Protocol

Implantable Bone-Conduction and Bone-Anchored Hearing Aids

(70103)

Medical Benefit		**Effective Date**: 01/01/17	**Next Review Date**: 09/19
Preauthorization	No	**Review Dates**: 11/07, 07/08, 05/09, 03/10, 03/11, 03/12, 01/13, 01/14, 01/15, 01/16, 09/16, 09/17, 09/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With conductive or mixed hearing loss	Interventions of interest are: • Implantable bone-anchored hearing aid with a percutaneous abutment	Comparators of interest are: • External hearing aid	Relevant outcomes include: • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With conductive or mixed hearing loss	Interventions of interest are: • Partially implantable bone-anchored hearing aid with transcutaneous coupling to the sound processor	Comparators of interest are: • External hearing aid	Relevant outcomes include: • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With unilateral sensorineural hearing loss	Interventions of interest are: • Fully or partially implantable bone-anchored hearing aid and contralateral routing of signal	Comparators of interest are: • Air-conduction hearing aid with contralateral routing of signal	Relevant outcomes include: • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction or bone-conduction external hearing aids. Air-conduction hearing aids may not be suitable for 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 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 (BAHAs) that use a percutaneous or transcutaneous connection to a sound processor have been investigated as alternatives to conventional bone-conduction hearing aids for patients with conductive or mixed hearing loss or for patients with unilateral single-sided sensorineural hearing loss.

SUMMARY OF EVIDENCE

For individuals who have conductive or mixed hearing loss who receive an implantable BAHA with a percutaneous abutment or a partially implantable BAHA with transcutaneous coupling to the sound processor, the evidence includes observational studies that have reported 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. 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. Studies of partially implantable BAHAs have similarly demonstrated within-subjects improvements in hearing. The single-arm studies have shown improvements in hearing in the device-aided state. No direct comparisons other than within-individual 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable BAHA with the contralateral routing of signal, the evidence includes a 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 nine to 180 patients, have generally reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone-conduction devices with contralateral routing of the signal. However, a well-conducted systematic review of studies comparing bone-anchored devices with hearing aids using 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.

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, the use of an implantable bone-conduction device with contralateral routing of the signal may be considered medically necessary in patients with unilateral sensorineural deafness.

POLICY

Unilateral or bilateral fully or partially 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 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 symmetrically conductive or mixed hearing loss as d efined 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 contralateral routing of signal 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**.

POLICY GUIDELINES

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.

In patients being considered for implantable bone-conduction (bone-anchored) hearing aid(s), skull bone quality and thickness should be assessed for adequacy to ensure implant stability. Additionally, patients (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.

BACKGROUND

HEARING LOSS

Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing detects sound at or below 20 decibels (dB). The American Speech-Language-Hearing Association has defined degree of hearing loss based on pure-tone average detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥ 80 dB). Pure-tone average is calculated by averaging hearing sensitivities (i.e., the minimum volume that a patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 to 8 kHz.

Sound amplification using 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 AC hearing aid on the normal or less affected side.

Treatment

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

A bone-anchored implant system combines 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 osseointegration through which living tissue integrates with titanium in the implant over three to six months, conducting amplified and processed sound 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 people with conductive or mixed sensorineural or conductive hearing loss. They may also be used with CROS as an alternative to an AC hearing aid 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. Because 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 four to five mm over the implant when it is surgically placed.

REGULATORY STATUS

Six Baha® sound processors manufactured by Cochlear Americas (Englewood, CO) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use with the Baha auditory osseointegrated implant system:

- Baha® 5
- Baha® Cordelle II
- Baha Divino®
- Baha Intenso® (digital signal processing)
- Baha® BP100
- Baha® 4 (upgraded from the BP100).

FDA cleared the Baha system for use in children ages five 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);
- Patients who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS device.

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, Askim, Sweden). Cleared in November 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 cleared by FDA through the 510(k) process are:

- Otomag® Bone-Conduction Hearing System (Sophono, Boulder, CO; now Medtronic, Minneapolis, MN),
- Cochlear Baha® 4 Attract System (Cochlear Americas, Centennial, CO).

The Bonebridge™ (MED-EL, 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 United States.

The SoundBite™ Hearing System (Sonitus Medical, San Mateo, CA) is an intraoral bone-conducting hearing prosthesis that consists 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. Sonitus Medical closed in 2015.

FDA product code (for bone-anchored hearing aid): LXB. FDA product code (for implanted bone-conduction hearing aid): MAH.

Baha sound processors can be used with the Baha® Softband™. With this application, there is no implantation surgery. The sound processor is attached to the head using a hard or soft headband. The amplified sound is transmitted transcutaneously to the cochlea via the bones of the skull. In 2002, the Baha® Softband™ was cleared for marketing by FDA for use in children younger than five years. Because this application has no implanted components, it is not addressed in this protocol.

RELATED PROTOCOLS

Cochlear Implant

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

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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.**

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

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