Page: 1 of 14

# **MEDICAL POLICY**



<b>Medical Policy Title</b>	Implantable Bone Conduction Hearing Aids
<b>Policy Number</b>	7.01.77
<b>Current Effective Date</b>	April 17, 2025
<b>Next Review Date</b>	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 <u>Product Disclaimer</u>)

# **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.

Policy Number: 7.01.77

Page: 2 of 14

III. <u>Contraindications</u>: 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.

Policy Number: 7.01.77

Page: 3 of 14

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).

Policy Number: 7.01.77

Page: 4 of 14

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

Policy Number: 7.01.77

Page: 5 of 14

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.).

Policy Number: 7.01.77

Page: 6 of 14

### 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  $42.8 \pm 4.9$  dB in the Osia group and  $38.8 \pm 8.5$  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  $11.1 \pm 14.9$  dB in the Osia group compared to  $-2.7 \pm 12.6$  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  $37.5 \pm 8.9$  dB in the Osia group,  $21.7 \pm 15.7$  dB in the BAHA Attract group, and  $29.0 \pm 13.0$  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.

Policy Number: 7.01.77

Page: 7 of 14

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

Policy Number: 7.01.77

Page: 8 of 14

Cochlear Americas	Mar 2016	K153245
Cochlear Americas	Mar 2015	K142907
Cochlear Americas	Nov 2013	K131240
Cochlear Americas	Jul 2015 Apr 2008	K150751 K080363
Cochlear Americas	Aug 2004	K042017
Cochlear Americas	Aug 2008	K081606
Cochlear Americas	Sep 2013	K132278
Cochlear Americas	Dec 2019	K191921
Oticon Medical	Nov 2011	K112053
Oticon Medical	Sep 2012	K121228
Oticon Medical	Dec 2021	K213733
Oticon Medical	May 2019	K190540
Oticon Medical	Sep 2016	K161671
Oticon	July 2024	K240614
MED-EL	Mar 2019	K183373
Medtronic (Formerly Sophono)	Nov 2013	K132189
Cochlear Americas	Oct 2012	K121317
Cochlear Americas	Sep 2016	K161671
	Cochlear Americas Oticon Medical	Cochlear Americas  Dec 2019  Oticon Medical  Oticon Medical  Coticon  Coticon  Coticon  Coticon  Coticon  Coticon  Cochlear Americas  Coct 2012

Policy Number: 7.01.77

Page: 9 of 14

# 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

Policy Number: 7.01.77

Page: 10 of 14

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)

Copyright © 2025 American Medical Association, Chicago, IL

# **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)

Policy Number: 7.01.77

Page: 11 of 14

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**

American Academy of Otolaryngology – Head and Neck Surgery [Internet]. Position Statement: bone conduction hearing devices.[Drafted 2016; Revised 2021 Apr 13; accessed 2025 Feb 17] Available from: https://www.entnet.org/resource/position-statement-bone-conduction-hearing-devices/

Policy Number: 7.01.77

Page: 12 of 14

American Speech-Language-Hearing Association (ASHA) [Internet]. Clinical topics: cochlear implants, hearing loss adults, and hearing loss childhood [accessed 2025 Feb 17] Available from: <a href="https://www.asha.org/practice-portal/clinical-topics/">https://www.asha.org/practice-portal/clinical-topics/</a>

American Speech-Language-Hearing Association (ASHA) [Internet]. The audiogram. [accessed 2025 Feb 17]. Available from: <a href="https://www.asha.org/public/hearing/Audiogram/">https://www.asha.org/public/hearing/Audiogram/</a>

Carnevale C, et al. Bonebridge bone conduction implant. Hearing outcomes and quality of life in patients with conductive/mixed hearing loss. Eur Arch Otorhinolaryngol. 2022 Sep 05. PMID 36063211

Dimitriadis PA, 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.

Ellsperman SE, et al. Review of Bone Conduction Hearing Devices. Audiol Res. 2021 May 18;11(2):207-219.

Gawecki, W, 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 May-Jun;88(3):289-295.

Goldstein MR, et al. Early Osia 2 bone conduction hearing implant experience: Nationwide controlled-market release data and single-center outcomes. Am J Otolaryngol. 2021 Jan-Feb;42(1):102828.

Hampton T, et al. Association of bone conduction devices for single sided sensorineural deafness with quality of life: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2022 Jan 1;148(1)35-42.

Heath E, et al. The outcomes of bilateral bone conduction hearing devices (BCHD) implantation in the treatment of hearing loss: A systematic review. Cochlear Implants Int. 2022 Mar;23(2):95-108. PMID 34852723

Kim Y, et al. A comparative study of audiological outcomes and compliance between the Osia system and other bone conduction hearing implants. Eur Arch Otorhinolaryngol. 2023 May;280(5):2217-2224. Epub 2022 Nov 01. PMID 36318324

Kruyt IJ, et al. The efficacy of bone-anchored hearing implant surgery in children: A systematic review. Int J Pediatr Otorhinolaryngol. 2020 Jan 28;132:109906.

Lin J, et al. Application of implantable hearing aids and bone conduction implant system in patients with bilateral congenital deformation of the external and middle ear. Int J Pediatr Otorhinolaryngol. 2019 Apr;119:89-95.

Maier H, et al. Consensus Statement on Bone Conduction Devices and Active Middle Ear Implants in Conductive and Mixed Hearing Loss. Otology & Neurotology. 2022 Jun; 43(5):p 513-529.

Ontario Health (Quality) [Internet]. Implantable devices for single-sided deafness and conductive or mixed hearing loss: a health technology assessment. [2020 Mar; accessed 2025 Feb 17] Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/implantable-devices-for-single-sided-deafness-and-conductive-or-mixed-hearing-loss

Policy Number: 7.01.77

Page: 13 of 14

Peters JPM, et al. Short-term outcomes of cochlear implantation for single-sided deafness compared to bone conduction devices and contralateral routing of sound hearing aids-results of a randomized controlled trial (CINGLE-trial). PLoS One. 2021; Oct 13;16(10).

Pla-Gil I, et al., Clinical performance assessment of a new active osseointegrated implant system in mixed hearing loss: results from a prospective clinical investigation. Otol Neurotol. 2021;42:1-6.

Sanchez-Perez J, et al. Osseointegrated bone-conducting hearing protheses. StatPearls [Internet]. Updated 2023 Apr 03 [accessed 2025 Mar 07]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK564385/

Schwab B, et al. Adverse events associated with bone-conduction and middle-ear implants: a systematic review. Eur Arch Otorhinolaryngol. 2020 Feb;277(2):423-438. PMID 31749056

Shohet JA, et al. Totally implantable active middle ear implant: Hearing and safety results in a large series. Laryngoscope. 2018 Dec:128(12):2872-2878.

Shohet JA, et al. Totally implantable hearing system: Five-year hearing results. Laryngoscope. 2018 Jan;128(1):210-216.

U.S. Food & Drug Administration. 510(k) premarket notification. Search database. [Last updated 2025 Feb 17; accessed 2025 Feb 17]. Available from:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

Verheij E, et al. A systematic review on complications of tissue preservation surgical techniques in percutaneous bone conduction hearing devices. Otol Neurotol. Aug 2016;37(7):829-837. PMID 27273402

# **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.

Policy Number: 7.01.77

Page: 14 of 14

- 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