Clinical Policy Bulletin: 
Bone-Anchored Hearing Aid

Number: 0403

Policy

I. Aetna considers implantable bone-anchored hearing aids (BAHAs) or temporal bone stimulators medically necessary prosthetics for persons aged 5 years and older with a unilateral or bilateral conductive or mixed conductive and sensorineural hearing loss who have any 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:

A. Congenital or surgically induced malformations of the external ear canal or middle ear (such as aural atresia); or
B. Dermatitis of the external ear, including hypersensitivity reactions to ear moulds used in air conduction hearing aids; or
C. Hearing loss secondary to otosclerosis in persons who can not undergo stapedectomy; or
D. Severe chronic external otitis or otitis media; or
E. Tumors of the external ear canal and/or tympanic cavity; or
F. Other conditions in which an air-conduction hearing aid is contraindicated.

Audiologic criteria:

A. 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).

B. 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 less than:
1. 10 dB average (measured at 0.5, 1, 2 and 4 kHz) or less than 15 dB at individual frequencies (BAHA Divino, BAHA BP100, Ponto Pro); or
2. 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).

II. Aetna considers an implantable BAHA for conductive or mixed hearing loss experimental and investigational when criteria are not met because of insufficient evidence in the peer-reviewed published medical literature.

III. Aetna considers the use of an implantable BAHA 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).

Aetna considers the use of an implantable BAHA experimental and investigational for bilateral pure sensorineural hearing loss, and for all other indications because its effectiveness for indications other than the ones listed above has not been established.

IV. Aetna considers intra-oral bone conduction hearing aids (e.g., the SoundBite hearing system) for the treatment of hearing loss experimental and investigational because their effectiveness has not been established.

V. Aetna considers partially implantable bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., BAHA Attract System and the Otomag Alpha 1(M) bone conduction hearing system) for the treatment of hearing loss medically necessary if regular BAHA cannot be used.

Note: Aetna follows Medicare rules in considering osseointegrated implants, such as implantable BAHAs 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.

See also CPB 0013 - Cochlear Implants and Auditory Brainstem Implants; and CPB 0612 - Implantable Hearing Aids.

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 BAHA 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. Pre-operative 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 BAHAs 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 Food and Drug Administration (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 meta-analysis 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 (BN). 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 BAHA 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 BAHA was always trialed after the CROS aid; (ii) CROS aids were only trialed for 4 weeks; (iii) none used any measure of hearing handicap when selecting subjects; (iv) 2 studies have a bias in terms of patient selection; (v) all studies were under-powered; and (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 2 problem areas in the children with
hearing impairment: (i) reactions to sounds, and (ii) intelligibility of speech. An additional BAHA 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 audio logical benefits and also renders high patient satisfaction.

When suggested indications for treatment with the BAHA 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.

An assessment of the BAHA device by the Institute for Clinical Effectiveness and Health Policy (Pichon-Rivere et al, 2009) concluded that there is evidence that BAHA is useful for people with conductive-type hearing loss who cannot undergo surgery or who have contraindications or adverse effects to hearing aids. If implantation is used, it should be implanted to patients over 5 years old and by specially trained staff in an operating room. Evidence comes, however, from observational studies, many of which include a few participants.

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 BAHA 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 BAHA 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), Speech, Spatial and Qualities of Hearing Scale (SSQ) and single-sided deafness (SSD) 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:

The SoundBite hearing system (Sonitus Medical, San Mateo, CA) allows people with 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 APHAB scores improved (p < 0.05) for all subjects for the Global and Background Noise subscales and for all but 1 subject for the Reverberation (RV) and Ease of Communication (EC) 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; APHAB 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 APHAB scores showed improvement (p < 0.01) for the BN, RV, and EC subscales and the Global scale at 3 and 6 months. 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.
In a prospective, multi-site, non-randomized study, Gurgel and Shelton (2013) determined the safety and effectiveness of the SoundBite for patients over a 6-month period of use. Patients with single-sided deafness were eligible for the study. Patients were fit with the standard SoundBite sound transducer and were asked to wear the device regularly for 6 months. At the end of the trial period, patients completed both a self-assessment and the APHAB questionnaires. A total of 34 subjects completed the study. Mean APHAB scores improved significantly for EC (p < 0.001), BN (p < 0.001), RV (p < 0.001), and global benefit (p < 0.001). Patients reported high rates of auditory benefit in a variety of listening situations and high rates of overall satisfaction with the device. One adverse event with a superficial mouth sore was reported and resolved after appropriate dental care. Twelve patients (35 %) reported acoustic feedback. In 6 of these patients, the feedback resolved after device adjustment. The authors concluded that the SoundBite is a new hearing prosthesis that delivers bone conduction energy. It offers advantages over traditional osseo-integrated devices that require surgical placement. Patient satisfaction with the device after 6 months of regular use is high. The SoundBite provided improvement in EC, hearing in BN, sound RV, and an overall global hearing benefit. Acoustic feedback is the most commonly reported problem with the SoundBite, and this is minimized with proper fitting.

Moore and Popelka (2013) compared the effectiveness of 2 types of treatment for unilateral hearing loss (UHL), bone-anchored hearing instruments (BAHI) and a dental device (SoundBite). Either BAHI or SoundBite was worn for 30 days, and then the devices were swapped and the second device was worn for 30 days. Measures included unaided and aided sound-field thresholds, sound localization, and perception of speech in babble. The APHAB questionnaire was administered for each trial period. A total of 9 adult BAHI wearers with UHL were included in this study. Mid-frequency aided thresholds were lower for SoundBite than for BAHI. Both devices gave benefits for localization after 30 days, but there was no difference between devices. Speech perception was better for both devices than for unaided listening when the target speech came from the poorer hearing side or in front, and the interfering babble came from the better-hearing side. There was no consistent difference between devices. APHAB scores were better for SoundBite than for BAHI. The authors concluded that speech perception and sound localization were similar for the 2 types of device, but the SoundBite led to lower aided thresholds and better APHAB scores than the BAHI.

The results of these 2 trials were encouraging. However, these studies were small (n = 34 and n = 9, respectively), non-randomized, and had only short-term follow-ups (6 months and 30 days, respectively), their findings need to be validated by well-designed studies. Furthermore, UpToDate reviews on "Sudden sensorineural hearing loss" (Weber, 2014) and "Treatment of hearing impairment in children" (Smith and Gooi, 2014) do not mention the use of SoundBite/dental device/non-osseous anchored hearing aid as a therapeutic option.

**The Otomag Bone Conduction Hearing System:**

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 to 5 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.

The BAHA Attract System:

The Baha Attract consists of a percutaneously placed implant magnet and an external sound processor magnet forming a magnetic connection across healed skin. A Baha sound processor is then attached to the sound processor magnet.

Iseri et al (2014) reported their experience with a new transcutaneous bone conduction hearing device, the Baha Attract System (Cochlear Bone Anchored Solutions AB, Molnlycke, Sweden). This multi-center clinical study included the first 12 patients (8 females, 4 males; mean age of 27.6 years; range of 5 to 65 years) in whom a new transcutaneous bone conduction system was implanted in Turkey. The mean air-bone gap was 41 dB. Bone smoothing around the implant was needed in 5 patients. These researchers placed a sound processor in the 4th post-operative week for all patients. The authors conclude that these findings suggested that the new bone conduction implant is promising for the patients with conductive or mixed hearing loss who are unable to wear conventional air conduction hearing aid and comparable to percutaneous systems.

Briggs et al (2015) prospectively evaluated, in a multi-center setting, the clinical performance of a new magnetic bone conduction hearing implant system. The test device was the Cochlear Baha Attract System. Instead of the skin-penetrating abutment of traditional bone conduction hearing implants, the test device uses an implantable and an external magnet to transmit sound from the sound processor (SP) through intact skin to the skull bone. A total of 27 adult patients with a conductive or mild mixed hearing loss or single-sided sensorineural deafness were included in the clinical investigation across 4 investigational sites. Patients were followed for 9 months after implantation. The study evaluated efficacy in terms of
hearing performance compared with unaided hearing and with hearing with the SP on a Softband. Patient benefit, soft tissue status, device retention, and safety parameters were monitored continuously throughout the investigation. Surgery and healing was uneventful. Statistically significant improvements in audibility and speech understanding in noise and quiet were recorded for the test device compared with pre-operative unaided hearing. Speech recognition was similar or better than tests performed with the same SP on a Softband. Good soft tissue outcomes were reported, without major pressure-related complications. At the end of the investigation, all patients continued to use and benefit from the device. The authors concluded that the test device provided good hearing performance in patients with a conductive hearing loss or single-sided sensorineural deafness, with good wearing comfort and minimal soft tissue complications. The finding of his small study (n = 27) need to be validated by well-designed studies.

The Ponto Pro:

Oeding and Valente (2013) determined if statistically significant differences existed in the mean Reception Threshold for Sentences (RTS in dB) in diffuse uncorrelated restaurant noise between unaided, an omnidirectional microphone (OM), split DM (SDM), and full DM (FDM) in the Oticon Medical Ponto Pro. A second goal was to assess subjective benefit using the APHAB comparing the Ponto Pro to the participant's current bone anchored hearing solutions (BAHSs), and the Ponto Pro and participant's own BAHS to unaided. The third goal was to compare RTS data of the Ponto Pro to data from an identical study examining Cochlear Americas' Divino. A total of 15 BAHS users with unilateral sensori-neural hearing loss (USNHL) were recruited for this study. The Ponto Pro was fit by measuring in-situ bone conduction thresholds and was worn for 4 weeks. An RTS was obtained utilizing HINT sentences in uncorrelated restaurant noise from an 8 - loudspeaker array, and subjective benefit was determined utilizing the APHAB. Analysis of variance (ANOVA) was used to analyze the results of the Ponto Pro HINT and APHAB data, and comparisons between the Ponto Pro and previous Divino data. No statistically significant differences existed in mean RTS between unaided, the Ponto Pro's OM, SDM, or FDM (p = 0.10). The Ponto Pro provided statistically significant benefit for the BN (p < 0.01) and RV (p < 0.05) subscales compared to the participant's own BAHS. The Ponto Pro (EC [p < 0.01], BN [p < 0.001], and RV [p < 0.01] subscales) and participant's own BAHS (BN [p < 0.01] and RV [p < 0.01] subscales) overall provided statistically significant benefit compared to unaided. Clinically significant benefit of 5 % was present for the Ponto Pro compared to the participant's own BAHS and 10 % for the Ponto Pro and the participant's own BAHS compared to unaided. The Ponto Pro's OM (p = 0.05), SDM (p = 0.05), and FDM (p < 0.01) were statistically significantly better than the Divino's OM. No significant differences existed between the Ponto Pro's OM, SDM, and FDM compared to the Divino's DM. The authors concluded that no statistically significant differences existed between unaided, OM, SDM, or FDM. Participants preferred the Ponto Pro compared to the participant's own BAHS and the Ponto Pro and participant's own BAHS compared to unaided. The RTS of the Ponto Pro's adaptive multi-channel DM was similar to the Divino's fixed hyper-cardioid DM, but the Ponto Pro's OM was statistically significantly better than the Divino's OM.
Bosman et al (2013) compared performance of a recently released sound processor for bone-anchored implants, the Ponto Pro Power from Oticon Medical (bone-conduction device 2 [BCD2]) with that of the BAHA Intenso from Cochlear (bone-conduction device 1 [BCD1]). Direct comparison of the subject's own device (BCD1) with the new device (BCD2) was examined in a non-randomized design. Subjects were initially tested with BCD1; BCD2 was tested after a 4-week acclimatization period. A total of 18 subjects with mixed hearing loss and with at least 4-month experience with BCD1 completed the study. Mean air-conduction and bone-conduction thresholds averaged across the frequencies of 500, 1,000, 2,000, and 4,000 Hz were 73.9 and 34.2 dB HL, respectively. Performance of the 2 devices was evaluated objectively by measuring aided free-field thresholds, speech perception in quiet, and speech perception in noise. A subjective evaluation was carried out with APHAB and the SSQ questionnaire. In addition, user experiences, user satisfaction, and device preference were obtained via proprietary questionnaires. Statistical significance was established with ANOVA and paired t-statistics with Bonferroni correction. Aided free-field thresholds and speech reception thresholds (SRTs) in quiet were not statistically significantly different for either device (p > 0.05). In contrast, SRTs in noise were 2.0 dB lower (p < 0.001) for BCD2 than for BCD1. APHAB questionnaire scores on all subscales provided statistically significantly greater benefit (p < 0.05) for BCD2 than for BCD1. Also, with the SSQ most items in the speech and sound quality domain were significantly more favorable (p < 0.05) for BCD2 than for BCD1. Finally, all subjects preferred BCD2 over BCD1 with 14 subjects reporting a strong preference and 4 subjects an average preference for the digital signal processing provided by BCD2 over previous technology provided by BCD1.

Hill-Feltham et al (2014) compared the performance of 2 new BAHAs with older BAHAs that were not fully digital. A total of 14 experienced BAHA users participated in this cross-over study. Performance of their existing BAHA was assessed using speech-in-noise testing and questionnaires. Participants were then fitted with either a Ponto Pro or a BP100 device. After 4 weeks of use with each new device, the same assessments were repeated. Speech-in-noise testing for the 50 % signal-to-noise ratio (the ratio at which 50 % of responses were correct) showed no significant differences between the Ponto Pro and the BP100 device (p = 0.1). However, both devices showed significant improvement compared with the participants’ previous BAHA devices (p < 0.001). There were no significant differences between the 2 new devices in the questionnaire data. The authors concluded that both fully digital BAHAs demonstrated superior speech processing compared with the previous generation of devices. There were no substantial differences between the 2 digital devices in either objective or subjective tests.

Miscellaneous Information:

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 0.0 % 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.

Huber et al (2013) evaluated the functional performance of the Bonebridge (BB, MED-EL), a newly-designed transcutaneous bone conduction implant that allows the skin to remain intact and to compare it with the current clinical model of choice, a percutaneous bone conduction implant (BAHA BP100, Cochlear Bone Anchored Solutions AG). The devices were compared using 2 methods: (i) Measurements of cochlear promontory acceleration in 5 cadaver heads: Accelerations of the cochlear promontories on both ipsilateral and contralateral sides were measured using a Laser Doppler system, with free-field sound stimuli of 90 dB SPL in the frequency range of 0.3 to 10 kHz, and (ii) Measurements of pure-tone sound field thresholds in 5 normally hearing human adult subjects under a condition of simulated hearing loss. For the latter measurements, the devices were applied to the head using a Softband, and measurements were performed in the frequency range of 0.25 to 8 kHz. Within investigation comparisons (i.e., in cadavers or listeners) and a cross-comparison analysis of the cadaver and human results were done. Results from the cadaver heads showed that the cochlear promontory acceleration with the BB was higher within 10 dB on the ipsilateral side and lower within 5 dB on the contralateral side than the acceleration with the BAHA, in the frequency range of 0.7 to 10 kHz. The transcranial attenuation of the acceleration for the BB was greater than for the BAHA within 20 dB. For the sound-field threshold assessments with human subjects, the BB and BAHA showed similar threshold improvements of more than 10 dB HL for the ipsilateral side. For the contralateral side, the threshold improvement with the BB was less than with the BAHA, indicating better separation between ipsilateral and contralateral sides. The authors concluded that pre-clinical results implied that the BB has functional performance similar to the BAHA and could be beneficial to patients suffering with conductive and mixed hearing losses as well as for those with unilateral impairment. Based on these preliminary results, a carefully designed clinical trial with conservative inclusion criteria can be recommended.
Table: Usual medically necessary frequency of replacement for BAHA parts

<table>
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<tr>
<th>Replacement Parts</th>
<th>Life Expectancy</th>
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<tbody>
<tr>
<td>Batteries</td>
<td>72 per 6 months</td>
</tr>
<tr>
<td>Headband</td>
<td>1 per year</td>
</tr>
<tr>
<td>Processor</td>
<td>1 per 5 years</td>
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Adapted from: Wisconsin Department of Health and Family Services, 2005.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

69710  Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone [temporal bone stimulator] [Audiant Bone Conductor]

69711  Removal or repair of electromagnetic bone conduction hearing device in temporal bone [temporal bone stimulator] [Audiant Bone Conductor]

69714  Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy [bone-anchored hearing aid (BAHA), Ponto Pro]

69715   with mastoidectomy [bone-anchored hearing aid (BAHA), Ponto Pro]

69717  Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy [bone-anchored hearing aid (BAHA), Ponto Pro]

69718   with mastoidectomy [bone-anchored hearing aid (BAHA), Ponto Pro]

Other CPT codes related to the CPB:

69550  - Excision aural glomus tumor

69554

69660  - Stapedectomy or stapedotomy

69662

92521  Evaluation of speech fluency (eg, stuttering, cluttering)
92522 Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria)

92523 Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)

92524 Behavioral and qualitative analysis of voice and resonance

92551 - 92557, 92558, 92567 - 92569, 92579, 92582 - 92587 Audiologic function tests

92626 - 92627 Evaluation of auditory rehabilitation status

92630 - 92633 Auditory rehabilitation

**HCPCS codes covered if selection criteria is met:**

L8690 Auditory osseointegrated device, includes all internal and external components

L8691 Auditory osseointegrated device, external sound processor, replacement

L8693 Auditory osseointegrated device abutment, any length, replacement only

**Other HCPCS codes related to the CPB:**

G0153 Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes

L8692 Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment [excluded under plans that exclude coverage of hearing aids]

S9128 Speech therapy, in the home, per diem

V5008 - V5299 Hearing services

**ICD-9 codes covered if selection criteria are met:**

160.1 Malignant neoplasm of auditory tube, middle ear, and mastoid air cells
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>171.0</td>
<td>Malignant neoplasm of head, face and neck</td>
</tr>
<tr>
<td>173.2</td>
<td>Malignant neoplasm of skin of ear and external auditory canal</td>
</tr>
<tr>
<td>212.0</td>
<td>Benign neoplasm of nasal cavities, middle ear, and accessory sinuses</td>
</tr>
<tr>
<td>215.0</td>
<td>Benign neoplasm of head, face, and neck</td>
</tr>
<tr>
<td>216.2</td>
<td>Benign neoplasm of ear and external auditory canal</td>
</tr>
<tr>
<td>232.2</td>
<td>Carcinoma in situ of ear and external auditory canal</td>
</tr>
<tr>
<td>380.32</td>
<td>Acquired deformities of auricle or pinna [surgically induced malformations of external ear canal or middle ear]</td>
</tr>
<tr>
<td>381.10</td>
<td>Chronic serous otitis media, simple or unspecified [severe]</td>
</tr>
<tr>
<td>381.20</td>
<td>Chronic mucoid otitis media [severe]</td>
</tr>
<tr>
<td>381.3</td>
<td>Other and unspecified chronic nonsuppurative otitis media [severe]</td>
</tr>
<tr>
<td>382.2</td>
<td>Chronic atticoanal supplicative otitis media [severe]</td>
</tr>
<tr>
<td>382.3</td>
<td>Unspecified chronic supplicative otitis media [severe]</td>
</tr>
<tr>
<td>382.9</td>
<td>Unspecified otitis media [chronic severe]</td>
</tr>
<tr>
<td>387.0 - 387.9</td>
<td>Otosclerosis [causing hearing loss in persons who cannot undergo stapedectomy]</td>
</tr>
<tr>
<td>389.00 - 389.08</td>
<td>Conductive hearing loss</td>
</tr>
<tr>
<td>389.15</td>
<td>Sensorineural hearing loss, unilateral</td>
</tr>
<tr>
<td>389.20 - 389.22</td>
<td>Mixed conductive and sensorineural hearing loss</td>
</tr>
<tr>
<td>691.8</td>
<td>Other atopic dermatitis and related conditions</td>
</tr>
<tr>
<td>692.0 - 692.6, 692.81, 692.83 - 692.9</td>
<td>Contact dermatitis and other eczema [external ear/hypersensitivity reactions]</td>
</tr>
<tr>
<td>744.02</td>
<td>Other anomalies of external ear with impairment of hearing [congenital malformations of external ear canal]</td>
</tr>
<tr>
<td>744.03</td>
<td>Anomaly of middle ear, except ossicles [congenital malformations of middle ear]</td>
</tr>
<tr>
<td>744.04</td>
<td>Anomalies of ear ossicles [congenital malformations of middle ear]</td>
</tr>
</tbody>
</table>
744.3 Unspecified anomaly of ear [congenital malformations of external ear canal or middle ear]

*SoundBite Hearing System [e.g., intra-oral bone conduction hearing aids]*
*excluded under plans that exclude coverage of hearing aids*

No specific code

*Otomag Alpha 1(M) Bone Conduction Hearing System [e.g., partially implantable bone conduction hearing systems]*

No specific code

**ICD-9 codes not covered for indications listed in the CPB:**

- 389.10 - Sensorineural hearing loss [other than unilateral]
- 389.14
- 389.16 - Hearing loss
- 389.18

The above policy is based on the following references:


36. U.S. Food and Drug Administration (FDA) 510(k). Branemark Bone Anchored Hearing Aid (BAHA) System. Summary of Safety and


48. Hol MK, Kunst SJ, Snik AF, Cremers CW. Pilot study on the effectiveness of the conventional CROS, the transcranial CROS and the BAHA


67. Weber PC. Sudden sensorineural hearing loss. Last reviewed February 2014. UpToDate Inc., Waltham, MA.


