MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Implantable Bone Conduction Hearing Aids**
Policy Number	**7.01.77**
Category	**Technology Assessment**
Original Effective Date	**07/19/07**
Committee Approval Date	**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, 5/20/21, 05/19/22, 04/20/23, 04/18/24**
Current Effective Date	**04/18/24**
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Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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.*

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

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, unilateral or bilateral implantable bone conduction (bone-anchored) hearing aid(s) have been medically proven to be effective and, therefore, are considered **medically appropriate** as an alternative to an air-conduction hearing aid in patients 5 years of age and older with conductive or mixed-hearing loss with speech discrimination scores of at least 60% at elevated sound pressure levels during standardized tests and 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, when ONE of the following conditions is present:
   A. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear;
   B. 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);
   C. 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 and/or tympanic cavity, dermatitis of the external canal).

II. Based upon our criteria and assessment of the peer-reviewed literature, an implantable bone conduction (bone-anchored) hearing aid has been medically proven to be effective and, therefore, is considered **medically appropriate** as an alternative to an air-conduction contralateral routing of signal (CROS) hearing aid in patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear.

III. Contraindications: Based upon our criteria and assessment of the peer-reviewed literature, the following are contraindications for implantable bone conduction (bone-anchored) hearing aids and, therefore, are considered **not medically necessary for**:
   A. Patients 5 years of age and younger;
   B. Patients with insufficient bone volume and bone quality to support successful implant placement;
   C. Patients 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. Based upon our criteria and the lack of peer-reviewed literature, all other uses of bone conduction (bone-anchored) hearing aids (e.g., use in patients with bilateral sensorineural hearing loss) have not been medically proven to be effective and, therefore, are considered **investigational**.

Repair and/or Replacement

V. Repair and/or replacement of a medically necessary implantable bone conduction (bone-anchored) hearing aid device, its components and/or accessories will be considered **medically appropriate** when the following criteria are met:
   A. Physician documentation that the patient has been compliant with the use of device and will continue to benefit from use of the device; **and**
   B. Repair of the currently used device when it is no longer functioning adequately, inadequate function interferes with activities of daily living, and repair is expected to make the equipment fully functional (as defined by manufacturer); **or**
   C. Replacement of the currently used device when it 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; **or**
   D. Replacement of the currently used device when 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.

Refer to Corporate Medical Policy #7.01.26 Cochlear Implants and Auditory Brainstem Implants

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINE

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

DESCRIPTION

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-anchored hearing aids (BAHA) are surgically implanted hearing aids to treat hearing loss through bone conduction. BAHAs allow bone conduction of sound vibration through a titanium implant and is an acceptable alternative if an air conduction hearing aid is contraindicated. 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.

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 decibels hearing level (dB HL) is considered a severe hearing loss, and above 90 dB HL is considered a profound hearing loss. A normal hearing range is up to 15 dB HL.

RATIONALE

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.

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.

Through the 510(k) premarket notification process, several implantable bone-conduction hearing systems have received U.S. Food and Drug Administration (FDA) clearance as a Class II device (U.S. FDA, 2024). FDA product code for bone-anchoring hearing aid: LXB. FDA product code for implanted bone-conduction hearing aid: MAH.

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
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 Apr 2008	K150751 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
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

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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, temporal bone, 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 osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69728	Removal, 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 (*effective 01/01/24*)
92623	each additional 15 minutes (List separately in addition to code for primary procedure) (*effective 01/01/24*)

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)
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

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*Key Article

KEY WORDS

BAHA, Bone anchored hearing aids, implantable bone conduction hearing aids, OBC bone anchored hearing aid system, Ponto Pro.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, implantable bone conduction hearing aids are not addressed in National or Regional Medicare coverage determinations or policies. However, the Medicare Benefit Policy Manual addresses osseointegrated hearing aids under Chapter 16, Section 100 of the manual. Please refer to the following website for Medicare Members: [http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf] accessed 03/12/24.