This policy addresses implantable bone conduction hearing aids only. It does not address semi-implantable or fully implantable middle ear hearing aids (e.g., Vibrant® Soundbridge™, Esteem® Implanted Hearing System) 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 (< 3mm of 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.
   D. Patients who already have one BAHA implant.

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.

POLICY GUIDELINES:

I. Coverage for a bone conduction hearing aid 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.
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® Cordelle II™, Baha® Divino™, Baha® Intenso™, Baha® 3, Baha® 3 Power) 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 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.

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:

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69714</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69715</td>
<td>with mastoidectomy</td>
</tr>
<tr>
<td>69717</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear</td>
</tr>
</tbody>
</table>

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.
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, 07/17/15

stimulator; without mastoidectomy

with mastoidectomy

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HCPCS:
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

ICD9:
380.15 Chronic mycotic otitis externa
380.16 Other chronic infective otitis externa NOS
380.23 Other chronic otitis externa NOS
380.52 Acquired stenosis of external ear canal, secondary to surgery
381.10-381.19 Chronic sensory otitis media (code range)
381.20-381.29 Chronic mucoid otitis media (code range)
381.3 Other and unspecified chronic non-suppurative otitis media
382.00-382.9 Suppurative and unspecified otitis media (code range)
389.00-389.08 Conductive hearing loss (code range)
744.03 Anomaly of middle ear, except ossicles

ICD10:
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:


* 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 includes hearing aids and auditory implants under Chapter 16, Section 100 of the manual which addresses general exclusions from coverage and can be viewed at: http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf.