

**Medical Policy**



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

**Professional**

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| Populations   | Interventions  | Comparators  | Outcomes  |
|---|--|--|---|
| Individuals:<br>• With conductive or mixed hearing loss | Interventions of interest are:<br>• Implantable bone-anchored hearing aid with a percutaneous abutment | Comparators of interest are:<br>• External hearing aid | Relevant outcomes include:<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With conductive or mixed hearing loss | Interventions of interest are:<br>• Partially implantable bone-anchored hearing aid with               | Comparators of interest are:<br>• External hearing aid | Relevant outcomes include:<br>• Functional outcomes<br>• Quality of life                                  |

| Populations   | Interventions  | Comparators  | Outcomes   |
|---|--|--|--|
|   | transcutaneous coupling to the sound processor   |  | <ul style="list-style-type: none"> <li>Treatment-related morbidity</li> </ul>  |
| Individuals: <ul style="list-style-type: none"> <li>With unilateral sensorineural hearing loss</li> </ul> | Interventions of interest are: <ul style="list-style-type: none"> <li>Fully or partially implantable bone-anchored hearing aid with contralateral routing of signal</li> </ul> | Comparators of interest are: <ul style="list-style-type: none"> <li>Air-conduction hearing aid with contralateral routing of signal</li> </ul> | Relevant outcomes include: <ul style="list-style-type: none"> <li>Functional outcomes</li> <li>Quality of life</li> <li>Treatment-related morbidity</li> </ul> |

## **DESCRIPTION**

Sensorineural, conductive, and mixed hearing loss may be treated with various devices, including conventional air-conduction (AC) or bone-conduction external hearing aids. AC 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 ( $\geq 80$  dB). Pure-tone average is calculated by averaging hearing sensitivities (ie, 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).

Product codes: MAH, LXB

**Table 1. Implantable Bone-Conduction Hearing Systems Approved by the FDA**

| Device  | Manufacturer      | Date Cleared         | 510(k) No.         |
|---|-------------------|----------------------|--------------------|
| Baha® Auditory Osseointegrated Implant System | Cochlear Americas |                      |                    |
| 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<br>Apr 2008 | K150751<br>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 4                                       |                   | May 2019             |                    |
| Ponto 3, Ponto 3 Power and Ponto 3 SuperPower |                   | Sep 2016             | K161671            |

The FDA cleared the majority of these systems for use in children ages 5 years and older and adults for the following indications:

- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally;
- Patients with sensorineural deafness in 1 ear and normal hearing in the other (ie, single-sided deafness);
- Patients who are candidates for an 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 FDA**

| <b>Device</b>                          | <b>Manufacturer</b>          | <b>Date Cleared</b> | <b>510(k) No.</b> |
|--|------------------------------|---------------------|-------------------|
| 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.

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## **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 patients 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 (eg, 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, patients should meet the above audiologic criteria, and have a symmetrically conductive or mixed hearing loss as defined by a difference between left and right side bone-conduction threshold of less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies, **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 patients 5 years of age and older with single-sided sensorineural deafness and normal hearing in the other ear. The pure tone average air conduction threshold of the normal ear should be better than 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 patients with bilateral sensorineural hearing loss, are considered **experimental / investigational**.

## **Policy Guidelines**

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.

## **RATIONALE**

This evidence has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 10, 2021.

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.

## **OVERALL EFFICACY OF BONE-ANCHORED HEARING AID DEVICES**

### **Review of Evidence**

#### **Systematic Reviews**

Two systematic reviews by the Health Technology Assessment Program (2011) were published on the use of bone anchored hearing aids (BAHAs) for bilateral hearing impairment.<sup>1,2</sup> The quality of available studies on the use of BAHAs was weak. No studies with control groups were identified. Cohort pre-post studies and cross-sectional comparative studies demonstrated improvements in hearing with use of BAHAs over conventional bone-conduction hearing aids or unaided hearing. However, whether improvements in hearing with BAHAs were greater than with air-conduction (AC) hearing aids was uncertain. Additionally, bilateral use of BAHAs improved hearing outcomes in some patients over unilateral use, but that evidence, too, was uncertain. Implant loss ranged between 6.1% and 19.4%. Reviewers noted that hearing-specific quality of life improved, but overall quality of life did not differ.

#### **Observational Studies**

Since the publication of the systematic reviews, a number of observational studies have evaluated specific aspects of BAHA implantation or reported outcomes in specific populations. Several have suggested that newer generation BAHAs with fully digital signal processors improve hearing to a greater degree than older generation devices.<sup>3,4</sup>

Farnoosh et al. (2014) retrospectively compared BAHA placement with the reconstruction of the external auditory canal for children and adolescents with congenital aural atresia or stenosis who were treated at a single institution from 1988 to 2011.<sup>5</sup> Sixty-eight patients were included; 49

underwent external auditory canal reconstruction, and 19 received a BAHA. Groups differed significantly regarding age, the presence of bilateral atresia, and presence of an associated syndrome. Audiologic data were available for 41 patients. At short-term (<6 months postsurgery) follow-up, the BAHA group (44.3 decibels [dB]) had larger hearing gains on AC than the external auditory canal reconstruction group (20.0 dB;  $p < 0.001$ ); similarly, the BAHA group had larger hearing gains at long-term (>1 year postsurgery) follow-up (44.5 dB vs. 15.3 dB;  $p < 0.001$ ). Quality of life scores and requirements for revision surgery did not differ significantly between groups.

Ramakrishnan et al. (2011) retrospectively reviewed BAHAs and Softband-held conductive hearing aids in 109 children and young adults in a single center.<sup>6</sup> The patient population was unique in that many had craniofacial or genetic syndromes and hearing loss (22/109). Criteria for selection of the implanted device or the Softband were not described, though authors noted an uneven distribution by age, sex, and syndromic comorbidity. Primary measures were the Glasgow Benefit Inventory or Listening Situation Questionnaire (parent version) administered at least 3 months after hearing aid intervention. Mean overall Glasgow Benefit Inventory scores were +29 (range, 11 to 72). Mean Listening Situation Questionnaire score was 17, which was less than a referral cutoff of 22. Based on mean scores, authors concluded that this population benefitted from BAHAs 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.<sup>7</sup>

Older case series have reported patient-reported benefits and satisfaction after BAHA placement.<sup>8,9</sup> Some have suggested that the BAHA improved hearing better than early bone-conducting devices and AC hearing aids<sup>10,11</sup>, and produced acceptable hearing outcomes in individuals unable to tolerate an AC hearing aid.<sup>12,13</sup>

### **Section Summary: Overall Efficacy of Bone-Anchored Hearing Aid Devices**

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

## **BILATERAL IMPLANTABLE BONE-ANCHORED HEARING AID DEVICES IN CONDUCTIVE OR MIXED HEARING LOSS**

### **Clinical Context and Therapy Purpose**

The purpose of implantable 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.

Patients with CHL or mixed hearing loss are actively managed by otolaryngologists in an outpatient clinical setting.

### ***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**

Janssen et al. (2012) conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent CHL.<sup>14</sup> 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, the severity of hearing loss, etiology of hearing loss, and previous amplification experience.

Examples of individual studies include the following. Bosman et al. (2001) reported on 25 patients who were using bilateral devices.<sup>15</sup> 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.<sup>16</sup> 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.<sup>17</sup> A number of other studies cited in the 2005 consensus statement found benefits similar to those noted by Bosman and by Priwin.<sup>15,16</sup> Positive outcomes continue to be reported: Dun et al (2010)<sup>18</sup>, identified improvements in the Glasgow Benefit Inventory scores in 23 children, while Ho et al. (2009)<sup>19</sup>, 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 MAGNETIC BONE-ANCHORED HEARING AID DEVICES**

### **Clinical Context and Therapy Purpose**

The purpose of partially implantable BAHAs with transcutaneous coupling to the sound processor 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 processor 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 populations 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.

Patients with CHL or mixed hearing loss are actively managed by otolaryngologists in an outpatient clinical setting.

### ***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 processor 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.<sup>20</sup> 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;  $p < 0.001$ ). Patients generally showed improvements in speech recognition in noise, although comparing results across test sites was difficult due to different languages and methodologies used for testing speech recognition at each site. Compared with the preoperative unaided state, scores on the Abbreviated Profile of Hearing Aid Benefit overall score ( $p = 0.038$ ) and reverberation ( $p = 0.016$ ) and background noise ( $p = 0.035$ ) subscales were significantly improved with the test device. Denoyelle et al. (2015) reported on a prospective trial of the Sophono device in children ages 5 to 18 years with uni- or bilateral congenital aural atresia with complete absence of the external auditory canal with pure CHL.<sup>21</sup> The study included a within-subject comparison of hearing results with the Sophono devices to those obtained with the Baha Softband preoperatively. All 15 patients enrolled were implanted (median age, 97 months). At 6-month follow-up, mean aided AC PTA was 33.49 dB (mean gain, 35.53 dB), with a mean aided sound reception threshold of 38.2 dB (mean gain, 33.47 dB). The difference in AC PTA between the Baha Softband and the Sophono device was 0.6 dB (confidence interval upper limit, 4.42 dB), which met the trial's prespecified noninferiority margin. Adverse events were generally mild, including skin erythema in 2 patients, which improved by using a weaker magnet, and brief episodes of pain or tingling in 3 patients.

### Nonrandomized Comparative Studies

A limited amount of data is available comparing transcutaneous with percutaneous bone-anchored conduction devices. Hol et al. (2013) compared percutaneous BAHA implants with partially implantable magnetic transcutaneous bone-conduction hearing implants using the Otomag Sophono device in 12 pediatric patients (age range, 5 to 12 years) who had congenital unilateral CHL.<sup>22</sup> 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.<sup>23</sup> 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).<sup>24</sup> Groups were generally similar at baseline, with most individuals undergoing BAHA placement for chronic otitis media. Operating time was longer in patients treated with the transcutaneous partially implantable devices (46 minutes vs. 26 minutes,  $p < 0.05$ ). Three patients treated with percutaneous devices had Holgers grade 2 skin reactions, and 2 stopped using their devices for reasons unrelated to skin reactions. Mean thresholds for frequencies 0.5 to 4.0 kHz were 64.4 dB without the BAHA and 31.6 dB with the BAHA in the percutaneous device group, and 58.3 dB without the BAHA and 27.2 dB with the BAHA in the transcutaneous device group. Frequency-specific threshold hearing gains did not differ significantly between groups. Mean hearing gain measured by speech reception threshold was statistically significantly smaller in the percutaneous group (24 dB vs. 36.7 dB,  $p = 0.02$ ).

Gerdes et al. (2016) published a retrospective single-center study comparing 10 patients who had CHL who received the transcutaneous Bonebridge device with an audiotologically matched control group of 10 patients who received the percutaneous BAHA BP100.<sup>25</sup> There were similar significant improvements in aided thresholds, word recognition scores, and speech reception thresholds in noise for both devices. There were also no differences in subjective ratings for the Abbreviated Profile of Hearing Aid Benefit. Mean functional gain was slightly higher (27.5 dB) for transcutaneous than for percutaneous (26.3 dB), but not significantly different.

### Observational Studies

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).<sup>26</sup> 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.<sup>27</sup> 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).<sup>28</sup> 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.<sup>29</sup> 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.<sup>30</sup> 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.<sup>31</sup> 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.<sup>32</sup> 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.<sup>33</sup> 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.<sup>34</sup> 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   |
|--|----|---|--|---|
| Bravo-Torres et al. (2018) <sup>35</sup> , | 15 | <ul style="list-style-type: none"> <li>Pediatric patients with bilateral CHL (microtia associated with external auditory canal atresia)</li> </ul>  | <ul style="list-style-type: none"> <li>Aided sound-field threshold improvement: 25.2 dB</li> </ul>   | Minor feedback (4), broken processors (4), mild skin redness (2) with 1 month follow-up               |
| Schmerber et al. (2017) <sup>36</sup> ,    | 25 | <ul style="list-style-type: none"> <li>SSD (n=12)</li> <li>Bilateral CHL (n=7)</li> <li>Bilateral mixed HL (n=6)</li> </ul>   | <ul style="list-style-type: none"> <li>SSD, in 5/7 patients speech reception threshold in noise lower with Bonebridge activated</li> <li>CHL and mixed, average functional gain: 26 dB HL; mean % of speech recognition in quiet improved from 74% unaided to 95% aided</li> </ul> | No complications, device failures, revision surgery, or skin injury reported with 1 y follow-up       |
| Rahne et al. (2015) <sup>37</sup> ,        | 11 | <ul style="list-style-type: none"> <li>SSD (n=6; 1 sensorineural, 3 mixed, 2 conductive)</li> <li>Bilateral CHL (n=2)</li> <li>Bilateral mixed HL or mixed/sensorineural (n=3)</li> </ul> | <ul style="list-style-type: none"> <li>Aided sound-field threshold improvement: 33.4 dB</li> <li>WRS improved from mean of 10% unaided to 87.5% aided</li> </ul>   | 1 case of chronic fibrosing mastoiditis requiring mastoidectomy and antrotomy; no other complications |
| Laske et al. (2015) <sup>38</sup> ,        | 9  | <ul style="list-style-type: none"> <li>Adults with SSD and normal contralateral hearing</li> </ul>  | <ul style="list-style-type: none"> <li>Speech discrimination signal-to-noise improvement for aided vs unaided condition, sound presented to aided ear: 1.7 dB</li> <li>Positive improvements on quality-of-life questions</li> </ul>   | Not reported  |
| Riss et al. (2014) <sup>39</sup> ,         | 24 | <ul style="list-style-type: none"> <li>Combined HL (n=9)</li> <li>EAC atresia (n=12)</li> <li>SSD (n=3)</li> </ul>  | <ul style="list-style-type: none"> <li>Average functional gain: 28.8 dB</li> <li>Monosyllabic word scores at 65-dB sound pressure increased from 4.6 to 53.7 percentage points</li> </ul>  | Not reported  |

| Study                                  | N  | Patient Population   | Main Hearing Results  | Safety Outcomes                                       |
|--|----|--|---|---|
| Manrique et al. (2014) <sup>40</sup> , | 5  | <ul style="list-style-type: none"> <li>Mixed HL (n=4)</li> <li>SSD (n=1)</li> </ul>                            | <ul style="list-style-type: none"> <li>PTA improvement: 35.62 dB (p=0.01)</li> <li>Disyllabic word discrimination improvement: 20% (p=0.016)</li> </ul>   | No perioperative complications reported               |
| Ihler et al. (2014) <sup>41</sup> ,    | 6  | <ul style="list-style-type: none"> <li>Mixed HL (n=4)</li> <li>CHL (n=2)</li> </ul>                            | <ul style="list-style-type: none"> <li>PTA functional gain (average, 0.5 to 4.0 kHz): 34.5 dB</li> <li>Speech discrimination at 65 dB improvement: <ul style="list-style-type: none"> <li>In quiet: 63.3 percentage points</li> <li>In noise: 37.5 percentage points</li> </ul> </li> </ul> | Prolonged wound healing in 1 case                     |
| Desmet et al. (2014) <sup>42</sup> ,   | 44 | <ul style="list-style-type: none"> <li>All unilaterally deaf adults</li> </ul>                                 | <ul style="list-style-type: none"> <li>Statistically significant improvement on APHAB and SHHIA</li> </ul>  | Not reported  |
| Iseri et al. (2014) <sup>43</sup> ,    | 12 | <ul style="list-style-type: none"> <li>CHL (n=9)</li> <li>"Primarily conductive hearing loss" (n=3)</li> </ul> | <ul style="list-style-type: none"> <li>Speech reception threshold increase: 19 dB</li> </ul>  | 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.

## BONE-ANCHORED HEARING AID DEVICES 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 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 single sided deafness. 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.

Patients with unilateral sensorineural hearing loss are actively managed by otolaryngologists in an outpatient clinical setting.

**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 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 single-sided deafness (SSD).<sup>44</sup> 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.<sup>45</sup> 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.<sup>46</sup> No statistically significant difference in audiological outcomes was seen between the 2 devices ( $p > 0.05$ ). 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.<sup>47</sup> 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.<sup>48</sup> 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.<sup>49</sup> 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.<sup>50,51,52,53,54,55,56,57</sup>

### **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.<sup>58</sup> 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.<sup>59</sup> 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.<sup>60</sup> 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 ages 2 to 15 years.<sup>61</sup> 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. 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, 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.<sup>62</sup> 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.<sup>63</sup> 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.<sup>64</sup> 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.<sup>65</sup>

Study investigators also examined device usage and compared different patient age groups (children, adults, elderly patients) over a 5-year follow-up. Implant loss was 8%. In close to 96% of cases, there were no adverse soft tissue reactions. Significantly more soft tissue reactions and implant failures were observed in children than in adults and elderly patients ( $p < 0.05$ ). Implant survival rates were lower in patients with than without mental retardation ( $p = 0.001$ ).

Hobson et al. (2010) reviewed complications of 602 patients at a tertiary referral center over 24 years and compared their observed rates with those published in 16 previous studies.<sup>66</sup> 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.<sup>67</sup> Implants were lost in 41 (27%) patients. Reasons for implant loss were: removal (16 patients), osseointegration failure (17 patients), and direct trauma (8 patients). In the 132 patients with implant survival, BAHAs were still being used by 119 (90%) patients at the 9-year follow-up. For children, implant complications were even more frequent, as reported by Kraai et al. (2011) in a follow-up evaluation of 27 implants placed in children ages 16 years or younger between 2002 and 2009.<sup>68</sup> 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.<sup>69</sup> Twenty-one subjects were treated with the 8.5-mm abutment implant from 2011 to 2012 and were compared with 23 subjects treated with a 5.5-mm abutment implant from 2010 to 2011. Groups were generally similar at baseline, except that patients with the 8.5-mm abutment implant were older (62 years vs. 48 years,  $p = 0.012$ ). Patients in the longer abutment group were less likely to experience infection (10% vs. 43%;  $p = 0.02$ ), skin overgrowth (5% vs. 41%;  $p = 0.007$ ), and need for revision (10% vs. 45%;  $p = 0.012$ ), respectively.

Other observational cohort studies, ranging in size from 47 to 974 subjects, have reported safety and adverse event outcomes after BAHA placement.<sup>70,71,72,73</sup> 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.<sup>74</sup> Fontaine et al. (2014) compared complication rates for 2 BAHA surgical implantation techniques among 32 patients treated from 2004 to 2011.<sup>75</sup> Complications requiring surgical revision occurred in 20% of cases who had a skin flap implantation method ( $n = 20$ ) and in 38% of cases who had a full-thickness skin graft implantation method ( $n = 21$ ;  $p = 0.31$ ). Hultcrantz and Lanis (2014) reported shorter surgical times and fewer cases of numbness and peri-implant infections in 12 patients treated with a non-skin-thinning technique, compared with 24 patients treated with a flap or a

dermatome implantation technique.<sup>76</sup> 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.<sup>77</sup> 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.<sup>78</sup> 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.<sup>79</sup> 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 (eg, linear incision).

### **Summary of Evidence**

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

For individuals who have unilateral sensorineural hearing loss who receive a fully or partially implantable BAHA with the contralateral routing of signal, the evidence includes an RCT, multiple prospective and retrospective case series, and a systematic review. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. Single-arm case series, with sample sizes ranging from 9 to 180 patients, have generally reported improvements in patient-reported speech quality, speech perception in noise, and satisfaction with bone-conduction devices with contralateral routing of the signal. However, a well-conducted systematic review of studies comparing bone-anchored devices with hearing aids using contralateral routing of signal found no evidence of improvement in speech recognition or hearing localization. The single RCT

included in the systematic review was a pilot study enrolling only 10 patients and, therefore, does not provide definitive evidence. Quality RCTs on BAHA for unilateral sensorineural hearing loss are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **SUPPLEMENTAL INFORMATION**

The purpose of the Supplemental Information is to provide reference material regarding clinical input, existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement or that the information is used in the evidence review.

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.

### **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**

In 2016, the American Academy of Otolaryngology Head and Neck Surgery updated its position statement on the use of implantable hearing devices.<sup>80</sup> It states that the Academy "considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngologist-head and neck surgeon."

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **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**

| <i><b>NCT No.</b></i>     | <i><b>Trial Name</b></i>   | <i><b>Planned Enrollment</b></i> | <i><b>Completion Date</b></i>              |
|---------------------------|--|----------------------------------|--|
| <i><b>Ongoing</b></i>     |  |                                  |  |
| NCT03533686               | Comparative Study of Non-invasive Adhear Bone Conduction System to Traditional Bone Conduction Hearing Devices | 90                               | Sep 2021                                   |
| <i><b>Unpublished</b></i> |  |                                  |  |
| NCT01858246               | A Randomised Controlled Trial Comparing Bone Anchored Hearing Aid With Bonebridge                              | 60                               | Dec 2017<br>(Completed, last updated 2018) |
| NCT02022085 <sup>a</sup>  | Post-market Clinical Follow-up of a Magnetic Bone Conduction Implant (Cochlear Baha Attract System)            | 2                                | Nov 2017<br>(Completed, last updated 2018) |

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. 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.**

### CPT/HCPCS

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|-------|--|
| 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/cochlear stimulator; without mastoidectomy |
| 69716 | Osseointegrated implant insertion with magnetic transcutaneous attachment to a speech processor (effective 01-01-22)                               |
| 69719 | Osseointegrated implant revision or replacement with magnetic (effective 01-01-22)   |
| 69726 | Osseointegrated implant insertion with magnetic transcutaneous attachment to a speech processor (effective 01-01-22)                               |
| 69727 | Osseointegrated implant removal with magnetic transcutaneous attachment to a speech processor (effective 01-01-22)                                 |
| 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   |

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| 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                              |

### ICD-10 Diagnoses

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| H60.61  | Unspecified chronic otitis externa, right ear  |
| H60.62  | Unspecified chronic otitis externa, left ear   |
| H60.63  | Unspecified chronic otitis externa, bilateral  |
| H60.8X1 | Other otitis externa, right ear  |
| H60.8X2 | Other otitis externa, left ear   |
| H60.8X3 | Other otitis externa, bilateral  |
| H60.91  | Unspecified otitis externa, right ear  |
| H60.92  | Unspecified otitis externa, left ear   |
| H60.93  | Unspecified otitis externa, bilateral  |
| H61.391 | Other acquired stenosis of right external ear canal  |
| H61.392 | Other acquired stenosis of left external ear canal   |
| H61.393 | Other acquired stenosis of external ear canal, bilateral                                     |
| H65.21  | Chronic serous otitis media, right ear   |
| H65.22  | Chronic serous otitis media, left ear  |
| H65.23  | Chronic serous otitis media, bilateral   |
| H65.31  | Chronic mucoid otitis media, right ear   |
| H65.32  | Chronic mucoid otitis media, left ear  |
| H65.33  | Chronic mucoid otitis media, bilateral   |
| H65.411 | Chronic allergic otitis media, right ear   |
| H65.412 | Chronic allergic otitis media, left ear  |
| H65.413 | Chronic allergic otitis media, bilateral   |
| H65.491 | Other chronic nonsuppurative otitis media, right ear   |
| H65.492 | Other chronic nonsuppurative otitis media, left ear  |
| H65.493 | Other chronic nonsuppurative otitis media, bilateral   |
| H66.001 | Acute suppurative otitis media without spontaneous rupture of ear drum, right ear            |
| H66.002 | Acute suppurative otitis media without spontaneous rupture of ear drum, left ear             |
| H66.003 | Acute suppurative otitis media without spontaneous rupture of ear drum, bilateral            |
| H66.004 | Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, right ear |
| H66.005 | Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, left ear  |
| H66.006 | Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, bilateral |
| H66.011 | Acute suppurative otitis media with spontaneous rupture of ear drum, right ear               |
| H66.012 | Acute suppurative otitis media with spontaneous rupture of ear drum, left ear                |
| H66.013 | Acute suppurative otitis media with spontaneous rupture of ear drum, bilateral               |
| H66.014 | Acute suppurative otitis media with spontaneous rupture of ear drum, recurrent, right ear    |
| H66.015 | Acute suppurative otitis media with spontaneous rupture of ear drum, recurrent, left ear     |
| H66.016 | Acute suppurative otitis media with spontaneous rupture of ear drum, recurrent, bilateral    |

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| H66.11  | Chronic tubotympanic suppurative otitis media, right ear  |
| H66.12  | Chronic tubotympanic suppurative otitis media, left ear   |
| H66.13  | Chronic tubotympanic suppurative otitis media, bilateral  |
| H66.21  | Chronic atticofurrow suppurative otitis media, right ear  |
| H66.22  | Chronic atticofurrow suppurative otitis media, left ear   |
| H66.23  | Chronic atticofurrow suppurative otitis media, bilateral  |
| H66.3X1 | Other chronic suppurative otitis media, right ear   |
| H66.3X2 | Other chronic suppurative otitis media, left ear  |
| H66.3X3 | Other chronic suppurative otitis media, bilateral   |
| H90.0   | Conductive hearing loss, bilateral  |
| H90.11  | Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side |
| H90.12  | Conductive hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side  |
| Q16.4   | Other congenital malformations of middle ear  |

## REVISIONS

|            |   |
|------------|---|
| 08-15-2014 | <p>Revised Title from Bone-Anchored Hearing Aids (BAHA) to Implantable Bone-Conduction and Bone-Anchored Hearing Aids (BAHA).</p> <p>Updated Description section</p> <p>In Policy section:</p> <ul style="list-style-type: none"> <li>▪ Replaced the following medical policy language with updated policy language:           <ul style="list-style-type: none"> <li>"A. Unilateral Conductive or mixed hearing Loss<br/>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:               <ol style="list-style-type: none"> <li>1. Average bone conduction threshold better (less) than 45 dB (at 500, 1000, 2000, 3000 Hz) in the indicated ear.</li> <li>2. Speech discrimination score greater than 60% in the indicated ear.</li> <li>3. Age 5 years or older.</li> </ol> </li> <li>B. Bilateral Conductive Hearing Loss<br/>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:               <ol style="list-style-type: none"> <li>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.</li> <li>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)</li> <li>3. Age 5 years or older.</li> </ol> </li> <li>C. Unilateral Sensorineural Hearing Loss (Single Sided Deafness; SSD)<br/>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:               <ol style="list-style-type: none"> <li>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.</li> </ol> </li> </ul> </li> </ul> |
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|            | <p>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).</p> <p>3. Age 5 years or older."</p>   |
|            | Added Rationale section   |
|            | <p>In Coding section:</p> <ul style="list-style-type: none"> <li>▪ Updated nomenclature for CPT codes: 69710, 69711, 69714, 69715, 69717, 69718</li> <li>▪ Added HCPCS Codes: L8690, L8691, L8693</li> <li>▪ Added Coding information</li> <li>▪ Added ICD-10 Diagnosis (Effective October 1, 2015)</li> </ul>  |
|            | 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.  |
|            | <p>In Policy section:</p> <ul style="list-style-type: none"> <li>▪ 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 (eg, Sophono Alpha 2 MPO, BAHA Attract) are considered experimental / investigational."</li> </ul>  |
|            | Updated Rationale section.  |
|            | Updated References section.   |
| 08-17-2016 | Updated Description section.  |
|            | <p>In Policy section:</p> <ul style="list-style-type: none"> <li>▪ 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:"</li> <li>▪ Removed Item E, "Partially implantable magnetic bone-conduction hearing systems using magnetic coupling for acoustic transmission (eg, Sophono Alpha 2 MPO, BAHA Attract) are considered experimental / investigational."</li> </ul> |
|            | Updated Rationale section.  |
|            | Updated References section.   |
| 03-15-2017 | Updated Description section.  |
|            | Updated Rationale section.  |
|            | Updated References section.   |
| 03-01-2018 | <p>In Coding section:</p> <ul style="list-style-type: none"> <li>▪ Added HCPCS codes: L8618, L8624, L8625, L8694.</li> <li>▪ Revised nomenclature to HCPCS code: L8691.</li> <li>▪ Removed ICD-9 codes.</li> </ul>  |
| 03-28-2018 | Updated Description section.  |
|            | Updated Rationale section.  |
|            | <p>In Coding section:</p> <ul style="list-style-type: none"> <li>▪ Removed coding bullets.</li> </ul>   |
|            | Updated References section.   |
| 03-27-2019 | Updated Description section.  |
|            | Updated Rationale section.  |
|            | Updated References section.   |
| 05-14-2021 | Updated Description section.  |
|            | Updated Rationale section.  |
|            | <p>In Coding section:</p> <ul style="list-style-type: none"> <li>• Add CPT code: 69799</li> </ul>   |

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|            | <ul style="list-style-type: none"> <li>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</li> </ul>   |
|            | Updated References section.  |
| 01-03-2022 | <p>In Coding section:</p> <p>Added CPT 69716, 69719, 69726, 69727 (effective 01-01-22)</p> <p>Removed CPT: 69715, 69717, 69718 (terminated 12-31-2021)</p> <p>Revised Cpt 69714 nomenclature "temporal bone" replaced with "skull"</p> |

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