Bone Anchored Hearing Aids AHM

Clinical Indications

- Implantable bone-anchored hearing aids (BAHAs) or temporal bone stimulators are medically necessary prosthetics for persons age 5 years and older with a unilateral or bilateral conductive or mixed conductive and sensorineural hearing loss who have ALL of the following conditions, where the condition prevents restoration of hearing using a conventional air-conductive hearing aid and who meet the audiologic criteria below
  - Member has **1 or more** of the following conditions:
    - Congenital or surgically induced malformations of the external ear canal or middle ear (such as aural atresia)
    - Dermatitis of the external ear, including hypersensitivity reactions to ear moulds used in air conduction hearing aids
    - Hearing loss secondary to otosclerosis in persons who cannot undergo stapedectomy
    - Severe chronic external otitis or otitis media
    - Tumors of the external ear canal and/or tympanic cavity
    - Other conditions in which an air-conduction hearing aid is contraindicated
  - Member meets **1 or more** of the following Audiologic criteria
    - Unilateral implant: Conductive or mixed (conductive and sensorineural) hearing loss with pure tone average bone conduction threshold (measured at 0.5, 1, 2, and 3 kHz) less than or equal to 45 dB HL (BAHA Divino, BAHA BP100), 55 dB HL (BAHA Intenso), Cochlear Baha 3 Power [BP110] or 65 dB HL (BAHA Cordelle II).
    - Bilateral implant: Moderate to severe bilateral symmetric conductive or mixed (conductive and sensorineural) hearing loss, meeting above-listed bone conduction thresholds in both ears. Symmetric bone conduction threshold is defined as **1 or more** of the following
      - Less than 10 dB average (measured at 0.5, 1, 2 and 4 kHz) or less than 15 dB at individual frequencies (BAHA Divino, BAHA BP100)
      - Less than 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies (BAHA Cordelle II, BAHA Intenso)
  - The use of an implantable BAHA is medically necessary in persons with unilateral sensorineural hearing loss (single-sided deafness, i.e. deafness in one ear while the other ear has normal hearing). The use of an implantable BAHA is investigational for bilateral pure sensorineural hearing loss, and for all other indications.
  - An implantable BAHA for conductive or mixed hearing loss is considered investigational when criteria are not met because of insufficient evidence in the peer-reviewed published medical literature.
  - Intra-oral bone conduction hearing aids (e.g., the SoundBite hearing system) for the treatment of hearing loss is considered experimental and investigational because their effectiveness have not been established
• A partially implantable bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., the Otomag Alpha 1(M) bone conduction hearing system) for the treatment of hearing loss is considered experimental and investigational because their effectiveness have not been established.

• It is important to follow Medicare rules in considering osseointegrated implants, such as implantable bone anchored hearing aids and temporal bone stimulators, as prosthetics. Medicare considers as prosthetics "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." Non-osseointegrated hearing devices (e.g., BAHA Soft Band, SoundBite) are not covered under plans that exclude coverage of hearing aids. Please check benefit plan descriptions.

Evidence Summary

• Background

The bone-anchored hearing aid (BAHA) is a bone-conduction hearing aid that allows direct bone-conduction through a titanium implant and has become available as an acceptable alternative if an air-conduction hearing aid is contraindicated. The bone-anchored hearing aid transmits sound vibrations through the skull bone via a skin-penetrating titanium implant, and then are further transmitted to the cochlea, bypassing the middle ear. Several clinical trials have shown its efficacy in patients with a conductive or mixed hearing loss. Indications for the BAHA include hearing loss from congenital ear problems, chronic suppurative otitis media, and in some cases otosclerosis as a third treatment option in those who cannot or will not undergo stapedectomy. A second group of potential candidates are patients who suffer from an almost instantaneous skin reaction to any kind of ear mold. In some patients, the benefits are not necessarily those in hearing ability but relate to cosmetic or comfort improvements. Preoperative assessment of the size of the air-bone gap is of some help to predict whether speech recognition may improve or deteriorate with the BAHA compared with the air-conduction hearing aid.

• There is evidence in the peer-reviewed published medical literature to support the use of bone anchored hearing aids over air conduction hearing aids, however, most of the studies have focused on individuals who suffer from single sided deafness, with unilateral sensorineural deafness in one ear while the other ear has normal hearing. The FDA has cleared for marketing the bone anchored hearing aid for individuals aged 5 years and older who have conductive or mixed hearing loss and for patients with sensorineural deafness in one ear and normal hearing in the other based on a 510(k) application. Such clearance was granted based on a determination that the BAHA was substantially equivalent to a contralateral routing of sound (CROS) air conduction hearing aid. A unilateral implant is used for individuals with unilateral conductive or mixed hearing loss and for unilateral sensorineural hearing loss. According to the FDA-approved indications, a bilateral implant is intended for patients with bilaterally symmetric moderate to severe conductive or mixed hearing loss.

• In a recently published metaanalysis of the evidence for BAHA for single sided deafness, Baguley and colleagues (2006) explained that acquired unilateral sensorineural hearing loss reduces the ability to localize sounds and to discriminate in background noise. Four controlled trials have been conducted to determine the
benefit of contralateral BAHAs over CROS hearing aids and over the unaided condition. Speech discrimination in noise and subjective questionnaire measures of auditory abilities showed an advantage for BAHAs over CROS and over unaided conditions. However, these studies did not find significant improvements in auditory localization with either aid. The investigators noted that these conclusions should be interpreted with caution because these studies have material shortfalls: (i) the BAHAs was always trialled after the CROS aid; (ii) CROS aids were only trialled for 4 weeks; (iii) none used any measure of hearing handicap when selecting subjects; (iv) two studies have a bias in terms of patient selection; (v) all studies were underpowered; (vi) double reporting of patients occurred (Baugley, et al., 2006).

- Priwin, et al. (2007) investigated (i) whether bilateral BAHAs in children with conductive bilateral hearing loss provided additional hearing benefits, (ii) the effects of unilateral hearing aids in children with conductive unilateral hearing loss, and (iii) the auditory problems of children with conductive unilateral or bilateral hearing loss. This prospective case series included 22 children with either conductive unilateral hearing loss (unaided or with unilateral hearing aid) or conductive bilateral hearing loss (with unilateral or bilateral BAHAs) and 15 controls. The investigators tested baseline audiometry, tone thresholds in a sound field, and speech recognition in noise and sound localization with and without unilateral and bilateral hearing aids. Two self-assessment questionnaires were completed. The investigators reported two problem areas in the children with hearing impairment: (i) reactions to sounds, and (ii) intelligibility of speech. An additional BAHAs in the children with bilateral hearing loss resulted in a tendency to have improved hearing in terms of better sound localization and speech recognition in noise. Fitting of unilateral hearing aids in the children with unilateral hearing loss gave some supplementary benefit in terms of better speech recognition in noise but no positive effect on ability to localize sound could be detected. Even so, all children fitted with hearing aids, either unilaterally or bilaterally, reported a positive outcome with their devices in the self-assessment questionnaire. The investigators concluded that the fitting of bilateral BAHAs in children with bilateral hearing loss and of a single-sided hearing aid in children with unilateral hearing loss appears to have some supplementary audiological benefits and also renders high patient satisfaction.

- When suggested indications for treatment with the BAHAs system are followed, the success rate is very high. The improved quality of life reported by the patients is a combination of improved quality of sound (warble tone threshold, speech reception threshold, and discrimination in noise), improved comfort, and relief from middle ear and ear canal disease occasioned by conventional hearing aids.

- Although no longer marketed, the Audiant (Medtronic Xomed, Inc., Jacksonville, FL) Bone Conductor, also known as the temporal bone stimulator, is an FDA-approved implanted device with an external processor that uses transcutaneous inductive electromagnetic energy to cause vibration of an implanted titanium magnet screwed into the temporal bone. Like the currently marketed BAHAs device, the Audiant Bone Conductor is also based on a bone conduction concept, and is also indicated for persons with conductive or mixed conductive and sensorineural hearing loss who have conditions that prevent restoration of hearing using a conventional air-conductive hearing aid.

- Hol et al (2010) evaluated the effectiveness of 3 CROS hearing aids in adults (n = 10 with unilateral inner ear deafness and normal hearing in the contralateral ear: (i) the CROS hearing aid, (ii) the completely in the canal hearing aid, and (iii) the BAHAs CROS (BAHA). Each of the 3 hearing aids was tried in a random order for a
period of 8 weeks. Audiometric performance, including speech-in-noise, directional hearing and subjective benefit were measured after each trial period, using the Abbreviated Profile of Hearing Aid Benefit (APHAB), SSQ and single-sided deafness questionnaire. Sound localization performance was essentially at chance level in all 4 conditions. Mixed results were seen on the other patient outcome measures that alternated in favor of one of the 3 CROS devices. After the trial, 3 patients chose to be fitted with the BAHA CROS and 1 with the conventional CROS.

- The authors concluded that most of the patients experienced some degree of benefit with each of the 3 hearing aids. Preference for one of the 3 hearing aids was independent of the order in which they were tried. It would be worthwhile to formulate selection criteria; still, the authors recommended that all patients with unilateral inner ear deafness should be offered a trial with at least the BAHA CROS.

- de Wolf and colleagues (2011a) stated that a study performed in the 1990s with analog linear hearing aids showed that in patients with mixed hearing loss and an air-bone gap that exceeded 25 to 30 dB, speech perception was better with a BAHA than with a conventional behind-the-ear (BTE) device. The objective of the present study was to examine if this conclusion applies to today's digital BTEs with feedback cancellation and whether the cross-over point still occurs at an air-bone gap of 25 to 30 dB. Experienced unilateral BAHA users with the latest digital Baha processors were fitted with a powerful BTE with feedback cancellation. After an acclimatization period of 4 weeks, aided thresholds and speech recognition scores were determined and compared to those recorded previously with the BAHA.

- To obtain patients' opinions, a disability-specific questionnaire was used. Participants comprised 16 subjects with bilateral mixed hearing loss. Audiometric and speech recognition data showed similar trends to those described previously, but the cross-over point had shifted to an air-bone gap of 30 to 35 dB. In the questionnaire, the BTE was rated higher than the BaHA, except by the patients with an air-bone gap that exceeded an average of 45 dB. The authors concluded that in patients with mixed hearing loss whose air-bone gap exceeded 35 dB, speech recognition is likely to be better with a BAHA than with a BTE. Thus, the BAHA should receive greater consideration when mixed hearing loss is combined with a significant air-bone gap, even when there are no contraindications for BTEs.

- de Wolf and colleagues (2011b) evaluated the benefits of a BAHA in the daily lives of hearing-impaired children. A total of 38 BAHA users with a minimum age of 4 years at BAHA fitting and 1 to 4 years of use 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. Main outcome measures included scores on the Glasgow Children's Benefit Inventory, APHAB, 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 APHAB 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 authors concluded that overall, BAHA fitting can be considered effective and beneficial in children with bilateral or unilateral hearing loss.
• The SoundBite hearing system (Sonitus Medical, San Mateo, CA) allows people with single-sided deafness (SSD) to wear an intra-oral device and a small microphone in the deaf ear to regain lost hearing. A piezoelectric activator in a small removable unilateral oral appliance conducts sound through the bone via the teeth to the good ear. Currently, there is insufficient evidence to support the use of an intra-oral bone conduction hearing aid for the treatment of hearing loss. The quality of the studies was low due to small study populations, short follow-up, and the lack of randomization and appropriate control groups. Future studies with larger populations of patients wearing the device for longer periods are needed to evaluate hearing benefits and device safety.

• Popelka et al (2010) stated that a new approach for SSD has been proposed that optimizes microphone location and delivers sound by bone conduction through a removable oral appliance. Measures in the laboratory using normal-hearing subjects indicated that the device provides useful gain and output for SSD patients, is comfortable, does not seem to have detrimental effects on oral function or oral health, and has several advantages over existing devices. Specifically, microphone placement is optimized for reducing the auditory deficit caused by SSD, frequency bandwidth is much greater, and the system does not require surgical placement. Auditory performance in a small sample of SSD subjects indicated a substantial advantage compared with not wearing the device. The authors noted that future studies will involve performance measures on SSD patients wearing the device for longer periods.

• Murray et al (2011a) determine the benefit, safety and effectiveness, of a new intra-oral conduction device (SoundBite Hearing System) for SSD. Adults (aged between greater than 18 and less than 80 years) with acquired, permanent SSD (n = 28) and no current use of any SSD device were included in this study. Intervention was continual daily wear of the new device over a 30-day trial period. Main outcome measures included the Hearing in Noise Test (HINT), the Abbreviated Profile of Hearing Aid Benefit (APHAB), comprehensive pre-trial and post-trial medical, audiologic, and dental examinations and an SSD questionnaire. The Hearing in Noise Test scores improved an average of -2.5 dB after 30 days, compared with wearing no device (p < 0.001).

• The Abbreviated Profile of Hearing Aid Benefit scores improved (p < 0.05) for all subjects for the Global and Background Noise subscales and for all but 1 subject for the Reverberation and Ease of Communication subscales. There were no medical, audiologic, or dental complications. The authors concluded that the SoundBite system is safe and effective and provided substantial benefit for SSD patients with continual daily use over a 30-day period.

• Murray et al (2011b) determined the long-term safety and benefit of the SoundBite Hearing System for SSD. Adults (n = 22) with acquired, permanent SSD and no current use of any other SSD device were included in this study. Main outcome measures included comprehensive medical, audiologic, and dental measures; aided thresholds; Abbreviated Profile of Hearing Aid Benefit scores, and an SSD questionnaire. There were no related adverse events or changes in the medical or audiologic findings at the end of the trial compared with the beginning. There were no significant changes in the mean aided thresholds (p > 0.01) or the mean dental measures (p > 0.05) at 3 or 6 months compared with pre-trial measures.

• The mean Abbreviated Profile of Hearing Aid Benefit scores showed improvement (p < 0.01) for the Background Noise, Reverberation, and Ease of Communication subscales and the Global scale at 3 and 6
The results of the SSD questionnaire indicated that the vast majority (greater than 90 %) of the subjects reported satisfaction and improvement in a variety of areas after wearing the device long-term. The authors concluded that the SoundBite system is safe and continues to provide substantial benefit for SSD patients with continual daily use over a 6-month period.

- The Otomag bone conduction hearing system (Sophono, Inc., Boulder, CO) is a partially implantable bone conduction hearing aid without a percutaneous abutment. The Otomag sound processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. The principle of these bone conduction hearing aids is a magnetic coupling and acoustic transmission between implanted and external magnets. Currently, there is insufficient evidence that the Otomag bone conduction hearing system is beneficial for patients with hearing loss. Further investigation with larger populations and long-term follow-up are needed to evaluate improvement of hearing with this device.

- Siegert (2011) developed new partially implantable bone conduction hearing aid without a percutaneous abutment and have been using them clinically for 4 years. The goal of this study was to evaluate clinical and audiological results. Magnets were implanted into shallow bone beds in a 1-step procedure. The skin area above the magnets was also reduced to a thickness of 4 to5 mm, which reduces the attenuation to less than 10 dB compared to direct bone stimulation. Over 100 patients have been implanted in the last 5 years. Except for temporary pressure marks in 4 %, which healed after careful shimming of the external base plate, there were no other complications. The author concluded that the holding strength of the external components is equivalent to partially implantable hearing aids and cochlea implants and the hearing improvement is similar to other bone conduction hearing aids.

- The author noted that the comfort and safety of this system is significantly improved compared to conventional or percutaneous bone conduction hearing aids. The main drawback of this study was the lack of a control group. These preliminary findings need to be validated by well-designed studies.

- Kiringoda and Lustig (2013) summarized available peer-reviewed literature to describe the range and rate of complications related to osseo-integrated hearing aids in adult and pediatric patients. These investigators searched PubMed using the terms bone-anchored hearing aid for articles published in English between 2000 and 2011. They included all articles reporting complications rates, except those that were case reports, general review (not systematic review), or commentary, as well as those that did not include patient outcomes, that reported outcomes associated with non-standard implantation (e.g., 8.5-mm abutment) or were of poor study or reporting quality. After excluding articles that did not meet criteria, a total of 20 articles were identified, comprising 2,134 patients who underwent a total of 2,310 osseo-implants. Complications reported in the literature were typically minor in nature. Skin reactions from Holgers Grade 2 to 4 ranged from 2.4 % to 38.1 %.

- Failure of osseo-integration ranged from 0 % to 18 % in adult and mixed populations, and 0 % to 14.3 % in pediatric populations. The rate of revision surgery ranges from 1.7 % to 34.5 % in adult and mixed populations and 0 % to 44.4 % in pediatric patients, whereas the total rate of implant loss ranged from 1.6 % to 17.4 % in adult and mixed populations and from 0.0 % to 25 % in pediatric patients. The authors concluded that
overall, the quality of large scale and/or prospective studies reporting the incidence of complications after osseo-integrated hearing aid surgery is poor and lacks uniformity.

- However, based on available data, which shows a lack of major complications, osseo-integrated implantation is a safe procedure in both adult and pediatric populations. Moreover, they stated that well-designed, prospective studies with uniform reporting standards would allow greater comparison between techniques and more reliable analysis of complications of osseo-integration surgery of the temporal bone for cochlear stimulation.

- Replacement Part: Batteries; Life Expectancy: 72 per 6 months
- Replacement Part: Headband; Life Expectancy: 1 per years
- Replacement Part: Processor; Life Expectancy: 1 per 5 years
- Adapted from: Wisconsin Department of Health and Family Services, 2005.

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ActiveHealth Management
Medical Management Guidelines

Reviewed by a Board Certified Internist
Reviewed by David Evans, MD, Medical Director, Active Health Management-Feb 2016
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