Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

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

Description/Background

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction or bone conduction external hearing aids. 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 (BAHAs) 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 for 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 detects 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 (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥80 dB). PTA is calculated by averaging hearing sensitivities (i.e., the minimum volume that a patient hears) at multiple frequencies (perceived as pitch), typically within the range of 0.25 to 8 kHz.

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

Treatment

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

A bone-anchored implant system combines 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 osseointegration through which living tissue integrates with titanium in the implant over a period of 3 to 6 months, conducting amplified and processed sound 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. They may also be used with CROS as an alternative to an AC hearing aid for individuals with unilateral sensorineural hearing loss.

Partially implantable magnetic bone-conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to bone-conduction hearing systems that connect 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.

The Baha Softband is an adjustable headband which was designed for children, under the age of 5, whose bone structure is still too immature for a partially implanted or bone anchored hearing device. In children under 5, the Baha Softband maximizes language development by providing hearing performance and amplification at a time when learning to communicate is crucial to development.(76)

Regulatory Status

Several implantable bone-conduction hearing systems have been approved by the U.S. Food and Drug Administration for marketing through the 510(k) process (Table 1).

Table 1. Implantable Bone-Conduction Hearing Systems Approved by the U.S Food and Drug Administration (FDA)

Device	Manufacturer	Date Cleared	510(k) No.
Baha 6 System	Cochlear Americas	Sept 2021	K212136
BA310 Abutment, BIA310 Implant/Abutment		Dec 2018	K182116
Baha 5 Power Sound Processor		May 2016	K161123
Baha 5 Super Power Sound Processor		Mar 2016	K153245
Baha® 5 Sound Processor		Mar 2015	K142907
Baha® Attract System		Nov 2013	K131240
Baha® Cordelle II		Jul 2015 Apr 2008	K150751 K080363
Baha Divino®		Aug 2004	K042017
Baha Intenso® (digital signal processing)		Aug 2008	K081606
Baha® 4 (upgraded from the BP100)		Sep 2013	K132278
Cochlear Osia System		July 2019	K190589
Cochlear Osia 2 Sound Processor		Nov 2019	K191921
OBC® Bone-Anchored Hearing Aid System	Oticon Medical	Nov 2011	K112053

Ponto™ Bone-Anchored Hearing System	Oticon Medical	Sep 2012	K121228
Ponto 5 SuperPower	Oticon Medical	Dec 2021	K213733
Ponto 4		May 2019	K190540
Ponto 3, Ponto 3 Power and Ponto 3 SuperPower		Sep 2016	K161671

The FDA cleared the majority of these systems for use in children age 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 (i.e., single-sided deafness);
- Patients who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS device.

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 the FDA for use in children younger than 5 years.

The most recently cleared Osia™2 system may be used by adults and children 12 years of age and older with conductive hearing loss, mixed hearing loss, and single-sided sensorineural deafness.

The FDA also cleared 3 partially implantable magnetic bone-conduction devices for marketing through the 510(k) process (Table 2)

Table 2. Partially Implantable Magnetic Bone-Conduction Devices Approved by the FDA

Device	Manufacturer	Date Cleared	510(k) No.
Bonebridge	MED-EL	Mar 2019	K183373
Otomag® Bone-Conduction Hearing System	Medtronic (Formerly Sophono)	Nov 2013	K132189
Cochlear Baha® 4 Sound Processor	Cochlear Americas	Oct 2012	K121317

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.

Medical Policy Statement

The safety and effectiveness of FDA approved unilateral or bilateral fully- or partially-implanted bone-conduction (bone-anchored) hearing aid(s) have been established. They may be considered a useful therapeutic option when indicated.

The use of a Baha® Softband may be considered established in children 5 years of age and younger meeting criteria for BAHA treatment, but who are determined to have inadequate skeletal maturity to sustain osteointegration of the BAHA device.

Inclusionary and Exclusionary Guidelines

Inclusions:

FDA approved devices when used according to approved indications and guidelines.

Conductive Hearing Loss:
FDA approved unilateral or bilateral fully- or partially-implantable bone-conduction (bone-anchored) hearing aid(s) may be necessary as an alternative to an air-conduction hearing aid in patients with conductive or mixed hearing loss 5 years of age and older (Baha 4, Baha 5, Baha 5 SuperPower, Baha Cordele II, Ponto™ Bone Anchored Hearing System, Ponto 4 and Otomag® Bone Conduction [OBC] devices) **or** 12 years of age and older (Cochlear OSIA and Cochlear OSIA 2 system) who also meet **one** of the following criteria:

- Congenital or surgically-induced malformations (e.g., atresia) of the external ear canal or middle ear;
- Chronic external otitis or otitis media;
- Tumors of the external canal and/or tympanic cavity;
- Chronic dermatitis of the external canal prohibiting the usage of an air conduction hearing aid

AND meet the following audiologic criteria:

- A pure-tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz or better than or equal to one of the following:
  - 45 dB (OBC and BP100, Baha 4 and Baha 5, Ponto, Ponto 3, Ponto Pro, Ponto Plus, and Ponto 4 devices)
  - 55 dB (Intenso, Cochlear OSIA and Cochlear OSIA 2, Ponto 3 power, Ponto Pro Power and Ponto Plus Power devices)
  - 65 dB (Cordele II, Baha 5 SuperPower, Ponto 3 SuperPower devices).

For bilateral implantation, patients should meet the above audiologic criteria in both ears and have 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, Ponto Bone Anchored Hearing System, Ponto 3, Ponto 3 Power, Ponto 3 SuperPower, Ponto 4 and Ponto Pro devices), or less than 15 dB at individual frequencies.

Sensorineural Hearing Loss:
A unilateral implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction contralateral routing of signal hearing aid in patients 5 years of age and older (Baha 4, Baha 5, Baha 5 SuperPower, Baha Cordele II, OBC, Ponto 3, Ponto 3 Power and Ponto 3 SuperPower and Ponto Bone Anchored Hearing devices) or 12 years of age and older (Cochlear OSIA and Cochlear OSIA 2 system) 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.

**The Audiant® bone conductor is a bone-conduction hearing device. While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.*

In patients being considered for implantable bone-conduction (bone-anchored) hearing aid(s), skull bone quality and thickness should be assessed for adequacy to ensure implant stability. Additionally, patients (or caregivers) must be able to perform proper hygiene to prevent infection and ensure the stability of the implants and percutaneous abutments.

Exclusions:
- Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in patients with bilateral sensorineural hearing loss, are considered experimental/investigational.
- Non FDA approved devices and/or indications

CPT/HCPCS Level II Codes ***(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)***

Established codes

69710	69711	69714	69716	69717	69719
69726	69727	69728	69729	69730	L8625
L8690	L8691	L8692	L8693	L8694	

Other codes (investigational, not medically necessary, etc.)

N/A

Note: The above code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

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 1 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.

BILATERAL IMPLANTABLE BONE-ANCHORED HEARING AID DEVICES WIH A PERCUTANEOUS ABUTMENT IN CONDUCTIVE OR MIXED HEARING LOSS

Clinical Context and Therapy Purpose

The purpose of implantable bone-anchored hearing aids (BAHAs) with a percutaneous abutment is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as external hearing aids, in individuals with conductive or mixed hearing loss.

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest are individuals with conductive or mixed hearing loss.

Interventions

The therapy being considered are implantable BAHAs with a percutaneous abutment.

Comparators

The main comparator of interest is external hearing aids.

Outcomes

The general outcomes of interest are functional outcomes, quality of life, and treatment-related morbidity.

The existing literature evaluating implantable BAHAs with a percutaneous abutment as a treatment for conductive or mixed hearing loss has varying lengths of follow-up. At least one year of follow-up is considered necessary to fully observe outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Heath et al (2022) conducted a systematic review of studies that compared outcomes between bilateral and unilateral BAHA for patients with no benefit from conventional hearing aids.(79) A total of 14 articles were included; all studies were retrospective with the exception of one case report, and all studies had a substantial risk of bias. A meta-analysis was not performed, but descriptive comparison found that bilateral BAHA were associated with greater improvement in hearing thresholds, understanding speech, and localization. Unilateral BAHA were more effective when noise was one-sided. All studies reported improvement in quality of life.

Janssen et al (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent CHL.(1) 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. 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 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. Heterogeneity of the methodologies between studies precluded meta-analysis, therefore a qualitative review was performed. Results from 3 (of 11) studies were excluded from synthesis because their patients had been included in multiple publications. Adverse events were not an outcome measure of any of the 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, 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.(2) 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.(3) 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.(4) A number of other studies cited in the 2005 consensus statement found benefits similar to those noted by Bosman and by Priwin.(2,3) Positive outcomes continue to be reported: Dun et al (2010) (5) identified improvements in the Glasgow Benefit Inventory in 23 children, while Ho et al (2009) (6) reported the same benefit in 93 adults.

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.

PARTIALLY IMPLANTABLE BONE-ANCHORED HEARING DEVICES WITH TRANSCUTANEOUS COUPLING

Clinical Context and Therapy Purpose
The purpose of partially implantable BAHAs with transcutaneous coupling to the sound processer is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as external hearing aids, in individuals with conductive or mixed hearing loss.

The following PICO was used to select literature to inform this review.

Populations
The relevant populations of interest are individuals with conductive or mixed hearing loss.

Interventions
The therapy being considered is partially implantable BAHAs with transcutaneous coupling to the sound processer, wherein acoustic transmission occurs transcutaneously via magnetic coupling of an external sound processor to the internally implanted device components.

Comparators
The main comparator of interest is external hearing aids.

Outcomes
The general outcomes of interest are functional outcomes, quality of life, and treatment-related morbidity.

The existing literature evaluating partially implantable BAHAs with transcutaneous coupling to the sound processer as a treatment for conductive or mixed hearing loss has varying lengths of follow-up. At least one year of follow-up is considered necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the principles described above.

Review of Evidence

Prospective Studies
Two prospective trials 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 on 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.(7) The choice of sound processor was based on patient preference and hearing tests with the various sound processors in conjunction with BAHA Softband prior to device implantation. All twenty-seven patients enrolled 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 hearing loss; p<.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=.038) and reverberation (p=.016) and background noise (p=.035) subscales were significantly improved with the test device.

Denoyelle et al (2015) reported on a prospective clinical trial of the Sophono device in children age 5 to 18 years with uni- or bilateral congenital aural atresia with complete absence of the external auditory canal with pure conductive hearing loss.(8) The study included a within-subject comparison of hearing results with the Sophono devices to those obtained with the BAHA Softband preoperatively. All fifteen patients enrolled and were implanted (median age, 97 months). At 6-month follow-up, mean aided air-conduction (AC) 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, (confidence interval upper limit, 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.

Gawecki et al (2022) performed a small randomized study that compared patients who received the Osia system (n=4) or the Baha Attract system (n=4) for bilateral mixed hearing loss.(80) After implantation, the mean gain in PTA was 42.8 ± 4.9 dB in the Osia group and 38.8 ± 8.5 dB in the Baha group. Patient ratings of hearing quality were better in the Osia group based on subjective Likert scores of sound loudness, sound distinctness, and hearing of own voice. Patient reported voice quality scores for reverberation were similar in the Osia and Baha groups. Both groups reported improved quality of life based on global Abbreviated Profile of Hearing Aid Benefit scores but there was a numerically larger improvement in the Osia group. Results for the Speech, Spatial and Qualities of Hearing Scale improved in both groups and were slightly better in the Baha group. The authors concluded that larger studies with longer follow-up are needed to evaluate differences in outcomes between these 2 systems.

Nonrandomized Comparative Studies

Limited data is available comparing transcutaneous with percutaneous bone-anchored conduction devices. Hol et al (2013) compared percutaneous BAHA implants to partially implantable magnetic transcutaneous bone-conduction hearing implants using the Otomag Sophono device in 12 pediatric patients, (age range, from 5 to 12 years) who had congenital unilateral CHL.(9) Sound field thresholds, speech recognition threshold, and speech comprehension at 65 dB were somewhat better in patients with the BAHA implant (n=6) than with the partially implantable hearing device (n=6). Using a skull simulator, output was 10 to 15 dB less 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.(10) 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).(11) 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<.05). Three patients treated with percutaneous devices had Holger grade 2 skin reactions, and 2 had 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=.02).

Gerdes et al (2016) published a retrospective single-center study comparing 10 patients who had CHL and received the transcutaneous Bonebridge device with an audiologically matched control group of 10 patients who received the percutaneous BAHA BP100.(12) 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.

Kim et al (2022) compared the effects of the Osia system with the Baha Attract and Bonebridge systems in 67 patients with CHL or mixed hearing loss or single-sided deafness (SSD).(81) Patients who received the Osia system (n=17) were prospectively recruited and retrospectively compared with patients who received the Baha Attract or Bonebridge systems (n=50). Effective gains in bone conduction threshold at 2 kHz were 11.1 ± 14.9 dB in the Osia group compared to -2.7 ± 12.6 dB in the Baha Attract and Bonebridge group (combined) among patients with CHL or mixed hearing loss (p=.01). Among patients with SSD, average functional gains at 4 kHz were 37.5 ± 8.9 dB in the Osia group, 21.7 ± 15.7 dB in the Baha Attract group, and 29.0 ± 13.0 dB in the Bonebridge group.

Observational Studies

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).(13) 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 post-implantation 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 that included all patients implanted in a single center between 2013 and 2015.(14) 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 an early (2011) study, Seigert reported on the use of a transcutaneous, partially implantable bone-conduction hearing system (Otomag).(15) Among 12 patients who received the system, there were average hearing gains of 31.2 dB 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.

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.(16) 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.

O'Niel et al (2014) reported outcomes for 10 pediatric patients with CHL treated with the Otomag Sophono device at a single center.(17) 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 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 (average daily use, of 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.(18) Etiologies of hearing loss were heterogeneous and included bilateral moderate or severe CHL and unilateral sensorineural hearing loss. 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 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.(19) 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 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.

Other 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.(20) 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 associated with a conductive hearing loss of 50 to 60 dB.(21) Post-surgery 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 Food and Drug Administration, a number of case series were 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 3.

Table 3. Case Series Evaluating the Bonebridge Implant

Study	N	Patient Population	Main Hearing Results	Safety Outcomes
Carnevale et al (2022)	52	• CHL • Mixed HL	• Mean gain in PTA after 6 months of31.83 dB	One implant failure, one implant exposure
Cywka et al (2022)	42	• CHL (n=19) • Mixed HL (n=23)	• APHAB questionnaire results showed improved word recognition in quiet and speech reception threshold in noise	None
Huber et al (2022)	17	• SSD	• Speech reception threshold in noise increased significantly for signals coming from the deaf side; no difference for signals coming from the front or normal hearing side	4 procedure or device-related events reported (impaired wound healing, localized swelling with and without pain, headaches)
Hundertpfund et al(2022)	31	• CHL (n=11) • Mixed HL (n=20)	• Mean PTA threshold decreased from64.7 dB to 43.4 dB at last follow-up	5 minor and 1 major implant-related events occurred during 1-yearfollow-up
Seiwerth et al(2022)	31	• CHL • Mixed HL • Malformation • After multiple ear surgery • SSD	• Mean sound field thresholds improved from 60 dB HL to 33dB HL at 3 months • Word recognition in quiet(p<.0001) and speech reception threshold in noise(p=.0018)	Minor complications in12.5%, major complications in 3.1%
Sikolova et al (2022)	12	• Pediatric patients with CHL(n=10) or SSD (n=2)	• Functional gain ranged from25 to 28 dB • Speech recognition threshold gains ranged from 23.2 to33.8 dB	No pain or skin irritation reported; one revision procedure was needed
Bravo-Torres et al (2018)	15	• Pediatric patients with bilateral CHL (microtia associated with external auditory canal atresia)	• Aided sound-field threshold improvement: 25.2 dB	Minor feedback (4), broken processors (4), mild skin redness (2) with 1 month follow-up

Schmerber et al (2017)	25	• SSD (n=12) • Bilateral CHL (n=7) • Bilateral mixed HL (n=6)	• 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	• SSD (n=6; 1 sensorineural, 3 mixed, 2 conductive) • Bilateral CHL (n=2) • Bilateral mixed HL or mixed/sensorineural (n=3)	• 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	• Adults with SSD and normal contralateral hearing	• 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	• Combined HL (n=9) • EAC atresia (n=12) • SSD (n=3)	• 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 et al (2014)	5	• Mixed HL (n=4) • SSD (n=1)	• PTA improvement: 35.62 dB (p=0.01) • Disyllabic word discrimination improvement: 20% (p=0.016)	No perioperative complications reported
Ihler et al (2014)	6	• Mixed HL (n=4) • CHL (n=2)	• PTA functional gain (average, 0.5-4.0 kHz): 34.5 dB • Speech discrimination at 65 dB improvement: oIn quiet: 63.3 percentage points oIn noise: 37.5 percentage points	Prolonged wound healing in 1 case
Desmet et al (2014)	44	• All unilaterally deaf adults	• Statistically significant improvement on APHAB and SHHIA	Not reported
Iseri et al (2014)	12	• CHL (n=9) • "Primarily conductive hearing loss" (n=3)	• 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 Bone-Anchored Hearing Aid 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.

FULLY OR PARTIALLY IMPLANTABLE BAHA DEVICES WITH CONTRALATERAL ROUTING OF SIGNAL FOR UNILATERAL SENSORINEURAL HEARING LOSS

Clinical Context and Therapy Purpose

The purpose of fully or partially implantable BAHAs with contralateral routing of signal (CROS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as air-conduction hearing aids with contralateral routing of signal, in individuals with unilateral sensorineural hearing loss.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with unilateral sensorineural hearing loss, also called single sided deafness. In this population, one ear has minimal to moderate hearing loss while the other ear has significant sensorineural hearing loss. Patients with unilateral sensorineural hearing loss often have difficulty hearing or understanding conversation on their impaired side, particularly in the presence of background noise.

Interventions

The therapy being considered is fully or partially implantable BAHAs with CROS, a system that transmits sound from the affected side to the normal or less affected side.

Comparators

The main comparator of interest is air-conduction hearing aids. Also referred to as acoustic hearing aids, the air-conduction hearing aid is a standard treatment for conductive, mixed, sensorineural, and medically and surgically unresponsive conductive hearing loss. They are rated as Class I by the FDA.

Outcomes

The general outcomes of interest are functional outcomes, quality of life, and treatment-related morbidity.

The existing literature evaluating partially implantable BAHAs with CROS as a treatment for conductive or mixed hearing loss has varying lengths of follow-up. At least one year of follow-up is considered necessary to fully observe outcomes.

Study Selection Criteria

Methodologically credible studies were selected using principles described above.

Review of Evidence

System Reviews

Peters et al (2015) reported results from a systematic review of studies comparing BAHA devices with contralateral routing of signal (CROS) systems to hearing aids with contralateral routing of sound for single-sided deafness (SSD).(31) Six studies 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 (n=91 patients) with low or moderate risk of bias; they were noted to have significant heterogeneity in the populations included. For speech perception in noise, there was no consistent improvement with aided hearing over unaided hearing in all environments. All studies reported equal sound localization and quality-of-life outcomes for both hearing conditions.

Baguley et al (2006) reviewed the evidence for contralateral BAHAs in adults with acquired unilateral sensorineural hearing loss.(32) 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 improvement than those obtained with conventional AC CROS systems.

Prospective Studies
Since publication of the Peters systematic review, 2 prospective, interventional studies have compared patient outcomes with transcutaneous BAHA devices to CROS hearing aids for SSD. den Besten et al (2018) assessed 54 adults with SSD, each of whom underwent a trial with the Baha Softband before a trial of the percutaneous, partially implantable Baha Attract device.(33) No statistically significant difference in audiological outcomes was seen between the 2 devices ($p > .05$). At a 6-month follow-up after implantation, patients reported numbness (20%) and slight pain/discomfort (38%) associated with the device. 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.(34) Most patients (72%), after completing trials of both devices, preferred the BAHA device to hearing aids with CROS. Glasgow Benefit Index and Abbreviated Profile of Hearing Aid Benefit (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.(35) 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 post-treatment residual disability or satisfaction as measured by the Glasgow Hearing Aid Benefit Profile.

Observational Studies
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.(36) 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 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 BAHA device for SSD. In general, these studies have indicated improvements in patient-reported speech quality, speech perception in noise, and patient satisfaction.(37-44)

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.

Bone-Anchored Hearing Aid Devices (BAHA) DEVICES IN CHILDREN YOUNGER THAN AGE 5 YEARS
The BAHA device has been investigated in children younger than 5 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 develop osseointegration. 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 identified for this review, described by Amonoo-Kuofi et al (2015), included 24 children identified from a single center's prospectively maintained database.(45) Most patients underwent a 2-stage surgical approach. Most patients (52%) 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). 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.

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.(46) Forty-even children (21 girls, 26 boys) were implanted; 7 of these 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 in terms of functional outcome between the 7 younger patients and the rest of the cohort. Based on these findings, the 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 are 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.(47) Children with cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for children having 2-stage procedures was significantly longer in the study group to allow implantation in younger patients without increasing surgical or postoperative morbidity. Two traumatic fractures occurred in the study group versus 4 in the older children. Three younger children required skin site revision. All children were wearing their BAHA devices at the time of writing. McDermott et al (2008) reported on the role of BAHAs in children with Down syndrome in a retrospective case analysis and postal survey of complication rates and quality-of-life outcomes for 15 children aged 2 to 15 years.(48) 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 use of BAHA devices in children younger than 5. Three case series with a total of fewer than 60 children younger than five 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 BONE-ANCHORED HEARING AIDS
In addition to the efficacy literature on the BAHA devices, studies have assessed complications with these devices.

Review of Evidence

Systematic Reviews
Schwab et al (2020) completed a systematic review of adverse events associated with bone-conduction and middle-ear implants.(49) The 10 most frequently reported adverse events for bone conduction hearing implants included skin reactions (Holgers grade 1 to 3), skin revision surgery due to overgrowth or cellulitis, minor soft tissue/skin overgrowth, skin infection, surgical revision, preimplantation, failure to osseointegrate, and minor skin complications.

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.(50) The implantation techniques reported in the studies were as follows: punch method, four studies (81 implants); linear incision technique without soft tissue reduction, 13 studies (288 implants); and Weber technique, one 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 II, red and moist tissue; grade III, granulation tissue; grade IV, 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 one 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 complication in 2134 adult and pediatric patients who received a total of 2310 BAHA implants.(51) 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 II to IV skin reactions ranged from 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 ranged from 1.6% to 17.4% in adult and mixed population studies and in 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 September 1988 and December 2007 at the University Medical Center in the Netherlands.(52) Study investigators also examined device usage and compared different patient age groups (children, adults, elderly patients) over a five-year follow-up period. 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<.05). Implant survival were lower in patients with than without mental retardation (p=.001).

Hobson et al (2010) 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.(53) The overall observed complication rate, 24%. 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. In 2011, Wallberg et al reported on the status of 150 implants placed between 1977 and 1986 at a mean follow-up of nine years.(54) 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 remaining 132 patients with implant survival, BAHAs were still being used by 119 (90%) patients at the nine-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.(55) In this retrospective report, soft tissue reactions occurred in 24 patients (89%); 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.

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.(56) 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 patients with the 8.5-mm abutment implant were older (62 years vs 48 years, p=.012). Patients in the longer abutment group were less likely to experience infection (10% vs 43%; p=.02), skin overgrowth (5% vs 41%; p=.007) and need for revision (10% vs 45%; p=.012), respectively.

Other observational cohort studies, ranging in size from 47-974 subjects, have reported safety- and adverse effects outcomes after BAHA placement.(57-60) 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.(61) Fontaine et al (2014) compared complication rates for 2 BAHA surgical implantation techniques among 32 patients treated from 2004 to 2011.(62) Complications requiring surgical revision occurred in 20% of cases who underwent a skin flap implantation method (n=20) and in 38% 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 dermatome implantation technique.(63) In a comparison of two types of BAHA devices, 1 with a 4.5-mm diameter implant and a rounded 6-mm abutment (n=25) and 1 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 3 years of follow-up, although the conically shaped abutment had greater stability.(64) 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.(65) 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.(66) 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 II to IV 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 (e.g., linear incision).

USE OF SOFTBAND WITH BONE-ANCHORED HEARING AIDS

Ramakrishnan et al (2011) retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in 109 children and young adults in a single center.(70) The patient population was unique in that many had craniofacial or genetic syndromes and hearing loss (22/109). Criteria for the 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 following hearing aid intervention. Mean overall Glasgow Benefit Inventory scores were +29 (range, 11-72). Mean Listening Situation Questionnaire score of 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.(71)

Older case series have reported patient-reported benefits and satisfaction after BAHA placement.(72,73) Some have suggested that the BAHA improved hearing better than early bone-conducting devices and AC hearing aids.(74,75) and produce acceptable hearing outcomes in individuals unable to tolerate an AC hearing aid.(76,77)

Section Summary: Overall Efficacy of BAHA Devices
The 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.

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 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 partial-implantable bone-anchored devices similarly demonstrate 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 an improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive a fully-or partially-implantable bone-anchored hearing devices with contralateral routing of signal, the evidence includes one 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 180 patients, generally have reported 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 to 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 enrolling only ten patients, and therefore, does not provide definitive evidence. The evidence is insufficient to determine the effects of the technology results in an improvement in the net health outcome.

Additional Information
Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05615649[a]	Expanded Indications in the Pediatric BONEBRIDGE Population	36	Jun 2025
NCT04427033[a]	The BCI 602 BONEBRIDGE Post-Market Clinical Follow-up Study	51	Dec 2024

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Supplemental Information

CLINICAL INPUT RECEIVED FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

In response to requests, BCBSA received input from 3 academic medical centers and 2 specialty societies, 1 of which provided four responses and 1 of which provided 3 responses while the policy was under review in 2016. Clinical input was focused on the categorization of partially-implantable bone-anchored devices relative to fully-implantable devices. There was strong consensus that partially-implantable devices are considered an evolution of earlier devices, and that direct trials comparing the two are not necessary.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Otolaryngology Head and Neck Surgery

The American Academy of Otolaryngology-Head and Neck Surgery (2021) updated its position statement on the use of implantable hearing devices.(67) It states that the Academy “considers bone conduction hearing devices (BCHD) as appropriate, and in some cases preferred, for the treatment of conductive and mixed hearing loss. BCHD may also be indicated in select patients with single-sided deafness. BCHD include semi-implantable bone conduction devices utilizing either a percutaneous or transcutaneous attachment, as well as bone conduction oral appliances and scalp-worn devices. The recommendation for BCHD should be determined by a qualified otolaryngology-head and neck surgeon. These devices are approved by the Food and Drug Administration (FDA) for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and the respective regulatory agencies in countries other than the United States."

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

Government Regulations
National/Local
There is no national or local coverage determination.

There is no national coverage determination. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage. However, devices producing 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 used. 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 implants, including cochlear implants, brain stem implants, and Osseointegrated implants, do not meet the definition of hearing aids that are excluded from coverage."(69)

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Auditory Brain Stem Implants
- Cochlear Implants
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

References

1. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. *Otolaryngol Head Neck Surg.* Sep 2012;147(3):412-422. PMID 22714424
2. Bosman AJ, Snik AF, van der Pouw CT, et al. Audiometric evaluation of bilaterally fitted bone-anchored hearing aids. *Audiology.* May-Jun 2001;40(3):158-167. PMID 11465298
3. Priwin C, Stenfelt S, Granstrom G, et al. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. *Laryngoscope.* Jan 2004;114(1):77-84. PMID 14709999
4. Snik AF, Mylanus EA, Proops DW, et al. Consensus statements on the BAHA system: where do we stand at present? *Ann Otol Rhinol Laryngol Suppl.* Dec 2005;195:2-12. PMID 16619473
5. Dun CA, de Wolf MJ, Mylanus EA, et al. Bilateral bone-anchored hearing aid application in children: the Nijmegen experience from 1996 to 2008. *Otol Neurotol.* Jun 2010;31(4):615-623. PMID 20393374
6. Ho EC, Monksfield P, Egan E, et al. Bilateral Bone-anchored Hearing Aid: impact on quality of life measured with the Glasgow Benefit Inventory. *Otol Neurotol.* Oct 2009;30(7):891-896. PMID 19692937

7. Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. *Otol Neurotol.* Jun 2015;36(5):834-841. PMID 25634465
8. Denoyelle F, Coudert C, Thierry B, et al. Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia. *Int J Pediatr Otorhinolaryngol.* Mar 2015;79(3):382-387. PMID 25617189
9. Hol MK, Nelissen RC, Agterberg MJ, et al. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. *Otol Neurotol.* Aug 2013;34(6):1071-1075. PMID 23598702
10. Nelissen RC, Agterberg MJ, Hol MK, et al. Three-year experience with the Sophono in children with congenital conductive unilateral hearing loss: tolerability, audiometry, and sound localization compared to a bone-anchored hearing aid. *Eur Arch Otorhinolaryngol*. Oct 2016;273(10):3149-3156. PMID 26924741
11. Iseri M, Orhan KS, Tuncer U, et al. Transcutaneous bone-anchored hearing aids versus percutaneous ones: multicenter comparative clinical study. *Otol Neurotol.* Jun 2015;36(5):849-853. PMID 25730451
12. Gerdes T, Salcher RB, Schwab B, et al. Comparison of audiological results between a transcutaneous and a percutaneous bone conduction instrument in conductive hearing loss. *Otol Neurotol*. Jul 2016;37(6):685-691. PMID 27093021
13. Dimitriadis PA, Farr MR, Allam A, et al. Three-year experience with the cochlear BAHA attract implant: a systematic review of the literature. *BMC Ear Nose Throat Disord*. 2016;16:12. PMID 27733813
14. Reddy-Kolanu R, Gan R, Marshall AH. A case series of a magnetic bone conduction hearing implant. *Ann R Coll Surg Engl*. Nov 2016;98(8):552-553. PMID 27490984
15. Siegert R. Partially implantable bone conduction hearing aids without a percutaneous abutment (Otomag): technique and preliminary clinical results. *Adv Otorhinolaryngol.* 2011;71:41-46. PMID 21389703
16. Powell HR, Rolfe AM, Birman CS. A comparative study of audiologic outcomes for two transcutaneous bone-anchored hearing devices. *Otol Neurotol.* Sep 2015;36(9):1525-1531. PMID 26375976
17. O'Niel MB, Runge CL, Friedland DR, et al. Patient outcomes in magnet-based implantable auditory assist devices. *JAMA Otolaryngol Head Neck Surg.* Jun 2014;140(6):513-520. PMID 24763485
18. Centric A, Chennupati SK. Abutment-free bone-anchored hearing devices in children: initial results and experience. *Int J Pediatr Otorhinolaryngol.* May 2014;78(5):875-878. PMID 24612554
19. Baker S, Centric A, Chennupati SK. Innovation in abutment-free bone-anchored hearing devices in children: Updated results and experience. *Int J Pediatr Otorhinolaryngol.* Oct 2015;79(10):1667-1672. PMID 26279245
20. Marsella P, Scorpecci A, Vallarino MV, et al. Sophono in pediatric patients: the experience of an Italian tertiary care center. *Otolaryngol Head Neck Surg.* Apr 8 2014;151(2):328-332. PMID 24714216
21. Magliulo G, Turchetta R, Iannella G, et al. Sophono Alpha System and subtotal petrosectomy with external auditory canal blind sac closure. Eur Arch Otorhinolaryngol. Sep 2015; 272(9): 2183-90. PMID 24908070
22. Bravo-Torres S, Der-Mussa C, Fuentes-Lopez E. Active transcutaneous bone conduction implant: audiological results in paediatric patients with bilateral microtia associated with external auditory canal atresia. Int J Audiol. Jan 2018;57(1):53-60. PMID 28857620

23. Schmerber S, Deguine O, Marx M, et al. Safety and effectiveness of the Bonebridge transcutaneous active direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol*. Jul 30, 2016. PMID 27475796
24. Rahne T, Seiwerth I, Gotze G, et al. Functional results after Bonebridge implantation in adults and children with conductive and mixed hearing loss. *Eur Arch Otorhinolaryngol.* Nov 2015;272(11):3263-3269. PMID 25425039
25. Laske RD, Roosli C, Pfiffner F, et al. Functional results and subjective benefit of a transcutaneous bone conduction device in patients with single-sided deafness. *Otol Neurotol.* Aug 2015;36(7):1151-1156. PMID 26111077
26. Riss D, Arnoldner C, Baumgartner WD, et al. Indication criteria and outcomes with the Bonebridge transcutaneous bone-conduction implant. *Laryngoscope.* Dec 2014;124(12):2802-2806. PMID 25142577
27. Manrique M, Sanhueza I, Manrique R, et al. A new bone conduction implant: surgical technique and results. *Otol Neurotol.* Feb 2014;35(2):216-220. PMID 24448280
28. Ihler F, Volbers L, Blum J, et al. Preliminary functional results and quality of life after implantation of a new bone conduction hearing device in patients with conductive and mixed hearing loss. *Otol Neurotol.* Feb 2014;35(2):211-215. PMID 24448279
29. Desmet J, Wouters K, De Bodt M, et al. Long-term subjective benefit with a bone conduction implant sound processor in 44 patients with single-sided deafness. *Otol Neurotol.* Jul 2014;35(6):1017-1025. PMID 24751733
30. Iseri M, Orhan KS, Kara A, et al. A new transcutaneous bone anchored hearing device - the Baha(R) Attract System: the first experience in Turkey. *Kulak Burun Bogaz Ihtis Derg.* Mar-Apr 2014;24(2):59-64. PMID 24835899
31. Peters JP, Smit AL, Stegeman I, et al. Review: Bone conduction devices and contralateral routing of sound systems in single-sided deafness. *Laryngoscope.* Jan 2015;125(1):218-226. PMID 25124297
32. Baguley DM, Bird J, Humphriss RL, et al. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. *Clin Otolaryngol.* Feb 2006;31(1):6-14. PMID 16441794
33. den Besten CA, Monksfield P, Bosman A, et al. Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: Six-month results from a multicentre study. Clin Otolaryngol. Oct 25 2018. PMID 30358920
34. Leterme G, Bernardeschi D, Bensemman A, et al. Contralateral routing of signal hearing aid versus transcutaneous bone conduction in single-sided deafness. *Audiol Neurootol.* 2015;20(4):251-260. PMID 26021779
35. Snapp HA, Holt FD, Liu X, et al. Comparison of speech-in-noise and localization benefits in unilateral hearing loss subjects using contralateral routing of signal hearing aids or bone-anchored implants. *Otol Neurotol*. Jan 2017;38(1):11-18. PMID 27846038
36. Zeitler DM, Snapp HA, Telischi FF, et al. Bone-anchored implantation for single-sided deafness in patients with less than profound hearing loss. *Otolaryngol Head Neck Surg.* Jul 2012;147(1):105-111. PMID 22368043
37. Pai I, Kelleher C, Nunn T, et al. Outcome of bone-anchored hearing aids for single-sided deafness: a prospective study. *Acta Otolaryngol.* Jul 2012;132(7):751-755. PMID 22497318
38. Saroul N, Nicolas S, Akkari M, et al. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an Osseointegrated bone-conduction device. *Otol Neurotol.* Jan 2013;34(1):111-114. PMID 23202156
39. Lin LM, Bowditch S, Anderson MJ, et al. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing

and contralateral routing of signal amplification. *Otol Neurotol.* Feb 2006;27(2):172-182. PMID 16436986
40. Kunst SJ, Leijendeckers JM, Mylanus EA, et al. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results. *Otol Neurotol.* Jan 2008;29(1):2-7. PMID 18199951
41. Kunst SJ, Hol MK, Mylanus EA, et al. Subjective benefit after BAHA system application in patients with congenital unilateral conductive hearing impairment. *Otol Neurotol.* Apr 2008;29(3):353-358. PMID 18494142
42. Gluth MB, Eager KM, Eikelboom RH, et al. Long-term benefit perception, complications, and device malfunction rate of bone-anchored hearing aid implantation for profound unilateral sensorineural hearing loss. *Otol Neurotol.* Dec 2010;31(9):1427-1434. PMID 20729779
43. Faber HT, Nelissen RC, Kramer SE, et al. Bone-anchored hearing implants in single-sided deafness patients: Long-term use and satisfaction by gender. *Laryngoscope.* Dec 2015;125(12):2790-2795. PMID 26152833
44. Monini S, Musy I, Filippi C, et al. Bone conductive implants in single-sided deafness. *Acta Otolaryngol.* Apr 2015;135(4):381-388. PMID 25720582
45. Amonoo-Kuofi K, Kelly A, Neeff M, et al. Experience of bone-anchored hearing aid implantation in children younger than 5 years of age. *Int J Pediatr Otorhinolaryngol.* Apr 2015;79(4):474-480. PMID 25680294
46. Marsella P, Scorpecci A, Pacifico C, et al. Pediatric BAHA in Italy: the "Bambino Gesu" Children's Hospital's experience. *Eur Arch Otorhinolaryngol.* Feb 2012;269(2):467-474. PMID 21739094
47. Davids T, Gordon KA, Clutton D, et al. Bone-anchored hearing aids in infants and children younger than 5 years. *Arch Otolaryngol Head Neck Surg.* Jan 2007;133(1):51-55. PMID 17224524
48. McDermott AL, Williams J, Kuo MJ, et al. The role of bone anchored hearing aids in children with Down syndrome. *Int J Pediatr Otorhinolaryngol.* Jun 2008;72(6):751-757. PMID 18433885
49. Schwab B, Wimmer W, Severens JL, et al. Adverse events associated with bone-conduction and middle-ear implants: a systematic review. Eur Arch Otorhinolaryngol. Feb 2020; 277(2): 423-438. PMID 31749056
50. Verheij E, Bezdjian A, Grolman W, et al. A systematic review on complications of tissue preservation surgical techniques in percutaneous bone conduction hearing devices. *Otol Neurotol.* Aug 2016;37(7):829-837. PMID 27273402
51. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with Osseointegrated hearing aids. Otol Neurotol. Jul 2013;34(5):790-794. PMID 23739555
52. Dun CA, Faber HT, de Wolf MJ, et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. *Otol Neurotol.* Feb 2012;33(2):192-198. PMID 22246385
53. Hobson JC, Roper AJ, Andrew R, et al. Complications of bone-anchored hearing aid implantation. *J Laryngol Otol.* Feb 2010;124(2):132-136. PMID 19968889
54. Wallberg E, Granstrom G, Tjellstrom A, et al. Implant survival rate in bone-anchored hearing aid users: long-term results. *J Laryngol Otol.* Nov 2011;125(11):1131-1135. PMID 21774847
55. Kraai T, Brown C, Neeff M, et al. Complications of bone-anchored hearing aids in pediatric patients. *Int J Pediatr Otorhinolaryngol.* Jun 2011;75(6):749-753. PMID 21470698

56. Allis TJ, Owen BD, Chen B, et al. Longer length Baha abutments decrease wound complications and revision surgery. *Laryngoscope.* Apr 2014;124(4):989-992. PMID 24114744
57. Calvo Bodnia N, Foghsgaard S, Nue Moller M, et al. Long-term results of 185 consecutive osseointegrated hearing device implantations: a comparison among children, adults, and elderly. *Otol Neurotol.* Dec 2014;35(10):e301-306. PMID 25122598
58. Rebol J. Soft tissue reactions in patients with bone anchored hearing aids. *Ir J Med Sci.* Jun 2015;184(2):487-491. PMID 24913737
59. Larsson A, Tjellstrom A, Stalfors J. Implant losses for the bone-anchored hearing devices are more frequent in some patients. *Otol Neurotol.* Feb 2015;36(2):336-340. PMID 24809279
60. den Besten CA, Nelissen RC, Peer PG, et al. A retrospective cohort study on the influence of comorbidity on soft tissue reactions, revision surgery, and implant loss in bone-anchored hearing implants. *Otol Neurotol.* Jun 2015;36(5):812-818. PMID 25811351
61. Mohamad S, Khan I, Hey SY, et al. A systematic review on skin complications of bone-anchored hearing aids in relation to surgical techniques. *Eur Arch Otorhinolaryngol.* Dec 14, 2014. PMID 25503356
62. Fontaine N, Hemar P, Schultz P, et al. BAHA implant: implantation technique and complications. *Eur Ann Otorhinolaryngol Head Neck Dis.* Feb 2014;131(1):69-74. PMID 23835074
63. Hultcrantz M, Lanis A. A five-year follow-up on the osseointegration of bone-anchored hearing device implantation without tissue reduction. *Otol Neurotol.* Sep 2014;35(8):1480-1485. PMID 24770406
64. Nelissen RC, Stalfors J, de Wolf MJ, et al. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation. *Otol Neurotol.* Sep 2014;35(8):1486-1491. PMID 25080037
65. Singam S, Williams R, Saxby C, et al. Percutaneous bone-anchored hearing implant surgery without soft-tissue reduction: up to 42 months of follow-up. Otol Neurotol. Oct 2014;35(9):1596-1600. PMID 25076228
66. Roplekar R, Lim A, Hussain SS. Has the use of the linear incision reduced skin complications in bone-anchored hearing aid implantation? *J Laryngol Otol*. Jun 2016;130(6):541-544. PMID 27160014
67. American Academy of Otolaryngology-Head and Neck Surgery. Implantable Hearing Devices. Position Statements 2013; retrieved January 31, 2022 from: http://www.entnet.org/content/position-statement-bone-conduction-hearing-devices.
68. Centers for Medicare and Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage. Rev.198; retrieved January 31, 2022 from: http://www.cms.gov/manuals/Downloads/bp102c16.pdf.
69. Centers for Medicare and Medicaid Services. Fact sheets: CMS Updates Policies and Payment Rates for End-Stage Renal Disease Facilities for CY 2015 and Implementation of Competitive Bidding-Based Prices for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. 2014; retrieved January 31, 2022 from: http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-10-31-3.html.
70. Ramakrishnan Y, Marley S, Leese D, et al. Bone-anchored hearing aids in children and young adults: the Freeman Hospital experience. *J Laryngol Otol.* Feb 2011;125(2):153-157. PMID 20849670

71. den Besten CA, Harterink E, McDermott AL, et al. Clinical results of Cochlear BIA300 in children: Experience in two tertiary referral centers. *Int J Pediatr Otorhinolaryngol.* Dec 2015;79(12):2050-2055. PMID 26455259
72. McLarnon CM, Davison T, Johnson IJ. Bone-anchored hearing aid: comparison of benefit by patient subgroups. *Laryngoscope.* May 2004;114(5):942-944. PMID 15126761
73. Tringali S, Grayeli AB, Bouccara D, et al. A survey of satisfaction and use among patients fitted with a BAHA. *Eur Arch Otorhinolaryngol.* Dec 2008;265(12):1461-1464. PMID 18415113
74. Snik AF, Mylanus EA, Cremers CW. The bone-anchored hearing aid compared with conventional hearing aids. Audiologic results and the patients' opinions. *Otaryngol Clin North Am.* Feb 1995;28(1):73-83. PMID 7739870
75. van der Pouw CT, Snik AF, Cremers CW. The BAHA HC200/300 in comparison with conventional bone conduction hearing aids. *Clin Otolaryngol Allied Sci.* Jun 1999;24(3):171-176. PMID 10384840
76. Wazen JJ, Caruso M, Tjellstrom A. Long-term results with the titanium bone-anchored hearing aid: the U.S. experience. *Am J Otol.* Nov 1998;19(6):737-741. PMID 9831146
77. Granstrom G, Tjellstrom A. The bone-anchored hearing aid (BAHA) in children with auricular malformations. *Ear Nose Throat J.* Apr 1997;76(4):238-240, 242, 244-237. PMID 9127523
78. Fan Y, Zhang Y, et al. Auditory development after placement of bone-anchored hearing aids Softband among Chinese Mandarin-speaking children with bilateral aural atresia. Int J Pediatr Otor. 2014 Jan;78(1):60-4. PMID: 24290950
79. Heath E, Dawoud MM, Stavrakas M, et al. The outcomes of bilateral bone conduction hearing devices (BCHD)implantation in the treatment of hearing loss: A systematic review. Cochlear Implants Int. Mar 2022; 23(2): 95-108. PMID34852723
80. Gawęcki W, Gibasiewicz R, Marszał J, et al. The evaluation of a surgery and the short-term benefits of a new active bone conduction hearing implant - the Osia®. Braz J Otorhinolaryngol. 2022; 88(3): 289-295. PMID 32713797
81. Kim Y, Choe G, Oh H, et al. A comparative study of audiological outcomes and compliance between the Osia system and other bone conduction hearing implants. Eur Arch Otorhinolaryngol. Nov 01 2022. PMID 36318324

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 21, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/31/04	3/31/04	3/26/04	Joint medical policy established
4/6/05	4/6/05	4/11/05	Routine maintenance
11/1/07	8/21/07	10/30/07	Routine maintenance
11/1/08	8/19/08	10/28/08	Routine maintenance added bilateral implants to inclusionary guidelines, description/background simplified. References updated.
11/1/09	8/18/09	8/18/09	Routine maintenance; unilateral sensorineural hearing loss added to inclusions.
5/1/10	2/16/10	2/16/10	Routine maintenance; code update: L8692 added to policy.
7/1/11	4/19/11	5/3/11	Routine maintenance; code update: L8693 added to policy.
9/1/12	6/12/12	6/19/12	Routine maintenance; references and regulatory status updated.
3/1/14	12/10/13	1/6/14	Routine maintenance
5/1/15	2/17/15	2/27/15	Routine maintenance; added “aged 5 years and older” to Inclusion section (to reflect FDA guidelines); exclusion added to MPS and Exclusion section for partially implantable bone-conduction hearing systems (e.g., Otomag® and BAHA® Attract); Description and Rationale sections revised; references updated
7/1/16	4/19/16	4/19/16	Routine maintenance References and rationale updated
3/1/17	12/13/16	12/13/16	• Routine maintenance • Mirrored BCBSA policy • “Fully and partially"- added to MPS statement: Unilateral or bilateral fully- or partially-implantable bone-conduction* (bone-anchored) hearing aid(s) may be necessary

			• Removed exclusion section for partially implantable bone-conduction hearing systems (e.g., Otomag® and BAHA® Attract); • Criteria added for bilateral conduction loss • Description and Rationale sections revised; references and FDA approved devices updated
3/1/18	12/12/17	12/12/17	• Routine maintenance • Title changed from Bone-Anchored Hearing Devices to Implantable Bone-Conduction and Bone-Anchored Hearing Devices • L8692 removed as it is NOT for implantable device
3/1/19	12/11/18		• Routine maintenance • Added L8692 – for independent review
3/1/20	1/10/20		• Routine maintenance • Softband technology added to background and references • Individual consideration language added to MPS
11/1/20	9/30/20		• OSIA 2 and Ponto devices added per FDA indications
11/1/21	8/17/21		• Routine maintenance • No change in policy status • Added Cochlear OSIA as covered. This device was FDA approved July 3, 2019. • This policy replaces the IMP policy “cochlear OSIA System for Hearing Loss”
11/1/22	8/16/22		• Routine maintenance • Code update: 69715 and 69718 deleted; 69717 – nomenclature revision; 69719, 69726, 69727 added as EST
11/1/23	8/15/23		• Routine maintenance • Per code update ○ Revised nomenclature – 69716, 69717, 69719, 69726 and 69727.

			◦ Added as EST – 69728, 69729, and 69730. • Vendor: N/A (ky)
11/1/24	8/20/24		• Routine maintenance • Vendor: N/A (ky)

Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: IMPLANTABLE BONE-CONDUCTION AND BONE-ANCHORED HEARING DEVICES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, criteria apply. Hearing aid rider is required. The BAHA Headband or Softband device is not a bone-anchored hearing device. It is a bone-conduction hearing aid, most often used in children, which is worn until the patient is able to undergo the bone-anchored surgical procedure. This device is a hearing aid and coverage requires a hearing aid rider.
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member’s certificate and is not guaranteed. Please consult the individual member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.