

Medical Policy



Title: Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Professional

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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 AC 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 3 to 6 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.

Partially implantable magnetic bone-conduction hearing systems are available as an alternative to bone-conduction hearing systems connected 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. Since 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 4 to 5 mm over the implant when it is surgically placed.

Regulatory Status

There are 5 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™
- BAHA 4 (upgraded from the BP100)

FDA cleared the BAHA system for the following indications:

1. Patients who have conductive or mixed hearing loss and can still benefit from sound amplification
2. Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally
3. Patients with sensorineural deafness in 1 ear and normal hearing in the other (i.e., single-sided deafness, SSD)
4. 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 younger than the age of 5 years. As this application has no implanted components, it is not addressed in the policy.

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.

The 2 partially implantable magnetic bone conduction devices that have received 510(k) clearance from the FDA are:

- Otomag Bone Conduction Hearing System, and
- BAHA Attract

POLICY

- A. 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 5 years of age and older with a conductive or mixed hearing loss who also meet at least one of the following medical criteria:

1. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear **or**
2. Chronic external otitis or otitis media **or**
3. Tumors of the external canal and/or tympanic cavity **or**
4. Dermatitis of the external canal **or**

AND

- B. Meet the following audiologic criteria:
1. A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 65 dB.
 2. 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, or less than 15 dB at individual frequencies.
 3. Speech discrimination score greater than 60% in the indicated ear.
- C. 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 5 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 or equal to 20 dB measured at 0.5, 1, 2, and 3 kHz.
- D. Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered **experimental / investigational**.
- E. Partially implantable magnetic bone-conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Otomag Alpha 1 and BAHA Attract) are considered **experimental / investigational**.

POLICY GUIDELINES

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.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

LITERATURE REVIEW

The most recent literature search was performed for the period December 7, 2012, through December 13, 2013. No randomized controlled trials (RCTs) have compared implantable bone-conduction hearing aids to other hearing augmentation devices, or sham devices. The literature is characterized by observational studies that report pre- and post-hearing outcomes in patients treated with bone-anchored hearing aids (BAHA). Many of these studies combine patients with differing underlying disease states and indications. Following is a summary of key findings.

MIXED ETIOLOGIES OF HEARING LOSS

Systematic Reviews and Meta-Analyses

A systematic review by the Health Technology Assessment Program was published in 2011 on the use of BAHAs for bilateral hearing impairment.(1,2) The authors noted that the quality of available studies on the use of BAHAs is weak. No studies with control groups were identified for the review. Cohort pre-post studies and cross-sectional comparative studies demonstrate improvements in hearing with use of BAHAs over conventional bone-conduction hearing aids or unaided hearing. However, whether improvements in hearing with BAHAs are greater than air-conduction hearing aids is uncertain. Additionally, bilateral use of BAHAs improved hearing outcomes in some patients over unilateral use, but the evidence was uncertain. Implant loss was noted to be between 6.1% and 19.4%. The authors noted hearing-specific quality of life improved, but overall quality of life did not differ.

In 2103 Kiringoda et al reported on a meta-analysis of complications related to BAHA implants. Included in the meta-analysis were 20 studies that evaluated complication in 2134 adult and pediatric patients who received a total of 2310 BAHA implants. While the quality of available studies was considered poor and lacking in uniformity, complications related to BAHA implants were mostly minor skin reactions.(3) Holgers Grade 2 to 4 skin reactions were reported to occur from 2.4% to 38.1% in all studies. Zero to 18% of implants failed osseointegration in adult and mixed population studies while 0% to 14.3% failed osseointegration in pediatric population studies. Adult and mixed population studies reported revision surgery was required in 1.7% to 34.5% of cases while pediatric population studies reported required revision surgery in 0.0% to 44.4% of cases. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and from 0.0% to 25% in pediatric studies.

Observational Studies

In 2010, Ramakrishnan et al retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in 109 children and young adults in a single center.(4) The patient population was somewhat unique in that many patients had craniofacial or genetic syndromes in addition to hearing loss (22 of 109). Criteria for the selection of the implanted device or the Softband were not described; however, the authors did note an uneven distribution by mean age, gender, and syndromic comorbidity. Primary measures were the Glasgow Benefit Inventory or Listening Situation Questionnaire (parent version) administered at least 3 months following hearing aid intervention. Mean overall Glasgow Benefit Inventory scores were reported as +29 (range, 11-72). The mean Listening Situation Questionnaire score of 17 was reported as less than a referral cutoff of 22. The authors conclude that this population benefits from bone-

anchored and Softband-held conductive hearing aids based on mean scores. However, the study is limited due to a heterogeneous patient population, a lack of pre-intervention measures, or a controlled comparator group.

In 2004, McLarnon et al reported outcomes (benefits) for BAHAs by patient subgroups based on 69 of 94 (73%) patients who completed a questionnaire.(5) This study noted the greatest benefit in those with congenital ear disorders. It also showed benefit to restoring stereo hearing to patients with an acquired unilateral hearing loss after acoustic neuroma surgery.

In 2008, Tringali et al surveyed patients using a BAHA to compare patient satisfaction by indication: 52 respondents with conductive or mixed hearing loss (44 with chronic otitis and 8 with malformation of the middle ear) compared with 118 with single-sided deafness (SSD) (2 after surgery for meningioma, idiopathic sudden deafness, sensorineural hearing loss complicating surgery of the middle ear).(6) Levels of satisfaction and quality of life were significantly poorer in the SSD than in the conductive hearing loss (CHL) group, although generally good with the exception of sound localization.

Moderate to Severe Conductive or Mixed Hearing Loss

Reported studies have suggested that the BAHA is associated with improved hearing outcomes compared to external bone-conduction hearing aids and equivalent outcomes compared to a conventional air-conduction hearing aid.(7-10)

Bilateral Devices in Conductive or Mixed Hearing Loss

Use of bilateral devices has been evaluated in patients with conductive or mixed hearing losses. A number of studies, published over several years, have demonstrated a consistent improvement in speech recognition in noise and in sound localization with bilateral devices.

Janssen et al (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent CHL.(11) Their search strategy included studies of all languages published between 1977 and July 2011. Studies were included if subjects of any age had permanent bilateral CHL and bilateral implanted BAHAs. Outcome measures of interest were any subjective or objective audiologic measures, quality-of-life indicators, or reports of adverse events. Eleven studies met their inclusion criteria. All 11 studies were observational. There were a total of 168 patients in the 11 studies, 155 of whom had BAHAs and 146 of whom had bilateral BAHAs. In most studies, comparisons between unilateral and bilateral BAHA were intrasubject. Patients ranged from 5 to 83 years of age; 46% were male, and 54% were female. Heterogeneity of the methodologies between studies precluded meta-analysis, therefore a qualitative review was performed. Results from 3 (of 11) studies were excluded from synthesis because their patients had been included in multiple publications. Adverse events were not an outcome measure of any of the included studies.(11) In general, bilateral BAHA was observed to provide additional objective and subjective benefit compared to unilateral BAHA. For example, the improvement in tone thresholds associated with bilateral BAHA ranged from 2 to 15 dB, the improvement in speech recognition patterns ranged from 4 to 5.4 dB, and the improvement in the Word Recognition Score ranged from 1% to 8%. However, these results were based on a limited number of small observational studies consisting of heterogeneous patient groups that varied in age, severity of hearing loss, etiology of hearing loss, and previous amplification experience.(11)

Examples of individual studies include the following. In 2001, Bosman et al reported on findings from 25 patients who were using bilateral devices.(12) They found that both speech recognition in noise and directional hearing improved with the second device. In a 2004 publication, Priwin et al reported similar findings in 12 patients with bilateral devices.(13) A consensus statement published in 2005 concluded that bilateral devices resulted in binaural hearing with improved directional hearing and improved speech-in-noise scores in those with bilateral CHL and symmetric bone-conduction thresholds.(14) A number of additional studies that are cited in this report found benefits similar to those noted in the studies of the Bosman et al and Priwin et al reports.(12,13) Positive outcomes continue to be reported: Dun et al(15) identified improvements in the Glasgow Benefit Inventory in children (n=23), while Ho et al(16) report the same benefit in adults (n=93). Thus, based on these numerous studies, bilateral devices may be considered medically necessary when there is bilateral conductive or mixed hearing loss with symmetric bone-conduction thresholds.

Unilateral Sensorineural Hearing Loss

Several centers have reported on findings from observational studies designed to evaluate the benefits of BAHA for patients with unilateral sensorineural hearing loss (SSD). Most of these studies have been retrospective. In 1 prospective study conducted within a hospital auditory implant center in the United Kingdom, Pai et al reported significant improvement in the average score in all 3 sections (speech hearing, spatial hearing, other qualities) of the Speech, Spatial and Qualities of hearing scale SSQ questionnaire following a BAHA implant in 25 adult patients.(17)

Zeitler et al reported on a retrospective case series of 180 patients undergoing unilateral or bilateral BAHA for SSD with residual hearing in the implanted ear within a university medical center in the U.S.(18) Significant improvement was reported in objective hearing measures (speech-in-noise and monosyllabic word tests) following BAHA implantation. Subjective benefits from BAHA varied across patients according to results from the Glasgow Hearing Aid Benefit Profile, but patients with residual hearing in the affected ear tended toward improved satisfaction with their device postoperatively.(18) Nicolas et al undertook a retrospective review of 36 patients implanted with a BAHA within a university medical center in France.(19) Their results showed an improvement in speech perception in noise with the BAHA, but no improvement in sound localization based on a 2-year follow-up period.(19)

Baguley et al reviewed the evidence for contralateral BAHAs in adults with acquired unilateral sensorineural hearing loss.(20) None of the 4 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 BAHAs resulted in greater improvement than that obtained with the conventional air-conduction contralateral routing of signal (CROS) systems. The authors of this review did note shortfalls in the studies reviewed.

Lin et al reported on use of the BAHAs in 23 patients with unilateral deafness and noted that speech recognition in noise was significantly better with the BAHA device than with the air-conduction CROS device.(21) While the report also comments that benefit was seen in those with moderate sensorineural hearing loss in the contralateral ear (25–50 dB), this conclusion was based on 5 patients. Larger studies are needed before changes can be considered in the policy statement regarding use in this clinical situation.

Two studies of BAHAs for congenital unilateral conductive hearing impairment are reported by Kunst et al. In 1 study, aided and unaided hearing was assessed in 20 patients using sound localization and speech recognition-in-noise tests.(22) Many patients showed unexpectedly good unaided performance; however, nonsignificant improvements were observed in favor of the BAHA. Six of 18 patients with a complete data set showed no improvement at all; however, compliance with BAHA use in this patient group was remarkably high, suggesting patient benefit. The same authors evaluated 10 adults and 10 children using 2 disability-specific questionnaires and found an overall preference for the BAHA over unaided hearing in several specific hearing situations.(22) Improvement on the Glasgow Children's Benefit Inventory was most prominent in the learning domain. The 10 adults showed an already good score on the Speech, Spatial, and Qualities of hearing scale in the unaided situation.

In 2010, Gluth et al reported on 21 patients with profound unilateral sensorineural hearing loss followed for an average of 3.2 years after BAHA implantation.(23) Perceived benefits and satisfaction were reported to improve significantly in BAHA users, and 81% continued using the device long term. However, severe local skin reactions were frequently experienced (38% Grade 2 and above).

Children Younger Than Age 5 Years

A 2008 review article notes that for children younger than age 5 years, other solutions (such as a bone conductor with transcutaneous coupling) should be utilized.(24) This recommendation is in agreement with FDA clearance of the osseointegration implant only for children 5 years of age and older, and adults. This is reflected in the policy statements.

The BAHA device has been investigated in children younger than 5 years in Europe and the United Kingdom. A number of reports describe experience with preschool children or children with developmental issues that might interfere with maintenance of the device and skin integrity. A 2-stage procedure may be used in young children. In the first stage, the fixture is placed into the bone and allowed to fully develop osseointegration. After 3 to 6 months, a second procedure is performed to connect the abutment through the skin to the fixture. Marsella et al have reported on their center's experience in Italy with pediatric BAHA from the inception of their program in 1995 to December 2009.(25) A total of 47 children (21 females and 26 males) were implanted; 7 of these were younger than 5 years. The functional gain was significantly better with BAHA than conventional bone-conduction hearing aids, and there was no significant difference in terms of functional outcome between the 7 patients receiving a BAHA at an age younger than 5 years and the rest of the patient cohort. Based on these findings, the study authors suggest that implantation of children at an age younger than 5 years can be conducted safely and effectively in such settings.(25) The conclusions are limited by the small number of children younger than 5 years of age in the study and the limited power to detect a difference between younger and older children.

Dauids et al at the University of Toronto provided BAHA devices to children younger than 5 years of age for auditory and speech-language development and retrospectively compared surgical outcomes for a study group of 20 children younger than 5 years and a control group of 20 older children.(26) Children with cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for children having 2-stage procedures was significantly longer in the study group to allow implantation in younger patients without increasing surgical or postoperative morbidity. Two traumatic fractures occurred in the study group versus 4 in the older children. Three younger children required skin site revision. All

children were wearing their BAHA devices at the time of writing. McDermott et al reported on the role of BAHAs in children with Down syndrome in a retrospective case analysis and postal survey of complication rates and quality-of-life outcomes for 15 children aged 2 to 15 years.(27) All patients were using their BAHA devices after a follow-up of 14 months. No fixtures were lost; skin problems were encountered in 3 patients. All 15 patients had improved social and physical functioning, attributed to improved hearing.

Adverse Events

In 2012, Dun et al assessed soft tissue reactions and implant stability of 1132 percutaneous titanium implants for bone-conduction devices through a retrospective survey of 970 patients undergoing implants between September 1988 and December 2007 at the University Medical Center in the Netherlands.(28) The study investigators also examined device usage and comparisons between different patient age groups (children, adults, elderly patients) over a 5-year follow-up period. Implant loss was 8.3%. In close to 96% of cases, there were no adverse soft tissue reactions. Significantly more soft tissue reactions and implant failures were observed in children compared with adults and elderly patients ($p < 0.05$). Implant survival was lower in patients with mental retardation compared with patients without mental retardation ($p = 0.001$). (28)

In 2010, Hobson et al reviewed complications on 602 patients at a tertiary referral center over 24 years and compared their observed rates to those published in 16 previous studies.(29) The overall observed complication rate of 23.9% (144 of 602) is similar to other published studies (complication rate, $24.9\% \pm 14.85$). The most common complications were soft tissue overgrowth, skin infection, and fixture dislodgement. The observed rate of revision surgery of 12.1% (73 of 602) was also similar to previously published rates of 12.7%. Top reasons for revision surgery were identical to observed complications. In 2011, Wallberg et al reported on the status of 150 implants placed between 1977 and 1986 and followed for a mean of 9 years.(30) Implants were lost in a total of 41 patients (27%). The reasons for implant loss were: removal in 16 patients, osseointegration failure in 17 patients, and direct trauma in 8 patients. In the remainder of 132 patients with implant survival, BAHAs were still being used by 119 patients (90%) at the end of follow-up. For children, implant complications were even more frequent, as reported by Kraai et al in a follow-up evaluation of 27 implants placed in children ages 16 years or younger between 2002 and 2009.(31) In this retrospective report, soft tissue reactions occurred in 24 patients (89%); removal of the implant or revision surgery was required in 10 patients (37%); 24 patients (89%) experienced soft tissue overgrowth and infection; and 7 patients experienced implant trauma. Chronic infection and overgrowth at the abutment prevented use of the implant in 3 patients (11%).

Partially Implantable Magnetic Bone-Conduction Hearing Aids

In 2011, Seigert reported on the use of a partially implantable bone-conduction hearing system (Otomag) that uses magnetic coupling for transcutaneous acoustic transmission.(32) This hearing system is reported to have been implanted in more than 100 patients followed in the past 5 years, but results are only presented on 12 patients. Since the acoustics must pass through the skin rather than by direct bone stimulation through a percutaneous abutment on the BAHA-type implants, Seigert reports sound attenuation is reduced by less than 10 dB. The preliminary results of the partially implantable hearing system in 8 unilaterally and 4 bilaterally implanted patients showed average hearing gains of 31.2 ± 8.1 dB in free field pure tone audiogram. The free field suprathreshold speech perception at 65 dB increased from 12.9% preimplantation to 72.1% postimplantation.

In 2013 Hol et al reported on a comparison of BAHA percutaneous implants to partially implantable magnetic transcutaneous bone-conduction hearing implants using the Otomag Sophono device in 12 pediatric patients, ranging in age from 5 to 12 years, with congenital unilateral CHL. (33) Sound field thresholds, speech recognition threshold and speech comprehension at 65 dB were somewhat better in patients with the BAHA implant (n=6) than the partially implantable hearing implant (n=6). Using a skull simulator, output was 10 to 15 dB lower with the partially implantable device than the BAHA device.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov on December 16, 2013, found several ongoing studies on bone-conduction hearing implant devices. A randomized trial of 10 patients will compare a BAHA device to a CROS hearing aid but is not yet recruiting patients. (NCT01715948) In order to compare the BAHA and CROS, users of BAHA will be given a 2-week trial period with the 'Unitron Tandem' CROS hearing aid. Participants will be randomly assigned to wear either their BAHA for 2 weeks or the trial CROS for 2 weeks. An osseointegrated bone-conduction device will be compared to a removable oral bone-conduction appliance in 15 patients in NCT01933386. A Phase IV open study will evaluate the effectiveness of BAHAs for conductive or mixed hearing loss, or unilateral deafness. (NCT01264510) The status of this study is ongoing, but the study is not recruiting participants. Expected enrollment for this study is 150 patients, with an estimated initial completion date of August 2013.

Two studies were identified that will evaluate a partially implantable transcutaneous bone-conduction hearing implant. One study will evaluate the BAHA Attract in 22 patients (NCT01822119). A conventional bone-conduction hearing device will be compared with a new partially implantable transcutaneous bone-conduction hearing implant (Vibrant Bonebridge™) in an RCT of 60 patients (NCT01858246).

SUMMARY

Bone-conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear. The available evidence for unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) consists of observational studies that report pre-post differences in hearing parameters after treatment with BAHA. While this evidence is not ideal, it is sufficient to demonstrate improved net health outcome for patients 5 years of age or older in certain situations. The evidence supports the use of these devices in patients with conductive or mixed hearing loss who meet other medical and audiologic criteria. 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 devices improve hearing to a greater degree than do unilateral devices. Bone-anchored hearing aids may be considered as an alternative to air-conduction devices in these patients and therefore, these devices may be considered medically necessary in these situations. Given the lack of both high-quality evidence and FDA approval, other uses of bone-conduction (bone-anchored) hearing aids, including use in children younger than 5 years and patients with bilateral sensorineural hearing loss, is considered investigational.

The available evidence for partially implantable magnetic bone-conduction hearing systems is preliminary and very limited. Therefore, conclusions on net health outcomes cannot be made, and partially implantable bone-conduction hearing systems are considered investigational.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing <u>device</u> in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment <u>to</u> of external speech processor/cochlear stimulator; without mastoidectomy
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment <u>to</u> of external speech processor/cochlear stimulator; with mastoidectomy
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

- The following CPT codes describe semi-implantable bone-conduction hearing aids: 69710*, 69711*, 69714**, 69715**.

*The Audiant bone conductor is a type of electromagnetic bone-conduction hearing device.

While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.

**Describe the BAHA device.

- There are HCPCS codes specific to this device: L8690, L8691, L8693.

ICD-9 Diagnoses

380.15	Infective otitis externa; chronic mycotic otitis externa
380.16	Infective otitis externa; other chronic infective otitis externa NOS
380.23	Other otitis externa; other chronic otitis externa NOS
380.52	Acquired stenosis of external ear canal; secondary to surgery
381.10	Chronic serous otitis media, simple or unspecified
381.19	Chronic serous otitis media; other
381.20	Chronic mucoid otitis media, simple or unspecified
381.29	Chronic mucoid otitis media; other
381.3	Nonsuppurative otitis media and Eustachian tube disorders; other and unspecified chronic non-suppurative otitis media
382.00	Acute suppurative otitis media; without spontaneous rupture of ear drum
382.01	Acute suppurative otitis media with spontaneous rupture of ear drum
382.02	Acute suppurative otitis media in diseases classified elsewhere
382.1	Chronic tubotympanic suppurative otitis media
382.2	Chronic atticofacial suppurative otitis media

382.3	Unspecified chronic suppurative otitis media
382.4	Unspecified suppurative otitis media
382.9	Unspecified otitis media
389.00	Conductive hearing loss; unspecified
389.01	Conductive hearing loss, external ear
389.02	Conductive hearing loss, tympanic membrane
389.03	Conductive hearing loss, middle ear
389.04	Conductive hearing loss, inner ear
389.05	Conductive hearing loss, unilateral
389.06	Conductive hearing loss, bilateral
389.08	Conductive hearing loss of combined types
744.03	Anomaly of middle ear, except ossicles

ICD-10 Diagnoses (Effective October 1, 2015)

H60.61	Unspecified chronic otitis externa, right ear
H60.62	Unspecified chronic otitis externa, left ear
H60.63	Unspecified chronic otitis externa, bilateral
H60.8x1	Other otitis externa, right ear
H60.8x2	Other otitis externa, left ear
H60.8x3	Other otitis externa, bilateral
H60.91	Unspecified otitis externa, right ear
H60.92	Unspecified otitis externa, left ear
H60.93	Unspecified otitis externa, bilateral
H61.391	Other acquired stenosis of right external ear canal
H61.392	Other acquired stenosis of left external ear canal
H61.393	Other acquired stenosis of external ear canal, bilateral
H62.8x1	Other disorders of right external ear in diseases classified elsewhere
H62.8x2	Other disorders of left external ear in diseases classified elsewhere
H62.8x3	Other disorders of external ear in diseases classified elsewhere, bilateral
H65.21	Chronic serous otitis media, right ear
H65.22	Chronic serous otitis media, left ear
H65.23	Chronic serous otitis media, bilateral
H65.31	Chronic mucoid otitis media, right ear
H65.32	Chronic mucoid otitis media, left ear
H65.33	Chronic mucoid otitis media, bilateral
H65.411	Chronic allergic otitis media, right ear
H65.412	Chronic allergic otitis media, left ear
H65.413	Chronic allergic otitis media, bilateral
H65.491	Other chronic nonsuppurative otitis media, right ear
H65.492	Other chronic nonsuppurative otitis media, left ear
H65.493	Other chronic nonsuppurative otitis media, bilateral
H66.001	Acute suppurative otitis media without spontaneous rupture of ear drum, right ear
H66.002	Acute suppurative otitis media without spontaneous rupture of ear drum, left ear
H66.003	Acute suppurative otitis media without spontaneous rupture of ear drum, bilateral
H66.004	Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, right ear
H66.005	Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, left ear
H66.006	Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent,

- bilateral
- H66.011 Acute suppurative otitis media with spontaneous rupture of ear drum, right ear
- H66.012 Acute suppurative otitis media with spontaneous rupture of ear drum, left ear
- H66.013 Acute suppurative otitis media with spontaneous rupture of ear drum, bilateral
- H66.014 Acute suppurative otitis media with spontaneous rupture of ear drum, recurrent, right ear
- H66.015 Acute suppurative otitis media with spontaneous rupture of ear drum, recurrent, left ear
- H66.016 Acute suppurative otitis media with spontaneous rupture of ear drum, recurrent, bilateral
- H66.11 Chronic tubotympanic suppurative otitis media, right ear
- H66.12 Chronic tubotympanic suppurative otitis media, left ear
- H66.13 Chronic tubotympanic suppurative otitis media, bilateral
- H66.21 Chronic atticoantral suppurative otitis media, right ear
- H66.22 Chronic atticoantral suppurative otitis media, left ear
- H66.23 Chronic atticoantral suppurative otitis media, bilateral
- H66.3x1 Other chronic suppurative otitis media, right ear
- H66.3x2 Other chronic suppurative otitis media, left ear
- H66.3x3 Other chronic suppurative otitis media, bilateral
- H66.41 Suppurative otitis media, unspecified, right ear
- H66.42 Suppurative otitis media, unspecified, left ear
- H66.43 Suppurative otitis media, unspecified, bilateral
- H66.91 Otitis media, unspecified, right ear
- H66.92 Otitis media, unspecified, left ear
- H66.93 Otitis media, unspecified, bilateral
- H67.1 Otitis media in diseases classified elsewhere, right ear
- H67.2 Otitis media in diseases classified elsewhere, left ear
- H67.3 Otitis media in diseases classified elsewhere, bilateral
- H90.0 Conductive hearing loss, bilateral
- H90.11 Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
- H90.12 Conductive hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
- Q16.4 Other congenital malformations of middle ear

REVISIONS

08-15-2014	Revised Title from Bone-Anchored Hearing Aids (BAHA) to Implantable Bone-Conduction and Bone-Anchored Hearing Aids (BAHA).
	Updated Description section
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Replaced the following medical policy language with updated policy language: "A. Unilateral Conductive or mixed hearing Loss These patients are unable, for various reasons, to wear a conventional hearing aid or undergo surgery to improve their hearing: Chronic otitic media (COM), Congenital malformations of the external/middle ear, other acquired malformations of the ear that preclude wearing of conventional hearing aids. The criteria as taken from the FDA 510(K) document (#992873) are: <ol style="list-style-type: none"> 1. Average bone conduction threshold better (less) than 45 dB (at 500, 1000, 2000, 3000 Hz) in the indicated ear.

	<p>2. Speech discrimination score greater than 60% in the indicated ear.</p> <p>3. Age 5 years or older.</p> <p>B. Bilateral Conductive Hearing Loss These patients have both ears involved in a conductive and mixed hearing loss and are not able to be treated with reconstructive surgery or conventional hearing aids for the above reasons. The criteria for the FDA 510(K) document #K011438 are:</p> <ol style="list-style-type: none"> 1. Moderate (40 dB) to severe (70 dB) conductive hearing loss that is symmetric. That there is less than 10dB difference in average bone conduction (at 500, 1000, 2000, 4000 Hz) or less than 15 dB difference in bone conduction at individual frequencies. 2. Patients with mixed hearing loss with an average bone conduction better (less) than 45 dB in either ear (at 500, 1000, 2000, 4000 Hz) 3. Age 5 years or older. <p>C. Unilateral Sensorineural Hearing Loss (Single Sided Deafness; SSD) These are patients where the nerve deafness in the indicated ear is so great that a conventional hearing aid no longer is useful. Typically, these patients are adults after acoustic neuroma surgery or sudden deafness and children with an unexplained deafness in one ear or after trauma. The implant is designed to stimulate the opposite (good ear) by bone conduction through the bones of the skull, therefore; the audiometric criteria are for the good ear. The criteria for the FDA 510(K) document #K021837 are:</p> <ol style="list-style-type: none"> 1. Severe (70 dB) to profound (90 dB) hearing loss on one side with poor speech discrimination and unable to use a conventional hearing aid in that ear. 2. Normal hearing in the good ear as defined by an air conduction threshold equal to or better (less) than 20 dB (at 500, 1000, 2000, 3000 Hz). 3. Age 5 years or older."
	Added Rationale section
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Updated nomenclature for CPT codes: 69710, 69711, 69714, 69715, 69717, 69718 ▪ Added HCPCS Codes: L8690, L8691, L8693 ▪ Added Coding information ▪ Added ICD-10 Diagnosis (Effective October 1, 2015)
	Added Revision section to the policy.
	Updated References

REFERENCES

1. Colquitt JL, Loveman E, Baguley DM et al. Bone-anchored hearing aids for people with bilateral hearing impairment: a systematic review. *Clin Otolaryngol* 2011; 36(5):419-41.
2. Colquitt JL, Jones J, Harris P et al. Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation. *Health Technol Assess* 2011; 15(26):1-200, iii-iv.
3. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. *Otol Neurotol* 2013; 34(5):790-4.
4. Ramakrishnan Y, Marley S, Leese D et al. Bone-anchored hearing aids in children and young adults: the Freeman Hospital experience. *J Laryngol Otol* 2011; 125(2):153-7.

5. McLarnon CM, Davison T, Johnson IJ. Bone-anchored hearing aid: comparison of benefit by patient subgroups. *Laryngoscope* 2004; 114(5):942-4.
6. Tringali S, Grayeli AB, Bouccara D et al. A survey of satisfaction and use among patients fitted with a BAHA. *Eur Arch Otorhinolaryngol* 2008; 265(12):1461-4.
7. Snik AF, Mylanus EA, Cremers CW. The bone-anchored hearing aid compared with conventional hearing aids. Audiologic results and the patients' opinions. *Otolaryngol Clin North Am* 1995; 28(1):73-83.
8. Wazen JJ, Caruso M, Tjellstrom A. Long-term results with the titanium bone-anchored hearing aid: the U.S. experience. *Am J Otol* 1998; 19(6):737-41.
9. van der Pouw CT, Snik AF, Cremers CW. The BAHA HC200/300 in comparison with conventional bone conduction hearing aids. *Clin Otolaryngol Allied Sci* 1999; 24(3):171-6.
10. Granstrom G, Tjellstrom A. The bone-anchored hearing aid (BAHA) in children with auricular malformations. *Ear Nose Throat J* 1997; 76(4):238-40, 42, 44-7.
11. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. *Otolaryngol Head Neck Surg* 2012; 147(3):412-22.
12. Bosman AJ, Snik AF, van der Pouw CT et al. Audiometric evaluation of bilaterally fitted bone-anchored hearing aids. *Audiology* 2001; 40(3):158-67.
13. Priwin C, Stenfelt S, Granstrom G et al. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. *Laryngoscope* 2004; 114(1):77-84.
14. Snik AF, Mylanus EA, Proops DW et al. Consensus statements on the BAHA system: where do we stand at present? *Ann Otol Rhinol Laryngol Suppl* 2005; 195:2-12.
15. Dun CA, de Wolf MJ, Mylanus EA et al. Bilateral bone-anchored hearing aid application in children: the Nijmegen experience from 1996 to 2008. *Otol Neurotol* 2010; 31(4):615-23.
16. Ho EC, Monksfield P, Egan E et al. Bilateral Bone-anchored Hearing Aid: impact on quality of life measured with the Glasgow Benefit Inventory. *Otol Neurotol* 2009; 30(7):891-6.
17. Pai I, Kelleher C, Nunn T et al. Outcome of bone-anchored hearing aids for single-sided deafness: a prospective study. *Acta Otolaryngol* 2012; 132(7):751-5.
18. Zeitler DM, Snapp HA, Telischi FF et al. Bone-anchored implantation for single-sided deafness in patients with less than profound hearing loss. *Otolaryngol Head Neck Surg* 2012; 147(1):105-11.
19. Nicolas S, Mohamed A, Yoann P et al. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device. *Otol Neurotol* 2013; 34(1):111-4.
20. Baguley DM, Bird J, Humphriss RL et al. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. *Clin Otolaryngol* 2006; 31(1):6-14.
21. Lin LM, Bowditch S, Anderson MJ et al. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. *Otol Neurotol* 2006; 27(2):172-82.
22. Kunst SJ, Leijendeckers JM, Mylanus EA et al. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results. *Otol Neurotol* 2008; 29(1):2-7.
23. Gluth MB, Eager KM, Eikelboom RH et al. Long-term benefit perception, complications, and device malfunction rate of bone-anchored hearing aid implantation for profound unilateral sensorineural hearing loss. *Otol Neurotol* 2010; 31(9):1427-34.
24. Snik A, Leijendeckers J, Hol M et al. The bone-anchored hearing aid for children: recent developments. *Int J Audiol* 2008; 47(9):554-9.

25. Marsella P, Scorpecci A, Pacifico C et al. Pediatric BAHA in Italy: the "Bambino Gesù" Children's Hospital's experience. *Eur Arch Otorhinolaryngol* 2012; 269(2):467-74.
26. Davids T, Gordon KA, Clutton D et al. Bone-anchored hearing aids in infants and children younger than 5 years. *Arch Otolaryngol Head Neck Surg* 2007; 133(1):51-5.
27. McDermott AL, Williams J, Kuo MJ et al. The role of bone anchored hearing aids in children with Down syndrome. *Int J Pediatr Otorhinolaryngol* 2008; 72(6):751-7.
28. Dun CA, Faber HT, de Wolf MJ et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. *Otol Neurotol* 2012; 33(2):192-8.
29. Hobson JC, Roper AJ, Andrew R et al. Complications of bone-anchored hearing aid implantation. *J Laryngol Otol* 2010; 124(2):132-6.
30. Wallberg E, Granstrom G, Tjellstrom A et al. Implant survival rate in bone-anchored hearing aid users: long-term results. *J Laryngol Otol* 2011; 125(11):1131-5.
31. Kraai T, Brown C, Neeff M et al. Complications of bone-anchored hearing aids in pediatric patients. *Int J Pediatr Otorhinolaryngol* 2011; 75(6):749-53.
32. Siegert R. Partially implantable bone conduction hearing aids without a percutaneous abutment (Otomag): technique and preliminary clinical results. *Adv Otorhinolaryngol* 2011; 71:41-6.
33. Hol MK, Nelissen RC, Agterberg MJ et al. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. *Otol Neurotol* 2013; 34(6):1071-5.

Other References

1. Blue Cross and Blue Shield of Kansas Otolaryngology Liaison Committee: September 2001, August 2003, September 2005, July 2014.
2. Blue Cross and Blue Shield of Kansas Otolaryngology Liaison Committee consent ballot 12-08-05.