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**
Current Effective Date	**04/20/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *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 semi-implantable or fully implantable middle ear hearing aids (e.g., Esteem Implanted Hearing System, Maxum, Vibrant Soundbridge); please refer to Policy Guideline I; nor does it apply to external bone-conduction hearing aids (e.g., Baha Headband, Baha Softband);please refer to Policy Guideline II.

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, unilateral or bilateral implantable bone conduction hearing aids have been medically proven to be effective and, therefore, are considered **medically appropriate** as an alternative to an air-conduction hearing aid in patients with conductive or mixed-hearing loss with speech discrimination scores of at least 60% at elevated sound pressure levels during standardized tests and an average bone conduction threshold (measured at 0.5, 1, 2, and 3 kHz) up to 70 decibels (dB) in the affected ear, when one of the following conditions is present:

   A. Congenital or surgically-induced malformations of the external ear canal or middle ear; or
   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); or
   C. Other acquired malformations of the middle or external ear canals that preclude the wearing of a conventional air conduction hearing aid.

II. Based upon our criteria and assessment of the peer-reviewed literature, an implantable bone-conduction 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 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 hearing aids and, therefore, are considered **not medically necessary for**:

   A. Patients aged five years or less;

B. Patients with insufficient bone volume and bone quality to support successful implant placement; or
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**.

V. Repair and/or replacement of a medically necessary implantable bone conduction 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**
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 and Investigational Services.

POLICY GUIDELINES

I. Coverage for implantable bone conduction hearing aids, or semi-implantable middle ear hearing aids, is provided under the member's prosthetic benefit. Please refer to your Customer (Member/Provider) Service Department to determine contract coverage.

II. Bone conduction hearing aids that are not surgically implanted (e.g., Baha Headband, Baha Softband, ADHEAR) are covered under the hearing aid benefit, if any, of the member's subscriber contract. Please refer to your Customer (Member/Provider) Service Department to determine contract coverage.

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.

The bone-anchored hearing aid, BAHA System, is an implantable hearing aid that allows direct bone conduction of sound vibration through a titanium implant and is an acceptable alternative if an air conduction hearing aid is contraindicated. The BAHA System combines a sound processor (e.g., Baha BP100, Baha Cordelle II, Baha Divino, Baha Intenso, Baha 3, Baha 3 Power, BAHA 4, BAHA 5) with a small titanium fixture implanted behind the ear. The sound processor is connected to the implant and abutment by means of a snap coupling. The device is placed on the deaf ear side behind the ear and transmits sound through bone conduction, stimulating the cochlea from the normal hearing ear.

The BAHA System is indicated for patients with conductive or mixed hearing loss or single-sided sensorineural deafness when there is normal hearing in the other ear. Sound transmits directly to the hearing auditory nerve without involving the ear canal. Therefore, it is suitable for patients with chronic infection or malformations of the middle or external ear.

In November 2008, the U.S. Food and Drug Administration (FDA) determined that the OBC Bone Anchored Hearing Aid System (Oticon Medical AB, Sweden) is substantially equivalent to the BAHA System and granted 510(k) approval for this device. The FDA then granted 510(k) approval for the Ponto Pro (Oticon Medical) in July 2009 as a substantial equivalent to the OBC system. The Ponto Bone Anchored Hearing System (Oticon Medical) was cleared in September

2012. A next-generation Ponto Pro device can be used with either Oticon or Baha implants. In December 2019, the FDA granted clearance of the new Cochlear Osia 2 System, introducing a new category of bone conduction hearing device that uses digital piezoelectric stimulation to bypass damaged areas of the natural hearing system to send sound vibrations directly to the inner ear (cochlea). It is indicated for treatment of single-sided deafness (for use in patients with air conduction PTA less than or equal to 20 dB at 0.5, 1, 2 and 3 kHz in the contralateral ear) as well as mixed/conductive hearing losses (when bone conduction PTA is less than or equal to 55dB at 0.5, 1, 2 and 3 kHz in the ipsilateral ear).

According to the American Speech-Language-Hearing Association (ASHA), a pure tone, average, 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.

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 2016, the American Academy of Otolaryngology - Head and Neck Surgery updated it position statement on the use of implantable hearing devices. It stated that the Academy "considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device, and use of a bone conduction oral appliance or bone conduction scalp device, to be acceptable, and, in many cases, preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngologist-head and neck surgeon."

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

Code	Description
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 *(effective 01/01/2023)*
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor *(effective 01/01/2023)*
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 *(effective 01/01/2023)*
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 *(effective 01/01/2023)*
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 *(effective 01/01/2023)*
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 *(effective 01/01/2023)*
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 *(effective 01/01/2023)*

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)

Code	Description
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

Neither a National nor a Local Medicare Coverage Determination has been identified that addresses Implantable Bone Conduction Hearing Aids. 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].