Medical Policy

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

Related Policies:	▪ *Cochlear Implant*

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Populations	Interventions	Comparators	Outcomes
Individuals: • With conductive or mixed hearing loss	Interventions of interest are: • Implantable bone-anchored hearing aid with a percutaneous abutment	Comparators of interest are: • External hearing aid	Relevant outcomes include: • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With conductive or mixed hearing loss	Interventions of interest are: • Partially implantable bone-anchored hearing aid with transcutaneous coupling to the sound processor	Comparators of interest are: • External hearing aid	Relevant outcomes include: • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With unilateral sensorineural hearing loss	Interventions of interest are: • Fully or partially implantable bone-anchored hearing aid with contralateral routing of signal	Comparators of interest are: • Air-conduction hearing aid with contralateral routing of signal	Relevant outcomes include: • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction or bone-conduction external hearing aids. Air-conduction hearing aids may not be suitable for patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. Bone-conduction hearing aids may be useful for individuals with conductive hearing loss, or (if used with contralateral routing of signal), for unilateral sensorineural hearing loss. Implantable, bone-anchored hearing aids (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.

OBJECTIVE

The objective of this evidence review is to examine whether implantable bone-anchored hearing aids improve the net health outcome for individuals with conductive, mixed, or sensorineural hearing loss.

BACKGROUND

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 decibels (dB). The American Speech Language Hearing Association has defined degree of hearing loss based on pure-tone average detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (≥80 dB). Pure-tone average 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 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 or conductive hearing loss. These 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 to bone 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.

REGULATORY STATUS

Several implantable bone-conduction hearing systems have been approved by the U.S. Food and Drug Administration (FDA) 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

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™2 System		Dec 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 FDA for use in children younger than 5 years. Because this application has no implanted components, it is not addressed in this evidence review.

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 U.S Food and Drug Administration

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. However, the manufacturer, Sonitus Medical, closed in 2015.

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

POLICY

A. Unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s) may be considered **medically necessary** as an alternative to an air-conduction hearing aid in individuals 5 years of age and older with conductive or mixed hearing loss who also meet at least one of the following medical criteria:

1. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear; **OR**

2. Chronic external otitis or otitis media; **OR**

3. Tumors of the external canal and/or tympanic cavity; **OR**

4. Dermatitis of the external canal;

AND

B. Meet the following audiologic criteria:

1. A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or equal to 65 dB, **AND**

2. For bilateral implantation, individuals 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, **AND**

3. Speech discrimination score greater than 60% in the indicated ear.

C. An implantable bone-conduction (bone-anchored) hearing aid may be considered **medically necessary** as an alternative to an air-conduction contralateral routing of signal hearing aid in individuals 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear. The pure tone average air conduction threshold of the normal ear should be better than or equal to 20 dB measured at 0.5, 1, 2, and 3 kHz.

D. Other uses of implantable bone-conduction (bone-anchored) hearing aids, including use in individuals with bilateral sensorineural hearing loss, are considered **experimental / investigational**.

POLICY GUIDELINES

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

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

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through December 9, 2022.

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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

BILATERAL IMPLANTABLE BONE-ANCHORED HEARING AID DEVICES WITH 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 patients with conductive hearing loss (CHL) or mixed hearing loss.

The question addressed in this evidence review is: Do implantable BAHAs with a percutaneous abutment improve the net health outcome for individuals with CHL or mixed hearing loss?

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

Populations
The relevant population of interest is individuals with CHL 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 CHL or mixed hearing loss has varying lengths of follow-up. At least 1 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.[1,] 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.[2,] 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, quality of life 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, 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.[3,] The authors 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.[4,] 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.[5,]A number of other studies cited in the 2005 consensus statement found benefits similar to those noted by Bosman and by Priwin.[3,4,] Positive outcomes continue to be reported: Dun et al (2010)[6,] identified improvements in the Glasgow Benefit Inventory scores in 23 children, while Ho et al (2009)[7,] reported the same benefit in 93 adults.

Section Summary: Bilateral Bone-Anchored Hearing Aid 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 AID 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 patients with CHL or mixed hearing loss.

The question addressed in this evidence review is: do partially implantable BAHAs with transcutaneous coupling to the sound processer improve the net health outcome for individuals with CHL or mixed hearing loss?

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

Populations

The relevant population of interest is individuals with CHL or mixed hearing loss.

Interventions

The therapy being considered is partially implantable BAHAs with transcutaneous coupling to the sound processor, 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 CHL or mixed hearing loss has varying lengths of follow-up. At least 1 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

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.[8,] The choice of sound processor was based on patient preference and hearing tests with various sound processors in conjunction with the 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<.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 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 CHL.[9,] 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 air conduction (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.

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.[10,] 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 with partially implantable magnetic transcutaneous bone-conduction hearing implants using the Otomag Sophono device in 12 pediatric patients (age range, 5 to 12 years) who had congenital unilateral CHL.[11,] Sound-field thresholds, speech recognition threshold, and speech comprehension at 65 dB were somewhat better in patients with 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.[12,] Two patients in each group had stopped using their hearing devices. Soft tissue tolerability with the Sophono device 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).[13,] 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 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=.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.[14] 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.

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).[15] 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 on a systematic review of observational studies of the Baha Attract device including 10 studies (N=89 patients; range, 1 to 27 patients).[16] 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 with the BAHA Attract (n=34) from a case series that included all patients implanted in a single center between 2013 and 2015.[17] 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).[18] 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.[19] 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.[20,] 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 to 10 hours).

Centric et al (2014) also reported on outcomes for 5 pediatric patients treated with the Otomag Sophono device at a single center.[21,] 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.[22,] Pre- and post-implant 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 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.[23,] Median improvement in PTA was 33-dB hearing loss, and median free-field PTA (0.5 to 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.[24,] 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 U.S. Food and Drug Administration (FDA), a number of case series identified evaluated the Bonebridge implant, which was recently cleared for marketing in the United States in March 2019. 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)[25,]	52	• CHL • Mixed HL	Mean gain in PTA after 6 months of 31.83 dB	One implant failure, one implant exposure

Study	N	Patient Population	Main Hearing Results	Safety Outcomes
Cywka et al (2022)[26,]	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)[27,]	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)[28,]	31	• CHL (n=11) • Mixed HL (n=20)	Mean PTA threshold decreased from 64.7 dB to 43.4 dB at last follow-up	5 minor and 1 major implant-related events occurred during 1-year follow-up
Seiwerth et al (2022)[29,]	31	• CHL • Mixed HL • Malformation • After multiple ear surgery • SSD	• Mean sound field thresholds improved from 60 dB HL to 33 dB HL at 3 months • Word recognition in quiet (p<.0001) and speech reception threshold in noise (p=.0018)	Minor complications in 12.5%, major complications in 3.1%
Sikolova et al (2022)[30,]	12	• Pediatric patients with CHL (n=10) or SSD (n=2)	• Functional gain ranged from 25 to 28 dB • Speech recognition threshold gains ranged from 23.2 to 33.8 dB	No pain or skin irritation reported; one revision procedure was needed
Bravo-Torres et al (2018)[31,]	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)[32,]	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	No complications, device failures, revision surgery, or skin injury

Study	N	Patient Population	Main Hearing Results	Safety Outcomes
			• CHL and mixed, average functional gain: 26 dB HL; mean % of speech recognition in quiet improved from 74% unaided to 95% aided	reported with 1 y follow-up
Rahne et al (2015)[33,]	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)[34,]	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)[35,]	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)[36,]	5	• Mixed HL (n=4) • SSD (n=1)	• PTA improvement: 35.62 dB (p=.01) • Disyllabic word discrimination improvement: 20% (p=.016)	No perioperative complications reported
Ihler et al (2014)[37,]	6	• Mixed HL (n=4) • CHL (n=2)	• PTA functional gain (average, 0.5 to 4.0 kHz): 34.5 dB • Speech discrimination at 65 dB improvement: • ○ In quiet: 63.3 percentage points	Prolonged wound healing in 1 case

Study	N	Patient Population	Main Hearing Results	Safety Outcomes
			○ In noise: 37.5 percentage points	
Desmet et al (2014)[38,]	44	• All unilaterally deaf adults	• Statistically significant improvement on APHAB and SHHIA	Not reported
Iseri et al (2014)[39,]	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 BONE-ANCHORED HEARING AID 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 AC hearing aids with CROS, in patients with unilateral sensorineural hearing loss.

The question addressed in this evidence review is: do fully or partially implantable BAHAs with CROS improve the net health outcome for 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 SSD. In this population, 1 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 AC hearing aids. Also referred to as acoustic hearing aids, the AC hearing aid is a standard treatment for conductive, mixed, sensorineural, and medically and surgically unresponsive CHL. These aids 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 CHL or mixed hearing loss has varying lengths of follow-up. At least 1 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

Systematic Reviews
Peters et al (2015) reported results from a systematic review of studies comparing BAHA devices using CROS systems with hearing aids using CROS for SSD.[40,] 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 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.[41,] 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.

Prospective Studies
Since the publication of the Peters systematic review, 3 prospective, interventional studies have compared patient outcomes using transcutaneous BAHA devices with 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.[42] 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.[43] 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.[44] 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.

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.[45] 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.[46,47,48,49,50,51,52,53,54]

Section Summary: Bone-Anchored Hearing Aid 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 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 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) and including 24 children from a single center's prospectively maintained database.[55,] 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). Quality of life 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.

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.[56,] 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.[57,] 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 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 age 2 to 15 years.[58,] 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: Bone-Anchored Hearing Aid Devices in Children Younger Than Age 5 Years
There are few data on the use of BAHA devices in children younger than 5 years. Three case series with a total of fewer than 60 children younger than 5 years have reported improvements in quality of life after implantation with BAHA devices. One comparative observational study, with 7 children younger than 5 years, 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 Aid 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.[59,] 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.[60,] The implantation techniques reported in the studies were as follows: punch method, 4 studies (81 implants); linear incision technique without soft tissue reduction, 13 studies (288 implants); and Weber technique, 1 study (12 implants). Indications for surgery were SSD (n=68), sensorineural hearing loss (n=4), mixed hearing loss (n=65), or CHL (n=66). The Holgers classification was used to grade soft tissue reactions (grade 0, no reaction; grade 2, red and moist tissue; grade 3, 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.[61,] 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.[62,] 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<.05). Implant survival rates were lower in patients with than without mental disability (p=.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.[63,] 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.[64,] 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 age 16 years or younger between 2002 and 2009.[65,] 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.

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.[66,] 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=.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 to 974 subjects, have reported safety and adverse event outcomes after BAHA placement.[67,68,69,70,] 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.[71,]Fontaine et al. (2014) compared complication rates for 2 BAHA surgical implantation techniques among 32 patients treated from 2004 to 2011.[72,] 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 fullthickness skin graft implantation method (n=21; p=.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.[73,] In a comparison of 2 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 a 3-year follow-up, although the conically shaped abutment had greater stability.[74,] 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.[75,] Twenty-five patients had no postoperative complications. Five subjects developed postoperative skin reactions, of whom 3 required soft tissue reduction. Roplekar et al. (2016) compared skin-related complications of the traditional skin flap method to the linear incision method performed by a single surgeon in 117 patients with at least 1 year of follow-up.[76,] 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 Bone-Anchored Hearing Aid 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 (e.g., linear incision).

SUPPLEMENTAL INFORMATION
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2016 Clinical Input
In response to requests, input was received from 2 specialty societies and 3 academic medical centers (1 of which provided 4 responses and 1 of which provided 3 responses) while this policy was under review in 2016. Input focused on the categorization of partially implantable bone-anchored devices relative to fully implantable devices. There was a strong consensus that partially implantable devices are considered an evolution of earlier devices, and that direct trials comparing the 2 are not necessary.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given

to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology Head and Neck Surgery

In 2021, the American Academy of Otolaryngology Head and Neck Surgery updated its position statement on the use of implantable hearing devices.[77,] 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and 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 (not yet recruiting)
NCT03533686	Comparative Study of Non-invasive Adhear Bone Conduction System to Traditional Bone Conduction Hearing Devices	90	Mar 2023 (Recruiting)

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

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69728	Removal, osseointegrated implant, skull; with attachment to external speech processor, outside the mastoid
69729	Implantation, osseointegrated implant, skull; with attachment to external speech processor, outside of the mastoid
69730	Replacement osseointegrated implant, skull; with attachment to external speech processor, outside the mastoid
69799	Unlisted procedure, middle ear (use for BAHA Attract)
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
L8690	Auditory osseointegrated device, includes all internal and external components

CPT/HCPCS	
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only
L8693	Auditory osseointegrated device abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each

REVISIONS	
08-15-2014	Revised Title from Bone-Anchored Hearing Aids (BAHA) to Implantable Bone-Conduction and Bone-Anchored Hearing Aids (BAHA).
	Updated Description section
	In Policy section: ▪ Replaced the following medical policy language with updated policy language: "A. Unilateral Conductive or mixed hearing Loss These patients are unable, for various reasons, to wear a conventional hearing aid or undergo surgery to improve their hearing: Chronic otitic media (COM), Congenital malformations of the external/middle ear, other acquired malformations of the ear that preclude wearing of conventional hearing aids. The criteria as taken from the FDA 510(K) document (#992873) are: 1. Average bone conduction threshold better (less) than 45 dB (at 500, 1000, 2000, 3000 Hz) in the indicated ear. 2. Speech discrimination score greater than 60% in the indicated ear. 3. Age 5 years or older. B. Bilateral Conductive Hearing Loss These patients have both ears involved in a conductive and mixed hearing loss and are not able to be treated with reconstructive surgery or conventional hearing aids for the above reasons. The criteria for the FDA 510(K) document #K011438 are: 1. Moderate (40 dB) to severe (70 dB) conductive hearing loss that is symmetric. That there is less than 10dB difference in average bone conduction (at 500, 1000, 2000, 4000 Hz) or less than 15 dB difference in bone conduction at individual frequencies. 2. Patients with mixed hearing loss with an average bone conduction better (less) than 45 dB in either ear (at 500, 1000, 2000, 4000 Hz) 3. Age 5 years or older. C. Unilateral Sensorineural Hearing Loss (Single Sided Deafness; SSD) These are patients where the nerve deafness in the indicated ear is so great that a conventional hearing aid no longer is useful. Typically, these patients are adults after acoustic neuroma surgery or sudden deafness and children with an unexplained deafness in one ear or after trauma. The implant is designed to stimulate the opposite (good ear) by bone conduction through the bones of the skull, therefore; the audiometric criteria are for the good ear. The criteria for the FDA 510(K) document #K021837 are: 1. Severe (70 dB) to profound (90 dB) hearing loss on one side with poor speech discrimination and unable to use a conventional hearing aid in that ear. 2. Normal hearing in the good ear as defined by an air conduction threshold equal to or better (less) than 20 dB (at 500, 1000, 2000, 3000 Hz). 3. Age 5 years or older."
	Added Rationale section
	In Coding section: ▪ Updated nomenclature for CPT codes: 69710, 69711, 69714, 69715, 69717, 69718 ▪ Added HCPCS Codes: L8690, L8691, L8693 ▪ Added Coding information

REVISIONS	
	▪ Added ICD-10 Diagnosis (Effective October 1, 2015)
	Added Revision section to the policy.
	Updated References
03-31-2015	Updated Description section.
	Updated Rationale section.
	Updated References section.
04-27-2016	Updated Description section.
	In Policy section: ▪ In Item E, removed "Otomag Alpha 1, and" and added "Sophono Alpha 2 MPO" to read "Partially implantable magnetic bone-conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Sophono Alpha 2 MPO, BAHA Attract) are considered experimental / investigational."
	Updated Rationale section.
	Updated References section.
08-17-2016	Updated Description section.
	In Policy section: ▪ In Item A, added "fully or partially" to read, "Unilateral or bilateral fully or partially implantable bone-conduction (bone-anchored) hearing aid(s) may be considered medically necessary as an alternative to an air-conduction hearing aid in patients 5 years of age and older with conductive or mixed hearing loss who also meet at least one of the following medical criteria:" ▪ Removed Item E, "Partially implantable magnetic bone-conduction hearing systems using magnetic coupling for acoustic transmission (e.g., Sophono Alpha 2 MPO, BAHA Attract) are considered experimental / investigational."
	Updated Rationale section.
	Updated References section.
03-15-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
03-01-2018	In Coding section: ▪ Added HCPCS codes: L8618, L8624, L8625, L8694. ▪ Revised nomenclature to HCPCS code: L8691. ▪ Removed ICD-9 codes.
03-28-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed coding bullets.
	Updated References section.
03-27-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.
05-14-2021	Updated Description section.
	Updated Rationale section.
	In Coding section: • Add CPT code: 69799 • Remove ICD-10 codes H62.8x1, H62.8x2, H62.8x3, H66.41, H66.42, H66.43, H66.91, H66.92, H66.93, H67.1, H67.2, H67.3
	Updated References section.
03-23-2022	Updated Description Sections
	Updated Rationale Section

REVISIONS	
	Updated Coding Section ▪ Added Codes: 69716, 69719, 69726, 69727 (effective 01-01-2022) ▪ Converted ICD-10 Codes to ranges
	Updated References Section
04-01-2022	In Coding Section: ▪ Removed CPT: 69715, 69718 (terminated 12-31-2021) ▪ Revised CPT nomenclature on 69714 and 69717
01-03-2023	Updated Coding Section ▪ Added 69728, 69729, 69730 (effective 01-01-2023) ▪ Updated nomenclature for 69716, 69717, 69719, 69726, 69727
03-28-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section

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