# MEDICAL POLICY

Excellus
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| **Medical Policy Title** | **Implantable Bone Conduction Hearing Aids** |
| **Policy Number** | **7.01.77** |
| **Current Effective Date** | April 17, 2025 |
| **Next Review Date** | April 2026 |

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

## POLICY STATEMENT(S)

This policy addresses implantable bone conduction hearing aids only. It does not address middle ear implants (partial or full) (e.g., Maxum System, Vibrant Soundbridge, or Esteem Implanted Hearing System) or nonsurgical bone-conduction hearing aids (e.g., Baha Headband, Baha Softband).

I. When used according to U.S. Food and Drug Administration (FDA) labeled indications, unilateral or bilateral implantable bone conduction (bone-anchored) hearing aid(s) are **medically appropriate** as an alternative to an air-conduction hearing aid when **ALL** of the following criteria are met:

   A. Individual is 5 years of age or older;

   B. Individual has conductive or mixed-hearing loss;

   C. Speech discrimination scores are at least 60% at elevated sound pressure levels during standardized tests;

   D. A pure-tone average (PTA) bone-conduction threshold (measured at 0.5, 1, 2, and 3 kilohertz [kHz]) up to 70 decibels (dB) in the affected ear; **and**

   E. **ONE** of the following conditions are present:

      1. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear;

      2. Chronic external otitis or otitis media (e.g., recurring, or persistent infection or inflammation that precludes the wearing of a conventional air conduction hearing aid);

      3. Other acquired malformations of the middle or external ear canals that preclude the wearing of a conventional air conduction hearing aid (e.g., tumor of the external canal or tympanic cavity, dermatitis of the external canal).

II. When used according to FDA labeled indications, implantable bone conduction (bone-anchored) hearing aids are **medically appropriate** as an alternative to an air-conduction contralateral routing of signal (CROS) hearing aid when **BOTH** of the following criteria are met:

   A. Individual is 5 years of age or older;

   B. Individual has single-sided sensorineural deafness in one ear and normal hearing in the contralateral ear.

III. Contraindications: Implantable bone conduction (bone-anchored) hearing aids are **not medically necessary** for individuals with **ANY** of the following:

A. Individual is under 5 years of age;

B. Individual has insufficient bone volume and bone quality to support successful implant placement;

C. Individuals who are unable, and have no caregiver who is able, to perform the hygienic activities necessary to maintain the abutment/skin interface of the bone conduction hearing aid.

IV. All other uses of bone conduction (bone-anchored) hearing aids (e.g., use in patients with bilateral sensorineural hearing loss) are **investigational**.

V. Device Repair

A. Repair of a medically necessary bone conduction hearing aid or components not under warranty will be considered **medically appropriate** when the following criteria are met:

1. Physician documentation includes **ALL** of the following:

a. date of device implantation/initiation;

b. manufacturer warranty information, if applicable;

c. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

2. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

a. inadequate function interferes with activities of daily living; and

b. repair is expected to make the equipment fully functional (as defined by manufacturer).

B. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is ineligible for coverage.

VI. Device Replacement

A. Replacement of a medically necessary bone conduction hearing aid or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

1. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;

2. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

B. The replacement of a properly functioning bone conduction hearing aid, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;

C. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VII. Accessories or components for bone conduction hearing aids that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

## RELATED POLICIES

Corporate Medical Policy

7.01.26 Cochlear Implants and Auditory Brainstem Implants

11.01.03 Experimental or Investigational Services

## POLICY GUIDELINE(S)

Coverage for implantable bone conduction (bone-anchored) hearing aids, is provided under the member's prosthetic benefit.

## DESCRIPTION

The American Speech-Language-Hearing Association (ASHA, n.d.) defines hearing loss (HL) within its practice portal available from: Hearing Loss in Adults [Accessed 2025 Feb 28].

HL refers to an audiologic diagnosis of hearing thresholds outside the range of typical hearing, and can be described by variation in type, degree, and configuration. The three basic types of HL are:

- Sensorineural hearing loss (SNHL): cochlear (sensory) or vestibulocochlear nerve/CN VIII (neural) auditory dysfunction.
- Conductive hearing loss: a problem conducting sound waves through the outer ear canal, tympanic membrane, or middle ear (ossicles).
- Mixed hearing loss is the result of damage to conductive pathways of the outer ~~and/~~or middle ear and to the nerves or sensory hair cells of the inner ear.

HL can be bilateral or unilateral, symmetrical (degree and configuration of HL are the same in each ear) or asymmetrical, progressive, or sudden in onset, fluctuating or stable, and present at birth or acquired. The degree of HL refers to level of severity, and is measured in decibels in hearing level, or dB HL. The degree of HL can have significant implications for an individual (e.g., limiting the ability to understand speech in background noise, decreasing the enjoyment of music, impacting overall quality of life).

The most widely accepted degree of hearing loss system in the audiology field (ASHA, n.d.) defines HL severity levels as the following:

- Normal: -10 to 15 dB HL
- Slight: 16 to 25 dB HL
- Mild: 26 to 40 dB HL
- Moderate: 41 to 55 dB HL
- Moderately severe: 56 to 70 dB HL
- Severe: 71 to 90 dB HL
- Profound: ≥ 91 dB HL

The World Health Organization (2024) identifies several causes of HL that span across the lifespan, and often occur during critical periods of life, including the following:

Prenatal Period

- genetic factors including hereditary and non-hereditary HL
- intrauterine infections, such as rubella and cytomegalovirus infection

Perinatal Period

- birth asphyxia
- hyperbilirubinemia
- low-birth weight
- other perinatal morbidities and their management

Childhood and Adolescence

- chronic suppurative otitis media
- chronic nonsuppurative otitis media
- meningitis and other infections

Adulthood and Older Age

- chronic diseases
- smoking
- otosclerosis
- age-related sensorineural degeneration
- sudden SNHL

Factors Across the Life Span

- cerumen impaction
- trauma to the ear or head
- loud noise/loud sounds
- ototoxic medicines

- work related ototoxic chemicals
- nutritional deficiencies
- viral infections and other ear conditions
- delayed onset or progressive genetic HL

Technologies for the treatment of HL are dependent on the cause and severity and include hearing aids (external or implanted), cochlear implants, and middle ear implants.

Conventional external hearing aids are subdivided into air conduction hearing aids and bone conduction hearing aids. Air conduction hearing aids require the use of ear molds, which may be problematic in patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. In these patients, bone conduction hearing aids may be an alternative.

Bone conduction devices for hearing were first utilized in the early 1900's with the invention of the carbon microphone. The devices were made to convert sound into a mechanical signal that vibrated the mastoid bone. They were held in place with a headband or eyeglasses, were cumbersome, inefficient for sound transmission, however, were found to be beneficial. Modern bone-anchored hearing aids (BAHA) are osseointegrated bone conduction prostheses, meaning they are surgically implanted into the temporal bone.

A BAHA combines a sound processor with a small titanium fixture implanted into the bone behind the ear. The sound processor is connected to the implant and abutment by means of coupling. The device is placed on the deaf side behind the ear and transmits sound through bone conduction, stimulating the cochlea from the normal hearing ear. Bahas are classified as percutaneous and transcutaneous devices dependent on whether or not the abutment penetrates the skin.

Several implantable BAHAs have been developed and are available to treat patients with conductive or mixed hearing loss, including the following:

Percutaneous or Direct-Drive: The device is coupled to the skull bone by a skin-penetrating abutment (e.g., Baha device and Ponto system).

Transcutaneous or Transcutaneous Passive or Skin-Driven: BAHA device is coupled with an implanted subcutaneous magnet (Sophono device and Baha Attract).

Active transcutaneous: a system with an implanted actuator, which communicates wirelessly with the external sound processor over the skin by an inductive link using radiofrequency transmission (e.g., Bonebridge or Osia device) (Maier 2022).

According to the American Speech-Language-Hearing Association (ASHA), a pure tone average (PTA) air conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of 71 - 90 dbHL (dB HL) is considered a severe hearing loss, and above 90 is considered a profound hearing loss. A normal hearing range is up to 15 dB HL (ASHA, n.d.).

## SUPPORTIVE LITERATURE

Published data have suggested that the BAHA device is associated with improved hearing outcomes compared to external bone conduction hearing aids, and equivalent outcomes compared to a conventional air conduction hearing aid.

Gawecki et al. (2022) performed a small, randomized study that compared patients who received the Osia system (n=4) or the Baha Attract system (n=4) for bilateral mixed hearing loss. After implantation, the mean gain in PTA was 42.8 ± 4.9 dB in the Osia group and 38.8 ± 8.5 dB in the BAHA group. Patient ratings of hearing quality were better in the Osia group based on subjective Likert scores of sound loudness, sound distinctness, and hearing of own voice. Patient reported voice quality scores for reverberation were similar in the Osia and BAHA groups. Both groups reported improved quality of life based on global Abbreviated Profile of Hearing Aid Benefit scores but there was a numerically larger improvement in the Osia group. Results for the Speech, Spatial and Qualities of Hearing Scale improved in both groups and were slightly better in the BAHA group. The authors concluded that larger studies with longer follow-up are needed to evaluate differences in outcomes between these 2 systems.

Kim et al. (2022) compared the effects of the Osia system with the Baha Attract and Bonebridge systems in 67 patients with conductive hearing loss (CHL) or mixed hearing loss (MHL) or single-sided deafness (SSD). Patients who received the Osia system (n=17) were prospectively recruited and retrospectively compared with patients who received the Baha Attract or Bonebridge systems (n=50). Effective gains in bone conduction threshold at 2 kHz were 11.1 ± 14.9 dB in the Osia group compared to -2.7 ± 12.6 dB in the Baha Attract and Bonebridge group (combined) among patients with CHL or mixed hearing loss (p=.01). Among patients with SSD, average functional gains at 4 kHz were 37.5 ± 8.9 dB in the Osia group, 21.7 ± 15.7 dB in the BAHA Attract group, and 29.0 ± 13.0 dB in the Bonebridge group.

Schwab et al. (2020) completed a systematic review of adverse events associated with bone-conduction and middle-ear implants. The ten most frequently reported adverse events for bone conduction hearing implants included skin reactions (Holgers grade 1 to 3), skin revision surgery due to overgrowth or cellulitis, minor soft tissue/skin overgrowth, skin infection, surgical revision, preimplantation, failure to osseointegrate, and minor skin complications.

Verheij et al. (2016) published a systematic review on complications of tissue preservation surgical techniques with percutaneous BAHA devices, including 18 studies with 381 devices. The implantation techniques reported in the studies were as follows: punch method, four studies (81 implants); linear incision technique without soft tissue reduction, 13 studies (288 implants); and Weber technique, one study (12 implants). Indications for surgery were SSD (n=68), sensorineural hearing loss (n=4), mixed hearing loss (n=65), or CHL (n=66). The Holgers classification was used to grade soft tissue reactions (grade 0, no reaction; grade 2, red and moist tissue; grade 3, granulation tissue; grade 4, removal of skin-penetrating implant necessary due to infection). The incidence of Holgers 3 was 2.5% with the punch technique, 5.9% with the linear incision technique, and 0% with the Weber technique. Holgers 4 was reported in one patient implanted with the linear incision technique.

Dimitriadis et al. (2016) reported a systematic review of observational studies of the BAHA Attract device, including 10 studies (total N=89 patients; range, 1-27 patients). Seventeen (19%) of the patients were children, of whom five had unilateral sensorineural hearing loss and four had CHL. Of the 27 (45%) adults, 22 had unilateral sensorineural hearing loss and 11 (18%) had bilateral mixed hearing loss. Audiologic and functional outcome measures and the timing of testing varied greatly in the studies. Summary measures were not reported. In general, audiologic and functional outcomes measured pre- and post-implantation showed improvement, although statistical comparisons were lacking in some studies.

Use of bilateral devices has been evaluated in patients with conductive or mixed hearing losses. A number of studies, published over several years, have demonstrated a consistent improvement in speech recognition in noise and in sound localization with bilateral devices.

## PROFESSIONAL GUIDELINE(S)

In 2021, the American Academy of Otolaryngology - Head and Neck Surgery revised the position statement on bone conduction hearing devices (BCHD), indicating the devices are 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.

## REGULATORY STATUS

BAHAs have received U.S. Food and Drug Administration (FDA) clearance as Class II devices. The following table is provided for convenience and may not be all inclusive. Visit Devices@fda.gov for updates and device specific indications regarding age and degree of HL. Additionally, the FDA maintains a list of recent device recalls [accessed 2025 Feb 19] Available from: Medical Device Safety FDA.

| **Implantable Bone-Conduction Hearing Systems** | | | |
|---|---|---|---|
| **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 |
| Baha 5 Power Sound Processor | Cochlear Americas | May 2016 | K161123 |

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|---|---|---|---|
| Baha 5 Superpower Sound Processor | Cochlear Americas | Mar 2016 | K153245 |
| Baha 5 Sound Processor | Cochlear Americas | Mar 2015 | K142907 |
| Baha Attract System | Cochlear Americas | Nov 2013 | K131240 |
| Baha Cordelle II | Cochlear Americas | Jul 2015<br>Apr 2008 | K150751<br>K080363 |
| 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 |
| Cochlear Osia 2 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, Ponto 3 SuperPower | Oticon Medical | Sep 2016 | K161671 |
| Sentio System | Oticon | July 2024 | K240614 |
| 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 |
| Ponto 3, Ponto 3 Power, Ponto 3 SuperPower | Cochlear Americas | Sep 2016 | K161671 |

## CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

**CPT Codes**

| Code | Description |
|---|---|
| 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 |

| Code | Description |
|---|---|
| 69728 | Removal, entire 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 |
| 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 |
| 92622 | Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes |
| 92623 | each additional 15 minutes (List separately in addition to code for primary procedure) |



**HCPCS Codes**

| Code | Description |
|---|---|
| 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 |

**ICD10 Codes**

| Code | Description |
|---|---|
| H60.391-H60.399 | Other infective otitis externa (code range) |

| Code | Description |
|---|---|
| H60.60 - H60.93 | Other or unspecified otitis externa (code range) |
| H61.391 - H61.399 | Other acquired stenosis of external ear canal (code range) |
| H62.8x1 - H62.8x9 | Other disorders of external ear in diseases classified elsewhere (code range) |
| H65.20 - H65.499 | Chronic otitis media (code range) |
| H66.001 - H66.019 | Acute suppurative otitis media with or without spontaneous rupture of ear drum (code range) |
| H66.10 - H66.43 | Suppurative otitis media (code range) |
| H66.90 - H66.93 | Otitis media, unspecified (code range) |
| H67.1 - H67.9 | Otitis media in diseases classified elsewhere (code range) |
| H90.0 - H90.2 | Conductive hearing loss (code range) |
| H90.41 - H90.42 | Sensorineural hearing loss, unilateral, with unrestricted hearing on the contralateral side |
| H90.6 - H90.8 | Mixed conductive and sensorineural hearing loss |
| 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 |

## REFERENCES

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## SEARCH TERMS

BAHA, Bone anchored hearing aids, implantable bone conduction hearing aids, OBC bone anchored hearing aid system, Ponto Pro, osseointegrated implant (unilateral and bilateral), unilateral percutaneous bone anchored hearing device (unilateral and bilateral), transcutaneous bone conduction hearing device (unilateral and bilateral).

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, implantable bone conduction hearing aids are not addressed in National or Regional Medicare coverage determinations or policies.

However, osseointegrated hearing aids are addressed under Chapter 16, Section 100 of the Medicare Benefit Policy Manual. Please refer to the following website for Medicare Members [updated 2014 Nov 06; accessed 2025 Feb 17]. Available from: Medicare Benefit Policy Manual- Chapter 16: General Exclusions from Coverage

## PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

| **POLICY HISTORY/REVISION** | |
|---|---|
| **Committee Approval Dates** | |
| 05/14/08, 08/20/09, 07/15/10, 07/21/11, 07/19/12, 07/18/13, 07/17/14, 07/16/15, 07/21/16, 07/20/17, 05/17/18, 05/16/19, 05/21/20, 05/20/21, 05/19/22, 04/20/23, 04/18/24, 04/17/25 | |
| **Date** | **Summary of Changes** |
| 04/17/25 | • Annual review. Policy intent unchanged. |
| 01/01/25 | • Summary of changes tracking implemented. |
| 07/19/07 | • Original effective date |