MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**IMPLANTABLE BONE CONDUCTION HEARING AIDS**
Policy Number	**7.01.77**
Category	**Technology Assessment**
Effective Date	**07/19/07**
Revised 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**
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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

This policy addresses fully implantable bone conduction hearing aids only. It does not address partially implantable magnetic bone-conduction hearing systems; (e.g. Baha Attract), **refer to Policy Guideline I; OR** ***semi-implantable, or fully implantable middle ear hearing aids (e.g., Esteem® Implanted Hearing System, Sophono® Alpha 2 MPO™, Vibrant® Soundbridge™),*** **refer to Policy Guideline I; OR** ***external bone-conduction hearing aids (e.g., Baha® Headband, Baha® Softband);*** **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 are **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 which 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 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 are **not medically appropriate** in the presence of the following conditions:
   A. Patient age less than 5 years;

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

   C. Inability of the patient or caregiver 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 are considered **investigational**.

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

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES

I. Coverage for partially, or fully implantable bone conduction hearing aids or semi-implantable middle ear hearing aids, is provided under the member's prosthetic benefit.

II. Bone conduction hearing aids that are not surgically implanted (e.g., Baha Headband, Baha Softband) are covered under the hearing benefit of the members policy.

III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Conventional external hearing aids are subdivided in to 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.

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 postimplantation showed improvement, although statistical comparisons were lacking in some studies.

In November 2008, the FDA determined 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 granted 510(k) approval for the Ponto Pro in July 2009 as a substantial equivalent to the OBC system. Ponto Bone Anchored Hearing System (Oticon Medical). Cleared in September 2012. A next-generation Ponto Pro device can be used with either Oticon or Baha implants.

In 2016, the American Academy of Otolaryngology - Head and Neck Surgery updated it position statement on the use of implantable hearing devices. It states 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."

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 to a conventional air conduction hearing aid.

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.

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.*

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/cochlear stimulator; without mastoidectomy
69715	with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69718	with mastoidectomy

HCPCS Codes

Code	Description
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external speech processor, replacement
L8693	Auditory osseointegrated device, abutment, any length, replacement only

ICD10 Codes

Code	Description
H60.399	Other infective otitis externa, unspecified ear
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)
Q16.4	Other congenital malformations of middle ear

REFERENCES

American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Bone Conduction Hearing Devices. Position Statements 2016; [http://www.entnet.org/content/position-statement-bone-conduction-hearing-devices] Accessed 4/9/2019.

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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.