Implantable Middle Ear and Bone-Anchored Hearing Aids

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<tr>
<th>Type:</th>
<th>Policy Specific Section:</th>
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<tbody>
<tr>
<td>Medical Necessity and Investigational / Experimental</td>
<td>Surgery</td>
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<tr>
<th>Original Policy Date:</th>
<th>Effective Date:</th>
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<tr>
<td>December 5, 2008</td>
<td>October 7, 2011</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Sound is received in two ways, by air conduction through the ear canal, eardrum, and ossicles and by bone conduction through the bones in the jaw and skull, bypassing the outer and middle ear. There are three basic types of hearing loss: conductive hearing loss, sensorineural hearing loss and mixed hearing loss. Conductive hearing loss occurs when sound is not conducted efficiently through the outer ear canal to the eardrum and the ossicles of the middle ear.
Sensorineural hearing loss occurs when there is damage to the cochlea or to the nerve pathways from the cochlear to the brain. A mixed hearing loss is a combination of both.

Conventional external hearing aids can be generally 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. External bone-conduction hearing aids function by transmitting sound waves through the bone and may be associated with pressure headaches and soreness.

Semi-implantable and fully-implantable middle ear hearing aids have been proposed as an alternative to conventional hearing aids for moderate to severe sensorineural hearing loss. Implantable, (bone-conduction) bone-anchored hearing aids (BAHA) have been investigated as an alternative to conventional hearing aids for conductive or mixed hearing loss, as well as, single-sided sensorineural deafness.

Policy

Blue Shield of California considers implantable (bone-conduction) bone-anchored hearing aids and the associated sound processor to be prosthetic devices. Conventional external air-conduction and bone-conduction hearing aids are not considered prosthetic devices and may be a benefit exclusion. Please refer to the applicable benefit plan or evidence of coverage.

Semi-implantable and fully-implantable middle ear hearing aids are considered investigational for all indications.

Unilateral or bilateral implantable bone-anchored hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in patients five years of age and older with a conductive or mixed hearing loss when both of the following criteria (medical and audiologic) are met:

- Medical condition (one of the following):
  - Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear
  - Chronic external otitis or otitis media
  - Tumors of the external canal and/or tympanic cavity
  - Dermatitis of the external canal

- Audiologic criteria (one of the following):
  - For a unilateral implant (both of the following):
    - Conductive or mixed hearing loss
    - Pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kilohertz (kHz)) of better than or equal to:
Medical Policy: Implantable Middle Ear and Bone-Anchored Hearing Aids

Original Policy Date: 12/5/2008
Effective Date: 10/7/2011

- 45 decibels (Oticon OBC, BAHA® BP100™, and BAHA® Divino™ devices)
- 55 decibels (BAHA® Intenso™ device)
- 65 decibels (BAHA® Cordelle II™ device)

For bilateral implants (both of the following):
- Both ears meet the criteria for a unilateral implant (as above)
- Symmetrical bone conduction threshold defined as one of the following:
  - Less than 10 decibels average difference between ears (measured at 0.5, 1, 2, and 3 kHz)
  - Less than 15 decibels on average difference between ears at individual frequencies

An implantable bone-anchored hearing aid may be considered medically necessary as an alternative to an air-conduction contralateral routing of signal (AC CROS) hearing aid in patients five years of age and older with single-sided sensorineural deafness and normal hearing in the other ear. Normal hearing is defined as a pure tone average air-conduction threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 decibels hearing loss.

Other uses of implantable bone-anchored hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered investigational.

Repair, replacement parts, or upgrades to an existing implantable bone-anchored hearing aid are considered not medically necessary for any of the following reasons:
- When the medically necessary criteria for the original implantable bone-anchored hearing aid were not met
- The device is under warranty
- Documentation of malfunction is not provided (e.g., repair logs)
- The request is for convenience or to upgrade to a newer technology when the current components are functional

Policy Guideline

Batteries for implantable bone-anchored hearing aids (BAHAs) are considered durable medical equipment.

The following HCPCS codes represent investigational semi-implantable and fully-implantable middle ear hearing aids:
- S2230: Implantation of the magnetic component of semi-implantable hearing device on ossicles in middle ear
- V5095: Semi-implantable middle ear hearing prosthesis

A generic CPT code may also be billed for semi-implantable or fully-implantable middle ear hearing aids.
The following CPT/HCPCS codes represent the implantation procedure and implantable BAHA device:

- CPT codes 69714 or 69715: Implantation of an osseointegrated implant, temporal bone, with percutaneous attachment to speech processor/cochlear; with or without mastoidectomy
- HCPCS code L8690: BAHA system components, including implant and sound processor

The following CPT/HCPCS codes represent BAHA system removal and replacement codes:

- CPT code 69717 or 69718: Removal and replacement of existing osseointegrated implant, with attachment to speech processor with or without mastoidectomy
- HCPCS code L8691: Replacement of BAHA external sound processor
- HCPCS code L8693: Replacement of BAHA external abutment

Note: The Audiant™ bone conductor (Medtronic Xomed Inc., Jacksonville, FL) is a type of implantable electromagnetic bone-conduction hearing device represented by CPT code 69710. The removal or repair is represented by CPT code 69711. While this product is no longer actively marketed, patients with existing Audiant™ devices may require replacement, removal, or repair.

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<tr>
<td>• History and physical or consultation notes including: type of hearing loss, past treatment, and medical condition requiring requested device</td>
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<td>• Audiologic reports</td>
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<td>• Additionally, for removal, repair or replacement of a device (if applicable): reason for the request, documentation of device malfunction and/or repairs, and device manufacturer warranty</td>
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Post Service

- Procedure report

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.