Name of Policy:
Implantable Bone Conduction and Bone-Anchored Hearing Aids (BAHA)

Policy #: 145       Latest Review Date: June 2014
Category: Surgery    Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Conventional external hearing aids can be generally subdivided into air conduction hearing aids and bone-conduction hearing aids. In patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal, bone-conduction hearing aids may be an alternative.

Hearing loss is described as conductive, sensorineural, or mixed and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB (decibel). The American Speech-Language-Hearing Association (ASLHA) has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (>80 dB).

Sound amplification through the use of an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an air-conduction hearing aid on the normal or less affected side.

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

The bone-anchored hearing aid (BAHA) implant system works by combining a vibrational transducer coupled directly to the skull via a percutaneous abutment that permanently protrudes through the skin from a small titanium implant anchored in the temporal bone. The system is based on the process of osseointegration through which living tissue integrates with titanium in the implant over a period of three to six months, allowing amplified and processed sound to be conducted via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing aids. The BAHA 4 Attract system utilizes the same bone/implant fixation system as other BAHA implants that connect to an external processor by an abutment. This system uses magnets to connect the sound processor to the titanium implant forming a magnetic connection across healed skin.

The Otomag Alpha 1 [M] is 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 a magnet that adheres 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.
Policy:
Effective for dates of service on or after August 10, 2012:
Unilateral or bilateral implantable bone-conduction (bone-anchored) hearing aid(s) meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage as an alternative to an air-conduction hearing aid in patients five years of age and older with a conductive or mixed hearing loss who also meet at least one of the following medical criteria:

- A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 45 dB (OBC and BP100 devices), 55 dB (Intenso device), or 65 dB (Cordele II device); and one of the following;
- Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear;
- Chronic external otitis or otitis media;
- Tumors of the external canal and/or tympanic cavity;
- Dermatitis of the external canal;

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 (4 kHz for OBC and Ponto Pro), or less than 15 dB at individual frequencies.

An implantable bone-conduction (bone-anchored) hearing aid meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage 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 20 dB measured at 0.5, 1, 2, and 3 kHz.

Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

Partially implantable bone conduction hearing systems using magnetic coupling for acoustic transmission (e.g., The Otomag Alpha 1 [M] does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Replacement upgraded processors meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:

- A letter is received from the physician or audiologist requesting a replacement and
- The original processor is out of warranty or malfunctioning.

Effective for dates of service December 7, 2007 and prior to August 10, 2012:
Unilateral or bilateral implantable bone-conduction and bone-anchored hearing aids as an alternative to an air conduction hearing aid in patients with pure tone average bone conduction threshold of up to 70dB and speech discrimination score better than 60% AND one of the following conditions:
• Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear; or
• Chronic external otitis or otitis media when a conventional hearing aid cannot be worn; or
• Tumors of the external canal and/or tympanic cavity; or
• Severe and chronic dermatitis of the external canal resistant to topical treatments.

OR

An implantable bone conduction hearing aid to treat unilateralsensorineural hearing loss or single sided deafness (SSD) with bone conduction of 35-40 dB or better in the contralateral ear.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
There are many articles (>600) in the published literature that look at the use of implantable bone conduction hearing aids in adults and children.

Wazen et al did a retrospective review of 24 patients implanted with the BAHA device from 1984 to1987. The results showed an overall satisfaction score of 4.5 out of 5, improved speech reception (mean threshold improved from 52 dB to 27 dB), and no major complications. The majority of patients analyzed (78%) were still using the device on average of 15.6 hours/day 10-13 years after implantation.

Tjellstrom et al published an article in 2001 on the current status of bone-anchored hearing aids. He noted that the BAHA device has been used clinically for 20 years and more than 7,000 patients have been fitted with the device. The BAHA device provides direct bone conduction, which is defined as “sound transmission via bone conduction without the skin and soft tissue being part of the vibration transmission path between the transducer and the skull bone.” They noted that if the bone conduction is 45 dB or better, more than 80% of the patients are satisfied. Also, a conductive hearing loss as high as 60 dB will not interfere with the outcome. If the patient becomes dissatisfied with the arrangement, the surgeon can easily remove the device.

Snik et al published an article in 2001 on bone conduction hearing aids. He noted that two types of BAHA are now available: the BAHA Classic HC 300 (ear-level device) and the BAHA Cordelle (the body-worn device). For the Classic HC 300, the average bone-conduction threshold should be better than 40 dB hearing level, and for the BAHA Cordelle, it should be better than about 60-70 dB hearing level.
Lustig et al looked at the first 40 patients in the U.S. with the BAHA device. The most common indications for implantation included chronic otitis media or draining ears (18 patients) and external auditory canal stenosis or aural atresia (seven patients). Overall, each patient had on average improvement of 32 +/- 19 dB with the use of the BAHA. Complications included local infection and inflammation at the implant site in three patients and failure to osseointegrate in one patient. Only one patient was dissatisfied with the device.

The FDA has given a 510K approval for the use of the BAHA for patients with unilateral sensorineural hearing loss or also known as Single-Sided Deafness. The study by Wazen et al published in 2003 had 18 patients with an eight week follow-up. His results stated that the cone-anchored stimulator appears to be an effective approach in patients with unilateral deafness. Niparko et al’s study had 10 patients with a four week follow-up. This study concluded, “Further understanding of bone conduction as implemented in transcranial stimulation will guide further options for patients with monaural hearing. Longer follow-up will help to determine whether communicative skill improvements with the bone anchored hearing aid outweigh the disadvantages of implantation surgery, costs, and device maintenance.”

However, more recent literature indicates that the vibro-mechanical stimulation of the BAHA overcomes some of the negative head shadow effects seen in patients with unilateral deafness. The advantages of head-shadow reduction in enhancing speech recognition with noise in the hearing ear outweigh disadvantages inherent in head-shadow reduction that can occur by introducing noise from the deaf side. The level of hearing impairment correlates with incremental benefit provided by the BAHA. Patients experience a higher level of subjective benefit with the BAHA, and have improved speech perception in noise. No serious complications have been reported. Patients continue to report satisfaction after one-year follow-up.

**In a 2007 literature search the following was noted:**
McLarnon reported outcomes for bone-anchored hearing aids by patient subgroups based on 69 of 94 (73%) patients who completed a questionnaire. 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. House reported on complications from bone-anchored hearing aids. No intraoperative or perioperative complications were noted in 149 patients who received the device between 2001 and 2005. Significant postoperative complications, requiring intervention, occurred in 19 patients (13%). Skin overgrowing the abutment occurred in 11 patients, and implant extrusion occurred in five patients.

Baguley et al reviewed the evidence for contralateral bone-anchored hearing aids in adults when acquired unilateral sensorineural hearing loss. None of the four 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. The authors of this review cited “material” shortfalls in all four studies reviewed. Lin reported on use of the bone-anchored hearing aids in 23 patients with unilateral deafness. While the paper comments that benefit was also seen in those with moderate sensorineural hearing loss in the contralateral ear (250-50dB), this conclusion was based on five patients. Larger studies are needed regarding use in this clinical situation.
Stenfelt described the potential benefits of bone-anchored devices fitted bilaterally and noted that because of cross-hearing of bone-conducted sound, the binaural processing for bilateral devices is less than for normal, binaural air conduction hearing. In a consensus statement on the BAHA system, the authors note that cross-hearing (contralateral stimulation) could be problematic for bilateral devices.

It is not unusual in pediatric patients or adults with craniofacial anomalies for insertion of BAHA devices to be performed in staged procedures. Generally, if bone is thinner than 2.5 mm, a 2-staged procedure is used. For the 2-staged procedure, a three-to-six month waiting period between stages has been traditionally used to allow time for appropriate osseointegration and minimize the risk of traumatic 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. In 2001, Bosman and others reported on findings from 25 patients who were using bilateral devices. 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 on 12 patients with bilateral devices. 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 conductive hearing loss and symmetric bone-conduction thresholds. A number of additional studies that are cited in the report found benefits similar to those noted in the studies of Boseman et al and Priwin et al.

Two studies of bone-anchored hearing aids for congenital unilateral conductive hearing impairment are reported by Kunst et al in one study aided and unaided hearing was assessed in 20 patients using sound localization and speech recognition-in-noise tests. Many patients showed unexpectedly good unaided performance, however non-significant improvements were observed in favor of the BAHA. Six of the 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 ten adults and ten children using two disability-specific questionnaires and found an overall preference for the BAHB over unaided hearing in several specific hearing situations. Improvement on the Glasgow children’s’ benefit inventory was most prominent in the learning domain. The ten adults showed an already good score on the Speech, Spatial and Qualities of hearing scale in the unaided situation. 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 eight with malformation of the middle ear) compared with 118 with single-sided deafness (two after surgery for meningioma, idiopathic sudden deafness, sensorineural hearing loss complicating surgery of the middle ear). Levels of satisfaction and quality of life were significantly poorer in the SSD than the CHL group, although generally good with the exception of sound localization.

The BAHA device has been used successfully in children younger than five years in Europe and the United Kingdom. The most recent (1999) update of the FDA notification lists age less than five years as a contraindication. 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 two-stage procedure is used in young children with the fixture placed into the bone at the first stage and, after three to six months to allow for osseointegration, a second procedure to connect the abutment through the skin to the fixture. Davids et al at the University of Toronto provided BAHA devices to children less than five years of age for auditory and speech-language development and retrospectively compared surgical outcomes for a study group of 20 children five years or younger and a control group of 20 older children. Children with cortical bone thickness greater than 4mm underwent a single-stage procedure. The inter-stage 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 fur in the older children. Three younger children required skin site revision. All children were wearing their BAHA devices at the time of publications. McDermott reported on the role of bone-anchored hearing aids 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 two to 15 years. All patients were using their BAHA devices after follow-up of 14 months. No fixtures were lost, and skin problems were encountered in three patients. All 15 patients had improved social and physical functioning as a result of better hearing.

**Literature Review June 2012**

A systematic review by the Health Technology Assessment Program was published in 2011 on the use of bone-anchored hearing aids (BAHAs) for bilateral hearing impairment. 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.

Also, 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. 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).

In 2011, Seigert reported on the use of a partially implantable bone conduction hearing system that uses magnetic coupling for acoustic transmission. This hearing system is reported to have been implanted in more than 100 patients followed in the past five years, but results are only presented on 12 patients. Since the acoustics must pass through the skin rather than by direct bone stimulation through an 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 eight unilaterally and four bilaterally implanted patients showed average hearing gains of $31.2 \pm 8.1$ 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.
March 2013 Update

Janssen and colleagues (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent conductive hearing loss (CHL). 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 intra-subject. Patients ranged from five 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 three (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. 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 15dB, the improvement in speech recognition patterns ranged from 4 to 5.4dB, 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.

Several centers have reported on findings from observational studies designed to evaluate the benefits of BAHA for patients with unilateral sensorineural hearing loss (single-sided deafness). Most of these studies have been retrospective. In one prospective study conducted within a hospital auditory implant center in the United Kingdom, Pai and colleagues reported significant improvement in the average score in all three sections (speech hearing, spatial hearing, other qualities) of the spatial and qualities of hearing scale SSQ questionnaire following a BAHA implant in 25 adult patients.

Zeitler and colleagues reported on a retrospective case series of 180 patients undergoing unilateral or bilateral BAHA for single-sided deafness with residual hearing in the implanted ear within a university medical center in the United States. 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. Nicolas and colleagues undertook a retrospective review of 36 patients implanted with a BAHA within a university medical center in France. Their results showed an improvement in speech perception in noise with the BAHA, but no improvement in sound localization based on a two-year follow-up period.

Marsella and colleagues have reported on their center’s experience in Italy with pediatric BAHA from the inception of their program in 1995 to December 2009. A total of 47 children (21 females and 26 males) were implanted; seven of these were younger than five 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 seven patients receiving a BAHA at an age younger than five 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 five years can be conducted safely and effectively in such settings. The conclusions are limited by the small number of children less than five years of age in the study and the limited power to detect a difference between younger and older children.

In 2012, Dun and colleagues assessed soft tissue reactions and implant stability of 1,132 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. The study investigators also examined device usage and comparisons between different patient age groups (children, adults, and elderly patients) over a five-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).

January 2014 Update

In 2013 Kiringoda et al reported on a meta-analysis of complications related to BAHA implants. Included in the meta-analysis were twenty studies that evaluated complication in 2,134 adult and pediatric patients who received a total of 2,310 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. 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.

In 2013 Hol et al reported on a comparison of BAHA percutaneous implants to partially implantable magnetic transcotaneous 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. 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.

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 five 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 five years and patients with bilateral sensorineural hearing loss, is considered investigational.

The available evidence for the Otomag Alpha 1 [M] hearing system is preliminary and very limited.

**Key Words:**

**Approved by Governing Bodies:**
There are four BAHA® sound processors for use with the BAHA auditory osseointegrated implant system manufactured by Cochlear Americas (Englewood, CO) that have received 510(k) clearance from the U.S. Food and Drug Administration (FDA):
- BAHA® Cordelle II™
- BAHA® Divino™
- BAHA® Intenso™ (digital signal processing)
- BAHA® BP100™

The FDA approved the BAHA system for the following indications:
- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally;
- Patients with sensorineural deafness in one ear and normal hearing in the other (i.e., single-sided deafness, SSD);
- Patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who cannot or will not wear an AC CROS device.

The BAHA implant is cleared for use in children aged five years and older, and in adults.

BAHA sound processors can also be used with the BAHA® Softband™. With this application, there is no implantation surgery. The sound processor is attached to the head using either a hard or soft headband. The amplified sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. The BAHA® Softband™ received FDA clearance in 2002 for
use in children younger than the age of five years. 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. In November 2013, Cochlear Americas received 510(k) marketing clearance from the FDA for the Baha 4 Attract System.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

PEEHIP: **Effective for dates of service on or after December 7, 2007**, bilateral BAHA devices are not covered for this group.

FEP contracts: Hearing aids (including implanted bone conduction hearing aids) are not covered.

**Current Coding:**

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<th>CPT codes</th>
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<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
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<th>HCPC Codes</th>
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<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
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Auditory osseointegrated device, external sound processor, replacement

Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment

Auditory osseointegrated device abutment, any length, replacement only

References:

Policy History:
Medical Policy Group, November 2003 (1)
Medical Policy Administration Committee, December 2003
Available for comment January 13-February 26, 2004
Medical Policy Group, March 2005
Medical Policy Group, April 2005 (2)
Medical Policy Administration Committee, April 2005
Available for comment, April 25-June 8, 2006
Medical Policy Group, August 2007 (2)
Medical Policy Administration Committee, August 2007
Available for comment August 25-October 8, 2007
Medical Policy Group, November 2007 (2)
Medical Policy Administration Committee, December 2007
Available for comment December 8, 2007-January 21, 2008
Medical Policy Group, April 2008 (2)
Medical Policy Administration Committee, May 2008
Medical Policy Group, December 2009 (2)
Medical Policy Administration Committee, February 2010
Coding update December 2010 (1); 2011 Code update-added L8693
Medical Policy Group, June 2012 (4); Updated policy section to include Otomag Alpha 1 [M]), partially implantable hearing aid, updated Description, Key Points, Approved by Governing Bodies, Key Words and References..
Medical Policy Administration Committee, June 2012.
Available for comment June 26 through August 10, 2012
Medical Policy Panel, January 2013
Proprietary Information of Blue Cross and Blue Shield of Alabama
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Medical Policy Group, August 2013 (2): Added language for coverage of replacement upgraded processors.
Medical Policy Administration Committee August 2013
Available for comment August 22 through October 5, 2013
Medical Policy Group, May 2014 (5): Updated policy section to include BAHA 4 Attract, partially implantable magnetic bone-conduction hearing system. Updated Description, Key Points, Approved by Governing Bodies, Key Words and References.
Medical Policy Administration Committee June 2014
Available for comment May 30 through July 13, 2014
Medical Policy Group, June 2014 (5): Removed BAHA 4 Attract and partially implantable magnetic bone-conduction hearing system from policy statement. Removed partially implantable magnetic bone-conduction hearing system from description, key points, and approved by Governing Bodies.
Medical Policy Administration Committee July 2014

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.