# MEDICAL POLICY

| POLICY TITLE | IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES |
|---|---|
| POLICY NUMBER | MP 1.019 |

| CLINICAL BENEFIT | ☐ MINIMIZE SAFETY RISK OR CONCERN.<br>☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.<br>☐ ASSURE APPROPRIATE LEVEL OF CARE.<br>☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.<br>☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.<br>☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
|---|---|
| Effective Date: | **7/1/2025** |



## I. 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.

### 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**

| Classification of Hearing Loss | Hearing Threshold |
|---|---|
| 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**

## II. PRODUCT VARIATIONS

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

**FEP PPO** - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

## III. DESCRIPTION/BACKGROUND

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### HEARING LOSS

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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.

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

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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.**

| Device | Manufacturer | Date Cleared | 510(k) No. |
|---|---|---|---|
| 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<br>Apr 2008 | K150751<br>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**

| 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 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.

## IV. RATIONALE

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### 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 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.

## V. DEFINITIONS

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**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.

## VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

## VII. DISCLAIMER

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*Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION

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**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 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 |

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| ICD-10-CM Diagnosis Codes | Description |
|---|---|
| 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 |
| 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 |

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| ICD-10-CM Diagnosis Codes | Description |
|---|---|
| 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 |
| 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 |

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## X. POLICY HISTORY

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|---|---|
| **MP 1.019** | **06/19/2018 Consensus Review**. No changes to the policy statements. Background and rationale revised. References reviewed**.** |
| | **05/08/2019 Consensus Review**. No changes to policy statements. References updated. |
| | **01/01/2020 Administrative Update.** FEP Variation information updated. |
| | **04/30/2020 Consensus Review.** No changes to policy statements. References updated; coding reviewed; unspecified diagnosis codes added. |
| | **03/12/2021 Consensus Review.** No changes to policy statements. References updated; coding reviewed |
| | **12/01/2021 Administrative Update.** Added codes 69716, 69719, 60726, and 69727. Deleted 69715 and 69718 |

| POLICY TITLE | IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING PROSTHETIC DEVICES |
|---|---|
| POLICY NUMBER | MP 1.019 |

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| | **05/20/2022 Consensus Review.** Rationale, reference and background updated. Coding updated. Added New codes for 7/1/2022 0727T, 0728T, 0725T, 0726T, 0729T |
| | **11/29/2022 Administrative Update.** Added codes 69728, 69729, 69730 effective 01/01/2023 |
| | **02/10/2023 Consensus Review.** No changes to policy statement. References and background reviewed and updated. Coding reviewed. |
| | **04/07/2023 Administrative Update.** 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. |
| | **04/12/2024 Consensus Review.** No change to policy stance. New table in Policy Guidelines. New definitions and new references. |
| | **01/09/2025 Consensus Review.** No change to policy stance. |

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