



BONE-ANCHORED HEARING AIDS (OSSEOINTEGRATED AUDITORY IMPLANTS)

Number: 200703-0003

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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 – 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.

Definitions

Conductive Hearing Loss: a loss of sensitivity to sound, resulting from an abnormality of the outer ear or the middle ear. The most common cause of conductive hearing loss is middle ear fluid or infection. Other causes include absence of the ear canal as a result of a congenital malformation (atresia), and tumors of the middle ear.

Hearing aid – Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

Mastoid Bone – the posterior portion of the temporal bone located behind the external ear. Bone-conduction stimulation often is applied to the mastoid bone.

Mixed Hearing Loss – a hearing loss with both conductive (middle ear pathology) and sensory (cochlear or eighth cranial nerve pathology) components.

Osseointegration – the process of forming a direct structural and functional bond between living bone and the surface of an artificial implant. Osseointegration is a property virtually unique to titanium.

Policy

Bone-anchored hearing aids require preauthorization 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. The plan member's Evidence of Coverage (EOC) states that coverage is provided for hearing aids.¹
2. 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.
3. 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.
4. 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:
 - a. Congenital or surgical malformation of the external ear canal or middle ear canal
 - b. Tumors of the external ear canal and/or tympanic cavity
 - c. Severe, chronic otitis externa or otitis media
 - d. 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
2. 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:

¹ Most FCHP plans exclude coverage for hearing aids. Unless otherwise specified, the exclusion for hearing aids includes implantable or semi-implantable bone conduction hearing aids and externally worn air or bone conduction hearing aids.

Manufacturer	FDA-Approved Indications
	<p>1. 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%.</p> <p>2. 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.</p> <p><u>For bilateral implants:</u></p> <p>1. 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.</p>
Cordelle II	<p><u>For unilateral implant:</u></p> <p>1. 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%.</p> <p><u>Not FDA-approved for unilateral sensorineural deafness or bilateral implants</u></p>
Divino	<p><u>For unilateral implant:</u></p> <p>1. 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%.</p> <p>2. 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.</p> <p><u>For bilateral implants:</u></p> <p>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.</p>

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

Codes	Number	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

Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ FHLAC Indemnity
- ⊕ Fallon Preferred Care
- ⊕ MassHealth
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

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.

Committee Review Dates:

Technology Assessment Subcommittee: 03/27/07, 05/22/07, 05/07/09

Technology Assessment Committee: 10/09/07, 09/30/09

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.