

Protocol

Implantable Bone-Conduction and Bone-Anchored Hearing Aids

(70103)

Medical Benefit	Effective Date: 04/01/13	Next Review Date: 01/15
Preauthorization	Yes	Review Dates: 11/07, 07/08, 05/09, 03/10, 03/11, 03/12, 01/13, 01/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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. Bone-conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear. Implantable, bone-anchored hearing aids (BAHA) and a partially implantable system have been investigated as alternatives to conventional bone-conduction hearing aids.

Background

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 (decibel). The American Speech-Language-Hearing Association (ASLHA) 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 (≥ 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 bone to the ossicles of the middle ear. 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 percutaneous abutment that permanently protrudes through the skin from 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 three to six 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.

A partially implantable bone conduction hearing system, the Otomag Alpha 1(M), is available as an alternative to the BAHA systems. With this technique, acoustic transmission occurs via magnetic coupling of the externally and internally implanted device components. The Otomag Alpha 1(M) bone conduction hearing vibrator contains twin magnets that adhere externally to titanium-encased twin magnets implanted in shallow bone beds. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment. To facilitate

greater transmission of acoustics between magnets, skin thickness must be reduced to 4-5 mm over the implant when it is surgically placed.

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 five years and older, and in adults.

The FDA noted that consideration must be given to the patients (or caregivers) psychological, physical, emotional and developmental capabilities to be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments. Also, for children and patients with congenital malformations, sufficient bone volume and bone quality must be present for successful fixture implantation.

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 younger than the age of five years. This application has no implanted components.

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.

Related Protocols

Cochlear Implant

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy (Formerly Corporate Medical Guideline)

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 five 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 (4kHz 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 five 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.

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

Partially implantable bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Otomag Alpha 1 [M]) are considered **investigational**.

Benefit Application

The above criteria would also be applied to the BAHA® Softband™ (transcutaneously worn BAHA) except for the age limitation of five years of age and older which does not apply. Tests used to determine hearing loss may vary dependent on the age of the child.

State programs consider this a hearing aid; Benefit limitations regarding hearing aids may apply.

All other business will consider this an implantable prosthetic.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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