Corporate Medical Policy

Implantable Bone Conduction Hearing Aids

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Origination:	6/2006
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Next CAP Review:	2/2017
Last Review:	2/2016

Description of Procedure or Service

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction (AC) or bone-conduction external hearing aids. Air conduction hearing aids may not be suitable patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. Bone-conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear and may be useful for individuals with conductive hearing loss, or (if used with contralateral routing of signal), for unilateral sensorineural hearing loss. Implantable, bone-anchored hearing aids (BAHA) that use a percutaneous or transcutaneous connection to a sound processorhave been investigated as alternatives to conventional bone-conduction hearing aids for patients with conductive or mixed hearing loss or in patients with unilateral single-sided sensorineural hearing loss.

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 decibels (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). PTA is calculated by averaging the hearing sensitivities (i.e., the minimum volume that the patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 – 8 kHz.

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" though 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. Implantable bone-conduction hearing systems are primarily indicated for individuals with conductive or mixed sensorineural/conductive hearing loss. They may also be used with CROS as an alternative to an air-conduction hearing aid with CROS for individuals with unilateral sensorineural hearing loss.

Partially implantable magnetic bone conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to bone conduction hearing systems that connect to bone percutaneously via an abutment. With this technique, acoustic transmission occurs transcutaneously via magnetic coupling of the external sound processor and the internally implanted device components. The

bone conduction hearing processor contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone conduction hearing implant. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment to physically connect the external and internal components. To facilitate greater transmission of acoustics between magnets, skin thickness may be reduced to 4-5 mm over the implant when it is surgically placed.

There are five 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 U.S. Food and Drug Administration (FDA):

- BAHA® Cordelle II™
- BAHA® Divino™
- BAHA® Intenso™ (digital signal processing)
- BAHA® BP100™
- BAHA 4 (upgraded from the BP100)

The FDA cleared the BAHA system for use in children aged 5 years and older and adults 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.

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.

Other implantable bone-conduction hearing systems that rely on an abutment and have similar indications as the Cochlear Americas' Baha devices:

- OBC Bone Anchored Hearing Aid System (Oticon Medical, Kongebakken, Denmark). Cleared in 2008.
- Ponto Bone Anchored Hearing System (Oticon Medical). Cleared in September 2012. A next-generation Ponto Pro device can be used with either Oticon or Baha implants.

Two partially implantable magnetic bone conduction devices that have received 510(k) clearance from the FDA are:

- Otomag Bone Conduction Hearing System (Sophono, Boulder, CO; now Medtronic, Minneapolis, MN), and
- Cochlear BAHA Attract (Cochlear Americas, Centennial, CO)

The BoneBridge™ (MedEl, Innsbruck, Austria) is another partially-implantable bone-conduction implant that is considered an active transcutaneous device. It has been cleared for marketing in Europe but has not received FDA approval for use in the U.S.

Implantable Bone Conduction Hearing Aids

The SoundBite™ Hearing System (Sonitus Medical, Inc., San Mateo, CA) is an intraoral bone conducting hearing prosthesis thatconsists of a behind-the-ear microphone and an in-the-mouth hearing device. In 2011, it was cleared for marketing by FDA through the 510(k) process for indications similar to the BAHA. As of January 15, 2015, Sonitus Medicalis in bankruptcy.

Related Policies:
Cochlear Implant
Semi-implantable Middle Ear Hearing Aid

******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;

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 must 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 (4 kHz for OBC and Ponto Pro), 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

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

Partially implantable magnetic bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Sophono Alpha 2 MPO and BAHA Attract) are considered **investigational.**

Non-implantable, intraoral bone conduction hearing aids are considered investigational.

Policy Guidelines

The evidence for implantable bone-anchored hearing devices with a percutaneous abutment in individuals who have conductive or mixed hearing loss includes observational studies that report pre-post differences in hearing parameters after treatment with BAHAs. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified, but observational studies reporting on within-subjects changes in hearing have generally reported hearing improvements with the devices. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement can be attributed to the device. No direct comparisons with external hearing aids were identified, but, for individuals unable to wear an external hearing aid, there may be few alternative treatments. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for implantable bone-anchored hearing devices with percutaneous abutment and contralateral routing of signal in individuals who have unilateral sensorineural hearing loss includes 1 randomized controlled trial (RCT), multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 145 patients, generally have reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of signal. However, a well-conducted systematic review of studies comparing bone-anchored devices to hearing aids with contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT included in the systematic review was a pilot study enrolling only 10 patients and, therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for partially implantable bone-anchored hearing device with transcutaneous coupling to sound processor in individuals with indications for a bone-anchored hearing device includes 2 prospective noncomparative trials, 2 nonrandomized studies comparing transcutaneous devices with percutaneous fully implantable devices, and multiple single-arm studies. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The single-arm studies have demonstrated improvements in hearing in the device-aided state, but the available evidence does not allow comparisons to percutaneous bone-anchored devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

For patients with single-sided sensorineural deafness, a binaural hearing benefit may be provided by way of contralateral routing of signals to the hearing ear. There is evidence that bilateral hearing assistance devices improve hearing to a greater degree than unilateral devices. BAHAs may be considered an alternative to external devices in patients who are not candidates for external devices. By extension, use of an implantable bone-conduction device with contralateral routing of signal may be considered medically necessary in patients with unilateral sensorineural deafness.

The available evidence evaluating the use of intraoral bone conduction hearing aids consists of nonrandomized trials involving small samples and short term follow-up.

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=Implant-able+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 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

Specialty Matched Consultant Advisory Panel review – 2/29/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 3/8/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 1/10/2013

Specialty Matched Consultant Advisory Panel review – 2/20/13

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 1/9/2014

Specialty Matched Consultant Advisory Panel review – 2/25/14

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 1/15/2015

Specialty Matched Consultant Advisory Panel review – 2/25/15

Specialty Matched Consultant Advisory Panel review – 2/24/16

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.03, 3/10/2016

Policy Implementation/Update Information

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 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 o.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)
3/30/12	Specialty Matched Consultant Advisory Panel 2/29/12. Policy guidelines updated.(sk)
3/12/13	Reference added. Added investigational policy statement for partially implantable hearing systems. Added information on partially implantable hearing system, OBC, and Ponto Pro to Description section. Updated Policy Guidelines to include information on partially implantable hearing systems. Specialty Matched Consultant Advisory Panel review 2/20/13. Notification given 3/12/13. Policy effective 6/11/13. (sk)
10/28/14	Reference added. Specialty Matched Consultant Advisory Panel review 2/25/14. Added "magnetic" and "BAHA Attract" to last Policy statement. Revised paragraph related to partially implantable magnetic bone conduction hearing systems in Description section. Added information regarding intra-oral bone conduction hearing aids. "Non-implantable, intraoral bone conduction hearing aids are considered investigational" added to When Not Covered statement. Notification given 10/28/2014 for effective date 12/30/2014. (sk)
3/10/15	Reference added. Specialty Matched Consultant Advisory Panel review 2/25/2015. (sk)
4/1/16	Specialty Matched Consultant Advisory Panel review 2/24/2016. Related Guideline removed. (sk)
5/31/16	Reference added. Description section and Policy Guidelines updated. (sk)