Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 9/1/12**
(See policy history boxes for previous effective dates)

Title: Bone-Anchored Hearing Device

Description / Background

There are three basic types of hearing loss:

- Conductive hearing loss occurs when sound is not conducted efficiently through the outer ear canal to the middle ear. This loss usually involves reduction in sound level or the ability to hear faint sounds. This type of hearing loss can often be medically or surgically corrected.
- Sensorineural hearing loss occurs when there is damage to the cochlea (inner ear) or to the nerve pathways from the retrocochlear (inner ear) to the brain. It is a permanent loss of hearing. This hearing loss not only involves a reduction in sound level it also affects the ability to hear clearly, which affects speech understanding.
- Mixed hearing loss occurs when there is a conductive hearing loss in combination with a sensorineural hearing loss.

External hearing aids are either air-conduction hearing aids or bone-conduction hearing aids. An air-conduction hearing aid (ACHA), also known as a conventional hearing aid, has an ear mold that fits into the ear canal and amplifies sounds that enter the ear. A bone-conduction hearing aid functions by transmitting sound to an oscillator or vibrator. The oscillator is held snugly against the skull with a headband and the vibrations are transmitted directly to the cochlea, bypassing the outer and middle ear. The cochlea (inner ear) is able to interpret the vibrations as sound.

The bone-anchored hearing aid (BAHA) is an alternative to the traditional bone-conduction hearing aid. The BAHA consists of a titanium fixture, a percutaneous abutment (screw) and a sound processor. The fixture is implanted in the mastoid bone, and through the process of osseointegration the external titanium fixture merges with surrounding cranial tissue. A

microphone in the external processor picks up sound and converts it to vibrations that are conducted, via the abutment, to the inner ear enabling the patient to hear.

While a good air-conduction hearing aid provides the best results, there are a number of patients for whom this type of hearing aid is not suitable. An implantable bone-conduction (bone-anchored) hearing aid may be an alternative to an air-conduction hearing aid in patients with a conductive or mixed hearing loss. Patients most likely to benefit from the bone-anchored hearing aid include those with congenital anomalies of the ear, chronic suppurative otitis media, otosclerosis, a previous middle ear procedure that results in increased volume and feedback from a conventional hearing aid or an inability to wear conventional bone-conduction hearing aids.

The use of bone-anchored hearing aids in those with unilateral sensorineural deafness has also been investigated. A bone-anchored device located near the deaf ear works as a transcranial contralateral routing of signal (CROS) to transmit sound to the contralateral functional cochlea via bone conduction. This application has been evaluated as an option to the traditional air-conduction CROS hearing aid.

Regulatory Status:

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 U.S. Food and Drug Administration (FDA):

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

The 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.

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 years.

In November 2008, the device “OBC Bone Anchored Hearing Aid System” (Oticon Medical, Kongebakken, Denmark) was cleared by the U.S. Food and Drug Administration (FDA) for marketing through the 510(k) process. Subsequently, additional bone conduction hearing systems have received 510(k) marketing clearance from the FDA including Otomag (Sophono, Inc., Boulder, CO) and Ponto (Oticon Medical). The Ponto Pro processor can be used with the Oticon or BAHA implants. In May 2011, Sophono,Inc. and Oticon Medical partnered to receive 510(k) marketing clearance from the FDA for the Otomag Alpha 1(M), a partially implantable bone conduction hearing system. All of these devices were determined to be substantially equivalent to existing devices (e.g., the Xomed Audiant, which was FDA cleared for marketing in 1986 but is no longer available). They share similar indications as the Cochlear Americas BAHA devices.

Medical Policy Statement

The safety and effectiveness of unilateral or bilateral bone-anchored hearing devices have been established. They may be considered a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:

Conductive Hearing Loss:

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

- 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
- Chronic dermatitis of the external canal prohibiting the usage of an air conduction hearing aid

Sensorineural Hearing Loss*:

A unilateral implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction CROS hearing aid in patients with single-sided sensorineural deafness and normal hearing in the other ear.

*The Audiant® bone conductor is a bone-conduction hearing device. While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.

Exclusions:

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

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

69710	69711	69714	69715	69717	69718
L8690	L8691	L8692	L8693		

Other codes (investigational, not medically necessary, etc.):

N/A

Note: The above code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

In 2011, de Wolf et al. evaluated 38 BAHA users with a minimum age of 4 years at BAHA fitting and 1 to 4 years of use. The subjects were divided into groups with bilateral conductive or mixed hearing loss and either normal cognition or mental disability and a group with unilateral conductive hearing loss. The main outcome measures were scores on the Glasgow Children's Benefit Inventory, Abbreviated Profile of Hearing Aid Benefit, and Health Utilities Index Mark 3. The Glasgow Children's Benefit Inventory showed a subjective overall benefit of +32, +16, and +26 in the 3 groups (on a scale of -100 to +100). The Abbreviated Profile of Hearing Aid Benefit also showed an overall mean benefit in the groups. On an individual level, a clinically significant benefit was reported by more children in the group with bilateral hearing loss and normal cognition (7 patients [70%]) than in the unilateral hearing loss group (4 patients [27%]). Overall mean health utility scores and disability index scores on the Health Utility Index Mark 3 were comparable among the 3 groups. The researchers concluded that the BAHA can be considered effective and beneficial in children with bilateral or unilateral hearing loss.

Kunst, et al., 2008, evaluated ten adults and ten children using two disability-specific questionnaires. The authors concluded that BAHA was well accepted by most of the patients with congenital unilateral conductive hearing impairment. A trial of the BAHA system with the BAHA on a headband is part of the preoperative procedure.

Lloyd, et al., 2007, found benefits both audiologically and in terms of quality of life in children who receive bone-anchored hearing aids. Hearing thresholds when using BAHAs had been comparable to those when using bone-conduction hearing aids. However, BAHAs had significant additional benefits in terms of sound quality, increased use and overall quality of life.

Baguley, et al., 2006, reviewed the evidence for contralateral bone-anchored hearing aids in adults with acquired unilateral sensorineural hearing loss. None of the four controlled

trials reviewed showed a significant improvement in auditory localization with the bone-anchored device. However, speech discrimination in noise and subjective measures improved with these devices. For these parameters, the bone-anchored devices resulted in greater improvement than that obtained with the conventional air-conduction CROS systems.

Perwin, et al., 2004, reported evidence for the use of bilateral devices. They found that both speech recognition in noise and directional hearing improved with the second device.

Government Regulations

National:

There is no national or local coverage determination.

Medicare Benefit Manual, Publication 100-02, Chapter 16 General Exclusions, Section 100

Hearing Aids and Auditory Implants (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05)

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefore. . ." This policy is further reiterated at 42 CFR 411.15(d) which specifically states that "hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids" are excluded from coverage.

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.

Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

The following are prosthetic devices:

- Cochlear implants and auditory brainstem implants, i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.
- Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

Michigan Department of Community Health:

Per the 2012 MDCH Practitioner and Medical Clinic Database, codes 69711-69718 have associated facility fees. Code 69710 requires prior authorization and documentation. Per the MDCH Hearing Services Database, January 2012, codes L8691-L8693 require prior authorization.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
- Cochlear Implants

References

- American Speech-Language-Hearing Association, "Type, Degree, and Configuration of Hearing Loss," <http://www.asha.org/public/hearing/disorders/types.htm> (May 14, 2012).
- Baguley, D. M., et al., "The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults," *Clinical Otolaryngology,* Vol. 31, 2005, pp 6-14.
- Battista, Robert A., MD, et al., "Revision BAHA Surgery," *Otolaryngologic Clinics of North America,* Vol. 39, 2006, pp. 801-813.
- Blue Cross Blue Shield Association, "Implantable Bone-Conduction and Bone-Anchored Hearing Aids," *Medical Policy Reference Manual* #7.01.03, Issue 1:2012, original policy date 12/01/95, last review date 3/8/12.
- Centers for Medicare & Medicaid Services (CMS), *Benefit Policy Manual,* Chapter 16 General Exclusions, Section 100 Hearing Aids and Auditory Implants, Effective date 11/10/05.
- de Wolf, MJ, et al., "Benefit and quality of life after bone-anchored hearing aid fitting in children with unilateral or bilateral hearing impairment," Arch Otolaryngol Head Neck Surg., 2011 Feb;137(2):130-8.
- *HAYES Medical Technology Directory*, "Bone-Anchored Hearing Aids," Lansdale, PA: HAYES, INC., June 3, 2005.
- *HAYES Search and Summary,* "Bone-Anchored Hearing Aids," Lansdale, PA: HAYES, Inc., September 4, 2009.
- Hol, Myrthe K. S., MD, et al., "The Bone-anchored Hearing Aid," *Arch Otolaryngol Head and Neck Surgery,* Vol. 120, April 2004, pp. 394-399.
- Kunst, Sylvia J. W., et al., "Subjective Benefit after BAHA System Application in Patients with Congenital Unilateral Conductive Hearing Impairment," *Otology & Neurotology*, Vol. 29, 2008, pp. 353-358.
- Lloyd, S., et al., "Updated surgical experience with bone-anchored hearing aids in children," *The Journal of Laryngology & Otology*, Vol. 121, January 2007, pp. 826-831.
- Niparko, John K., et al., "Comparison of the Bone Anchored Hearing Aid Implantable Hearing Device with 'Contralateral Routing of Offside Signal Amplification in the Rehabilitation of Unilateral Deafness," *Otology & Neurotology,* Vol. 24, 2003, pp. 73-78.
- Priwin, Claudia, MD, et al., "Bilateral Bone-Anchored Hearing Aids (BAHAs): An Audiometric Evaluation," *Laryngoscope*, Vol. 114, January 2004, pp. 77-84.
- Snik, Ad F. M., et al., "Candidacy for the Bone-Anchored Hearing Aid," *Audiology & Neurology*, Vol. 9, No. 4, 2004, pp. 190-196.

- Stenfelt, Stefan, “Bilateral fitting of BAHAs and BAHA® Fitted in Unilateral Deaf Persons: Acoustical Aspects,” *International Journal of Audiology*, Vol. 44, 2005, pp. 178-189.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/14/12, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/31/04	3/31/04	3/26/04	Joint medical policy established
4/6/05	4/6/05	4/11/05	Routine maintenance
11/1/07	8/21/07	10/30/07	Routine maintenance
11/1/08	8/19/08	10/28/08	Routine maintenance, added bilateral implants to inclusionary guidelines, description/background simplified. References updated.
11/1/09	8/18/09	8/18/09	Routine maintenance; unilateral sensorineural hearing loss added to inclusions.
5/1/10	2/16/10	2/16/10	Routine maintenance; code update: L8692 added to policy.
7/1/11	4/19/11	5/3/11	Routine maintenance; code update: L8693 added to policy.
9/1/12	6/12/12	6/19/12	Routine maintenance; references and regulatory status updated.

Next Review Date: 2nd Qtr, 2013

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BONE-ANCHORED HEARING DEVICE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, criteria apply. Hearing aid rider is required. **Conductive Hearing Loss** <u>Inclusions</u>: A. Unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) may be necessary as an alternative to an air-conduction hearing aid in members with a conductive or mixed hearing loss who also meet at least one of the following criteria: • 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 • Chronic dermatitis of the external canal prohibiting the usage of an air conduction hearing aid In addition, the patient must meet all of the following: • 5 yrs of age or older • Pure tone average (PTA) bone conduction threshold better than (less than) or equal to 45dB HL (measured by taking the combined average of 500Hz, 1Khz, 2KHz and 3KHz) • Speech discrimination score of 60 percent or better **Sensorineural Hearing Loss** B. A unilateral implantable bone-conduction (bone-anchored) hearing aid may be necessary as an alternative to an air-conduction CROS hearing aid in members who meet all the following criteria: • One ear with profound sensorineural hearing loss • One ear pure tone average (PTA) air conduction (AC) threshold better than or equal to 20dB HL (measured at 500Hz, 1Khz, 2KHz and 3KHz) <u>Exclusions</u>: Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered

	experimental/investigational. The BAHA Headband or Softband device is not a bone-anchored hearing device. It is a bone-conduction hearing aid, most often used in children, which is worn until the patient is able to undergo the bone-anchored surgical procedure. This device is a hearing aid and coverage requires a hearing aid rider.
BCNA (Medicare Advantage)	Criteria apply. Covered as a P&O benefit.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	Covered; criteria apply

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- *Duplicate (back-up) equipment is not a covered benefit.*