



Louisiana

Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Policy # 00004

Original Effective Date: 06/24/2002

Current Effective Date: 10/17/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s) as an alternative to air-conduction hearing aid in patients with a conductive or mixed hearing loss to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aids as an alternative to an air-conduction hearing aid in patients 5 years of age and older with a conductive or mixed hearing loss will be considered when at least 1 of the following criteria are met:

- 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; **AND**

Meet the following audiologic criteria:

- A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kilohertz (kHz) of better than or equal to 45 decibel (dB) (OBC and BP100 devices), 55 decibel (dB) (Intenso device) or 65 decibel (dB) (Cordele II device).
- 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 decibel (dB) on average measured at 0.5, 1, 2 and 3 kilohertz (kHz), (4 kHz for OBC and Ponto Pro) or less than 15 decibel (dB) at individual frequencies.

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When Services Are Eligible for Coverage

Based on review of available data, the Company may consider an implantable bone-conduction (bone-anchored) hearing aid as an alternative to an air-conduction contralateral routing of signal hearing aid in patients five 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 decibel (dB) measured at 0.5, 1, 2, and 3 kilohertz (kHz) to be **eligible for coverage**.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, to be **investigational**.*

Based on review of available data, the Company considers implantable bone conduction hearing aids when patient selection criteria are not met to be **investigational**.*

Background/Overview

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. The American Speech-Language-Hearing Association has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥ 80 dB). PTA is calculated by averaging the hearing sensitivities (ie, 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 AC hearing aid can provide benefit to patients with sensorineural or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an AC hearing aid on the normal or less affected side.

Treatment

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

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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, or as an alternative to an AC hearing aid with CROS for individuals with unilateral sensorineural hearing loss.

Partially implantable magnetic bone-conduction hearing systems are available as an alternative to bone-conduction hearing systems connected percutaneously via an abutment. With this technique, acoustic transmission occurs transcutaneously via magnetic coupling of the external sound processor and the internally implanted device components. The bone-conduction hearing processor contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Because 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Six Baha[®] sound processors manufactured by Cochlear Americas (Englewood, CO) have been cleared for marketing by the U.S. 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).

FDA cleared the Baha system for use in children ages 5 years and older and adults 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 1 ear and normal hearing in the other (ie, single-sided deafness);
- 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.

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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, Askim, Sweden). Cleared in November 2008.
- Ponto Bone Anchored Hearing System (Oticon Medical). Cleared in September 2012. A next-generation Ponto Pro device can be used with either Oticon or Baha implants.

Two partially implantable magnetic bone-conduction devices cleared by FDA through the 510(k) process are:

- Otomag^{®‡} Bone Conduction Hearing System (Sophono, Boulder, CO; now Medtronic, Minneapolis, MN),
- Cochlear Baha^{®‡} 4 Attract System (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 has been cleared for marketing in Europe but has not received FDA approval for use in the United States.

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. In 2011, it was cleared for marketing by FDA through the 510(k) process for indications similar to the Baha. Sonitus Medical closed in 2015.

FDA product code (for bone-anchored hearing aid): LXB. FDA product code (for implanted bone-conduction hearing aid): MAH.

Baha sound processors can be used with the Baha^{®‡} Softband^{™‡}. With this application, there is no implantation surgery. The sound processor is attached to the head using a hard or soft headband. The amplified sound is transmitted transcutaneously to the cochlea via the bones of the skull. In 2002, the Baha Softband was cleared for marketing by FDA for use in children younger than 5 years. Because this application has no implanted components, it is not addressed in this evidence review.

Centers for Medicare and Medicaid Services (CMS)

No national coverage determination. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage, including air-conduction and bone-conduction devices. However, devices which produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized. Along with cochlear and auditory brainstem implants, the benefit manual specifically refers to osseointegrated implants as prosthetic devices. In 2014, Medicare clarified its hearing aid coverage to state that certain auditory

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implants, including cochlear implants, brain stem implants, and osseointegrated implants, do not meet the definition of hearing aids that are excluded from coverage.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The evidence related to the use of implantable bone-conduction devices also referred to as BAHAs, is characterized by observational studies that report pre- and postimplant hearing outcomes for patients treated with these devices. Many of these studies combine patients with different underlying disease states and indications. No RCTs have compared implantable bone-conduction hearing aids with 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. This evidence review first describes the efficacy of BAHA devices as a group, which includes studies using both percutaneous and transcutaneous devices, although most devices used in the studies were percutaneous. Second, the review describes studies that focus on transcutaneous devices. The following is a summary of key findings.

Overall Efficacy of BAHAs

Systematic Reviews

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

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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 were 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 that evidence, too, was uncertain. Implant loss ranged between 6.1% and 19.4%. The authors noted that hearing-specific quality of life (QOL) improved, but overall QOL did not differ.

Observational Studies

Since the publication of the systematic reviews, 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 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 postsurgery) 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 postsurgery) follow-up (44.5 dB vs 15.3 dB; $p<0.001$). QOL scores and requirements for revision surgery did not differ significantly between the groups.

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 unique in that many had craniofacial or genetic syndromes and hearing loss (22/109). Criteria for selection of the implanted device or the Softband were not described, though authors noted an uneven distribution by age, sex, and syndromic comorbidity. Primary measures were the Glasgow Benefit Inventory or Listening Situation Questionnaire (parent version) administered at least 3 months after hearing aid intervention. Mean overall Glasgow Benefit Inventory scores were +29 (range, 11-72). Mean Listening Situation Questionnaire score was 17, which was less than a referral cutoff of 22. Based on mean scores, authors concluded that this population benefitted from bone-anchored and Softband-held conductive hearing aids. Conclusions were affected by the heterogeneous patient population, lack of preintervention measures, and lack of a controlled comparator group. Other series describing outcomes for pediatric patients treated with bone-anchored devices have reported a benefit in hearing scores, including den Besten et al (2015) in 79 children ages 17 and under.

Older case series have reported patient-reported benefits and satisfaction after BAHA placement. Some have suggested that the BAHA improved hearing better than early bone-conducting devices and AC

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hearing aids and produced acceptable hearing outcomes in individuals unable to tolerate 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 nonimplanted 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 have demonstrated a consistent improvement in speech recognition in noise and sound localization using bilateral devices for people with conductive (CHL) or mixed hearing loss.

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

Examples of individual studies include the following. Bosman et al (2001) reported on 25 patients who were using bilateral devices. They found that both speech recognition in noise and directional hearing improved with the second device. Priwin et al (2004) reported similar findings in 12 patients with bilateral devices. A 2005 consensus statement 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 other studies cited in the 2005 consensus statement found benefits similar to those noted by Bosman and by Priwin. Positive outcomes continue to be reported: Dun et al

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(2010) identified improvements in the Glasgow Benefit Inventory scores in 23 children, while Ho et al (2009) reported the same benefit in 93 adults.

Section Summary: Bilateral BAHA Devices in Conductive or Mixed Hearing Loss

The evidence on bilateral vs 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

Peters et al (2015) reported results from a systematic review of studies comparing BAHA devices using CROS systems with hearing aids using CROS for single-sided deafness (SSD). Six studies met eligibility criteria, including 1 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 (n=91 patients) with low or moderate risk of bias were noted to have significant heterogeneity in the populations included. For speech perception in noise, there was no consistent improvement with aided hearing over an unaided hearing in all environments. All studies reported equal sound localization and QOL outcomes for both hearing conditions.

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: the BAHAs resulted in greater improvements than those obtained with the conventional AC CROS systems.

Since the publication of the Peters systematic review, 2 prospective, interventional studies have compared patient outcomes using transcutaneous BAHA devices with CROS hearing aids for SSD. Leterme et al (2015) assessed 24 adults with SSD, 18 of whom were evaluated with trials of both hearing aids with CROS and bone-conduction–assisted hearing using the Baha Softband. Most (72%) patients, after completing trials of both devices, preferred the BAHA device to hearing aids with CROS. Glasgow Benefit Inventory and Abbreviated Profile of Hearing Aid Benefit 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 on 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.

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Several centers have reported on findings from observational studies that evaluated the benefits of BAHAs for patients with unilateral SSD. Most were retrospective. Studies representative of this group 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 U.S. university medical center. Significant improvement was reported in objective hearing measures (speech-in-noise and monosyllabic word tests) following BAHA implantation. Subjective benefits from BAHAs varied across patients based on 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.

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

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 investigated in children younger than five years in Europe. Reports have described experiences with preschool children or children with developmental issues that might interfere with device maintenance and skin integrity. A 2-stage procedure may be used in young children. In the first stage, the fixture is placed into the bone and allowed to fully osseointegrate. After 3 to 6 months, a second procedure is performed to connect the abutment through the skin to the fixture.

The largest series in children under 5 years were identified, described by Amonoo-Kuofi et al (2015), included 24 children from a single center's prospectively maintained database. Most patients underwent a 2-stage surgical approach. Most (52%) patients received the implant for isolated microtia or Goldenhar syndrome (16%). Following implantation, 13 (54%) patients had grade 2 or 3 local reactions assessed on the Holgers Classification System (redness, moistness, and/or granulation tissue) and 7 (29%) had grade 4 local reactions on this scale (extensive soft tissue reaction requiring removal of the abutment). QOL scores (Glasgow Children's Benefit Inventory; scoring range, -100 to 100) were obtained in 18 subjects/parents, with a final 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.

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Marsella et al (2012) reported on a single-center experience in Italy with pediatric BAHAs from the inception of their program in 1995 to December 2009. Forty-seven children (21 girls, 26 boys) were implanted; 7 were younger than 5 years. The functional gain was significantly better with BAHAs than with conventional nonimplanted bone-conduction hearing aids, and there was no significant difference regarding functional outcomes between the 7 younger patients and the rest of the cohort. Based on these findings, study authors suggested that implantation of children at an age younger than 5 years can be conducted safely and effectively in such settings. Report conclusions were limited by the small number of very young children in the sample and the limited statistical power to detect a difference between younger and older children.

Davids et al (2007) provided BAHA devices to children younger than 5 years of age for auditory and speech-language development, and retrospectively compared surgical outcomes for a study group of 20 children younger than 5 years and a control group of 20 older children. Children with a cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for children having 2-stage procedures was significantly longer in the study group to allow implantation in younger patients without increasing surgical or postoperative morbidity. Two traumatic fractures occurred in the study group vs four in the older children. Three younger children required skin site revision. All children were wearing their BAHA devices at the time of writing. McDermott et al (2008) reported on the role of BAHAs in children with Down syndrome in a retrospective case analysis and postal survey of complication rates and QOL outcomes for 15 children ages 2 to 15 years. All used their BAHA devices at a 14-month follow-up. No fixtures were lost; skin problems were encountered in 3 patients. All 15 patients had improved social and physical functioning, attributed to improved hearing.

Section Summary: BAHA Devices in Children Younger Than Age 5 Years

There are few data on the 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 nonimplanted bone-conduction hearing aids in an analysis including all ages.

SAFETY AND ADVERSE EVENTS RELATED TO BAHA DEVICES

In addition to the efficacy literature on the BAHA devices, studies have assessed complications with these devices.

Systematic Reviews

Verheij et al (2016) published a systematic review on complications of surgical tissue preservation 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

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reaction; grade 2, red and moist tissue; grade 3, granulated tissue; grade 4, removal of skin-penetrating implant necessary due to infection). The incidence of Holgers grade 3 was 2.5% with the punch technique, 5.9% with the linear incision technique, and 0% with the Weber technique. Holgers grade 4 was reported in 1 patient implanted with the linear incision technique.

Kiringoda and Lustig (2013) reported on a meta-analysis of complications related to BAHA implants. Selected were 20 studies that evaluated complications in 2134 adult and pediatric patients who received a total of 2310 BAHA implants. 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 Classification System grade 2, 3 or 4 skin reactions ranged from 2.4% to 38.1% in all studies. The incidence of failed osseointegration ranged from 0% to 18% in adult and mixed population studies and from 0% to 14.3% in pediatric population studies. The incidence of revision surgery ranged from 1.7% to 34.5% in adult and mixed population studies and from 0.0% to 44.4% in pediatric population studies. Implant loss ranged from 1.6% to 17.4% in adult and mixed population studies and from 0.0% to 25% in pediatric studies.

Observational Studies

Dun et al (2012) assessed soft tissue reactions and implant stability of 1132 percutaneous titanium implants for bone-conduction devices in a retrospective survey of 970 patients undergoing implants between 1988 and 2007 at a university medical center in the Netherlands. Study investigators also examined device usage and compared different patient age groups (children, adults, elderly patients) over a 5-year follow-up. Implant loss was 8%. 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 than in adults and elderly patients ($p < 0.05$). Implant survival rates were lower in patients with than without mental retardation ($p = 0.001$).

Hobson et al (2010) reviewed complications of 602 patients at a tertiary referral center over 24 years and compared their observed rates with those published in 16 previous studies. The overall observed complication rate of 23.9% (144/602) was similar to other published studies (weighted mean complication rate, 24.9%). The most common complications were soft tissue overgrowth, skin infection, and fixture dislodgement. The observed rate of surgical revision of 12.1% (73/602) was also similar to previously published rates (weighted mean, 12.7%). Top reasons for revision surgery were identical to observed complications. Wallberg et al (2011) reported on the status of 150 implants placed between 1977 and 1986 at a mean follow-up of 9 years. Implants were lost in 41 (27%) patients. Reasons for implant loss were: removal (16 patients), osseointegration failure (17 patients), and direct trauma (8 patients). In the 132 patients with implant survival, BAHAs were still being used by 119 (90%) patients at the 9-year 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 (89%) patients; implant removal or surgical revision was required in 10 (37%) patients; 24 (89%) patients experienced soft tissue overgrowth and infection; and 7 (26%) patients experienced implant trauma. Chronic infection and overgrowth at the abutment prevented use of the implant in 3 (11%) patients.

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Allis et al (2014) 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, except that patients with the 8.5-mm abutment implant 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%; $p=0.012$), respectively.

Other observational cohort studies, ranging in size from 47 to 974 subjects, have reported safety and adverse event outcomes after BAHA placement. Across these studies, implant loss ranged from 4% to 18%.

Different surgical techniques for implanting BAHA devices and specific BAHA designs have yielded better safety outcomes. In a 2016 systematic review of 30 articles on the association between surgical technique and skin complications following BAHA implantation, the dermatome technique (vs a skin graft or linear technique) was linked to more frequent skin complications. Fontaine et al (2014) compared complication rates for 2 BAHA surgical implantation techniques among 32 patients treated from 2004 to 2011. Complications requiring surgical revision occurred in 20% of cases who had a skin flap implantation method ($n=20$) and in 38% of cases who had a full-thickness skin graft implantation method ($n=21$; $p=0.31$). Hultcrantz and Lanis (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 a flap or a dermatome implantation technique. In a comparison of 2 types of BAHA devices, one with a 4.5-mm diameter implant and a rounded 6-mm abutment ($n=25$) and one with a 3.75-mm diameter implant and a conically shaped 5.5-mm abutment ($n=52$), Nelissen et al (2014) reported that implant survival was high for both groups over a 3-year 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 postoperative complications. Five subjects developed postoperative skin reactions, of whom three 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 complications from surgical procedures for BAHA insertion are adverse skin reactions, with an incidence of Holgers grade 2, 3 or 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 reductions in complication rates and their severity with newer surgical techniques (eg, linear incision).

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PARTIALLY IMPLANTABLE MAGNETIC BAHA DEVICES

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 on percutaneous bone-anchored devices, most 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 (discussed below) evaluating different transcutaneous systems were identified. Both trials were small (27 and 15 individuals), but both demonstrated improvements in hearing outcomes.

Briggs et al (2015) reported on a prospective interventional evaluation of the percutaneous, partially implantable Baha Attract System among 27 adults with CHL 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 various sound processors in conjunction with Baha Softband before device implantation. All 27 patients enrolled received an implant. Sound processor fitting occurred 4 weeks postimplantation in all but 1 patient. At 9-month follow-up, pure-tone audiometry (PTA; means of 500, 1000, 2000, and 4000 Hz) was significantly improved with the implant and sound processor compared with unaided hearing (18.4-dB hearing loss; $p < 0.001$). Patients generally showed improvements in speech recognition in noise, although comparing results across test sites was 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 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 trial of the Sophono device in children ages 5 to 18 years with uni- or bilateral congenital aural atresia with complete absence of the external auditory canal with pure CHL. The study included a within-subject comparison of hearing results with the Sophono devices to those obtained with the Baha Softband preoperatively. All 15 patients enrolled were implanted (median age, 97 months). At 6-month follow-up, mean aided AC PTA was 33.49 dB (mean gain, 35.53 dB), with a mean aided sound reception threshold of 38.2 dB (mean gain, 33.47 dB). The difference in AC PTA between the Baha Softband and the Sophono device was 0.6 dB (confidence interval upper limit, 4.42 dB), which met the trial's prespecified noninferiority margin. Adverse events 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. Hol et al (2013) compared percutaneous BAHA implants with partially implantable magnetic transcutaneous bone-conduction hearing implants using the Otomag Sophono device in 12 pediatric patients (age range, 5-12 years) who had congenital unilateral CHL. Sound-field thresholds, speech recognition threshold, and speech comprehension at 65 dB were somewhat better in patients with

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the BAHA implant (n=6) than in those with the partially implantable hearing device (n=6). Using a skull simulator, output was 10 to 15 dB lower with the partially implantable device than with 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 with BAHA. Both groups showed improvements in sound localization compared with 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 using a transcutaneous, fully implantable BAHA with 16 patients treated using 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 Holgers grade 2 skin reactions, and 2 stopped using their devices for reasons unrelated to skin reactions. 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 who had CHL who received the transcutaneous Bonebridge device with an audiologically matched control group of 10 patients who received 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 Abbreviated Profile of Hearing Aid Benefit. 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 at a single center and with fewer than 10 patients—has 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.

Dimitriadis et al (2016) reported on 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

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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 with the BAHA Attract (n=34) from a case series that included all patients implanted in a single center between 2013 and 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; another had the implant changed to an abutment system due to infection, and a third 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 an early (2011) study, Seigert reported on the use of a transcutaneous, partially implantable bone-conduction hearing system (Otomag). Among 12 patients who received the system, there were average hearing gains of 31.2 dB in free-field PTA. The free-field suprathreshold speech perception at 65 dB increased from 12.9% preimplantation to 72.1% postimplantation.

Powell et al (2015) reported on outcomes from a retrospective study that included 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 AC 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.

O'Niel et al (2014) reported on outcomes for 10 pediatric patients with CHL treated with the Otomag Sophono device at a single center. Fourteen 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 sufficient difficulties to discontinue device use for a period. Mean aided PTA was a 20.2-dB hearing level, with a mean functional gain of a 39.9-dB hearing level. Patients without skin complications consistently used their devices (average daily use, 8-10 hours).

Centric et al (2014) also reported on 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 CHL and unilateral sensorineural hearing loss. The average improvement in PTA was a 32-dB hearing level, and the average improvement in speech response threshold was a 28-dB hearing level. All patients responded in the normal-to-mild hearing loss range in the implanted ear after device activation. In a follow-up study from the same institution, Baker et al (2015) 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 ears in the Sophono group and 5 in the Baha Attract group. Average improvement over all frequencies ranged from a 24- to 43-dB hearing level in the Sophono

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group and from a 32- to 45-dB hearing level in the Baha Attract group. The average improvement in PTA was a 38-dB hearing level in the Sophono group and a 41-dB hearing level in the Baha Attract group.

Other single-center observational series have described clinical experience with transcutaneous partially implantable BAHA devices. Marsella et al (2014) reported on outcomes for 6 pediatric patients treated with the Otomag Sophono device for CHL or mixed hearing loss. Median improvement in PTA was 33-dB hearing loss, and median free-field PTA (0.5-3 kHz) with the device was 32.5-dB hearing loss. Magliulo et al (2015) reported on outcomes for 10 patients treated with the Otomag Sophono device after subtotal petrosectomy for recurrent chronic middle ear disease, a procedure associated with a CHL of 50 to 60 dB. Postsurgery with the Sophono device, 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).

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

Table 1. Case Series Evaluating the Bonebridge Implant

Study	N	Patient Population	Main Hearing Results	Safety Outcomes
Schmerber et al (2017)	25	<ul style="list-style-type: none"> • SSD (n=12) • Bilateral CHL (n=7) • Bilateral mixed HL (n=6) 	<ul style="list-style-type: none"> • SSD, in 5/7 patients speech reception threshold in noise lower with Bonebridge activated • CHL and mixed, average functional gain: 26 dB HL; mean % of speech recognition in quiet improved from 74% unaided to 95% aided 	No complications, device failures, revision surgery, or skin injury reported with 1 y follow-up
Rahne et al (2015)	11	<ul style="list-style-type: none"> • SSD (n=6; 1 sensorineural, 3 mixed, 2 conductive) • Bilateral CHL (n=2) • Bilateral mixed HL or mixed/sensorineural (n=3) 	<ul style="list-style-type: none"> • Aided sound-field threshold improvement: 33.4 dB • WRS improved from mean of 10% unaided to 87.5% aided 	1 case of chronic fibrosing mastoiditis requiring mastoidectomy and antrotomy; no other complications
Laske et al (2015)	9	<ul style="list-style-type: none"> • Adults with SSD and normal contralateral hearing 	<ul style="list-style-type: none"> • Speech discrimination signal-to-noise improvement for aided vs unaided condition, sound presented to aided ear: 1.7 dB • Positive improvements on quality-of-life questions 	Not reported
Riss et al (2014)	24	<ul style="list-style-type: none"> • Combined HL (n=9) • EAC atresia (n=12) • SSD (n=3) 	<ul style="list-style-type: none"> • Average functional gain: 28.8 dB • Monosyllabic word scores at 65-dB sound pressure increased from 4.6 to 53.7 percentage points 	Not reported
Manrique	5	<ul style="list-style-type: none"> • Mixed HL (n=4) 	<ul style="list-style-type: none"> • PTA improvement: 35.62 dB (p=0.01) 	No perioperative

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Study	N	Patient Population	Main Hearing Results	Safety Outcomes
et al (2014)		<ul style="list-style-type: none"> • SSD (n=1) 	<ul style="list-style-type: none"> • Disyllabic word discrimination improvement: 20% (p=0.016) 	complications reported
Ihler et al (2014)	6	<ul style="list-style-type: none"> • Mixed HL (n=4) • CHL (n=2) 	<ul style="list-style-type: none"> • PTA functional gain (average, 0.5-4.0 kHz): 34.5 dB • Speech discrimination at 65 dB improvement: <ul style="list-style-type: none"> ○ In quiet: 63.3 percentage points ○ In noise: 37.5 percentage points 	Prolonged wound healing in 1 case
Desmet et al (2014)	44	<ul style="list-style-type: none"> • All unilaterally deaf adults 	<ul style="list-style-type: none"> • Statistically significant improvement on APHAB and SHHIA 	Not reported
Iseri et al (2014)	12	<ul style="list-style-type: none"> • CHL (n=9) • "Primarily conductive hearing loss" (n=3) 	<ul style="list-style-type: none"> • Speech reception threshold increase: 19 dB 	Postoperative hematoma requiring aspiration in 1 case

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

Section Summary: Partially Implantable Magnetic BAHAs

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 BAHAs with a percutaneous abutment or a partially implantable BAHAs with transcutaneous coupling to the sound processor, the evidence includes observational studies that have reported pre-post differences in hearing parameters after treatment with BAHAs. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. No prospective trials were identified. Observational studies reporting on within-subjects changes in hearing have generally reported 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 BAHAs have similarly demonstrated within-subjects improvements in hearing. The single-arm studies have shown improvements in hearing in the device-aided state. No direct comparisons other than within-individual comparisons with external hearing aids were identified, but, for individuals unable to wear an external hearing aid, there may be few alternative treatments. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable BAHA with the contralateral routing of signal, the evidence includes an RCT, multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 180 patients, have generally reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone-conduction devices with contralateral routing of the signal. However, a well-conducted systematic review of studies comparing bone-anchored devices with hearing aids using 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 enrolling only 10 patients and, therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy History

Original Effective Date:	06/24/2002
Current Effective Date:	10/17/2018
06/11/2002	Medical Director review
06/20/2002	Medical Policy Committee review
06/24/2002	Managed Care Advisory Council approval. Format revision. No substance change to policy.
07/06/2004	Medical Director review
07/20/2004	Medical Policy Committee review. Format revision, Rationale/Source added to policy. No substance change to policy.
07/26/2004	Managed Care Advisory Council approval
06/07/2005	Medical Director review
06/21/2005	Medical Policy Committee review. Clinical criteria change. Coverage for single sided deafness and bilateral fittings added as investigational indication.
07/15/2005	Managed Care Advisory Council approval
06/13/2006	Format revisions. No changes to policy statement.
08/02/2006	Medical Director review
08/09/2006	Medical Policy Committee approval. Patient selection criteria updated to include age limitations.
10/10/2007	Medical Director review
10/17/2007	Medical Policy Committee approval. Policy statements updated and clarified related to eligibility for coverage for unilateral and bilateral sensorineural hearing loss. Policy statement added concerning investigational uses, including bilateral sensorineural hearing loss. Policy title changed to add "and Bone-Anchored".
10/01/2008	Medical Director review
10/22/2008	Medical Policy Committee approval. No change to coverage eligibility.
10/01/2009	Medical Policy Committee approval
10/14/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
10/14/2010	Medical Policy Committee review
10/20/2010	Medical Policy Implementation Committee approval. The age requirement in the coverage language changed to be consistent with FDA-approved labeling from "patients over five years of age" to "patients five years of age and older". Coverage that stands alone without criteria placed under the subtitle "When Services Are Eligible for Coverage".
02/01/2011	Coding updated
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Audiologic criteria revised to read: 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). For bilateral implantation, patients should meet the above audiologic criteria, and have a symmetrically conductive or mixed hearing loss as defined by a difference between left and right side bone conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz, or less than 15 dB at individual frequencies.

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10/11/2012 Medical Policy Committee review
 10/31/2012 Medical Policy Implementation Committee approval. Added investigational statement for partially implantable hearing systems.
 02/04/2013 Coding updated
 10/03/2013 Medical Policy Committee review
 10/16/2013 Medical Policy Implementation Committee approval. No change to coverage.
 10/02/2014 Medical Policy Committee review
 10/15/2014 Medical Policy Implementation Committee approval. No change to coverage.
 10/08/2015 Medical Policy Committee review
 10/21/2015 Medical Policy Implementation Committee approval. No change to coverage.
 10/06/2016 Medical Policy Committee review
 10/19/2016 Medical Policy Implementation Committee approval. Policy statements changed to remove investigational statement for partially implantable devices.
 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
 10/05/2017 Medical Policy Committee review
 10/18/2017 Medical Policy Implementation Committee approval. No change to coverage.
 01/01/2018 Coding update
 10/04/2018 Medical Policy Committee review
 10/17/2018 Medical Policy Implementation Committee approval. No change to coverage.
 Next Scheduled Review Date: 10/2019

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Code Type	Code
CPT	69710, 69711, 69714, 69715, 69717, 69718

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HCPCS	L8690, L8691, L8693 Codes added eff 1/1/18: L8625, L8694			
ICD-10 Diagnosis	H60.399	H60.60-H60.63	H60.8X1-H60.8X9	H60.90-H60.93
	H61.391-H61.399	H62.8X1-H62.8X9	H65.20-H65.23	H65.30-H65.33
	H65.411-H65.419	H65.491-H65.499	H66.001-H66.009	H66.011-H66.019
	H66.10-H66.13	H66.20-H66.23	H66.3X1-H66.3X9	H66.40-H66.43
	H66.90-H66.93	H67.1-H67.9	H90.0	H90.11-H90.12
	H90.2	H90.6	H90.71-H90.72	H90.8
	Q16.4			

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

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