction Hearing Systems Approved by the FDA.**

<b>Device</b>	<b>Manufacturer</b>	<b>Date Cleared</b>	<b>510(k) No.</b>
Baha 6 System	Cochlear Americas	Sept 2021	K212136

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

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
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

FDA cleared the Baha system 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 3). Partially Implantable Magnetic Bone-Conduction Devices Approved by the FDA.

**Table 3. Partially Implantable Magnetic Bone-Conduction Devices Approved by the FDA**

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

<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.

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

### RATIONALE

#### SUMMARY OF EVIDENCE

For individuals who have conductive or mixed hearing loss who receive an implantable 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 an randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 180 patients, 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

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

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 patients 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.

### DEFINITIONS

**CONDUCTIVE HEARING LOSS** refers to a form of hearing loss when sounds cannot get through the outer and middle ear.

**HEARING AID** is any device that does not produce as its output an electrical signal that directly stimulates the auditory nerve. Examples of hearing aids are devices that produce air-conducted sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window. Devices such as cochlear implants, which produce as their output an electrical signal that directly stimulates the auditory nerve, are not considered to be hearing aids.

**MIXED HEARING LOSS** is when conductive and sensorineural hearing loss are both present.

**OSSICLE** refers to any small bone, especially one of the three bones of the ear.

**SENSORINEURAL HEARING LOSS** refers to a form of hearing loss in which sound is conducted normally through the external and middle ear but a defect in the inner ear or auditory nerve results in hearing loss. The loss is measured in decibels and may be described as mild, moderate, severe, or profound.

**SUBCUTANEOUS** refers to beneath the skin.

### DISCLAIMER

*Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.*

### CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

### Covered when medically necessary:

Procedure Codes								
69710	69711	69714	69716	69717	69719	69726	69727	69728
69729	69730	L8618	L8624	L8690	L8691	L8693	L8694	

ICD-10-CM Diagnosis Codes	Description
C30.1	Malignant neoplasm of middle ear
D23.21	Other benign neoplasm of skin of right ear and external auricular canal
D23.22	Other benign neoplasm of skin of left ear and external auricular canal
H60.60	Unspecified chronic otitis externa, unspecified ear
H60.61	Unspecified chronic otitis externa, right ear
H60.62	Unspecified chronic otitis externa, left ear
H60.63	Unspecified chronic otitis externa, bilateral
H61.301	Acquired stenosis of right external ear canal, unspecified
H61.302	Acquired stenosis of left external ear canal, unspecified
H61.303	Acquired stenosis of external ear canal, unspecified, bilateral
H61.309	Acquired stenosis of external ear canal, unspecified, unspecified ear
H61.311	Acquired stenosis of right external ear canal secondary to trauma
H61.312	Acquired stenosis of left external ear canal secondary to trauma
H61.313	Acquired stenosis of external ear canal secondary to trauma, bilateral
H61.319	Acquired stenosis of external ear canal secondary to trauma, unspecified ear
H61.321	Acquired stenosis of right external ear canal secondary to inflammation and infection
H61.322	Acquired stenosis of left external ear canal secondary to inflammation and infection
H61.323	Acquired stenosis of external ear canal secondary to inflammation and infection, bilateral
H61.329	Acquired stenosis of external ear canal secondary to inflammation and infection, unspecified ear
H61.391	Other acquired stenosis of right external ear canal
H61.392	Other acquired stenosis of left external ear canal
H61.393	Other acquired stenosis of external ear canal, bilateral
H61.399	Other acquired stenosis of external ear canal, unspecified ear
H65.20	Chronic serous otitis media, unspecified ear
H65.21	Chronic serous otitis media, right ear

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
H65.22	Chronic serous otitis media, left ear
H65.23	Chronic serous otitis media, bilateral
H65.30	Chronic mucoid otitis media, unspecified ear
H65.31	Chronic mucoid otitis media, right ear
H65.32	Chronic mucoid otitis media, left ear
H65.33	Chronic mucoid otitis media, bilateral
H65.411	Chronic allergic otitis media, right ear
H65.412	Chronic allergic otitis media, left ear
H65.413	Chronic allergic otitis media, bilateral
H65.419	Chronic allergic otitis media, unspecified ear
H65.491	Other chronic nonsuppurative otitis media, right ear
H65.492	Other chronic nonsuppurative otitis media, left ear
H65.493	Other chronic nonsuppurative otitis media, bilateral
H65.499	Other chronic nonsuppurative otitis media, unspecified ear
H66.11	Chronic tubotympanic suppurative otitis media, right ear
H66.12	Chronic tubotympanic suppurative otitis media, left ear
H66.13	Chronic tubotympanic suppurative otitis media, bilateral
H66.21	Chronic atticoantral suppurative otitis media, right ear
H66.22	Chronic atticoantral suppurative otitis media, left ear
H66.23	Chronic atticoantral suppurative otitis media, bilateral
H66.3X1	Other chronic suppurative otitis media, right ear
H66.3X2	Other chronic suppurative otitis media, left ear
H66.3X3	Other chronic suppurative otitis media, bilateral
H66.3X9	Other chronic suppurative otitis media, unspecified ear
H71.11	Cholesteatoma of tympanum, right ear
H71.12	Cholesteatoma of tympanum, left ear
H71.13	Cholesteatoma of tympanum, bilateral
H90.0	Conductive hearing loss, bilateral
H90.11	Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.12	Conductive hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
H90.71	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.72	Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.A11	Conductive hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A12	Conductive hearing loss, unilateral, left ear with restricted hearing on the contralateral side
H90.A31	Mixed conductive and sensorineural hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A32	Mixed conductive and sensorineural hearing loss, unilateral, left ear with restricted hearing on the contralateral side
L30.8	Other specified dermatitis
Q16.0	Congenital absence of (ear) auricle
Q16.1	Congenital absence, atresia, and stricture of auditory canal (external)
Q16.3	Congenital malformation of ear ossicles
Q16.4	Other congenital malformations of middle ear
Q17.8	Other specified congenital malformations of ear

## REFERENCES

1. Heath E, Dawoud MM, Stavarakas M, et al. The outcomes of bilateral bone conduction hearing devices (BCHD) implantation in the treatment of hearing loss: A systematic review. *Cochlear Implants Int.* Mar 2022; 23(2): 95-108. PMID 34852723
2. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. *Otolaryngol Head Neck Surg.* Sep 2012; 147(3): 412-22. PMID 22714424
3. Bosman AJ, Snik AF, van der Pouw CT, et al. Audiometric evaluation of bilaterally fitted bone-anchored hearing aids. *Audiology.* 2001; 40(3): 158-67. PMID 11465298
4. Priwin C, Stenfelt S, Granström G, et al. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. *Laryngoscope.* Jan 2004; 114(1): 77-84. PMID 14709999
5. Snik AF, Mylanus EA, Proops DW, et al. Consensus statements on the BAHA system: where do we stand at present?. *Ann Otol Rhinol Laryngol Suppl.* Dec 2005; 195: 2-12. PMID 16619473
6. Dun CA, de Wolf MJ, Mylanus EA, et al. Bilateral bone-anchored hearing aid application in children: the Nijmegen experience from 1996 to 2008. *Otol Neurotol.* Jun 2010; 31(4): 615-23. PMID 20393374

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

7. Ho EC, Monksfield P, Egan E, et al. Bilateral Bone-anchored Hearing Aid: impact on quality of life measured with the Glasgow Benefit Inventory. *Otol Neurotol.* Oct 2009; 30(7): 891-6. PMID 19692937
8. Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. *Otol Neurotol.* Jun 2015; 36(5): 834-41. PMID 25634465
9. Denoyelle F, Coudert C, Thierry B, et al. Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia. *Int J Pediatr Otorhinolaryngol.* Mar 2015; 79(3): 382-7. PMID 25617189
10. Gawęcki W, Gibasiewicz R, Marszał J, et al. The evaluation of a surgery and the short-term benefits of a new active bone conduction hearing implant - the Osia®. *Braz J Otorhinolaryngol.* 2022; 88(3): 289-295. PMID 32713797
11. Hol MK, Nelissen RC, Agterberg MJ, et al. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. *Otol Neurotol.* Aug 2013; 34(6): 1071-5. PMID 23598702
12. Nelissen RC, Agterberg MJ, Hol MK, et al. Three-year experience with the Sophono in children with congenital conductive unilateral hearing loss: tolerability, audiometry, and sound localization compared to a bone-anchored hearing aid. *Eur Arch Otorhinolaryngol.* Oct 2016; 273(10): 3149-56. PMID 26924741
13. Iseri M, Orhan KS, Tuncer U, et al. Transcutaneous Bone-anchored Hearing Aids Versus Percutaneous Ones: Multicenter Comparative Clinical Study. *Otol Neurotol.* Jun 2015; 36(5): 849-53. PMID 25730451
14. Gerdes T, Salcher RB, Schwab B, et al. Comparison of Audiological Results Between a Transcutaneous and a Percutaneous Bone Conduction Instrument in Conductive Hearing Loss. *Otol Neurotol.* Jul 2016; 37(6): 685-91. PMID 27093021
15. Kim Y, Choe G, Oh H, et al. A comparative study of audiological outcomes and compliance between the Osia system and other bone conduction hearing implants. *Eur Arch Otorhinolaryngol.* Nov 01 2022. PMID 36318324
16. Dimitriadis PA, Farr MR, Allam A, et al. Three year experience with the cochlear BAHA attract implant: a systematic review of the literature. *BMC Ear Nose Throat Disord.* 2016; 16: 12. PMID 27733813
17. Reddy-Kolanu R, Gan R, Marshall AH. A case series of a magnetic bone conduction hearing implant. *Ann R Coll Surg Engl.* Nov 2016; 98(8): 552-553. PMID 27490984
18. Siegert R. Partially implantable bone conduction hearing aids without a percutaneous abutment (Otomag): technique and preliminary clinical results. *Adv Otorhinolaryngol.* 2011; 71: 41-46. PMID 21389703
19. Powell HR, Rolfe AM, Birman CS. A Comparative Study of Audiologic Outcomes for Two Transcutaneous Bone-Anchored Hearing Devices. *Otol Neurotol.* Sep 2015; 36(9): 1525-31. PMID 26375976
20. O'Neil MB, Runge CL, Friedland DR, et al. Patient Outcomes in Magnet-Based Implantable Auditory Assist Devices. *JAMA Otolaryngol Head Neck Surg.* Jun 2014; 140(6): 513-20. PMID 24763485

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

21. Centric A, Chennupati SK. Abutment-free bone-anchored hearing devices in children: initial results and experience. *Int J Pediatr Otorhinolaryngol.* May 2014; 78(5): 875-8. PMID 24612554
22. Baker S, Centric A, Chennupati SK. Innovation in abutment-free bone-anchored hearing devices in children: Updated results and experience. *Int J Pediatr Otorhinolaryngol.* Oct 2015; 79(10): 1667-72. PMID 26279245
23. Marsella P, Scorpecci A, Vallarino MV, et al. Sophono in Pediatric Patients: The Experience of an Italian Tertiary Care Center. *Otolaryngol Head Neck Surg.* Aug 2014; 151(2): 328-32. PMID 24714216
24. Magliulo G, Turchetta R, Iannella G, et al. Sophono Alpha System and subtotal petrossectomy with external auditory canal blind sac closure. *Eur Arch Otorhinolaryngol.* Sep 2015; 272(9): 2183-90. PMID 24908070
25. Carnevale C, Morales-Olavarría C, Til-Pérez G, et al. Bonebridge® bone conduction implant. Hearing outcomes and quality of life in patients with conductive/mixed hearing loss. *Eur Arch Otorhinolaryngol.* Sep 05 2022. PMID 36063211
26. Cywka KB, Skarzynski PH, Krol B, et al. Evaluation of the Bonebridge BCI 602 active bone conductive implant in adults: efficacy and stability of audiological, surgical, and functional outcomes. *Eur Arch Otorhinolaryngol.* Jul 2022; 279(7): 3525-3534. PMID 35182185
27. Huber AM, Strauchmann B, Caversaccio MD, et al. Multicenter Results With an Active Transcutaneous Bone Conduction Implant in Patients With Single-sided Deafness. *Otol Neurotol.* Feb 01 2022; 43(2): 227-235. PMID 34816809
28. Hundertpfund J, Meyer JE, Ovari A. Long-term audiological benefit with an active transcutaneous bone-conduction device: a retrospective cohort analysis. *Eur Arch Otorhinolaryngol.* Jul 2022; 279(7): 3309-3326. PMID 34424382
29. Seiwerth I, Fröhlich L, Schilde S, et al. Clinical and functional results after implantation of the bonebridge, a semi-implantable, active transcutaneous bone conduction device, in children and adults. *Eur Arch Otorhinolaryngol.* Jan 2022; 279(1): 101-113. PMID 33674927
30. Šikolová S, Urík M, Hošnová D, et al. Two Bonebridge bone conduction hearing implant generations: audiological benefit and quality of hearing in children. *Eur Arch Otorhinolaryngol.* Jul 2022; 279(7): 3387-3398. PMID 34495351
31. Bravo-Torres S, Der-Mussa C, Fuentes-López E. Active transcutaneous bone conduction implant: audiological results in paediatric patients with bilateral microtia associated with external auditory canal atresia. *Int J Audiol.* Jan 2018; 57(1): 53-60. PMID 28857620
32. Schmerber S, Deguine O, Marx M, et al. Safety and effectiveness of the Bonebridge transcutaneous active direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol.* Apr 2017; 274(4): 1835-1851. PMID 27475796
33. Rahne T, Seiwerth I, Götze G, et al. Functional results after Bonebridge implantation in adults and children with conductive and mixed hearing loss. *Eur Arch Otorhinolaryngol.* Nov 2015; 272(11): 3263-9. PMID 25425039

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

34. Laske RD, Rösli C, Pfiffner F, et al. Functional Results and Subjective Benefit of a Transcutaneous Bone Conduction Device in Patients With Single-Sided Deafness. *Otol Neurotol.* Aug 2015; 36(7): 1151-6. PMID 26111077
35. Riss D, Arnoldner C, Baumgartner WD, et al. Indication criteria and outcomes with the Bonebridge transcutaneous bone-conduction implant. *Laryngoscope.* Dec 2014; 124(12): 2802-6. PMID 25142577
36. Manrique M, Sanhueza I, Manrique R, et al. A new bone conduction implant: surgical technique and results. *Otol Neurotol.* Feb 2014; 35(2): 216-20. PMID 24448280
37. Ihler F, Volbers L, Blum J, et al. Preliminary functional results and quality of life after implantation of a new bone conduction hearing device in patients with conductive and mixed hearing loss. *Otol Neurotol.* Feb 2014; 35(2): 211-5. PMID 24448279
38. Desmet J, Wouters K, De Bodt M, et al. Long-term subjective benefit with a bone conduction implant sound processor in 44 patients with single-sided deafness. *Otol Neurotol.* Jul 2014; 35(6): 1017-25. PMID 24751733
39. İşeri M, Orhan KS, Kara A, et al. A new transcutaneous bone anchored hearing device - the Baha® Attract System: the first experience in Turkey. *Kulak Burun Bogaz İhtis Derg.* 2014; 24(2): 59-64. PMID 24835899
40. Peters JP, Smit AL, Stegeman I, et al. Review: Bone conduction devices and contralateral routing of sound systems in single-sided deafness. *Laryngoscope.* Jan 2015; 125(1): 218-26. PMID 25124297
41. Baguley DM, Bird J, Humphriss RL, et al. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. *Clin Otolaryngol.* Feb 2006; 31(1): 6-14. PMID 16441794
42. den Besten CA, Monksfield P, Bosman A, et al. Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: Six-month results from a multicentre study. *Clin Otolaryngol.* Mar 2019; 44(2): 144-157. PMID 30358920
43. Leterme G, Bernardeschi D, Bensemman A, et al. Contralateral routing of signal hearing aid versus transcutaneous bone conduction in single-sided deafness. *Audiol Neurootol.* 2015; 20(4): 251-60. PMID 26021779
44. Snapp HA, Holt FD, Liu X, et al. Comparison of Speech-in-Noise and Localization Benefits in Unilateral Hearing Loss Subjects Using Contralateral Routing of Signal Hearing Aids or Bone-Anchored Implants. *Otol Neurotol.* Jan 2017; 38(1): 11-18. PMID 27846038
45. Zeitler DM, Snapp HA, Telischi FF, et al. Bone-anchored implantation for single-sided deafness in patients with less than profound hearing loss. *Otolaryngol Head Neck Surg.* Jul 2012; 147(1): 105-11. PMID 22368043
46. Pai I, Kelleher C, Nunn T, et al. Outcome of bone-anchored hearing aids for single-sided deafness: a prospective study. *Acta Otolaryngol.* Jul 2012; 132(7): 751-5. PMID 22497318
47. Saroul N, Akkari M, Pavier Y, et al. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device. *Otol Neurotol.* Jan 2013; 34(1): 111-4. PMID 23202156
48. Lin LM, Bowditch S, Anderson MJ, et al. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

- and contralateral routing of signal amplification. Otol Neurotol. Feb 2006; 27(2): 172-82. PMID 16436986*
49. Kunst SJ, Leijendeckers JM, Mylanus EA, et al. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results. *Otol Neurotol. Jan 2008; 29(1): 2-7. PMID 18199951*
  50. Kunst SJ, Hol MK, Mylanus EA, et al. Subjective benefit after BAHA system application in patients with congenital unilateral conductive hearing impairment. *Otol Neurotol. Apr 2008; 29(3): 353-58. PMID 18494142*
  51. Gluth MB, Eager KM, Eikelboom RH, et al. Long-term benefit perception, complications, and device malfunction rate of bone-anchored hearing aid implantation for profound unilateral sensorineural hearing loss. *Otol Neurotol. Dec 2010; 31(9): 1427-34. PMID 20729779*
  52. Faber HT, Nelissen RC, Kramer SE, et al. Bone-anchored hearing implants in single-sided deafness patients: Long-term use and satisfaction by gender. *Laryngoscope. Dec 2015; 125(12): 2790-5. PMID 26152833*
  53. Monini S, Musy I, Filippi C, et al. Bone conductive implants in single-sided deafness. *Acta Otolaryngol. Apr 2015; 135(4): 381-8. PMID 25720582*
  54. AlFarraj A, Allbrahim M, AlHajjaj H, et al. Transcutaneous Bone Conduction Implants in Patients With Single-Sided Deafness: Objective and Subjective Evaluation. *Ear Nose Throat J. May 02 2022: 1455613221099996. PMID 35499947*
  55. Amonoo-Kuofi K, Kelly A, Neeff M, et al. Experience of bone-anchored hearing aid implantation in children younger than 5 years of age. *Int J Pediatr Otorhinolaryngol. Apr 2015; 79(4): 474-80. PMID 25680294*
  56. Marsella P, Scorpecci A, Pacifico C, et al. Pediatric BAHA in Italy: the "Bambino Gesù" Children's Hospital's experience. *Eur Arch Otorhinolaryngol. Feb 2012; 269(2): 467-74. PMID 21739094*
  57. Davids T, Gordon KA, Clutton D, et al. Bone-anchored hearing aids in infants and children younger than 5 years. *Arch Otolaryngol Head Neck Surg. Jan 2007; 133(1): 51-5. PMID 17224524*
  58. McDermott AL, Williams J, Kuo MJ, et al. The role of bone anchored hearing aids in children with Down syndrome. *Int J Pediatr Otorhinolaryngol. Jun 2008; 72(6): 751-7. PMID 18433885*
  59. Schwab B, Wimmer W, Severens JL, et al. Adverse events associated with bone-conduction and middle-ear implants: a systematic review. *Eur Arch Otorhinolaryngol. Feb 2020; 277(2): 423-438. PMID 31749056*
  60. Verheij E, Bezdjian A, Grolman W, et al. A Systematic Review on Complications of Tissue Preservation Surgical Techniques in Percutaneous Bone Conduction Hearing Devices. *Otol Neurotol. Aug 2016; 37(7): 829-37. PMID 27273402*
  61. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. *Otol Neurotol. Jul 2013; 34(5): 790-4. PMID 23739555*
  62. Dun CA, Faber HT, de Wolf MJ, et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. *Otol Neurotol. Feb 2012; 33(2): 192-8. PMID 22246385*

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

63. Hobson JC, Roper AJ, Andrew R, et al. Complications of bone-anchored hearing aid implantation. *J Laryngol Otol.* Feb 2010; 124(2): 132-6. PMID 19968889
64. Wallberg E, Granström G, Tjellström A, et al. Implant survival rate in bone-anchored hearing aid users: long-term results. *J Laryngol Otol.* Nov 2011; 125(11): 1131-5. PMID 21774847
65. Kraai T, Brown C, Neeff M, et al. Complications of bone-anchored hearing aids in pediatric patients. *Int J Pediatr Otorhinolaryngol.* Jun 2011; 75(6): 749-53. PMID 21470698
66. Allis TJ, Owen BD, Chen B, et al. Longer length Baha™ abutments decrease wound complications and revision surgery. *Laryngoscope.* Apr 2014; 124(4): 989-92. PMID 24114744
67. Calvo Bodnia N, Foghsgaard S, Nue Møller M, et al. Long-term results of 185 consecutive osseointegrated hearing device implantations: a comparison among children, adults, and elderly. *Otol Neurotol.* Dec 2014; 35(10): e301-6. PMID 25122598
68. Rebol J. Soft tissue reactions in patients with bone anchored hearing aids. *Ir J Med Sci.* Jun 2015; 184(2): 487-91. PMID 24913737
69. Larsson A, Tjellström A, Stalfors J. Implant losses for the bone-anchored hearing devices are more frequent in some patients. *Otol Neurotol.* Feb 2015; 36(2): 336-40. PMID 24809279
70. den Besten CA, Nelissen RC, Peer PG, et al. A Retrospective Cohort Study on the Influence of Comorbidity on Soft Tissue Reactions, Revision Surgery, and Implant Loss in Bone-anchored Hearing Implants. *Otol Neurotol.* Jun 2015; 36(5): 812-8. PMID 25811351
71. Mohamad S, Khan I, Hey SY, et al. A systematic review on skin complications of bone-anchored hearing aids in relation to surgical techniques. *Eur Arch Otorhinolaryngol.* Mar 2016; 273(3): 559-65. PMID 25503356
72. Fontaine N, Hemar P, Schultz P, et al. BAHA implant: implantation technique and complications. *Eur Ann Otorhinolaryngol Head Neck Dis.* Feb 2014; 131(1): 69-74. PMID 23835074
73. Hultcrantz M, Lanis A. A five-year follow-up on the osseointegration of bone-anchored hearing device implantation without tissue reduction. *Otol Neurotol.* Sep 2014; 35(8): 1480-5. PMID 24770406
74. Nelissen RC, Stalfors J, de Wolf MJ, et al. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation. *Otol Neurotol.* Sep 2014; 35(8): 1486-91. PMID 25080037
75. Singam S, Williams R, Saxby C, et al. Percutaneous bone-anchored hearing implant surgery without soft-tissue reduction: up to 42 months of follow-up. *Otol Neurotol.* Oct 2014; 35(9): 1596-600. PMID 25076228
76. Roplekar R, Lim A, Hussain SS. Has the use of the linear incision reduced skin complications in bone-anchored hearing aid implantation?. *J Laryngol Otol.* Jun 2016; 130(6): 541-4. PMID 27160014
77. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Bone Conduction Hearing Devices. Position Statements 2016

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

78. Centers for Medicare & Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage (Rev. 198). 2014; Rev. 189
79. Centers for Medicare & Medicaid Services. Fact sheets: CMS Updates Policies and Payment Rates for End- Stage Renal Disease Facilities for CY 2015 and Implementation of Competitive Bidding-Based Prices for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. 2014
80. Clark JG. Uses and abuses of hearing loss classification. ASHA. 1981;23(7):493-500
81. Bento RF, Kiesewetter A, Ikari LS, Brito R. Bone-anchored hearing aid (BAHA): indications, functional results, and comparison with reconstructive surgery of the ear. *Int Arch Otorhinolaryngol.* 2012;16(3):400-405.
82. Ellsperman SE, Nairn EM, Stucken EZ. Review of Bone Conduction Hearing Devices. *Audiol Res.* 2021;11(2):207-219. Published 2021 May 18.

### POLICY HISTORY

<b>MP 1.019</b>	<b>06/19/2018 Consensus Review.</b> No changes to the policy statements. Background and rationale revised. References reviewed.
	<b>05/08/2019 Consensus Review.</b> No changes to policy statements. References updated.
	<b>01/01/2020 Administrative Update.</b> FEP Variation information updated.
	<b>04/30/2020 Consensus Review.</b> No changes to policy statements. References updated; coding reviewed; unspecified diagnosis codes added.
	<b>03/12/2021 Consensus Review.</b> No changes to policy statements. References updated; coding reviewed
	<b>12/01/2021 Administrative Update.</b> Added codes 69716, 69719, 60726, and 69727. Deleted 69715 and 69718
	<b>05/20/2022 Consensus Review.</b> Rationale, reference and background updated. Coding updated. Added New codes for 7/1/2022 0727T, 0728T, 0725T, 0726T, 0729T
	<b>11/29/2022 Administrative Update.</b> Added codes 69728, 69729, 69730 effective 01/01/2023
	<b>02/10/2023 Consensus Review.</b> No changes to policy statement. References and background reviewed and updated. Coding reviewed.
	<b>04/07/2023 Administrative Update.</b> Codes 0725T, 0726T, 0727T, 0728T, 0729T have been removed as they do not apply to policy and are housed in MP 4.002 Experimental and Investigational Procedures.
	<b>04/12/2024 Consensus Review.</b> No change to policy stance. New table in Policy Guidelines. New definitions and new references.
	<b>01/09/2025 Consensus Review.</b> No change to policy stance.
<b>02/12/2026 Consensus Review.</b> No change to policy stance.	

*Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance*

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES</b>
<b>POLICY NUMBER</b>	<b>MP 1.019</b>

*Company<sup>®</sup> and Keystone Health Plan<sup>®</sup> Central. Independent licensees of the Blue Cross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.*