

Corporate Medical Policy

Implantable Bone Conduction Hearing Aids

File Name:	implantable_bone_conduction_hearing_aids
Origination:	6/2006
Last CAP Review:	2/2011
Next CAP Review:	2/2012
Last Review:	2/2011

Description of Procedure or Service

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. An implantable, bone-anchored hearing aid has been investigated as an alternative to conventional bone-conduction hearing aids.

Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB. The American Speech Language Hearing Association has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (greater or equal to 80 dB).

Sound amplification through the use of an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an air-conduction hearing aid on the normal or less affected side

External bone conduction hearing aids function by transmitting sound waves through the temporal bone directly to the inner ear (cochlea). The external devices must be closely applied to the temporal bone, with either a steel spring over the top of the head or with the use of a spring-loaded arm on a pair of spectacles. These devices may be associated with either pressure headaches or soreness.

The bone-anchored hearing aid (BAHA) implant system works by combining a vibrational transducer coupled directly to the skull via a small titanium implant anchored in the temporal bone. The system is based on the process of "osseointegration" through which living tissue integrates with titanium in the implant over a period of 3 to 6 months, allowing amplified and processed sound to be conducted via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing aids.

There are four BAHA® sound processors for use with the BAHA auditory osseointegrated implant system manufactured by Cochlear Americas (Englewood, CO) that have received 510(k) clearance from the FDA:

- BAHA® Cordelle II™
- BAHA® Divino™
- BAHA® Intenso™ (digital signal processing)
- BAHA® BP100™

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The U.S. Food and Drug Administration (FDA) approved the BAHA system for the following indications:

- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally;
- Patients with sensorineural deafness in one ear and normal hearing in the other (i.e., single-sided deafness, SSD);
- Patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who cannot or will not wear an AC CROS device.

The BAHA implant is cleared for use in children aged 5 years and older, and in adults.

In November 2008, the device “OBC Bone Anchored Hearing Aid System” (Oticon Medical, Kongebakken, Denmark) was cleared by the FDA for marketing through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices. It shares the same indications as the BAHA device.

BAHA sound processors can also be used with the BAHA® Softband™. With this application there is no implantation surgery. The sound processor is attached to the head using either a hard or soft headband. The amplified sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. The BAHA® Softband™ received FDA clearance in 2002 for use in children under the age of 5. As this application has no implanted components, it is not addressed in the policy.

Related Policies:

Cochlear Implant

Semi-implantable Middle Ear Hearing Aid

Auditory Brain Stem Implant

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for the Implantable Bone Conduction Hearing Aid when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Implantable Bone Conduction Hearing Aids are covered

Unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older with a conductive or mixed hearing loss who also meet at least one of the following medical criteria:

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

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and meet the following audiologic criteria:

- A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device) or 65 dB (Cordele II device).
- For bilateral implantation, patients should meet the above audiologic criteria, and have a symmetrically conductive or mixed hearing loss as defined by a difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz, or less than 15 dB at individual frequencies.

An implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction CROS hearing aid in patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear. The pure tone average air conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2 and 3 kHz

When Implantable Bone Conduction Hearing Aids are not covered

An implantable bone conduction hearing aid is not covered for indications other than those listed above.

The use of bilateral bone-anchored hearing aids in patients with bilateral sensorineural hearing loss is considered investigational.

Policy Guidelines

Hearing aids make sounds louder (amplifies) and deliver sounds to the ear canal or external auditory canal. The ear mold or hearing aid generally fits the ear canal closely so that only sound from the hearing aid enters the ear. The amplified sounds are then heard normally through a process known as "air conduction". When you hear normally, sound passes along the ear canal to the tympanic membrane (eardrum) making it vibrate. That is what is meant by "air conduction". These vibrations are passed to three small bones or ossicles (the malleus, incus, and stapes) in the middle ear. The small bones amplify the sound and send it through the entrance to the inner ear (oval window) and into the fluid-filled hearing organ (cochlea). The vibrations create ripples in the fluid that bend projections from tiny hair cells in the cochlea, causing electrical impulses that the auditory (hearing) nerve or eighth cranial nerve, sends to the brain. The brain translates these impulses into what we experience as sound.

A bone conduction hearing aid works by conducting - or carrying - sound through the bone in the skull. This process is known as "bone conduction". The sounds are heard when the vibrations of the sound are transmitted directly from the vibrating part of the bone conduction hearing aid through the skin to the skull to the cochlea, bypassing the external and middle ears. A traditional bone conduction hearing aid consists of a body-worn aid and bone conductor or vibrator fitted to a headband or a pair of specially strengthened spectacles.

Bone-anchored hearing aids are different from other forms of implanted devices used to treat hearing loss, including cochlear implants and auditory brainstem implants. A bone-anchored hearing aid (BAHA) consists of a permanent titanium fixture, or implant, which is surgically inserted into the part of the skull bone that is behind the ear. It has a separate directional microphone and a detachable external sound processor. The surgery is usually carried out in two stages. The first stage involves the insertion of a 3-4 mm titanium implant into the mastoid bone, which is the part of the skull located directly behind the ear. The second stage will be done three or four months after stage one. By this time the titanium implant should have bonded strongly to the skull bone. This is known as "osseointegration". During this stage, the implant will be connected through the skin to a small screw called a "percutaneous abutment". This is the vibrating part, which conducts sound through the skull bone to the inner ear. About a month after the second stage, the processor may be used. The patient will be shown how to attach and remove the processor, which can be snapped on and off, how to use the controls and how to clean the area around the screw.

Cochlear implants and auditory brainstem implants are devices that replace the function of cochlear structures or auditory (hearing) nerves and provide electrical energy to auditory (hearing) nerve fibers and

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other neural tissue via implanted electrode arrays. (Refer to policies titled “Cochlear Implant” and “Auditory Brainstem Implants”.)

Osseointegrated implants are devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. The Implantable Bone Conduction Hearing Aid (BAHA) is an osseointegrated implant (sound is transmitted directly through the bones of the skull to the cochlea, bypassing the middle ear) and payable as a prosthetic device if the medical necessity criteria above is met.

The available evidence for unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) is sufficient to demonstrate improved net health outcome for patients 5 years of age or older in certain situations. The evidence supports the use of these devices in patients with conductive or mixed hearing loss who meet other medical and audiologic criteria. A binaural hearing benefit may be provided to patients with single-sided sensorineural deafness by way of contralateral routing of signals to the hearing ear. Bone-anchored hearing aids may be considered as an alternative to air-conduction devices in these patients. Therefore, the policy statement for the use of these devices may be considered medically necessary in these situations. Given the lack of both high quality evidence and FDA approval, other uses of bone-conduction (bone-anchored) hearing aids, including use in children under 5 years and patients with bilateral sensorineural hearing loss, is considered investigational

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 69710, 69711, 69714, 69715, 69717, 69718, L8690, L8691, L8692, L8693

69710 and 69711 describe semi-implantable bone-conduction hearing aids.

69714 and 69715 describe the BAHA device.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 9/27/05

ECRI Hotline Response - Bone-Anchored Hearing Aid Implants (09/15/2005) retrieved on 1/19/06 from http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?e=6&doc_id=7918&q=Implantable+bone+anchored+hearing+aid&anm

Specialty Matched Consultant Advisory Panel review - 6/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 12/12/06

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 8/2/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 9/18/07

Specialty Matched Consultant Advisory Panel review - 6/23/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 10/07/08.

Dumper J, Hodgetts B, Liu R, Brandner N. Indications for bone-anchored hearing AIDS: a functional outcomes study. *J Otolaryngol Head Neck Surg.* 2009 Feb;38(1):96-105.

Baguley DM, Bird J, Humphriss RL, Prevost AT. The evidence base for the application of contralateral

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bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. Clin Otolaryngol 2006 Feb;31(1):6-14.

Kunst SJ, Hol MK, Mylanus EA, Leijendeckers JM, Snik AF, Cremers CW. Subjective benefit after BAHA system application in patients with congenital unilateral conductive hearing impairment. Otol Neurotol. 2008 Apr;29(3):353-58.

Kunst SJ, Leijendeckers JM, Mylanus EA, Hol MK, Snik AF, Cremers CW. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results. Otol Neurotol. 2008 Jan;29(1):2-7.

Newman CW, Sandridge SA, Wodzisz LM. Longitudinal benefit from and satisfaction with the BAHA system for patients with acquired unilateral sensorineural hearing loss. Otol Neurotol. 2008 Dec;29(8):1123-31.

Hol MK, Spath MA, Krabbe PF, van der Pouw CT, Snik AF, Cremers CW, Mylanus EA. The bone-anchored hearing aid: quality-of-life assessment. Arch Otolaryngol Head Neck Surg. 2004 Apr;130(4):394-9.

Andersen HT, Schroder SA, Bonding P. Unilateral deafness after neuroma surgery: subjective hearing handicap and the effect of the bone-anchored hearing aid. Otol Neurotol. 2006 Sep;27(6):809-14.

Yuen HW, Bodmer D, Smilsky K, Nedzelski JM, Chen JM. Management of single-sided deafness with the bone-anchored hearing aid. Otolaryngol Head Neck Surg. 2009 Jul;141(1):16-23.

Hol MK, Bosman AJ, Snik AF, Mylanus EA, Cremers CW. Bone-anchored hearing aids in unilateral inner ear deafness; an evaluation of audiometric and patient outcome measurements. Otol Neurotol. 2005 Sept;26(5):999-1006.

Senior Medical Director review - 9/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 1/13/2011

Policy Implementation/Update Information

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| 6/19/06 | New policy issued. Policy will be effective 7/1/06. Specialty Matched Consultant Advisory Panel review 6/1/06. |
| 1/3/07 | HCPCS codes L8690 and L8691 effective January 1, 2007 added to Billing/Coding section. (pmo) |
| 6/18/07 | CPT codes 69717 and 69718 added to Billing/Coding section. Reference source added. (pmo) |
| 7/28/08 | Specialty Matched Consultant Advisory Panel review 6/23/08. Reference sources added. No changes to criteria. (pmo) |
| 9/22/08 | Under "When Not Covered", removed "sensorineural" from statement "The use of an implantable bone conduction hearing aid in persons with single-sided deafness (unilateral sensorineural deafness in one ear while the other ear has serviceable hearing) is considered not medically necessary." Notification given 9/22/08. Effective date 12/29/08. (pmo) |
| 10/26/09 | Reference sources added. No changes to criteria. (pmo) |
| 1/5/2010 | HCPCS code L8692 effective January 1, 2010 added to Billing/Coding section. (pmo) |
| 6/22/10 | Policy Number(s) removed. (amw) |
| 7/6/2010 | Specialty Matched Consultant Advisory Panel review 5/24/10. No change to policy statement or coverage criteria. (adn) |
| 1/04/11 | Added HCPCS code L8693 to the Billing/Coding section. (adn) |
| 3/29/11 | Description section revised. Coverage criteria in the When Covered section was changed to |

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read: “Unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older with a conductive or mixed hearing loss who also meet at least one of the following medical criteria: Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear; or Chronic external otitis or otitis media; or Tumors of the external canal and/or tympanic cavity; or Dermatitis of the external canal; and meet the following audiologic criteria: A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device) or 65 dB (Cordele II device). For bilateral implantation, patients should meet the above audiologic criteria, and have a symmetrically conductive or mixed hearing loss as defined by a difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz, or less than 15 dB at individual frequencies. An implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction CROS hearing aid in patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear. The pure tone average air conduction threshold of the normal ear should be better than 20 dB measured at 0.5, 1, 2 and 3 kHz.” Information in the When Not Covered section was replaced with the following: “An implantable bone conduction hearing aid is not covered for indications other than those listed above. The use of bilateral bone-anchored hearing aids in patients with bilateral sensorineural hearing loss is considered investigational.” Policy Guidelines updated. Added CPT codes 69710 and 69711 to the Billing/Coding section. Specialty Matched Consultant Advisory Panel 2/23/11. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.