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

Policy #: 145       Latest Review Date: February 2017
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:
Sensorineural, conductive, and mixed hearing loss may be treated with a variety of devices, including conventional air-conduction (AC) or bone-conduction external hearing aids. AC hearing aids 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 may be useful for individuals with conductive hearing loss, or (if used with contralateral routing of signal), for unilateral sensorineural hearing loss. Implantable, bone-anchored hearing aids (BAHA) that use a percutaneous or transcutaneous connection to a sound processor have been investigated as alternatives to conventional bone-conduction hearing aids for patients with conductive or mixed hearing loss or in patients with unilateral single-sided sensorineural hearing loss.

Hearing Loss
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). PTA is calculated by averaging the hearing sensitivities (i.e., the minimum volume that the patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 to 8 kHz.

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.

Bone-Conduction Hearing Devices
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 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. Implantable bone-conduction hearing systems are primarily indicated for people with conductive or mixed sensorineural/conductive hearing loss. However, they may also be used with CROS as an alternative to an AC hearing aid with CROS for individuals with unilateral sensorineural hearing loss.

Partially implantable magnetic bone-conduction hearing system, also referred to as transcutaneous bone-anchored systems, are available as an alternative to bone-conduction hearing aids.
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.

**Policy:**

**Effective for dates of service on or after August 10, 2012:**

Unilateral or bilateral fully or partially 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; **or**
  - Chronic external otitis or otitis media; **or**
  - Tumors of the external canal and/or tympanic cavity; **or**
  - 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 contralateral routing of signal 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**.

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 or upgrade** of existing properly functioning durable medical equipment (including prosthetics), even if the warranty has expired is a **contract exclusion**.*

*Always check benefits for self-funded groups as it relates to contract exclusions.

*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:**
This policy is updated regularly with searches of the MEDLINE database through December 20, 2016.

The evidence related to the use of implantable bone-conduction devices, also referred to as bone-anchored hearing aids (BAHA), and is characterized by observational studies that report pre- and post-implant hearing outcomes in patients treated with these devices. Many of these studies combine patients with differing underlying disease states and indications. No randomized controlled trials (RCT’s have compared implantable bone-conduction hearing aids to other hearing augmentation devices, or sham devices. However, given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, a within-subjects comparison of hearing before and after device placement may be a reasonable study design. Following is an example of key findings.

**Overall Efficacy of BAHA Devices**

**Systematic Reviews and Meta-Analyses**
Two systematic reviews by the Health Technology Assessment Program were published in 2011 on the use of BAHAs for bilateral hearing impairment. The quality of available studies on the use of BAHAs was weak. No studies with control groups were identified. Cohort pre-post studies and cross-sectional comparative studies demonstrated 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 with air-conduction (AC) hearing aids was 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.
**Observational Studies**
Since the publication of the Health Technology Assessment Program systematic review, a number of observational studies have evaluated specific aspects of BAHA implantation or reported outcomes in specific populations. Several observational studies have suggested that newer-generation BAHAs with fully digital signal processors improve hearing to a greater degree than earlier-generation devices.

In 2011, Ramakrishnan et al retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in 109 children and young adults in a single center. The patient population was somewhat unique in that many patients had craniofacial or genetic syndromes in addition to hearing loss (22/109). 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, sex, 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 concluded that this population benefitted from bone-anchored and Softband-held conductive hearing aids based on mean scores. However, the study is limited due to a heterogeneous patient population and lack of pre-intervention measures and a controlled comparator group. Other series describing outcomes for pediatric patients treated with bone-anchored devices have also reported a benefit in hearing scores, including den Besten et al (2015) in 79 children aged 17 and under.

In 2014, Farnoush et al retrospectively compared BAHA placement with reconstruction of the external auditory canal for children and adolescents with congenital aural atresia or stenosis who were treated at a single institution from 1988 to 2011. Sixty-eight patients were included, 49 who underwent external auditory canal reconstruction (EACR) and 19 who received a BAHA. Groups differed significantly in terms of age, presence of bilateral atresia, and presence of an associated syndrome. Audiologic data were available for 41 patients. At short-term (<6 months post-surgery) follow-up, the BAHA group had larger hearing gains on AC than the EACR group (44.3 dB vs 20.0 dB; p<0.001); similarly, the BAHA group had larger hearing gains at long term (>1 year post-surgery) follow-up (44.5 dB vs 15.3 dB; p<0.001). Quality-of-life scores and requirements for revision surgery did not differ significantly between the groups.

Older case studies have reported on patient-reported benefits and patient satisfaction after BAHA placement. Earlier case series suggested that the BAHA was associated with improved hearing compared with earlier generations of bone-conducting devices and AC hearing aids, and produce acceptable hearing outcomes in individuals unable to receive an AC hearing aid.

**Section Summary: Overall Efficacy of BAHA Devices**
The available studies on the use of BAHAs are observational pre-post designs without control groups and cross-sectional comparative studies. Although the study designs were generally weak, in general, use of BAHAs was associated with larger improvements in hearing than conventional non-implanted bone-conduction hearing devices or unaided hearing. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in
individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement are likely attributable to the device.

Bilateral BAHA Devices in Conductive or Mixed Hearing Loss
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 conductive (CHL) or mixed hearing loss.

Janssen et al (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent conductive hearing loss (CHL). The literature search 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 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 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.

Examples of individual studies include the following. In 2001, Bosman et al 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 in 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 CHL and symmetric bone-conduction thresholds. 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. Positive outcomes continue to be reported: Dun et al (2010) identified improvements in the Glasgow Benefit Inventory in children (n=23), while Ho et al (2009) reported the same benefit in adults (n=93).

Section Summary: Bilateral BAHA Devices in Conductive or Mixed Hearing Loss
The evidence on bilateral versus unilateral BAHAs for individuals with CHL or mixed hearing loss consists of small observational studies with heterogeneous participants. In general, bilateral BAHAs seem to provide additional objective and subjective benefit compared with unilateral BAHAs.
BAHA Devices for Unilateral Sensorineural Hearing Loss

Baguley et al (2006) reviewed the evidence for contralateral BAHAs in adults with acquired unilateral sensorineural hearing loss. 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 AC contralateral routing of signal (CROS) systems.

Several centers have reported on findings from observational studies designed to evaluate the benefits of BAHA for patients with unilateral sensorineural hearing loss, or SSD. Most of these studies have been retrospective. Representative observational studies describing the use of BAHA devices for SSD are described next.

Zeitler et al (2012) reported on a retrospective case series of 180 patients with SSD and residual hearing in the implanted ear who underwent unilateral or bilateral BAHA placement at 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.

In 2015, Peters et al reported results from a systematic review of studies comparing BAHA devices with contralateral routing of sound systems with hearing aids with contralateral routing of sound for single sided deafness (SSD). The authors included 6 studies that met eligibility criteria, including 1 randomized controlled trial (RCT) and 3 prospective and 2 retrospective case series, 5 of which were considered to have moderate to high directness of evidence and low to moderate risk of bias. The 5 studies with low or moderate risk of bias included a total of 91 patients and were noted to have significant heterogeneity in the populations included. For speech perception in noise, there was not consistent improvement with aided hearing over unaided hearing in all environments. All studies reported equal sound localization in the aided and unaided conditions, and quality-of-life measures were similar for the aided and unaided conditions.

Additional series from various countries, with sample sizes ranging from 9 to 145 patients, have reported on outcomes after implantation of BAHA device for SSD. In general, studies have reported improvements in patient-reported speech quality, speech perception in noise, and patient satisfaction.

Since publication of the Peters systematic review, 2 prospective, interventional studies compared outcomes with transcutaneous BAHA devices to CROS hearing aids for SSD. Leterme et al enrolled 24 adults with SSD, 18 of who were evaluated with trials of both hearing aids with CROS and bone conduction–assisted hearing using the BAHA Softband. Most patients (72%), after completing trials of both devices, preferred the BAHA device to hearing aid with CROS. Glasgow Benefit Index (GBI) and APHAB scores did not differ significantly between devices. Sixteen of the 18 subjects elected to undergo implantation of a percutaneous BAHA device. In general, hearing improvement with the BAHA Softband trial correlated with hearing
improvements following device implantation. Snapp et al (2017) reported a prospective single-center study of 27 patients with unilateral severe-profound sensorineural hearing loss who had either a CROS (n=13) or transcutaneous BAHA (n=14) device. Mean device use was 66 months for the BAHAs and 34 months for CROS devices. Both BAHA and CROS groups had significant improvement in speech-in-noise performance, but neither showed improvement in localization ability. There were no differences between the devices for subjective measures of posttreatment residual disability or satisfaction as measured by the Glasgow Hearing Aid Benefit Profile (GHABP).

Section Summary: BAHA Devices for Unilateral Sensorineural Hearing Loss
Single-arm case series with sample sizes ranging from 9 to 180 patients have generally reported some improvements in patient-reported outcomes after implantation of bone conduction devices, but no improvements in speech recognition or hearing localization. However, in studies with comparators, outcomes for patients with bone-anchored devices were similar to those for patients with hearing aids with CROS.

BAHA Devices in Children Younger Than Age 5 Years
The BAHA device has been used successfully in children younger than 5 years in Europe. 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 is used in young children with the fixture placed into the bone at the first stage and, after 3 to 6 months to allow for osseointegration, a second procedure to connect the abutment through the skin to the fixture.

Davids et al (2007) at the University of Toronto provided BAHA devices to children less than 5 years of age for auditory and speech-language development and retrospectively compared surgical outcomes for a study group of 20 children 5 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 2 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 3 patients. All 15 patients had improved social and physical functioning, attributed to improved hearing.

Marsella et al (2012) 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; 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 seven 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. The conclusions are limited by the small number of children less than 5 years of age in the study and the limited power to detect a difference between younger and older children.

The largest series in children under 5 years identified for this review, described by Amonoo-Kuofi et al (2015), included 24 children identified from a single center’s prospectively maintained database. Most patients underwent a 2-stage surgical approach. The largest proportion of patients (52%) received the implant for isolated microtia, followed by Goldenhar syndrome (16%). Following implantation, 13 patients (54%) had Grade 2 or 3 local reactions on the Holgers Scale (redness, moistness, and/or granulation tissue) and 7 (29%) had Grade 4 local reactions on the Holgers Scale (extensive soft-tissue reaction requiring removal of the abutment). Quality of life scores (Glasgow Children’s Benefit Inventory [GCBI]; scoring range, -100 to 100) were obtained in 18 subjects/parents with a finale mean score change of +40 points. Audiologic testing indicated that the average performance of the device fell within the range of normal auditory perception in noisy and quiet environments.

Section Summary: BAHA Devices in Children Younger Than Age 5 Years
There are few data on use of BAHA devices in children younger than 5. Three case series with a total of fewer than 60 children younger than 5 years have reported improvements in QOL after implantation with BAHA devices. One comparative observational study, with 7 children younger than 5, reported significantly better improvement in functional gain with BAHAs than with conventional non-implanted bone-conduction hearing aids in an analysis including all ages.

Safety and Adverse Events Related to Bone-Anchored Hearing Aids
In addition to the literature evaluating the effectiveness of BAHA devices in improving hearing, studies have evaluated or reported specifically on complications related to BAHAs.

Systematic Reviews
In 2013, 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. The incidence of Holgers Grade 2 to 4 skin reactions was 2.4% to 38.1% in all studies. The incidence of failed osseointegration was 0% to 18% in adult and mixed population studies and 0% to 14.3% in pediatric population studies. The incidence of revision surgery was 1.7% to 34.5% in adult and mixed population studies and 0.0% to 44.4% in pediatric population studies. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and in 0.0% to 25% in pediatric studies.

Verheij et al (2016) published a systematic review on complications of tissue preservation surgical techniques with percutaneous BAHA devices including 18 studies with 381 devices. The implantation techniques reported in the studies were as follows: punch method, 4 studies (81 implants); linear incision technique without soft tissue reduction, 13 studies (288 implants); and Weber technique, 1 study (12 implants). Indications for surgery were SSD (n=68), sensorineural hearing loss (n=4), mixed hearing loss (n=65), or CHL (n=66). The Holgers classification was used to grade soft tissue reactions (grade 0, no reaction; grade 2, red and moist tissue; grade 3,
granulation tissue; grade 4, removal of skin-penetrating implant necessary due to infection). The incidence of Holgers 3 was 2.5% with the punch technique, 5.9% with the linear incision technique, and 0% with the Weber technique. Holgers 4 was reported in 1 patient implanted with the linear incision technique.

Observational Studies
In 2010, Hobson et al reviewed complications of 602 patients at a tertiary referral center over 24 years and compared their observed rates to those published in 16 previous studies. The overall observed complication rate of 23.9% (144/602) is similar to other published studies (complication rate, 24.9%±14.85). The most common complications were soft tissue overgrowth, skin infection, and fixture dislodgement. The observed rate of revision surgery of 12.1% (73/602) 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 nine years. Implants were lost in a total of 41 patients (27%). Reasons for implant loss were: removal in 16 patients, osseointegration failure in 17 patients, and direct trauma in 8 patients. In the remaining 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 (2011) in a follow-up evaluation of 27 implants placed in children ages 16 years or younger between 2002 and 2009. 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 (26%) experienced implant trauma. Chronic infection and overgrowth at the abutment prevented use of the implant in 3 patients (11%).

In 2012, Dun et al 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 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).

In 2014, Allis et al conducted a prospective observational cohort study with a retrospective historical control to evaluate complication rates of skin overgrowth, infection, and the need for revision surgery associated with a Baha implant with a longer (8.5 mm) abutment. Twenty-one subjects were treated with the 8.5 mm abutment implant from 2011 to 2012 and were compared with 23 subjects treated with a 5.5 mm-abutment implant from 2010 to 2011. Groups were generally similar at baseline, with the exception that the 8.5 mm abutment implant patients were older (62 years vs 48 years, p=0.012). Patients in the longer abutment group were less likely to experience infection (10% vs 43%; p=0.02), skin overgrowth (5% vs 41%; p=0.007), and need for revision (10% vs 45%; p=0.012).
Other observational cohort studies, ranging in size from 47-974 subjects, have reported safety- and adverse effects outcomes after BAHA placement. Across these studies, implant loss ranged from 3.8% to 18%.

Different techniques for surgically implanting BAHA devices and specific BAHA designs are under investigation to yield improved safety outcomes. In a systematic review focusing on the association between surgical technique and skin complications following BAHA implantation, which included 30 articles, dermatome technique (compared with a skin graft or linear technique) was linked to greater skin complications. Fontaine et al (2014) compared complication rates after two different surgical techniques for BAHA implantation among 32 patients treated from 2004 to 2011. Complications requiring surgical revision occurred in 20% of cases who underwent a skin flap implantation method (N=20) and in 38% of cases who underwent a full-thickness skin graft implantation method (N=21; P=0.31). Hultcrantz et al (2014) reported shorter surgical times and fewer cases of numbness and peri-implant infections in 12 patients treated with a non-skin-thinning technique, compared with 24 patients treated with either a flap or dermatome implantation technique. In a comparison of 2 types of BAHA devices, one with a 4.5 mm diameter implant with a rounded 6mm abutment (N=25) and one with a 3.75mm diameter implant with a conically-shaped 5.5mm abutment (N=52), Nelissen et al (2014) reported that implant survival was high for both groups over 3 years of follow-up, although the conically-shaped abutment had greater stability. Singam et al (2014) reported results of a BAHA implantation technique without soft tissue reduction in conjunction with a longer device abutment in 30 patients. Twenty-five patients had no post-operative complications. Five subjects developed post-operative skin reactions, of who 3 required soft tissue reduction.

Roplekar et al (2016) compared skin-related complications of the traditional skin flap method to the linear incision method performed by a single surgeon in 117 patients with at least 1 year of follow-up. Twenty-one (24%) patients experienced skin-related complications in the skin flap group (12 skin overgrowths, 8 wound infections, 1 numbness) and 3 (10%) patients experienced complications in the linear incision group (3 wound infections).

**Section Summary: Safety and Adverse Events Related to BAHA Devices**

The quality of available data for adverse events is generally poor with high heterogeneity. The most frequently reported complication from surgical procedures for BAHA insertion are adverse skin reactions, with an incidence of Holgers grade 2 to 4 reactions ranging from less than 2% to more than 34%, and implant loss ranging from less than 2% to more than 17%. There is some evidence of improvement in complication rates and severity with newer surgical techniques such as linear incision.

**Partially Implantable Magnetic BAHAs**

A smaller body of literature addresses outcomes associated with transcutaneous, partially implantable bone-anchored devices that magnetically-couple the sound processor with the implant. Similar to the literature available for percutaneous bone-anchored devices, the majority of studies use a within-subjects comparison of hearing thresholds with and without the device. The indications for partially implantable systems are the same as those for transcutaneous bone-anchored devices.
Prospective Studies
Two prospective studies evaluating different transcutaneous systems were identified. Both trials were small (27 and 15 individuals, respectively), but both demonstrated improvements in hearing outcomes.

Briggs et al (2015) reported results of a prospective interventional evaluation of the percutaneous, partially implantable Baha Attract system among 27 adults with a conductive or mild mixed hearing loss in the ear to be implanted. The choice of sound processor was based on patient preference and hearing tests with the use of various sound processors with a BAHA Softband prior to device implantation. Twenty-seven patients were enrolled and received an implant. Sound processor fitting occurred at 4 weeks post-implantation in all but 1 patient. At 9-month follow-up, pure tone audiometry (PTA; mean of 500, 1000, 2000, and 4000 Hz) was significantly improved with the implant and sound processor compared with unaided hearing (18.4 dB HL; SD=6.9 dB; p<0.001). Patients generally showed improvements in speech recognition in noise, although comparing results across test sites is difficult due to different languages and methodologies used for testing speech recognition at each site. Compared with the preoperative unaided state, scores on the Abbreviated Profile of Hearing Aid Benefit (APHAB) overall score (p=0.038) and Reverberation (p=0.016) and Background noise (p=0.035) subscales.

Denoyelle et al (2015) reported on a prospective clinical trial of the Sophono device in children aged 5 to 18 years with uni- or bilateral congenital aural atresia with complete absence of the external auditory canal with pure conductive hearing loss. The study included a within-subject comparison of hearing results with the Sophono devices with those obtained with the BAHA Softband preoperatively. Fifteen patients were enrolled and implanted (median age, 97 months). At 6-month follow-up, mean aided air-conduction PTA was 33.49 (mean gain, 35.53 dB), with a mean aided sound reception threshold of 38.2 (mean gain, 33.47 dB). The difference in air conduction PTA between the BAHA Softband and the Sophono device was 0.6 dB, with a confidence interval upper limit of 4.42 dB, which met the study’s prespecified noninferiority margin. Adverse effects were generally mild, including skin erythema in 2 patients, which improved by using a weaker magnet, and brief episodes of pain or tingling in 3 patients.

Nonrandomized Comparative Studies
A limited amount of data is available comparing transcutaneous with percutaneous bone-anchored conduction devices. 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. Sound field thresholds, speech recognition threshold and speech comprehension at 65dB 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. After following the same 12 patients for more than 3 years, Nelissen et al (2016) reported on soft tissue tolerability, hearing results, and sound localization abilities. Two patients in each group had stopped using their hearing devices. Soft tissue tolerability with the Sophono was favorable compared to BAHA. Both groups showed improvements in sound localization compared to the unaided situation. Aided thresholds with the Sophono were not as good as expected, with a mean pure-
Tone average of about 30 dB hearing loss; ideally aided thresholds should be 10 to 20 dB hearing loss.

Iseri et al (2015) described a retrospective, single-center study from Turkey comparing 21 patients treated with a transcutaneous, fully implantable BAHA with 16 patients treated with a percutaneous device (the Baha Attract). Groups were generally similar at baseline, with most individuals undergoing BAHA placement for chronic otitis media. Operating time was longer in patients treated with the transcutaneous partially implantable devices (46 minutes vs 26 minutes, p<0.05). Three patients treated with percutaneous devices had Holger grade 2 skin reactions, and 2 had stopped using their devices. Mean thresholds for frequencies 0.5 to 4.0 kHz were 64.4 dB without the BAHA and 31.6 dB with the BAHA in the percutaneous device group, and 58.3 dB without the BAHA and 27.2 dB with the BAHA in the transcutaneous device group. Frequency-specific threshold hearing gains did not differ significantly between groups. Mean hearing gain measured by speech reception threshold was statistically significantly smaller in the percutaneous group (24 dB vs 36.7 dB, p=0.02).

Gerdes et al (2016) published a retrospective single-center study comparing 10 patients with CHL implanted with the transcutaneous Bonebridge device to an audiologically matched control group of 10 patients with the percutaneous BAHA BP100. There were similar significant improvements in aided thresholds, word recognition scores, and speech reception thresholds in noise for both devices. There were also no differences in subjective ratings for the APHAB scale. Mean functional gain was slightly higher (27.5 dB) for transcutaneous than for percutaneous (26.3 dB), but not significantly different.

Observational Studies
A moderately-sized body of observational studies – most of which are single center and with fewer than 10 patients – have reported outcomes for transcutaneous, partially-implantable hearing systems. These studies are briefly described here to provide an overview of the functional gain and complications seen with the transcutaneously-coupled devices.

In an early report on the device, 2011, Seigert reported on the use of a transcutaneous, partially implantable bone-conduction hearing system (Otomag). Preliminary results of the partially implantable hearing system in 8 unilaterally and 4 bilaterally implanted patients showed average hearing gains of 31.2dB in free-field pure-tone audiogram. The free-field suprathreshold speech perception at 65 dB increased from 12.9% preimplantation to 72.1% post-implantation.

O’Niel et al (2014) reported outcomes for 10 pediatric patients with conductive hearing loss treated with the Otomag Sophono device at a single center. A total of 14 ears were implanted with no surgical complications. The skin complication rate was 35.7%, including skin breakdown (n=2) and pain and erythema (n=5); negative outcomes resulted in 5 (36%) of 14 ears having significant enough difficulties to discontinue use for a period. The mean aided pure-tone average (PTA) was 20.2 dB hearing level, with a mean functional gain of 39.9 -dB hearing level. Patients without skin complications consistently used their devices, with an average daily use of 8 to 10 hours.
Centric et al (2014) also reported outcomes for 5 pediatric patients treated with the Otomag Sophono device at a single center. Etiologies of hearing loss were heterogeneous and included bilateral moderate or severe conductive hearing loss and unilateral sensorineural hearing loss. The average improvement in PTA was 32 dB hearing level, and the average improvement in speech response threshold was 28 dB hearing level. All patients were responding in the normal to mild hearing loss range in the operated ear after device activation. In a follow-up study from the same institution, Baker et al reported pooled outcomes for the first 11 patients treated with the Otomag Sophono and the first 6 patients treated with the Baha Attract. Pre- and postimplant audiometric data were available for 11 years in the Sophono group and 5 in the Baha Attract group. Average improvement over all frequencies ranged from 24 to 43 decibel hearing level (dB HL) in the Sophono group and 32 to 45 dB HL in the Baha Attract group. Average improvement in PTA was 38 dB HL in the Sophono group and 41 dB HL in the Baha Attract group.

Additional single-center observational series have described clinical experience with transcutaneous partially implantable BAHA devices. Marsella et al (2014) reported outcomes for 6 pediatric patients treated with the Otomag Sophono device for conductive or mixed hearing loss. Median improvement in PTA was 33 dB HL and median free-field PTA (0.5-3 kHz) with the device was 32.5 dB HL. Magliulo et al (2015) reported outcomes for 10 patients treated with the Otomag Sophono device after subtotal petrosectomy for recurrent chronic middle ear disease, a procedure that is associated with a conductive hearing loss of 50 to 60 dB. With the Sophono device postsurgery, there was an average acoustic improvement in AC of 29.7 dB, which was significantly better than the improvement seen with traditional AC hearing aids (18.2 dB).

Powell et al (2015) reported outcomes from a retrospective study, including 6 patients treated with the Otomag Sophono device and 6 treated with the BAHA Attract device. Ten subjects were identified as the primary author’s patients and the remaining were identified through an Australian national hearing database. In the BAHA Attract group, mean air conduction thresholds across 4 frequencies (0.5, 1, 2, and 4 kHz) improved from 60.8 dB in the unaided state to 30.6 dB in the aided state. In the Sophono group, the mean 4-frequency AC thresholds improved from 57.8 dB in the unaided state to 29.8 dB in the aided state. Speech discrimination in noise scores did not differ significantly between devices.

Dimitriadis et al (2016) reported a systematic review of observational studies of the BAHA Attract device including 10 studies (total N=89 patients; range, 1-27 patients). Seventeen (19%) of the patients were children, of whom 5 had unilateral sensorineural hearing loss and 4 had CHL. Of the 27 (45%) adults, 22 had unilateral sensorineural hearing loss and 11 (18%) had bilateral mixed hearing loss. Audiologic and functional outcome measures and the timing of testing varied greatly in the studies. Summary measures were not reported. In general, audiologic and functional outcomes measured pre- and postimplantation showed improvement, although statistical comparisons were lacking in some studies.

Reddy-Kolanu et al (2016) reported on complications of the BAHA Attract (n=34) from a case series included all patients implanted in a single center between October 2013 and April 2015. Patients ranged in age from 8 to 64 years, and follow-up ranged from 3 to 20 months. Twenty-three patients had no significant postoperative problems. Five patients required an alteration in magnet strength primarily due to implant site tenderness. One patient reported distressing
tinnitus; 1 had the implant changed to an abutment system due to infection; and 1 had the magnet removed following trauma to the implant site. One patient has ongoing psoriasis problems. Two patients were converted to a newer, lighter sound processor.

In addition to studies of currently FDA-approved partially-implantable bone-conduction devices, a number of case series were identified which evaluate the Bonebridge implant, which is not currently cleared for marketing in the U.S. Case series with at least 5 patients are summarized in Table 1.

**Table 1: Case Studies Evaluating the BoneBridge Implant**

<table>
<thead>
<tr>
<th>Study</th>
<th>Overall N</th>
<th>Patient Population</th>
<th>Main Hearing Results</th>
<th>Safety Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schmerber et al (2016)</td>
<td>25</td>
<td>SSD (n=12)</td>
<td>SSD, in 5/7 patients speech reception threshold in noise lower with Bonebridge activated</td>
<td>No complications, device failures, revision surgery or skin injury reported with 1 y follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bilateral CHL (n=7)</td>
<td>CHL and mixed, average functional gain: 26 dB HL; mean % of speech recognition in quiet improved from 74% unaided to 95% aided</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bilateral mixed hearing loss (n=6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rahne et al (2015)</td>
<td>11</td>
<td>SSD (n=6; 1 sensorineural, 4 mixed, 2 conductive Bilateral conductive hearing loss (n=2) Bilateral mixed hearing loss or mixed/sensorineural (n=3)</td>
<td>Aided sound-field threshold improvement : 33.4 dB WRS improved from the mean of 10% unaided to 87.5% aided</td>
<td>1 case of chronic fibrosing mastoiditis requiring mastoidectomy and antrotomy; no other major/minor complications</td>
</tr>
<tr>
<td>Laske et al (2015)</td>
<td>9</td>
<td>Adults with SSD and normal contralateral hearing</td>
<td>Speech discrimination signal-to-noise improvement for aided condition vs unaided, sounded presented to aided ear: 1.7dB Positive improvements on quality-of-life questions</td>
<td>Not reported</td>
</tr>
<tr>
<td>Riss et al (2014)</td>
<td>24</td>
<td>Combined hearing loss (N=9) EAC atresia (N=12) SSD (N=3)</td>
<td>Average functional gain: 28.8 dB. Monosyllabic word scores at 65 dB sound pressure increased from 4.6 to 53.7 percentage points.</td>
<td>Not reported</td>
</tr>
<tr>
<td>Manrique et al (2014)</td>
<td>5</td>
<td>Mixed hearing loss (N=4) SSD (N=1)</td>
<td>PTA improvement: 35.62 dB (p=0.01) Disyllabic word discrimination improvement: 20% (p=0.016)</td>
<td>No perioperative complications reported.</td>
</tr>
<tr>
<td>Ihler et al (2014)</td>
<td>6</td>
<td>Mixed hearing loss (N=4)</td>
<td>PTA functional gain (avg. 0.5-4.0 kHz): 34.5 dB</td>
<td>Prolonged wound healing</td>
</tr>
</tbody>
</table>
Conductive hearing loss (N=2) | Speech discrimination at 65 dB improvement. In quiet: 63.3% percentage points. In noise: 37.5 percentage points | in one case. |  
| Desmet et al (2014) | 44 | All unilaterally deaf adults. | Statistically significant improvement on Abbreviated Profile of Hearing Aid Benefit and Short Hearing Handicap Inventory for Adults. | Not reported |


APHAB: Abbreviated Profile of Hearing Aid Benefit; CHL: conductive hearing loss; EAC: external auditory canal; PTA: pure-tone average; SHHIA: Short Hearing Handicap Inventory for Adults; SSD: single-sided deafness; WRS: word recognition score

**Section Summary: Partially Implantable Magnetic BAHA Devices**

Studies of transcutaneous, partially implantable BAHAs have typically used a retrospective within-subjects comparison of hearing thresholds with and without the device, although there have been 2 small (27 and 15 participants) prospective studies. There was heterogeneity in the audiologic and functional outcome measures used in the studies and the timing of testing. Studies of partially implantable BAHAs have generally demonstrated within-subjects improvements in hearing.

**Summary of Evidence**

For individuals who have conductive or mixed hearing loss who receive an implantable bone-anchored hearing device with a percutaneous abutment or a partially-implantable bone-anchored hearing device with transcutaneous coupling to the sound processor, the evidence includes observational studies that report pre-post differences in hearing parameters after treatment with BAHA. Relevant outcomes include functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified, but observational studies reporting on within-subjects changes in hearing generally report hearing improvements with the devices. Given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, the demonstrated improvements in hearing after device placement can be attributed to the device. Studies of partially-implantable bone-anchored devices similarly demonstrate within-subjects improvements in hearing. The single-arm studies have demonstrated improvements in hearing in the device-aided state. No direct comparisons other than with within-individual comparisons with external hearing aids were identified, but for individuals who are unable to wear an external hearing aid, there may be limited alternative treatments. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully- or partially-implantable bone-anchored hearing device with percutaneous abutment and contralateral routing of signal, the evidence includes 1 randomized controlled trial (RCT), multiple prospective and
retrospective case series, and a systematic review. Relevant outcomes include functional outcomes, quality of life, and treatment-related morbidity. Single arm case series, with sample sizes ranging from 9 to 145 patients, generally report improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone conduction devices with contralateral routing of signal. However, a well-conducted systematic review of studies comparing bone anchored devices with hearing aids with contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT included in the systematic review was a pilot study that enrolled only 10 patients and therefore does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For patients with single-sided sensorineural deafness, a binaural hearing benefit may be provided by way of contralateral routing of signals to the hearing ear. There is evidence that bilateral hearing assistance devices improve hearing to a greater degree than unilateral devices. BAHAs may be considered an alternative to external devices in patients who are not candidates for external devices. By extension, use of an implantable bone-conduction device with contralateral routing of signal may be considered in patients with unilateral sensorineural deafness. (See policy statement for coverage)

**Practice Guidelines and Position Statements**
The American Academy of Otolaryngology-Head and Neck Surgery has a position statement on the use of implantable hearing devices that was revised in 2016 and states that the Academy “considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngologist-head and neck surgeon.”

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Key Words:**
Bone conduction hearing aid, bone-anchored hearing aid (BAHA), implantable bone conduction hearing aid, air conduction hearing aid, single-sided deafness, and hearing aid, Otomag Sophono, partially implantable hearing aid, BAHA 4 Attract, BoneBridge™

**Approved by Governing Bodies:**
Six Baha® sound processors manufactured by Cochlear Americas (Englewood, CO) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use with the Baha auditory osseointegrated implant system:
- Baha® 5
- Baha Cordelle® II
- Baha Divino®
- Baha Intenso® (digital signal processing)
• Baha BP100®
• Baha 4® (upgraded from the BP100)

The FDA approved the BAHA system for use in children aged 5 years and older 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.

Other implantable bone-conduction hearing systems that rely on an abutment and have similar indications as the Cochlear Americas’ Baha devices:

• OBC Bone Anchored Hearing Aid System (Oticon Medical, Kongebakken, Denmark). Cleared November 2008.
• Ponto Bone Anchored Hearing System (Oticon Medical). Cleared September 2012. A next-generation Ponto Pro device can be used with either Oticon or Baha implants.

Two partially implantable magnetic bone-conduction devices that have received 510(k) clearance from FDA are:
• Otomag® Bone Conduction Hearing System (Sophono, Boulder, CO, now owned by Medtronic, Minneapolis, MN).
• Cochlear Baha Attract (Cochlear Americas, Centennial, CO)

The BoneBridge™ (MED-EL, Innsbruck, Austria) is another partially-implantable bone-conduction implant that is considered an active transcutaneous device. It is cleared for marketing in Europe but has not received FDA approval for use in the U.S.

The SoundBite™ Hearing System (Sonitus Medical, San Mateo, CA) is an intraoral bone-conducting hearing prosthesis that consists of a behind-the-ear microphone and an in-the-mouth hearing device and was cleared for marketing through FDA’s 510(k) clearance process in 2011 for similar indications as the BAHA. As of January 2015, Sonitus Medical is in bankruptcy.

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. In 2002, the BAHA® Softband™ was cleared for marketing by FDA for use in children younger than the age of 5 years. Because this application has no implanted components, it is not addressed in the policy.
**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:**
CPT codes:
- **69710**: Implantation or replacement of electromagnetic bone-conduction hearing device in temporal bone
- **69711**: Removal or repair of electromagnetic bone-conduction hearing device 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 to external speech processor/cochlear stimulator; without mastoidectomy
- **69718**: Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy

HCPC Codes:
- **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

**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
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
Current criteria remain unchanged. Key Points and References updated.
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
Medical Policy Panel, January 2015
Medical Policy Group, January 2015 (6): 2015 Updates to Description, Key Points, Approved
by Governing Bodies, and References; no change to policy statement
Medical Policy Panel, March 2016
Medical Policy Group, March 2016 (6): Updates to Description, Key Points, Key Words,
Approved by Governing Bodies, Coding (added codes 69710 and 69711) and References; no
changes to policy statement.
Medical Policy Panel, July 2016
Medical Policy Group, August 2016 (6): Updates to Summary and References. Removed Otomag Alpha 1 from policy statement, added fully or partially implantable in policy statement.

Medical Policy Group, September 2016 (6): Updated replacement verbiage in policy statement, no change to policy intent.

Medical Policy Group, October 2016 (6): Removed L8692 from coding section.

Medical Policy Administration Committee, October 2016

Medical Policy Panel, February 2017

Medical Policy Group, February 2017 (6): Updates to Key Points, Position Statements and References.

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.