Bone-Anchored Hearing Aids (Osseointegrated Auditory Implants)

Clinical Coverage Criteria

Overview

A bone conduction hearing aid works by transmitting sound through the mastoid bone to the inner ear (cochlea), bypassing the outer and middle ear. Hearing through bone conduction is helpful for people with conductive or mixed hearing loss that cannot be correctly surgically, and for people with chronic, severe middle ear infection. A traditional bone-conduction hearing aid requires the use of a bone-conductor or vibrating pad. The vibrating pad is held in place on the mastoid bone by a removable headband. Because of advances in the treatment of outer and middle ear disorders, bone conduction hearing aids are rarely used today.

A bone-anchored hearing aid (BAHA) is an alternative to a traditional bone conduction hearing aid that eliminates the need for the headband. A BAHA consists of a small titanium fixture, a percutaneous abutment (a screw), and a sound processor (a hearing aid). The titanium fixture is implanted in the mastoid bone during a minor outpatient surgical procedure. Over a period of several months, the titanium fixture bonds with the surrounding tissue &endash; a process known as osseointegration. The osseointegrated titanium fixture and abutment provide secure retention for the sound processor and transmit sound through the bone to the cochlea.

Policy

Bone-anchored hearing aids require prior authorization by FCHP.

Commercial Plan:

FCHP covers bone-anchored hearing aids and the professional and facility charges related to the implantation and fitting of the bone-anchored hearing aid, subject to the following terms and conditions:

1. *Coverage for bone-anchored hearing aids and the professional and facility charges are subject to the hearing aid benefit limit specified in the member's EOC. Members should be advised that there may be significant member cost-sharing.*
2. *Coverage for replacement of a titanium implant, percutaneous abutment and/or sound processor, and any and the professional and facility charges, is subject to the hearing aid benefit limit specified in the member's EOC. Members should be advised that there may be significant member cost-sharing.*
3. *The plan member meets the Medical Criteria listed below.*

Fallon Senior Plan and MassHealth

FCHP covers bone-anchored hearing aids for Fallon Senior Plan and MassHealth members when the plan member meets the Medical Criteria listed below.

Medical Criteria

1. *Patient is 5 years of age or older and is unable to use conventional air conduction hearing aid(s) or undergo surgical repair because of one of the following conditions:*
   - *Congenital or surgical malformation of the external ear canal or middle ear canal*
   - *Tumors of the external ear canal and/or tympanic cavity*

- *Severe, chronic otitis externa or otitis media*
- *Other acquired malfunction of the external ear canal or middle ear canal which precludes the use of a conventional air-conduction hearing aid, such as hypersensitivity to ear molds used in air conduction hearing aids*

Currently there are three FDA-approved bone-anchored hearing aids marketed in the U.S. (the Branemark, the Cordelle II and the Divino). All three are devices are manufactured by Entific Medical Systems (www.entific.com). On March 4, 2005, Entific Medical Systems was acquired by Cochlear Corporation. Despite many similarities in these devices, there are important features that distinguish them from one another. Coverage for bone-anchored hearing aids is premised upon the use of an FDA-approved device in accordance with its FDA-approved indications (see chart below):

Manufacturer	*FDA Approved Indications*
Branemark	*For unilateral implant:* *The patient has a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone air (PTA) bone conduction threshold in the indicated ear is equal to or greater than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz), and the speech discrimination score for the indicated ear is greater than 60%.* *The patient has unilateral sensorineural deafness in one ear while the other ear has normal hearing. Normal hearing is defined as PTA air conduction (AC) threshold equal to or better than 20 dB measured at 0.5, 1, 2, and 3 kHz.* *For bilateral implants:* *The patient has moderate to severe bilateral symmetric conductive or mixed hearing loss. Symmetric conductive hearing loss is defined as less than 10 dB difference (PTA), or less than 15 dB difference at individual frequencies. Frequencies used to determine thresholds are .5, 1, 2, and 4 kHz.*
Cordelle II	*For unilateral implant:* *The patient has a conductive or mixed hearing loss and can still benefit from sound amplification. The PTA bone conduction threshold in the indicated ear should be equal to or better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz), and the speech discrimination score for the indicated ear is greater than 60%.Not FDA-approved for unilateral sensorineural deafness or bilateral implants*
Divino	*For unilateral implant:* *The patient has a conductive or mixed hearing loss and can still benefit from sound amplification. The PTA bone conduction*

	threshold in the indicated ear is equal to or greater than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz), and the speech discrimination score for the indicated ear is greater than 60%. *The patient has unilateral sensorineural deafness in one ear while the other ear has normal hearing. Normal hearing is defined as PTA AC threshold equal to or greater than 20 dB measured at 0.5, 1, 2, and 3 kHz.* *For bilateral implants:* *The patient has moderate to severe bilateral symmetric conductive or mixed hearing loss. Symmetric conductive hearing loss is defined as less than 10 dB difference (PTA), or less than 15 dB difference at individual frequencies. Frequencies used to determine thresholds are .5, 1, 2, and 4 kHz.*

Exclusions

1. *Semi-implantable hearing aids (also known as middle-ear implants) in which the hearing aid is surgically implanted into the middle ear, such as the Vibrant® Soundbridge™ and the Soundtec® Direct System™.*
2. *A BAHA® "sleeper fixture" or other accessories which are not medically necessary.*

Codes

Code type	*Code*	*Description*
CPT	69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy.
	69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; 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	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy.
HCPCS	L8690	Auditory osseointegrated device, includes all internal and external components.
	L8691	Auditory osseointegrated device, external sound processor, replacement.

References

1. *Centers for Medicare & Medicaid Services (CMS), Medicare Benefit Policy Manual Chapter 16 General Exclusions From Coverage, Section 100; Hearing Aids and Auditory Implants, effective 11-10-2005.*

2. *U. S. Food and Drug Administration (FDA) Center For Devices and Radiological Health, 510(k) Premarket Notification Database. Branemark Bone-Anchored Hearing Aid (BAHA®) System. K984162. 06/28/1999.*
3. *Snik AF, Mylanus EA, Proops DW, Wolfaardt JF, Hodgetts WE, Somers T, Niparko JK, Wazen JJ, Sterkers O, Cremers CW, Tjellstrom A. Consensus statements on the BAHA system: where do we stand at present? Ann Otol Rhinol Laryngol Suppl. 2005 Dec;195:2-12.*
4. *Hol MK, Snik AF, Mylanus EA, Cremers CW. Long-term results of bone-anchored hearing aid recipients who had previously used air-conduction hearing aids. Arch Otolaryngol Head Neck Surg. 2005 Apr;131(4):321-5.*
5. *Snik AF, Bosman AJ, Mylanus EA, Cremers CW. Audiol Neurootol. Candidacy for the bone-anchored hearing aid.2004 Jul-Aug;9(4):190-6.*
6. *McLarnon CM, Davison T, Johnson IJ. Bone-anchored hearing aid: comparison of benefit by patient subgroups. Laryngoscope. 2004 May;114(5):942-4.*
7. *Hayes Directory. Bone-Anchored Hearing Aids. June 3, 2005. © 2005 Winifred S. Hayes, Inc.*
8. *Hayes Update Search. Bone-Anchored Hearing Aids. November 3, 2008. © 2008 Winifred S. Hayes, Inc*

Policy History

Origination date:	05/22/2007
Approval(s):	Technology Assessment Subcommittee: 03/27/07, 05/22/07, 05/07/09 Technology Assessment Committee: 10/09/07, 09/30/09, 03/26/2013, 5/28/2014: Amended to remove hearing aid benefit as part of criteria, new template added, references updated.