Implantable Bone Conduction Hearing Devices *

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DESCRIPTION

Note: Implantable Bone Conduction Hearing Devices (BAHA) are considered a hearing aid but are reviewed as medical benefit rather than a durable medical equipment (DME) because the "anchor" is surgically implanted.

Hearing loss (deafness, hearing impairment) refers to the partial or complete inability to hear sounds in one or both ears.

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 the degree of hearing loss based on pure-tone average detection thresholds.

Degree of Hearing Loss: Degree of Hearing Loss	Range (dbHL = decibels hearing level)
Normal Hearing	-10 to 15 dBHL
Slight Loss	16 to 25 dBHL
Mild Loss	26 to 40 dBHL
Moderate Loss	41 to 55 dBHL
Moderately Severe Loss	56 to 70 dBHL
Severe Loss	71 to 90 dBHL
Profound Loss	91 dBHL or more

Classifications of Hearing Loss

Conductive Hearing Loss

Conductive hearing loss is the poor transmission of sound waves through the external ear canal to the bones (ossicles) of the middle ear. It may be caused by obstruction (impacted earwax, or cerumen), accumulation of fluid in the middle ear (middle ear effusion), or disturbances affecting the continuity of the ossicles of the middle ear (otosclerosis). Temporary conductive hearing loss usually results from impacted earwax and acute middle ear infection (acute otitis media) with effusion. Persistent conductive loss may be caused by chronic otitis media, trauma, or otosclerosis.

Sensorineural Hearing Loss (SNHL)

Sensorineural hearing loss (SNHL) (sensory organ or nerve-related hearing loss) is the poor transmission of sound waves because of damage to the essential organ of hearing (cochlea) within the inner ear and/or damage to the eighth cranial nerve (vestibulocochlear nerve). Sensorineural hearing loss can be caused by drugs that harm some part of the hearing mechanism (ototoxic drugs), endolymphatic hydrops (Ménière's syndrome), brain tumors, and head trauma. It can also result from problems affecting the eighth cranial nerve (vestibulocochlear nerve) such as acoustic neuroma; systemic diseases like multiple sclerosis, diabetes, Paget's disease, cerebrovascular disease; and immunosuppressive diseases. Sensorineural hearing loss may be caused by noise trauma from damaging hair cells such as industrial noise, gunshots, and loud music. Aging can also result in progressive age-related hearing loss (presbycusis), which occurs as degenerative changes manifest within the cochlea.

Mixed Hearing Loss

Mixed hearing loss happens when the conductive hearing loss occurs at the same time as a SNHL. Damage may be present in the outer, middle, and/or inner ear (cochlea), as well as the auditory nerve. In individuals with mixed hearing loss, it is important to note that although the conductive portion of the hearing loss may be helped by medical or surgical treatment, the sensorineural hearing loss is permanent. (Mixed hearing loss with average bone-conduction thresholds better than 45 dB hearing loss.)

Treatment of Hearing Loss

Treatment for hearing loss may include conventional air-conduction or bone-conduction external hearing aids.

- *Air-conduction hearing aids* may not be suitable for individuals 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.
  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.

- *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 individuals with conductive or mixed hearing loss or for individuals with unilateral single-sided sensorineural hearing loss.

Pure Tone Audiometry (PTA)
(PTA) is the key hearing measurement used to identify hearing threshold levels of an individual, enabling determination of the degree, type, and configuration of a hearing loss. Thus, providing the basis for diagnosis and management.

A convenient summary of the audiogram for each ear is the pure-tone average (PTA) of thresholds measured at specific frequencies.

The most common PTA definition found in epidemiological, or population-based, studies is the four-frequency average of 500, 1000, 2000, and 4000 Hz.

As the PTA increases, the hearing ability decreases. Normal hearing for speech is observed in adults with PTAs of 25 dB HL (hearing loss) or less. At a PTA of around 40 dB HL in both ears, most people are considered functionally impaired and could benefit from amplification. Severe to profound losses are present when PTAs are greater than 70 dB HL.

Device Types

CROS/BiCROS
Contralateral Routing of Signal (CROS) is a hearing aid technology for people with unilateral hearing. The technology allows two implementations: CROS and BiCROS.

Using this technology, a hearing aid-like device on the user's deaf side uses its microphone to pick up sound from that side and sends it to another instrument at the better ear. The sound is then inserted into the good ear.

The CROS implementation is for a user who has relatively normal hearing in the good side and has hearing that can't be aided on the bad side. The receiving BTE device on the bad side transmits the sound to a device on the good side. The user hears the amplified sound from the bad side in their good ear. The user hears the sound from the good side naturally in their good ear, without amplification.

The BiCROS implementation is for a user with little or no hearing on one side and with some hearing loss in their better ear. It works just like the CROS implementation, except

that the device on the good side is a fully capable hearing aid for hearing sounds from the good side that is also capable of receiving the sound transmitted from the CROS aid on the other side.

Implantable Bone-Conducted/Bone-Anchored Hearing Aids (BAHA)
These devices are referred to as a Hearing Aid, Bone-Conduction in FDA approval. The BAHA is a bone-conduction type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone-conduction technology.

The BAHA is connected to a fixture pillar, which has been surgically placed in the bone behind the deaf ear. Sound is transmitted through the bones of the skull to the hearing ear. It 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.

They are indicated for the following scenarios:

- Individuals who have conductive or mixed hearing loss and can still benefit from sound amplification or;
- Individuals with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally or;
- Individuals with sensorineural deafness in one ear and normal hearing in the other (i.e., single-sided deafness) or;
- Individuals who are candidates for an AC CROS hearing aid but who cannot or will not wear an AC CROS device.

Note: 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. When used in a non-implantable manner (e.g., Softband™) the BAHA system is categorized as a ***hearing aid.*** *Please refer to the individual's benefit document to determine coverage.*

Miscellaneous Products

Adhesive Bone-Conduction Hearing System (ADHEAR)
An adhesive bone-conduction hearing system (ADHEAR) has been developed for conductive hearing loss or single-sided deafness (SSD). The ADHEAR System consists of the ADHEAR Audio Processor and the ADHEAR Adhesive Adapter. The device has a non-implantable status, and it would be classified as a **hearing aid,** thus refer to the individual's benefit document to determine coverage.

Partially Implanted/Non-fully Implanted Hearing Devices
Partially implantable magnetic bone-conduction hearing systems also referred to as transcutaneous bone-anchored systems, are available as an alternative to the bone-conduction hearing systems connected percutaneously via an abutment. With this technique, acoustic transmission occurs via magnetic coupling of the external sound processor and internally implanted device components. The bone-conduction hearing processor contains magnets that adhere externally to magnets implanted in shallow bone beds with the bone-conduction hearing implant. Since the processor adheres magnetically to the implant, there is no need for a percutaneous abutment to physically connect the external and internal components. To facilitate greater transmission of acoustics between magnets, skin thickness may be reduced to 4 to 5 mm over the implant when it is surgically placed.

Semi- and Fully Implantable Middle Ear Hearing Aids
Semi-implantable and fully implantable middle ear hearing aids are alternatives to external acoustic hearing aids. Two semi-implantable devices have the U.S. Food and Drug Administration (FDA) approval: the Vibrant Soundbridge and the Maxum System. The devices consist of components: a magnet that is implanted onto the ossicles of the middle ear, a receiver, and a sound processor. The Soundbridge device is implanted subcutaneously behind the ear while the processor is worn externally on the scalp over the receiver unit and held in place by a magnet. The Maxum System device is placed in the user's ear canal while the processor rests over the external ear. In general, the sound processor receives and amplifies the sound vibrations and transforms the sound pressure into electrical signals received by the receiver unit. The receiver unit then transduces these electrical signals into electromagnetic energy and creates an alternating electromagnetic field with the magnetic component (floating mass transducer) implanted on the ossicles of the middle ear. This electromagnetic field results in attractive and repulsive forces on the magnetic implant, causing vibration of the bones of the middle ear similar to normal hearing.

One fully implantable middle ear hearing aid has the FDA approval: the Esteem Implantable Hearing System. Similar to the semi-implantable devices, the fully implantable device consists of a sensor, a sound processor, and a driver connected to the ossicles. The sensor detects vibrations of the tympanic membrane and transforms the vibrations into electrical signals that are processed by the sound processor. The processor transduces these signals via piezoelectric transduction, as opposed to the electromagnetic transduction used in the semi-implantable devices. A piezoelectric transducer (the sensor)

is placed at the head of the incus and converts mechanical vibrations detected from the tympanic membrane into electrical signals delivered to the stapes by another piezoelectric transducer (the driver).

Clinical Context and Therapy Purpose
The purpose of partially/fully implantable BAHAs or a transcutaneous worn bone-anchored device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as external hearing aids, in individuals with conductive, mixed, or sensorineural hearing loss.

The question addressed in this evidence review is: do partially/fully implantable BAHAs or a transcutaneous worn bone-anchored device improve the net health outcome for individuals with conductive, mixed, or sensorineural hearing loss?

Populations
The relevant population of interest is individuals with conductive, mixed, or sensorineural hearing loss.

Interventions
The therapy being considered is a partially/fully implantable BAHAs or a transcutaneous worn bone-anchored device.

Individuals with conductive, mixed, or sensorineural hearing loss and an implantable bone conduction hearing device 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 for conductive, mixed, or sensorineural hearing loss has varying lengths of follow-up. At least one year of follow-up is considered necessary to fully observe outcomes.

Bilateral Implantable Bone-Anchored Hearing Aid Devices in Conductive or Mixed Hearing Loss
(2012) Janssen et al. conducted a systematic review to assess the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent CHL. The literature search included studies in all languages published between 1977 and July 2011. Studies were selected if subjects of any age had permanent bilateral CHL and bilateral implanted BAHAs. Outcomes of interest were any subjective or objective audiologic measures,

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.

Partially Implantable Bone-Anchored Hearing Aid Devices with Transcutaneous Coupling

(2017) Bravo-Torres et al. completed a retrospective case study for individuals under 18 years old. All patients implanted with the Bonebridge were included (N = 15). Individuals who had bilateral conductive hearing loss, secondary to external ear malformations, were considered as candidates. The results noted the average hearing threshold one month after switch on was 25.2 dB (95%CI 23.5-26.9). Hearing thresholds between 0.5 and 4 kHz were better when compared with bone conduction hearing aids. Best performance was observed at 4 kHz, where improvements to hearing were observed throughout the adaptation process. There was evidence of a significant increase in the recognition of monosyllables. The authors concluded the Bonebridge implant showed improvements to hearing thresholds and word recognition in pediatric patients with congenital conductive hearing loss.

(2017) Schmerber et al. completed a multicenter study to o evaluate the safety and efficacy of a new transcutaneous bone-conduction implant (BCI BB) in patients with conductive and mixed hearing loss or with single-sided deafness (SSD), 1 year after surgical implantation. The study design is multicentric prospective, intra-subject measurements. Each subject is his/her own control. The setting is nine university hospitals: 7 French and 2 Belgian. Sixteen subjects with conductive or mixed hearing loss with bone-conduction hearing thresholds under the upper limit of 45 dB HL for each frequency from 500 to 4000 Hz, and 12 subjects with SSD (contralateral hearing within normal range) were enrolled in the study. All subjects were older than 18 years. The intervention is rehabilitative. The main outcome measure is the evaluation of skin safety, audiological measurements, benefit, and satisfaction questionnaires with a 1-year follow up. Skin safety was rated as good or very good. For the mixed or conductive hearing loss groups, the average functional gain (at 500 Hz, 1, 2, 4 kHz) was 26.1 dB HL (SD 13.7), and mean percentage of speech recognition in quiet at 65 dB was 95 % (vs 74 %

unaided). In 5/6 SSD subjects, values of SRT in noise were lower with BB. Questionnaires revealed patient benefit and satisfaction. The transcutaneous BCI is very well tolerated at 1-year follow up, improves audiometric thresholds and intelligibility for speech in quiet and noise, and gives satisfaction to both patients with mixed and conductive hearing loss and patients with SSD.

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

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

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

(2015) Briggs et al. reported on a prospective interventional evaluation of the percutaneous, partially implantable Baha Attract System among 27 adults with CHL or mild mixed hearing loss in the ear to be implanted. The choice of sound processor was based on patient preference and hearing tests with various sound processors in conjunction with the Baha Softband before device implantation. All 27 patients enrolled received an implant. Sound processor fitting occurred 4 weeks post implantation 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.

(2015) Denoyelle et al. reported on a prospective trial of the Sophono device in children ages 5 to 18 years with uni- or bilateral congenital aural atresia with complete absence of the external auditory canal with pure CHL. The study included a within-subject comparison of hearing results with the Sophono devices to those obtained with the Baha Softband preoperatively. All 15 patients enrolled were implanted (median age, 97 months). At 6-month follow-up, mean aided AC PTA was 33.49 dB (mean gain, 35.53 dB), with a mean aided sound reception threshold of 38.2 dB (mean gain, 33.47 dB). The difference in AC PTA between the Baha Softband and the Sophono device was 0.6 dB (confidence interval upper limit, 4.42 dB), which met the trial's prespecified noninferiority margin. Adverse events were generally mild, including skin erythema in 2 patients, which improved by using a weaker magnet, and brief episodes of pain or tingling in 3 patients.

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

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

Section Summary: Partially Implantable Magnetic Bone-Anchored Hearing Aid Devices with Transcutaneous Coupling
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
(2018) den Besten et al. completed a review since the publication of the Peters systematic review (identified below), 3 prospective, interventional studies have compared patient outcomes using transcutaneous BAHA devices with CROS hearing aids for SSD. 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. 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. 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.

(2017) Snapp et al reported on a prospective single-center study of 27 patients with unilateral severe-profound sensorineural hearing loss who had either a CROS (n=13) or transcutaneous BAHA (n=14) device. Mean device use was 66 months for the BAHAs and 34 months for CROS devices. Both BAHA and CROS groups had significant improvement in speech-in-noise performance, but neither showed improvement in localization ability. There were no differences between the devices for subjective measures of posttreatment residual disability or satisfaction as measured by the Glasgow Hearing Aid Benefit Profile.

(2015) Peters et al. reported results from a systematic review of studies comparing BAHA devices using CROS) systems with hearing aids using CROS for single-sided deafness (SSD). Six studies met eligibility criteria, including 1 RCT and 3 prospective and 2 retrospective case series, 5 of which were considered to have moderate-to-high directness of evidence and low-to-moderate risk of bias. The 5 studies (n=91 patients) with low or moderate risk of bias were noted to have significant heterogeneity in the populations included. For speech perception in noise, there was no consistent

improvement with aided hearing over an unaided hearing in all environments. All studies reported equal sound localization and quality of life outcomes for both hearing conditions.

(2012) Zeitler et al. reported on a retrospective case series of 180 patients with SSD and residual hearing in the implanted ear who underwent unilateral or bilateral BAHA placement at a U.S. university medical center. Significant improvement was reported in objective hearing measures (speech-in-noise and monosyllabic word tests) following BAHA implantation. Subjective benefits from BAHAs varied across patients based on results from the Glasgow Hearing Aid Benefit Profile, but patients with residual hearing in the affected ear tended toward improved satisfaction with their device postoperatively.

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

Section Summary: 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.

Summary of Evidence: Bone-Anchored Hearing Aid Devices in Conductive, Mixed, or Sensorineural 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. For individuals who have conductive or mixed hearing loss who receive an implantable BAHA or a partially implantable BAHA, 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. 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 outcomes.

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 outcomes.

Middle Ear Devices: Semi/Partially or Fully Implantable Hearing Aids

Clinical Context and Therapy Purpose
The purpose of semi/partially and fully implantable middle ear hearing aids for the treatment of hearing loss is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: does the use of semi-implantable middle ear hearing aids for the treatment of hearing loss improve net health outcomes?

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

Populations
The relevant population of interest is individuals with hearing loss who are unable to use external hearing aids or who are not candidates for cochlear implants.

Interventions
The therapy being considered is the use of semi/partially and fully implantable middle ear hearing aids as treatment of hearing loss.

Comparators
The following therapies and practices are currently being used to make decisions about treatment of external hearing aids. Externally worn acoustic hearing aids are widely accepted devices for patients with hearing loss. Therefore, this review of semi-implantable and fully implantable hearing aids focuses on comparisons of various audiologic outcome measures between an externally worn hearing aid and a semi- or

fully implantable hearing aid in the same patient. Studies of semi- and fully implantable middle ear hearing aids have frequently reported a patient preference for an implantable device compared with an externally worn device. However, it must be determined to what extent patient preference is based on convenience compared with improved hearing.

Outcomes

The general outcomes of interest include symptoms, functional outcomes, quality of life, and treatment-related morbidity. Only minimal safety concerns are related to external hearing aids. In contrast, an implantable hearing aid requires a surgical procedure. Potential risks cited for semi-implantable middle ear hearing aids include a decrease in residual hearing in the implanted ear, infection in the ear and adjacent structures, and risks associated with general anesthesia. Major ear surgery may also result in numbness, swelling, or discomfort around the ear, the possibility of facial paresis, neck pain, and disturbance of balance and taste. Therefore, equivalency or improvement in audiologic outcomes associated with an implantable hearing aid must be balanced against the potential risks inherent in a surgical procedure. Patients with hearing loss who receive a semi-implantable middle ear hearing aid will require acute post-procedure follow-up and at least 6-12 months to ascertain the impact on hearing.

Trials Supporting Regulatory Approval of Semi-Implantable Middle Ear Hearing Aids for Sensorineural Hearing Loss

The U.S. Food and Drug Administration (FDA) approvals of the Soundbridge and Soundtec (now marketed as the Maxum System) devices were based in part on clinical trials of 53 and 108 patients, respectively, who had a moderate-to-severe sensorineural hearing loss and who were dissatisfied with their existing external acoustic hearing aids. Results of these trials are available in the FDA Summary of Safety and Effectiveness. The results of the Soundbridge and Soundtec trials have also been reported in the peer-reviewed published literature. The principal outcome measures were audiologic before (with the hearing aid in use) and after the implant. The following audiologic outcomes were reported: functional gain, speech recognition, patient assessments, and safety. Each is discussed below.

Middle Ear Devices: Semi-Implantable/Partially Implantable: Functional Gain

Functional gain is defined as the difference in sound-field thresholds (measured in decibels [dB]) and is an indicator of functional benefit from an amplification device. For the Soundbridge device, the improvement in functional gain was 14.1 dB; for the Soundtec device, it was 7.9 dB. Both gains were considered modest improvements. The clinical significance of the improvements is difficult to determine. For example, this level of improvement may be more clinically significant in patients with moderate hearing loss, for whom a 14-dB improvement in threshold might move them into the normal range for the spoken voice.

Middle Ear Devices: Semi-Implantable/Partially Implantable: Speech Recognition
Speech recognition is assessed using the Speech Perception in Noise test and the Northwestern University 6 test, which consists of a 50-item word list. For the Soundbridge device, no significant difference in word recognition was found in quiet or noisy conditions between the implant and the acoustic hearing aid. For the Soundtec device, a statistically significant improvement was noted in Northwestern University 6 and Speech Perception in Noise test results at 52 weeks compared with an optimally fitted hearing aid. However, only 12 patients had completed the 52-week follow-up.

Middle Ear Devices: Semi-Implantable/Partially Implantable: Patient Assessments
Patient self-evaluation was performed in a variety of ways. The Profile of Hearing Aid Performance measure consists of 7 subscales that assess several dimensions of hearing aid effectiveness, such as ease of communications, reverberation, and distortion of sounds. The Hearing Device Satisfaction Scale was developed by Symphonix, the manufacturer. This scale evaluates hearing aid and Soundbridge use and general satisfaction level. The number of subjects who reported improvements was significant across all 7 Profile of Hearing Aid Performance subscales. The largest improvements in the Soundbridge compared with the acoustic hearing aid were reported for the reverberation, reduced cues, and background noise subscales. Based on Hearing Device Satisfaction Scale scores, 94% reported improved overall sound quality for the Soundbridge. For the Soundtec device, patient satisfaction was based on the Hough Ear Institute Profile. This profile assesses patient preference, acoustic feedback, the perception of speech quality, occlusion, and tinnitus. At 20 weeks postimplant, improvements in all parameters were clinically significant. For example, 89% of patients preferred the implantable hearing aid to the acoustic hearing aid, although this result is not surprising because only patients who were dissatisfied with their previous acoustic hearing participated in the trial. A total of 67% of patients reported feedback with their previous acoustic hearing aid, while only 9% reported feedback with the implanted device. The clinical significance of the improvements in functional gain and speech perception is uncertain, although there appeared to be a clear patient preference for the implantable devices.

Middle Ear Devices: Semi-Implantable/Partially Implantable: Safety
Minimal safety issues were associated with either device. For the Soundbridge device, the most common complication was a fullness sensation in 18, which did not resolve in 13. Altered taste sensation was reported in 7 and transient pain in 13. Two patients reported a reduction in residual hearing. In the Soundtec device, the most common complication included device noise, ear pain, ear irritation, and processor failure. These complications resolved in almost all patients; no patient requested removal of the device. However, risks can only be adequately evaluated in broader populations over time.

(2020) Schwab et al. completed a systematic review of adverse events associated with bone-conduction and middle-ear implants. 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.

Middle Ear Devices: Semi-Implantable/Partially Implantable: Nonrandomized Studies

(2020) Rahne et al. performed a retrospective cohort analysis of 21 patients with sensorineural or mixed hearing loss implanted with the Vibrant Soundbridge. The mean word recognition score improved from baseline by 57.8%. Results were not reported by each type of hearing loss. There were no significant differences between coupler types (round window membrane, long process, or incus body and short process of the incus).

(2020) Seebacher et al. performed a retrospective cohort study in 21 patients with sensorineural, conductive, or mixed hearing loss implanted with unilateral Vibrant Soundbridge implantation to analyze patient-reported quality of life outcomes after bilateral implantation (Tables 4 and 5).10, Measures used included the Speech, Spatial, and Qualities of Hearing Scale (SSQ12-B, with 12 items scored from -5 to +5 to rate benefit in listening situations) and the Glasgow Benefit Inventory (GBI, with 18 items scored on a 5-point Likert scale normalized from -100 to +100 measuring generic quality of life in otolaryngological interventions). Improvements in SSQ12-B and GBI scores were statistically significant following bilateral implantation. Results were not by each type of hearing loss.

Middle Ear Devices: Semi-Implantable/Partially Implantable: Systematic Reviews

(2017) Bruchhage et al. reported on a systematic review of the Vibrant Soundbridge for the treatment of sensorineural hearing loss. Reviewers included comparative and noncomparative studies with 5 or more patients published through 2012, which resulted in 24 studies reported in 22 articles, a conference proceeding, and an FDA report, with a total of 679 subjects (range, 5-125 subjects) in the articles and 1,100 in the conference proceeding. In total, 14 studies had level 4, and 9 studies had level 3 evidence. Regarding adverse events, reviewers concluded: “Adverse events occurring with VSB (Vibrant Soundbridge) implantation were in general low, presenting mainly aural fullness (27%) or taste disturbances (9%).” Studies varied in the audiologic outcomes, but all reported functional gains and improvements in speech perception in noise and quiet.

(2016) Ernst et al. reported on a systematic review of the Vibrant Soundbridge for the treatment of mixed or conductive hearing loss.6, Thirty-four studies were selected: 19 studies (n=294 patients) reporting on Vibrant Soundbridge outcomes; 13 studies (n=666 patients) reporting on bone-conduction hearing implants; and 4 studies (n=43 patients) reporting on middle ear surgery plus hearing aid outcomes. No studies directly compared methods. The functional gains with the Vibrant Soundbridge at 3 months ranged from 12.5 to 43.4 dB hearing loss, averaging 29.6 dB. Significant improvements in speech recognition occurred, although methods of measuring speech differed across studies.

(2014) Kahue et al. completed a systematic review which evaluated studies of 3 FDA approved middle ear hearing aids, the Vibrant Soundbridge, the Maxum System, and the Envoy Esteem (discussed in the following section on conductive and mixed hearing loss). Studies eligible for inclusion addressed purely sensorineural hearing loss, had at least 5 implanted ears, and reported comparative data between preoperative and postoperative audiometric performance. Seventeen studies (503 ears) were included, 3 of which evaluated the Soundtec System (now Maxum System, 190 ears), 5 of which evaluated the Envoy Esteem (102 ears), and 9 of which evaluated the Vibrant Soundbridge (211 ears). The 14 studies comparing preoperative unaided hearing with postoperative middle ear implant-assisted hearing demonstrated improvement in hearing thresholds (weight mean, 25.2 dB improvement; range, 15.6-48.2 dB). However, for the 12 studies that compared the best-aided preoperative condition with the postoperative assisted performance, the functional gain was smaller (weighted mean, 8.1 dB improvement; range, -9.4 to 13 dB), and only 1 reported statistically significant improvements over optimally fitting hearing aids. Similarly, studies that compared the preoperative unaided condition with the postoperative middle ear implant-assisted hearing demonstrated improvements in speech recognition (weighted average, 44.8% improvement; range, 8.8%-64.0%), while speech recognition was similar for the middle ear implant-assisted condition and best-aided preoperative condition. Ten studies reported on safety outcomes, including 5 studies that focused on partially implantable middle ear implants; in those studies, 15 (11.4%) of 132 implants malfunctioned and were explanted.

(2013) Butler et al. published the results of a systematic review of comparative studies evaluating partially and fully implantable middle ear hearing devices for sensorineural hearing loss. Reviewers included 14 studies, none of which was an RCT, 13 of which evaluated a semi-implantable device (most often the Vibrant Soundbridge), with 1 study evaluating the Envoy fully implantable system. Outcomes reported across studies were heterogeneous. Among the 9 studies reporting on the primary outcome (functional hearing gain), 1 found that middle ear implants were statistically significantly better than hearing aids, 1 found that hearing aids were statistically significantly better than implants, and 6 found that middle ear implants were better than hearing aids, but without a clinically significant difference. Reviewers concluded that middle ear implants were at least as effective as hearing aids in improving hearing outcomes.

Section Summary: Middle Ear: Semi/Partially-Implantable Hearing Aids
The evidence for the use of semi-implantable middle ear hearing aids includes the clinical trials that supported the FDA approval of the Vibrant Soundbridge and the Soundtec devices, along with a large number of observational series. Most available studies have addressed the Vibrant Soundbridge device. For the use of semi-implantable middle ear hearing aids in patients with sensorineural hearing loss, the body of evidence has suggested these devices may be associated with a modest improvement in functional gain compared with external hearing aids, with similar improvements in speech recognition scores.

Case series reporting on off-label alternative coupling methods for the Vibrant Soundbridge for patients with conductive or mixed hearing loss have also reported improved hearing thresholds and word recognition.

Although the devices appear to have a good safety profile in the short-term, given existing alternatives, studies in larger series reporting on longer-term durability, safety, and efficacy are needed to permit conclusions about the devices' risks and benefits relative to external hearing aids.

Middle Ear: Fully Implantable Hearing Aid for Sensorineural Hearing Loss

Trials Supporting Regulatory Approval of a Fully Implantable Hearing Aid
The FDA approval of the Esteem Hearing System was based on a prospective, nonrandomized, multicenter trial of 60 patients with moderate-to-severe sensorineural hearing loss designed to assess safety and efficacy. Patients served as both control and test subjects as hearing was tested before (with and without hearing assistive devices) and after Esteem implantation. Results of this trial are available in the FDA Summary of Safety and Effectiveness. In this trial, patients experienced an improvement of 11.4 dB in mean speech reception threshold at 10 months post implantation compared with preimplant-aided speech reception thresholds. Overall, word recognition scores were equal to or better than preimplant-aided scores in 93% of patients. The other 7% experienced lower word recognition scores postimplant. Ninety-six adverse device events occurred and were not considered serious. Taste disturbance was the most common, reported at 42%, followed by tinnitus at 18% and facial paralysis/paresis at 7% of patients. Severe adverse device events were experienced by 6 of the 57 patients implanted and included 3 revisions due to fibrous adhesions that limited implant benefit, 1 incision breakdown that required explantation, and 1 wound infection and 1 case of severe pain and facial weakness, both of which resolved with medication. Overall, 70% of all adverse events resolved at 10-month follow-up. However, the serious adverse event of facial paralysis/palsy had not resolved in 2 patients by the time of reporting.

Middle Ear: Fully Implantable Hearing Aid for Sensorineural Hearing Loss: Systematic Reviews
(2014) Pulcherio et al. reported on results of a systematic review of studies of 2 fully implantable middle ear hearing devices: the FDA-approved Esteem device and the Carina device. Reviewers included 22 studies with a total of 244 patients, 134 implanted with the Esteem device and 110 with the Carina device. No RCTs were identified, and most studies were small, with the largest series including 57 subjects and 12 series including fewer than 10 subjects. All studies showed improvements in sound-field threshold from unaided to aided conditions with the fully implantable device, but the magnitudes of the improvements varied.

Section Summary: Middle Ear: Fully Implantable Middle Ear Hearing Aids for Sensorineural Hearing Loss

The evidence on the use of fully implantable middle ear hearing aids includes the clinical trial supporting the FDA approval of the Esteem device, along with systematic reviews and observational series reporting short-term results. These studies have generally found improved hearing over unaided hearing, with modest improvements over hearing with best-fit aids.

Summary of Evidence: Middle Ear Devices Semi-/Partially or Fully Implantable Hearing Aids

For individuals who have hearing loss who receive semi-implantable or fully implantable middle ear hearing aids, the evidence includes the single-arm interventional studies submitted to the U.S. Food and Drug Administration, systematic reviews, and a number of observational series. The relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The data have suggested implantable middle ear hearing aids may provide some improvement in hearing compared with conventional external acoustic hearing aids in individuals with sensorineural hearing loss. However, given the safety and effectiveness of external acoustic hearing aids and the increased risks inherent in a surgical procedure, the semi- and fully implantable device must be associated with clinically significant improvement in various hearing parameters compared with external hearing aids. While safety concerns appear to be minimal, only a limited number of individuals have been included in the clinical trials, and with a median duration of follow-up less than 5 years. Studies of individuals with conductive or mixed hearing loss and aural atresia, when external acoustic hearing aids are not an option, have also demonstrated a hearing benefit with semi-implantable middle ear hearing aids. However, these studies are few and limited to small numbers of individuals. Therefore, conclusions on the safety and effectiveness of semi-implantable hearing aids are limited. Comparisons of semi-implantable devices with alternative hearing devices such as implantable bone-conduction and bone-anchored hearing aids would also be useful to determine device appropriateness for patients who are unable to use external air-conduction hearing aids. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Miscellaneous

Miscellaneous: Bone-Anchored Hearing Aid Devices in Children Younger Than Five Years Old

The BAHA device has been investigated in children younger than five years old 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 three to six months, a second procedure is performed to connect the abutment through the skin to the fixture.

(2015) Amonoo-Kuofi et al. completed the largest series in children under five years were identified including 24 children from a single center's prospectively maintained database. Most patients underwent a 2-stage surgical approach. Most (52%) patients received the implant for isolated microtia or Goldenhar syndrome (16%). Following implantation, 13 (54%) patients had grade two or three local reactions assessed on the Holgers Classification System (redness, moistness, and/or granulation tissue) and seven (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.

(2012) Marsella et al. reported on a single-center experience in Italy with pediatric BAHAs from the inception of their program in 1995 to December 2009. forty-seven children (21 girls, 26 boys) were implanted; seven were younger than five 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 seven younger patients and the rest of the cohort. Based on these findings, study authors suggested that implantation of children at an age younger than five 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.

(2008) McDermott et al. 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. 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.

(2007) Davids et al. provided BAHA devices to children younger than five years of age for auditory and speech-language development, and retrospectively compared surgical outcomes for a study group of 20 children younger than five years and a control group of 20 older children. Children with a cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for children having two-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.

Summary of Evidence: Bone-Anchored Hearing Aid Devices in Children Younger Than Five Years Old

There are few data on the use of BAHA devices in children younger than five. Three case series with a total of fewer than 60 children younger than five years have reported improvements in quality of life after implantation with BAHA devices. One comparative observational study, with seven children younger than five, reported significantly better improvement in functional gain with BAHAs than with conventional nonimplanted bone-conduction hearing aids in an analysis including all ages. The evidence is insufficient to determine the effects of the technology on net health outcomes. Also, the current FDA approved devices are not indicated or approved for children less than 5 years of age.

Miscellaneous: Safety and Adverse Events Related to Bone-Anchored Hearing Aid Devices

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.

(2014) Allis et al. conducted a prospective observational cohort study with a retrospective historical control to evaluate complication rates of skin overgrowth, infection, and the need for revision surgery associated with a BAHA implant with a longer (8.5-mm) abutment. Twenty-one subjects were treated with the 8.5-mm abutment implant from 2011 to 2012 and were compared with 23 subjects treated with a 5.5-mm abutment implant from 2010 to 2011. Groups were generally similar at baseline, 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.

(2014) Fontaine et al. compared complication rates for 2 BAHA surgical implantation techniques among 32 patients treated from 2004 to 2011. Complications requiring surgical revision occurred in 20% of cases who had a skin flap implantation method (n=20) and in 38% of cases who had a full-thickness skin graft implantation method (n=21; p=0.31).

(2014) Hultcrantz and Lanis reported shorter surgical times and fewer cases of numbness and peri-implant infections in 12 patients treated with a non-skin-thinning technique, compared with 24 patients treated with a flap or a dermatome implantation technique. In a comparison of 2 types of BAHA devices, 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.

(2014) Singam et al. reported results of a BAHA implantation technique without soft tissue reduction in conjunction with a longer device abutment in 30 patients. Twenty-five patients had no postoperative complications. Five subjects developed postoperative skin reactions, of whom 3 required soft tissue reduction. Roplekar et al. (2016) compared skin-related complications of the traditional skin flap method to the linear incision method performed by a single surgeon in 117 patients with at least 1 year of follow-up. Twenty-one (24%) patients experienced skin-related complications in the skin flap group (12 skin overgrowths, 8 wound infections, 1 numbness) and 3 (10%) patients experienced complications in the linear incision group (3 wound infections).

(2012) Dun et al. assessed soft tissue reactions and implant stability of 1132 percutaneous titanium implants for bone-conduction devices in a retrospective survey of 970 patients undergoing implants between 1988 and 2007 at a university medical center in the Netherlands, Study investigators also examined device usage and compared different patient age groups (children, adults, elderly patients) over a 5-year follow-up. Implant loss was 8%. In close to 96% of cases, there were no adverse soft tissue reactions. Significantly more soft tissue reactions and implant failures were observed in children than in adults and elderly patients ($p<0.05$). Implant survival rates were lower in patients with than without mental retardation ($p=0.001$).

(2011) Wallberg et al. reported on the status of 150 implants placed between 1977 and 1986 at a mean follow-up of 9 years. Implants were lost in 41 (27%) patients. Reasons for implant loss were removal (16 patients), osseointegration failure (17 patients), and direct trauma (8 patients). In the 132 patients with implant survival, BAHAs were still being used by 119 (90%) patients at the 9-year follow-up.

(2011) Kraai et al. reported for children, implant complications were even more frequent, by a follow-up evaluation of 27 implants placed in children ages 16 years or younger between 2002 and 2009. In this retrospective report, soft tissue reactions occurred in 24 (89%) patients; implant removal or surgical revision was required in 10 (37%) patients; 24 (89%) patients experienced soft tissue overgrowth and infection; and 7 (26%) patients experienced implant trauma. Chronic infection and overgrowth at the abutment prevented use of the implant in 3 (11%) patients.

(2010) Hobson et al. reviewed complications of 602 patients at a tertiary referral center over 24 years and compared their observed rates with those published in 16 previous studies. The overall observed complication rate of 23.9% (144/602) was similar to other published studies (weighted mean complication rate, 24.9%). The most common complications were soft tissue overgrowth, skin infection, and fixture dislodgement. The observed rate of surgical revision of 12.1% (73/602) was also similar to previously published rates (weighted mean, 12.7%). Top reasons for revision surgery were identical to observed complications.

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

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).

Practice Guidelines and Position Statements

American Academy of Audiology (AAA)
(2015) Clinical Practice Guidelines Adult Patients with Severe-to-Profound Unilateral Sensorineural Hearing Loss Recommendations

1. For bone-conduction (BC) devices, the audiological candidacy guidelines recommend a PTA of ≤ 20 dB hearing loss (HL) PTA at 500, 1000, 2000, and 3000 Hz by AC in the better hearing ear.

2. TA should be measured for any patient considering treatment with a BC device by measuring the difference between the BC threshold at the good mastoid and the BC threshold at the stimulation site. The use of the power device is recommended to provide additional output to overcome TA, as well as attenuation from the skin, during candidacy assessment using a headband. It is recommended that speech-in-noise measures are used to predict post-treatment performance in noise for devices intended to eliminate the head shadow effect (i.e., CROS, AOIS, etc.).

Pre-treatment evaluation should be completed using a power processor. To provide a best aided performance estimate for the purpose of demonstrating the elimination of the head shadow effect, the recommended test configuration for speech-in-noise assessment should include speech at 45° or 90° azimuth to the side of the poorer ear and noise at 45° or 90° azimuth to the side of the better ear.

Due to inherent limitations in clinical assessment of patients with hearing loss (i.e., equipment, time, etc.), additional assessment of performance in noise may not be feasible. As such, counseling regarding the impact of diffuse noise or noise directed at the aided ear is critical for establishing realistic expectations.

3. It is recommended that clinicians utilize validated subjective measures that are specific to the deficit and needs of patients with severe-to-profound UNSNHL.

4. At home test band trials should be reserved for those individuals who have met candidacy requirements including meeting initial audiometric criteria, a measured TA of less than 10 dB, and improved aided performance on speech in-noise measures. The clinician should ensure that a BC device is programmed to accommodate the patient's TA and it is recommended to use a power device for all at-home trials, that all hearing devices are electro acoustically verified for optimal performance (where possible), and patients are adequately trained on device use and placement.

Background Treatment begins with the selection of an appropriate device. In the unique case of severe-to-profound USNHL, patients attempt to resolve the loss of the primary advantages of binaural hearing, including localization, release from the head shadow effect, binaural squelch, and binaural summation. Due to the presence of severe-to-profound hearing loss, very poor word recognition, and possibly hyperacusis in the poorer ear, these patients are typically unable to benefit from a conventional hearing device. Research has demonstrated that these patients may benefit from a variety of hearing devices that may improve their auditory experience primarily by eliminating the head shadow effect. These device options utilize different modalities of hearing including AC (e.g., CROS/BICROS), transcranial BC (e.g., transcranial CROS, TransEar®, SoundBite™, AOIS), and electric stimulation (e.g., cochlear implant (CI)).
(Accessed July 2022)

American Academy of Otolaryngology Head and Neck Surgery (AAO -HNS)
(2021) The position statement was updated on the use of *implantable hearing devices*. It stated,

- "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."(*Accessed August 2022*)

(2021) The American Academy of Otolaryngology Head and Neck Surgery issued a position statement on Active Middle Ear Implants, which stated:

- "The American Academy of Otolaryngology-Head and Neck Surgery considers *active middle ear implants* as appropriate treatment for adults with moderate to severe hearing loss when performed by a qualified otolaryngologist-head and neck surgeon.

- Based on available literature demonstrating that clinically selected adults receive substantial benefit, implanting active middle ear implants is accepted medical practice in those who benefit from amplification but are unable to benefit from the amplification provided by conventional hearing aids. Use of active middle ear implants, which have been U.S. Food and Drug Administration (FDA)-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the Food and Drug Administration in the United States and other similar regulatory agencies in countries other than the United States." (*Accessed July 2022*)

Regulatory Status

Hearing Aids
Hearing aids are sound-amplifying devices designed to aid people who have a hearing impairment. Most hearing aids share several similar electronic components, and technology used for amplification may be analog or digital. (Semi-implantable electromagnetic hearing aids and bone-anchored hearing aids are classified by the U.S. Food and Drug Administration (FDA) as hearing aids. Some non-wearable hearing devices are described as hearing devices or hearing systems. Because their function is to bring sound more effectively into the ear of a person with hearing loss, for the purposes of this policy, they are hearing aids).

FDA Summary for Baha (Bone Anchored Hearing Aid)
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. Such clearance was granted based on a determination that the BAHA was substantially equivalent to a contralateral routing of sound (CROS) air conduction hearing aid. FDA review also indicates that this device has substantially equivalent technology as air-conduction hearing aids with digital sound processing.

Implantable Bone-Conduction Hearing Systems Approved by the FDA

Device	Manufacturer	Date Cleared	510(k) No.
Baha® Auditory Osseointegrated Implant System	Cochlear Americas		
Baha® 6 Max Sound Processor	Cochlear Americas	Feb 2021	K202048
Cochlear™ Osia™ 2 System	Cochlear Americas	Dec 2019	K191921
BA310 Abutment, BIA310 Implant/Abutment	Cochlear Americas	Dec 2018	K182116
Baha® 5 Power Sound Processor	Cochlear Americas	May 2016	K161123

Baha® 5 Super Power Sound Processor	Cochlear Americas	Mar 2016	K153245
Baha® 5 Sound Processor	Cochlear Americas	Mar 2015	K142907
Baha® 4	Cochlear Americas	Sep 2013	K132278
Baha® Attract System	Cochlear Americas	Nov 2013	K131240
Baha® Cordelle II	Cochlear Americas	Jul 2015 Apr 2008	K150751 K080363
Baha Intenso® (digital signal processing)	Cochlear Americas	Aug 2008	K081606
Baha Divino®		Aug 2004	K042017
Ponto Bone-Anchored Hearing System	Oticon Medical	Sep 2012	K121228
Ponto 3, Ponto 3 Power and Ponto 3 SuperPower	Oticon Medical	Sep 2016	K161671
Ponto 4	Oticon Medical	Mar 2019	K190540
Ponto 5 Mini	Oticon Medical	Aug 2021	K211640
Ponto 5 Superpower	Oticon Medical	Dec 2021	K213733
OBC Bone-Anchored Hearing Aid System	Oticon Medical	Nov 2011	K112053

Please note this table is not intended to be all-inclusive.

The FDA cleared **Semi-Implantable (Partially) Magnetic Bone-Conduction Devices** through the 510(k) process.

Device	Manufacturer	Date Cleared	510(k) No.
Bonebridge	MED-EL	2019	K183373 K191457
The Otomag Alpha ™ System	Medtronic (Formerly Sophono)	May 2010	K100193
Otomag® Bone-Conduction Hearing System	Medtronic (Formerly Sophono)	Nov 2013	K132189
Cochlear Baha® 4 Sound Processor	Cochlear Americas	Oct 2012	K121317

Please note this table is not intended to be all-inclusive.

Miscellaneous Devices cleared by the FDA:

Device	Manufacturer	Date Cleared	510(k) No.
Esteem® Implantable Hearing System (*Middle Ear, Totally Implanted*)	Envoy	Mar 2010	P090018 S038
Maxum™ System (*Middle Ear, Partially Implanted*)	Ototronix	May 2016	P010023 S012
Soundtec Direct System (*Middle Ear Device*, Partially Implanted - n*ow discontinued due to performance issues and re-released under the name Maxum™ System*.)	Ototronix	2001	P010023
Streamer Accessory (*Check the individual's benefits; typically, not a contract benefit*)	Oticon Medical	_____	_____
Vibrant® Soundbridge™ (Middle Ear, Semi/Partially Implanted)	MED-EL Corp.	2000	P990052

Please note this table is not intended to be all-inclusive.

Note:

- *The Carina® Fully Implantable Hearing Device is in development (Otologics, now Cochlear), but does not have the FDA approval. Phase 1 and 2 trials have been conducted in the United States under investigational device exemptions.*
- *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.*

PRIOR APPROVAL

Prior approval is required.

POLICY

Related Medical Policy

- 01.03.02 Cochlear Implant Replacement

Note: Implantable Bone Conduction Hearing Devices (BAHA) are considered a hearing aid but are reviewed as medical benefit rather than a durable medical equipment (DME) because the "anchor" is surgically implanted.

For an Implantable Bone Anchored Hearing Aid (BAHA) to be considered a **contract benefit** there must be a *medical reason* the identified hearing loss is **not** correctable by other covered procedures or devices.

- Please refer to the individual's benefit document to determine coverage.
  - Streamers for the processor to connect to wireless devices (i.e., Ponto, Oticon Medical Streamer) may be considered a *convenience item* and may **not** be a **covered benefit.**

Unilateral Conductive or Mixed Hearing Loss	

Medically Necessary	A unilateral, 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 when **all of the following** are met:
	• The requested device meets the specific FDA approved indication.
	  ○ *(How to: View the FDA Premarket Notification site, search the 510K number (provided in the FDA table above), click, "Summary".)*
	• The individual is **five years of age and older** *or* meets the **FDA approved age requirement** for the requested device**; and**
	  ○ *(Note: For example, based on the FDA indications the Osia™ 2 system may be used by individuals 12 years of age and older. FDA indications may differ per device, see the FDA site for the specific indications.)*
	• Has been diagnosed with a **conductive or mixed hearing loss** when **one of the following** medical criteria is present:
	  ○ Congenital or surgically induced ear malformations of the external ear canal or middle ear (e.g., atresia); **or**
	  ○ Chronic external otitis or otitis media; **or**
	  ○ Otosclerosis in individuals who cannot undergo stapedectomy; **or**

	○ Tumors of the external canal and/or tympanic cavity; **or** ○ Dermatitis of the external canal; **or** ○ Other conditions in which an air-conduction hearing aid is contraindicated **And all of the following audiologic criteria is met:** • The individual has a pure-tone average (PTA) bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz. **and**; ○ *(Note: The FDA has cleared certain devices for specific parameters; 45 dB HL (e.g., and BP100 sound processor), 55 dB HL (e.g., Intenso™ and BP110 Power sound processor), 65 db HL (e.g., Cordele II™ Sound Processor. Review the PTA indications specific to the requested device.)* • There is a documented **mild to moderate** hearing loss (26-70 dB).
Investigational/ Not Medically Necessary	An implantable Bone Anchored Hearing Aid (BAHA) is considered **not medically necessary** for **unilateral conductive or mixed hearing loss** when the above criteria are not met except for the following: • The use in **children younger than five years of age** is considered **investigational** due to a lack of evidence demonstrating an impact on net health outcomes. • The use of bone-anchored hearing implants is considered **investigational** for **severe hearing loss** due to a lack of evidence demonstrating an impact on net health outcomes.

Bilateral Conductive or Mixed Hearing Loss	
Medically Necessary	A bilateral fully or partially implantable bone-conduction/bone-anchored hearing aid(s) device may be considered **medically necessary** as an alternative to an air-conduction hearing aid when **all of the following** are met: • The requested device meets the specific FDA approved indication. ○ *(How to: View the FDA Premarket Notification site, search the 510K number and click, "Summary".)* • The individual is **five years of age and older** or meets the **FDA age indication requirement** for the requested device**; and**

	○ *(Note: For example, based on the FDA indications the Osia™ 2 system may be used by individuals 12 years of age and older. FDA indications may differ per device, see the FDA site for the specific indications*.) • Has been diagnosed with a **conductive or mixed hearing loss** when **one of the following** medical criteria is present: ○ Congenital or surgically induced ear malformations of the external ear canal or middle ear (e.g., atresia); **or** ○ Chronic external otitis or otitis media; **or** ○ Otosclerosis in individuals who cannot undergo stapedectomy; **or** ○ Tumors of the external canal and/or tympanic cavity; **or** ○ Dermatitis of the external canal; **or** ○ Other conditions in which an air-conduction hearing aid is contraindicated **And a symmetrical conductive or mixed hearing loss** is present as defined by **one of the following**: • 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** ○ *(Note: 4 kHz for OBC and Ponto™ Pro devices. Review the threshold indications specific to the requested device.)* • Individual frequencies less than 15 dB. **And all of the following audiologic criteria is met:** • The individual has a pure-tone average (PTA) bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz. **and**; ○ *(Note: The FDA has cleared certain devices for specific parameters; 45 dB HL (e.g., and BP100 sound processor), 55 dB HL (e.g., Intenso™ and BP110 Power sound processor), 65 db HL (e.g., Cordele II™ Sound Processor) Review the PTA indications specific to the requested device.)* • There is a documented **mild to moderate** hearing loss (26-70 dB).
Investigational/ Not Medically Necessary	An implantable Bone-Anchored Hearing Aid (BAHA) is considered **not medically necessary** for **bilateral conductive or mixed**

	hearing loss when the above criteria are not met except for the following: • The use in **children younger than five years** of age is considered **investigational** due to a lack of evidence demonstrating an impact on net health outcomes. • The use of bone-anchored hearing implants is considered **investigational** for **severe hearing loss** due to a lack of evidence demonstrating an impact on net health outcomes.

Unilateral Sensorineural Hearing Loss	

Medically Necessary	An implantable bone-conduction (bone-anchored) hearing aid may be considered medically necessary as an alternative to an air-conduction hearing aid when **all of the following** are met:
	• The requested device meets the specific FDA approved indications.
	  ○ *(How to: View the FDA Premarket Notification site, search the 510K number and click, "Summary".)*
	• The individual is **five years of age and older** *or* meets the **FDA age indication requirement** for the requested device**; and**
	  ○ *(Note: For example, based on the FDA indications the Osia™ 2 system may be used by individuals 12 years of age and older. FDA indications may differ per device, see the FDA site for the specific indications.)*
	• The individual has **unilateral/single-sided sensorineural deafness**; **and**
	• **Normal hearing** in the ear opposite of the requested implanted device with pure tone average air-conduction threshold of the normal ear better than **20 dB** measured at 0.5, 1, 2, and 3 kHz.

Investigational/ Not Medically Necessary	An implantable Bone-Anchored Hearing Aid (BAHA) is considered **not medically necessary** for **unilateral sensorineural hearing loss** when the above criteria are not met except for the following: • The use in children **younger than five years** of age is considered **investigational** due to a lack of evidence demonstrating an impact on net health outcomes.

	• The use of bone-anchored hearing implants is considered **investigational** for **severe** hearing loss due to a lack of evidence demonstrating an impact on net health outcomes.

Transcutaneous Worn Bone-Anchored Device	
Medically Necessary	A device utilizing a headband/Softband is considered a hearing aid (not implantable) can be used in any **age group** and may be considered **medically necessary** when **all of** the following criteria are met: • ***The individual's contract has a hearing aid benefit; and*** • Is requested for **one of the following** diagnoses: o Unilateral conductive/mixed hearing loss o Bilateral conductive/mixed hearing loss o Unilateral sensorineural hearing loss • **And** meets the criteria for the **specific type hearing loss** diagnosed ***as noted above***. *(Note: See each specific criteria subset above is dependent on the type of hearing loss the individual has. The remainder of the criteria should be met as described above.)*

Replacement	
Medically Necessary	Replacement part(s) to the current device is considered **medically necessary** when the following criteria is met: • The currently used device is **not** under warranty **and**; o Documentation is provided to include **all of the following**: ▪ Date of device implantation; **and** ▪ Manufacturer warranty information; **and** ▪ Determination of the device to be non-repairable including objective documentation from the audiologist on how the device is non-repairable/malfunctioning; **and** ▪ The device currently used is no longer functional as evidenced by interfering with the individual's activities of daily living (ADLs); **and** ▪ There is no evidence to suggest that the device has been lost, abused, or neglected; **and**

	▪ The individual has been compliant with the use of the device and will continue to benefit from the device; **and** ▪ The device was being used daily until malfunction.
Investigational/ Not Medically Necessary	The replacement of the current device is considered **not medically necessary** including but not limited to the following: • The replacement is not solely for better technology or improved aesthetics. • When the above criteria are not met.

Other Uses of Implantable Bone-Conduction/Bone-Anchored Hearing Aids	
Investigational	The use of implantable bone-conduction (bone-anchored) hearing aids are considered **investigational** due to a lack of evidence demonstrating an impact on net health outcomes including but not limited the following indications: • Bilateral sensorineural hearing loss • Semi - and totally implantable middle ear hearing aids

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 69710 Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
- 69711 Removal or repair of electromagnetic bone conduction hearing device in temporal bone
- 69799 Unlisted procedure, middle ear
- 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, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
- 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
- L8690 Auditory osseointegrated device, includes all internal and external components
- L8691 Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
- L8692 Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
- L8693 Auditory osseointegrated device abutment, any length, replacement only
- L8694 Auditory osseointegrated device, transducer/actuator, replacement only, each
- S2230 Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
- V5095 Semi-implantable middle ear hearing prosthesis

SELECTED REFERENCES

- Colquitt JL, Jones J, Harris P et al. Bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf: a systematic review and economic evaluation. Health Technol Assess 2011; 15(26):1-200, iii-iv.
- McLarnon CM, Davison T, Johnson IJ. Bone-anchored hearing aid: comparison of benefit by patient subgroups. Laryngoscope 2004; 114(5):942-4.
- Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. Otolaryngol Head Neck Surg 2012; 147(3):412-22.
- Zeitler DM, Snapp HA, Telischi FF et al. Bone-anchored implantation for single-sided deafness in patients with less than profound hearing loss. Otolaryngol Head Neck Surg 2012; 147(1):105-11.
- Dun CA, Faber HT, de Wolf MJ et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. Otol Neurotol 2012; 33(2):192-8.
- Hol MK, Nelissen RC, Agterberg MJ et al. Comparison between a new implantable transcutaneous bone conductor and percutaneous bone-conduction hearing implant. Otol Neurotol 2013; 34(6):1071-5.
- Centers for Medicare and Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage.

- Gunduz B, Atas A, Bayazit YA et al. Functional outcomes of Vibrant Soundbridge applied on the middle ear windows in comparison with conventional hearing aids. Acta Otolaryngol 2012; 132(12):1306-10. PMID 23039370.
- Esteem Implantable Hearing System. FDA Summary of Safety and Effectiveness.
- Monini S, Biagini M, Atturo F et al. Esteem((R)) middle ear device versus conventional hearing aids for rehabilitation of bilateral sensorineural hearing loss. Eur Arch Otorhinolaryngol 2012.
- Zwartenkot JW, Hashemi J, Cremers CW, et al. Active middle ear implantation for patients with sensorineural hearing loss and external otitis: long-term outcome in patient satisfaction. Otol Neurotol. 2013;34(5):855-61. PMID 23739560
- Peters JP, Smit AL, Stegeman I, et al. Review: Bone conduction devices and contralateral routing of sound systems in single-sided deafness. Laryngoscope. Aug 14 2014. PMID 25124297
- Pai I, Kelleher C, Nunn T et al. Outcome of bone-anchored hearing aids for single-sided deafness: a prospective study. Acta Otolaryngol 2012; 132(7):751-755. PMID 22497318
- Crukley, J. & Goyette, A. (2016). Basic and advanced considerations in CROS and BiCROS fitting: streaming control and counseling. Innovations, 6 (1).
- Wiliams, V. A., McArdle, R. A., & Chisolm, T.H. (2012). Subjective and objective outcomes from new BiCROS technology in a veteran sample. Journal of the American Academy of Audiology, 23(10), 789-806.
- Peters JP, Smit AL, Stegeman I, et al. Review: Bone conduction devices and contralateral routing of sound systems in single-sided deafness. Laryngoscope. Jan 2015;125(1):218-226. PMID 25124297
- Hol MK, Bosman AJ, Snik AF, Mylanus EA, Cremers CW. Bone-anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements. Otol Neurotol. 2005;26(5):999–1006.
- Ernst A, Todt I, Wagner J. Safety and effectiveness of the Vibrant Soundbridge in treating conductive and mixed hearing loss: A systematic review. Laryngoscope. 2016;126(6):1451-7. PMID 26468033.
- Shohet JA. Implantable hearing devices. Medscape, July 14, 2017.
- Van Zon A, Peters JPM, Stegeman I, Smit AL, Grolman W. (2015) Cochlear Implantation for Patients with Single-Sided Deafness or Asymmetrical Hearing Loss—A Systematic Review of the Evidence. Otology & Neurotology 36:209-219.
- Van de Heyning, P., Tavora-Viera, D., et al. A Proposed Protocol: Assessment for Patients with Single-Sided Deafness or Asymmetric Hearing Loss (2016). Audiol Neurotol 21(6):391–398.
- Faber HT1, Nelissen RC1, Kramer SE2, Cremers CW1, Snik AF1, Hol MK1.Bone-anchored hearing implants in single-sided deafness patients: Long-term use and satisfaction by gender. Laryngoscope. 2015 Jul 7. doi: 10.1002/lary.25423. [Epub ahead of print]

- Wazen JJ1, Babu S2, Daugherty J3, Metrailer A2.Three-week loading of the 4.5mm wide titanium implant in bone anchored hearing systems. Am J Otolaryngol. 2016 Mar-Apr;37(2):132-5. doi: 10.1016/j.amjoto.2015.08.005. Epub 2015 Aug 18.
- American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Bone Conduction Hearing Devices. Position Statements 2016. http://www.entnet.org/content/position-statement-bone-conduction-hearing-devices
- Schmerber S, Deguine O, Marx M, et al. Safety and effectiveness of the Bonebridge transcutaneous active direct-drive bone-conduction hearing implant at 1-year device use. Eur Arch Otorhinolaryngol. Apr 2017;274(4):1835-1851. PMID 27475796
- ECRI Institute. Bonebridge Bone Conduction Implant System (Med-El Corp.) for Treating Conductive or Mixed Hearing Loss or Single-sided Deafness. Plymouth Meeting (PA): ECRI Institute; 2019 Mar 25. (Custom Product Brief).
- U.S. Food and Drug Administration (FDA). Bonebridge Bone Conduction Hearing Implant. De Novo 510(k) No. DEN170009. Silver Spring, MD: FDA; July 20, 2018.
- Yang, J, Wang, Z, Huang, M, Chai, Y, Jia, H, Wu, Y, Dai, Y, Li, Y, et al. BoneBridge implantation in patients with single-sided deafness resulting from vestibular schwannoma resection: objective and subjective benefit evaluations. Acta Otolaryngol. 2018;138(10):877-885.
- Zernotti, ME, Chiaraviglio, MM, Mauricio, SB, Tabernero, PA, Zernotti, M, and Di Gregorio, MF. Audiological outcomes in patients with congenital aural atresia implanted with transcutaneous active bone conduction hearing implant. Int J Pediatr Otorhinolaryngol. 2019;119:54-58.
- Choi, JE, Ma, SM, Park, H, Cho, YS, Hong, SH, Moon, IJ. A comparison between wireless CROS/BiCROS and soft-band BAHA for patients with unilateral hearing loss. PLoS One. 2019;14(2):e0212503. PMID: 30789931
- den Besten, CA, Monksfield, P, Bosman, A, et al. Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: Six-month results from a multicenter study. Clin Otolaryngol. 2019 Mar;44(2):144-57. PMID: 30358920
- Kohan D, Ghossaini SN. Osseointegrated auditory devices-transcutaneous: Sophono and Baha Attract. Otolaryngol Clin North Am. 2019;52(2):253-263.
- Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. Otol Neurotol. Jun 2015; 36(5): 834-41. PMID 25634465
- Denoyelle F, Coudert C, Thierry B, et al. Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia. Int J Pediatr Otorhinolaryngol. Mar 2015; 79(3): 382-7. PMID 2561718900
- Amonoo-Kuofi K, Kelly A, Neeff M, et al. Experience of bone-anchored hearing aid implantation in children younger than 5 years of age. Int J Pediatr Otorhinolaryngol. Apr 2015; 79(4): 474-80. PMID 25680294

- Marsella P, Scorpecci A, Pacifico C, et al. Pediatric BAHA in Italy: the Bambino Gesu Children's Hospital's experience. Eur Arch Otorhinolaryngol. Feb 2012; 269(2): 467-74. PMID 21739094
- McDermott AL, Williams J, Kuo MJ, et al. The role of bone anchored hearing aids in children with Down syndrome. Int J Pediatr Otorhinolaryngol. Jun 2008; 72(6): 751-7. PMID 18433885
- Davids T, Gordon KA, Clutton D, et al. Bone-anchored hearing aids in infants and children younger than 5 years. Arch Otolaryngol Head Neck Surg. Jan 2007; 133(1): 51-5. PMID 17224524
- Schwab B, Wimmer W, Severens JL, et al. Adverse events associated with bone-conduction and middle-ear implants: a systematic review. Eur Arch Otorhinolaryngol. Feb 2020; 277(2): 423-438. PMID 31749056
- Briggs R, Van Hasselt A, Luntz M, et al. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. Otol Neurotol. Jun 2015; 36(5): 834-41. PMID 25634465
- Denoyelle F, Coudert C, Thierry B, et al. Hearing rehabilitation with the closed skin bone-anchored implant Sophono Alpha1: results of a prospective study in 15 children with ear atresia. Int J Pediatr Otorhinolaryngol. Mar 2015; 79(3): 382-7. PMID 25617189
- Schwab B, Wimmer W, Severens JL, et al. Adverse events associated with bone-conduction and middle-ear implants: a systematic review. Eur Arch Otorhinolaryngol. Feb 2020; 277(2): 423-438. PMID 31749056
- Verheij E, Bezdjian A, Grolman W, et al. A Systematic Review on Complications of Tissue Preservation Surgical Techniques in Percutaneous Bone Conduction Hearing Devices. Otol Neurotol. Aug 2016; 37(7): 829-37. PMID 27273402
- Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. Otol Neurotol. Jul 2013; 34(5): 790-4. PMID 23739555
- Dun CA, Faber HT, de Wolf MJ, et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. Otol Neurotol. Feb 2012; 33(2): 192-8. PMID 22246385
- Hobson JC, Roper AJ, Andrew R, et al. Complications of bone-anchored hearing aid implantation. J Laryngol Otol. Feb 2010; 124(2): 132-6. PMID 19968889
- Wallberg E, Granstrom G, Tjellstrom A, et al. Implant survival rate in bone-anchored hearing aid users: long-term results. J Laryngol Otol. Nov 2011; 125(11): 1131-5. PMID 21774847
- Kraai T, Brown C, Neeff M, et al. Complications of bone-anchored hearing aids in pediatric patients. Int J Pediatr Otorhinolaryngol. Jun 2011; 75(6): 749-53. PMID 21470698
- Allis TJ, Owen BD, Chen B, et al. Longer length Baha abutments decrease wound complications and revision surgery. Laryngoscope. Apr 2014; 124(4): 989-92. PMID 24114744

- Calvo Bodnia N, Foghsgaard S, Nue Moller M, et al. Long-term results of 185 consecutive osseointegrated hearing device implantations: a comparison among children, adults, and elderly. Otol Neurotol. Dec 2014; 35(10): e301-6. PMID 25122598
- Rebol J. Soft tissue reactions in patients with bone anchored hearing aids. Ir J Med Sci. Jun 2015; 184(2): 487-91. PMID 24913737
- Larsson A, Tjellstrom A, Stalfors J. Implant losses for the bone-anchored hearing devices are more frequent in some patients. Otol Neurotol. Feb 2015; 36(2): 336-40. PMID 24809279
- den Besten CA, Nelissen RC, Peer PG, et al. A Retrospective Cohort Study on the Influence of Comorbidity on Soft Tissue Reactions, Revision Surgery, and Implant Loss in Bone-anchored Hearing Implants. Otol Neurotol. Jun 2015; 36(5): 812-8. PMID 25811351
- Mohamad S, Khan I, Hey SY, et al. A systematic review on skin complications of bone-anchored hearing aids in relation to surgical techniques. Eur Arch Otorhinolaryngol. Mar 2016; 273(3): 559-65. PMID 25503356
- Fontaine N, Hemar P, Schultz P, et al. BAHA implant: implantation technique and complications. Eur Ann Otorhinolaryngol Head Neck Dis. Feb 2014; 131(1): 69-74. PMID 23835074
- Hultcrantz M, Lanis A. A five-year follow-up on the osseointegration of bone-anchored hearing device implantation without tissue reduction. Otol Neurotol. Sep 2014; 35(8): 1480-5. PMID 24770406
- Nelissen RC, Stalfors J, de Wolf MJ, et al. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled, clinical investigation. Otol Neurotol. Sep 2014; 35(8): 1486-91. PMID 25080037
- Singam S, Williams R, Saxby C, et al. Percutaneous bone-anchored hearing implant surgery without soft-tissue reduction: up to 42 months of follow-up. Otol Neurotol. Oct 2014; 35(9): 1596-600. PMID 25076228
- Roplekar R, Lim A, Hussain SS. Has the use of the linear incision reduced skin complications in bone-anchored hearing aid implantation?. J Laryngol Otol. Jun 2016; 130(6): 541-4. PMID 27160014
- Hearing loss Association of America. Treatment of Sensorineural Hearing Loss. Irreversible sensorineural hearing loss. Accessed 08/2021
- Bosman AJ, Snik AF, van der Pouw CT, et al. Audiometric evaluation of bilaterally fitted bone-anchored hearing aids. Audiology. May-Jun 2001; 40(3): 158-67. PMID 11465298
- Priwin C, Stenfelt S, Granstrom G, et al. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. Laryngoscope. Jan 2004; 114(1): 77-84. PMID 14709999
- Snik AF, Mylanus EA, Proops DW, et al. Consensus statements on the BAHA system: where do we stand at present?. Ann Otol Rhinol Laryngol Suppl. Dec 2005; 195: 2-12. PMID 16619473

- Ho EC, Monksfield P, Egan E, et al. Bilateral Bone-anchored Hearing Aid: impact on quality of life measured with the Glasgow Benefit Inventory. Otol Neurotol. Oct 2009; 30(7): 891-6. PMID 19692937
- Nelissen RC, Agterberg MJ, Hol MK, et al. Three-year experience with the Sophono in children with congenital conductive unilateral hearing loss: tolerability, audiometry, and sound localization compared to a bone-anchored hearing aid. Eur Arch Otorhinolaryngol. Oct 2016; 273(10): 3149-56. PMID 26924741
- Iseri M, Orhan KS, Tuncer U, et al. Transcutaneous Bone-anchored Hearing Aids Versus Percutaneous Ones: Multicenter Comparative Clinical Study. Otol Neurotol. Jun 2015; 36(5): 849-53. PMID 25730451
- Gerdes T, Salcher RB, Schwab B, et al. Comparison of Audiological Results Between a Transcutaneous and a Percutaneous Bone Conduction Instrument in Conductive Hearing Loss. Otol Neurotol. Jul 2016; 37(6): 685-91. PMID 27093021
- Dimitriadis PA, Farr MR, Allam A, et al. Three year experience with the cochlear BAHA attract implant: a systematic review of the literature. BMC Ear Nose Throat Disord. 2016; 16: 12. PMID 27733813
- Reddy-Kolanu R, Gan R, Marshall AH. A case series of a magnetic bone conduction hearing implant. Ann R Coll Surg Engl. Nov 2016; 98(8): 552-553. PMID 27490984
- Siegert R. Partially implantable bone conduction hearing aids without a percutaneous abutment (Otomag): technique and preliminary clinical results. Adv Otorhinolaryngol. 2011; 71: 41-46. PMID 21389703
- Powell HR, Rolfe AM, Birman CS. A Comparative Study of Audiologic Outcomes for Two Transcutaneous Bone-Anchored Hearing Devices. Otol Neurotol. Sep 2015; 36(9): 1525-31. PMID 26375976
- O'Niel MB, Runge CL, Friedland DR, et al. Patient Outcomes in Magnet-Based Implantable Auditory Assist Devices. JAMA Otolaryngol Head Neck Surg. Jun 2014; 140(6): 513-20. PMID 24763485
- Centric A, Chennupati SK. Abutment-free bone-anchored hearing devices in children: initial results and experience. Int J Pediatr Otorhinolaryngol. May 2014; 78(5): 875-8. PMID 24612554
- Baker S, Centric A, Chennupati SK. Innovation in abutment-free bone-anchored hearing devices in children: Updated results and experience. Int J Pediatr Otorhinolaryngol. Oct 2015; 79(10): 1667-72. PMID 26279245
- Marsella P, Scorpecci A, Vallarino MV, et al. Sophono in Pediatric Patients: The Experience of an Italian Tertiary Care Center. Otolaryngol Head Neck Surg. Aug 2014; 151(2): 328-32. PMID 24714216
- Magliulo G, Turchetta R, Iannella G, et al. Sophono Alpha System and subtotal petrosectomy with external auditory canal blind sac closure. Eur Arch Otorhinolaryngol. Sep 2015; 272(9): 2183-90. PMID 24908070
- Bravo-Torres S, Der-Mussa C, Fuentes-Lopez E. Active transcutaneous bone conduction implant: audiological results in paediatric patients with bilateral microtia associated with external auditory canal atresia. Int J Audiol. Jan 2018; 57(1): 53-60. PMID 28857620

- Rahne T, Seiwerth I, Gotze G, et al. Functional results after Bonebridge implantation in adults and children with conductive and mixed hearing loss. Eur Arch Otorhinolaryngol. Nov 2015; 272(11): 3263-9. PMID 25425039
- Laske RD, Roosli C, Pfiffner F, et al. Functional Results and Subjective Benefit of a Transcutaneous Bone Conduction Device in Patients With Single-Sided Deafness. Otol Neurotol. Aug 2015; 36(7): 1151-6. PMID 26111077
- Riss D, Arnoldner C, Baumgartner WD, et al. Indication criteria and outcomes with the Bonebridge transcutaneous bone-conduction implant. Laryngoscope. Dec 2014; 124(12): 2802-6. PMID 25142577
- Manrique M, Sanhueza I, Manrique R, et al. A new bone conduction implant: surgical technique and results. Otol Neurotol. Feb 2014; 35(2): 216-20. PMID 24448280
- Ihler F, Volbers L, Blum J, et al. Preliminary functional results and quality of life after implantation of a new bone conduction hearing device in patients with conductive and mixed hearing loss. Otol Neurotol. Feb 2014; 35(2): 211-5. PMID 24448279
- Desmet J, Wouters K, De Bodt M, et al. Long-term subjective benefit with a bone conduction implant sound processor in 44 patients with single-sided deafness. Otol Neurotol. Jul 2014; 35(6): 1017-25. PMID 24751733
- Baguley DM, Bird J, Humphriss RL, et al. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. Clin Otolaryngol. Feb 2006; 31(1): 6-14. PMID 16441794
- Leterme G, Bernardeschi D, Bensemman A, et al. Contralateral routing of signal hearing aid versus transcutaneous bone conduction in single-sided deafness. Audiol Neurootol. 2015; 20(4): 251-60. PMID 26021779
- Snapp HA, Holt FD, Liu X, et al. Comparison of Speech-in-Noise and Localization Benefits in Unilateral Hearing Loss Subjects Using Contralateral Routing of Signal Hearing Aids or Bone-Anchored Implants. Otol Neurotol. Jan 2017; 38(1): 11-18. PMID 27846038
- Saroul N, Nicolas S, Akkari M, et al. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device. Otol Neurotol. Jan 2013; 34(1): 111-4. PMID 23202156
- Lin LM, Bowditch S, Anderson MJ, et al. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otol Neurotol. Feb 2006; 27(2): 172-82. PMID 16436986
- Kunst SJ, Leijendeckers JM, Mylanus EA, et al. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results. Otol Neurotol. Jan 2008; 29(1): 2-7. PMID 18199951
- Kunst SJ, Hol MK, Mylanus EA, et al. Subjective benefit after BAHA system application in patients with congenital unilateral conductive hearing impairment. Otol Neurotol. Apr 2008; 29(3): 353-58. PMID 18494142
- Gluth MB, Eager KM, Eikelboom RH, et al. Long-term benefit perception, complications, and device malfunction rate of bone-anchored hearing aid

implantation for profound unilateral sensorineural hearing loss. Otol Neurotol. Dec 2010; 31(9): 1427-34. PMID 20729779
- Faber HT, Nelissen RC, Kramer SE, et al. Bone-anchored hearing implants in single-sided deafness patients: Long-term use and satisfaction by gender. Laryngoscope. Dec 2015; 125(12): 2790-5. PMID 26152833
- Monini S, Musy I, Filippi C, et al. Bone conductive implants in single-sided deafness. Acta Otolaryngol. Apr 2015; 135(4): 381-8. PMID 25720582
- den Besten CA, Nelissen RC, Peer PG, et al. A Retrospective Cohort Study on the Influence of Comorbidity on Soft Tissue Reactions, Revision Surgery, and Implant Loss in Bone-anchored Hearing Implants. Otol Neurotol. Jun 2015; 36(5): 812-8. PMID 25811351
- enters for Medicare & Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage (Rev. 198). 2014; Rev. 189. http://www.cms.gov/manuals/Downloads/bp102c16.pdf
- Centers for Medicare & Medicaid Services. Fact sheets: CMS Updates Policies and Payment Rates for End- Stage Renal Disease Facilities for CY 2015 and Implementation of Competitive Bidding-Based Prices for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. 2014; https://www.cms.gov/newsroom/fact-sheets/cms-updates-policies-and-payment-rates-end-stage-renal-disease-facilities-cy-2015-and-implementation
- U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products. Feb 25, 2009. https://www.fda.gov/media/75418/download.
- U.S. Food and Drug Administration (FDA). Premarket Approval Database. Rockville, MD: FDA. Bonebridge Active Implantable Bone Conduction Hearing System. No: K183373. March 7, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183373.pdf.
- U.S. Food and Drug Administration (FDA). Premarket Approval Database. Rockville, MD: FDA. ADHEAR System. No. K172460. April 27, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172460.pdf.
- Uhler K, Anderson MC, Jenkins HA. Long-Term Outcome Data in Patients following One Year's Use of a Fully Implantable Active Middle Ear Implant. Audiol Neurootol. 2016; 21(2): 105-12. PMID 27031589
- Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Esteem Implantable Hearing System. 2010; https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090018b.pdf.
- Luetje CM, Brackman D, Balkany TJ, et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: a prospective controlled multicenter study. Otolaryngol Head Neck Surg. Feb 2002; 126(2): 97-107. PMID 11870337
- Sterkers O, Boucarra D, Labassi S, et al. A middle ear implant, the Symphonix Vibrant Soundbridge: retrospective study of the first 125 patients implanted in France. Otol Neurotol. May 2003; 24(3): 427-36. PMID 12806295

- Bruchhage KL, Leichtle A, Schonweiler R, et al. Systematic review to evaluate the safety, efficacy and economical outcomes of the Vibrant Soundbridge for the treatment of sensorineural hearing loss. Eur Arch Otorhinolaryngol. Apr 2017; 274(4): 1797-1806. PMID 27796557
- Kahue CN, Carlson ML, Daugherty JA, et al. Middle ear implants for rehabilitation of sensorineural hearing loss: a systematic review of FDA approved devices. Otol Neurotol. Aug 2014; 35(7): 1228-37. PMID 24643033
- Butler CL, Thavaneswaran P, Lee IH. Efficacy of the active middle-ear implant in patients with sensorineural hearing loss. J Laryngol Otol. Jul 2013; 127 Suppl 2: S8-16. PMID 23790515
- Rahne T, Skarzynski PH, Hagen R, et al. A retrospective European multicenter analysis of the functional outcomes after active middle ear implant surgery using the third generation vibroplasty couplers. Eur Arch Otorhinolaryngol. Jan 2021; 278(1): 67-75. PMID 32451668
- Seebacher J, Weichbold V, Schorg P, et al. Subjective Hearing Impression and Quality of Life in Patients With Bilateral Active Middle Ear Implants. Otol Neurotol. Jul 2020; 41(6): e641-e647. PMID 32569243
- Zwartenkot JW, Hashemi J, Cremers CW, et al. Active middle ear implantation for patients with sensorineural hearing loss and external otitis: long-term outcome in patient satisfaction. Otol Neurotol. Jul 2013; 34(5): 855-61. PMID 23739560
- Hough JV, Matthews P, Wood MW, et al. Middle ear electromagnetic semi-implantable hearing device: results of the phase II SOUNDTEC direct system clinical trial. Otol Neurotol. Nov 2002; 23(6): 895-903. PMID 12438853
- Silverstein H, Atkins J, Thompson JH, et al. Experience with the SOUNDTEC implantable hearing aid. Otol Neurotol. Mar 2005; 26(2): 211-7. PMID 15793407
- Frenzel H, Sprinzl G, Streitberger C, et al. The Vibrant Soundbridge in Children and Adolescents: Preliminary European Multicenter Results. Otol Neurotol. Aug 2015; 36(7): 1216-22. PMID 26107139
- Marino R, Linton N, Eikelboom RH, et al. A comparative study of hearing aids and round window application of the vibrant sound bridge (VSB) for patients with mixed or conductive hearing loss. Int J Audiol. Apr 2013; 52(4): 209-18. PMID 23527900
- Colletti L, Mandala M, Colletti V. Long-term outcome of round window Vibrant SoundBridge implantation in extensive ossicular chain defects. Otolaryngol Head Neck Surg. Jul 2013; 149(1): 134-41. PMID 23585147
- Vyskocil E, Riss D, Honeder C, et al. Vibroplasty in mixed and conductive hearing loss: comparison of different coupling methods. Laryngoscope. Jun 2014; 124(6): 1436-43. PMID 24338550
- Atas A, Tutar H, Gunduz B, et al. Vibrant SoundBridge application to middle ear windows versus conventional hearing aids: a comparative study based on international outcome inventory for hearing aids. Eur Arch Otorhinolaryngol. Jan 2014; 271(1): 35-40. PMID 23400404
- Skarzynski H, Olszewski L, Skarzynski PH, et al. Direct round window stimulation with the Med-El Vibrant Soundbridge: 5 years of experience using a technique

without interposed fascia. Eur Arch Otorhinolaryngol. Mar 2014; 271(3): 477-82. PMID 23512431
- de Abajo J, Sanhueza I, Giron L, et al. Experience with the active middle ear implant in patients with moderate-to-severe mixed hearing loss: indications and results. Otol Neurotol. Oct 2013; 34(8): 1373-9. PMID 24005166
- Dillon MT, Tubbs RS, Adunka MC, et al. Round window stimulation for conductive and mixed hearing loss. Otol Neurotol. Oct 2014; 35(9): 1601-8. PMID 25111522
- Beltrame AM, Martini A, Prosser S, et al. Coupling the Vibrant Soundbridge to cochlea round window: auditory results in patients with mixed hearing loss. Otol Neurotol. Feb 2009; 30(2): 194-201. PMID 19180678
- Bernardeschi D, Hoffman C, Benchaa T, et al. Functional results of Vibrant Soundbridge middle ear implants in conductive and mixed hearing losses. Audiol Neurootol. 2011; 16(6): 381-7. PMID 21228566
- Colletti L, Carner M, Mandala M, et al. The floating mass transducer for external auditory canal and middle ear malformations. Otol Neurotol. Jan 2011; 32(1): 108-15. PMID 21131892
- Mandala M, Colletti L, Colletti V. Treatment of the atretic ear with round window vibrant soundbridge implantation in infants and children: electrocochleography and audiologic outcomes. Otol Neurotol. Oct 2011; 32(8): 1250-5. PMID 21897320
- Roman S, Denoyelle F, Farinetti A, et al. Middle ear implant in conductive and mixed congenital hearing loss in children. Int J Pediatr Otorhinolaryngol. Dec 2012; 76(12): 1775-8. PMID 22985678
- Sziklai I, Szilvassy J. Functional gain and speech understanding obtained by Vibrant Soundbridge or by open-fit hearing aid. Acta Otolaryngol. Apr 2011; 131(4): 428-33. PMID 21401449
- Zernotti ME, Arauz SL, Di Gregorio MF, et al. Vibrant Soundbridge in congenital osseous atresia: multicenter study of 12 patients with osseous atresia. Acta Otolaryngol. Jun 2013; 133(6): 569-73. PMID 23448351
- Kraus EM, Shohet JA, Catalano PJ. Envoy Esteem Totally Implantable Hearing System: phase 2 trial, 1-year hearing results. Otolaryngol Head Neck Surg. Jul 2011; 145(1): 100-9. PMID 21493292
- Pulcherio JO, Bittencourt AG, Burke PR, et al. Carina(R) and Esteem(R): a systematic review of fully implantable hearing devices. PLoS One. 2014; 9(10): e110636. PMID 25329463
- Klein K, Nardelli A, Stafinski T. A systematic review of the safety and effectiveness of fully implantable middle ear hearing devices: the carina and esteem systems. Otol Neurotol. Aug 2012; 33(6): 916-21. PMID 22772013
- Barbara M, Biagini M, Monini S. The totally implantable middle ear device 'Esteem' for rehabilitation of severe sensorineural hearing loss. Acta Otolaryngol. Apr 2011; 131(4): 399-404. PMID 21198340
- Barbara M, Manni V, Monini S. Totally implantable middle ear device for rehabilitation of sensorineural hearing loss: preliminary experience with the Esteem, Envoy. Acta Otolaryngol. Apr 2009; 129(4): 429-32. PMID 19117172

- Chen DA, Backous DD, Arriaga MA, et al. Phase 1 clinical trial results of the Envoy System: a totally implantable middle ear device for sensorineural hearing loss. Otolaryngol Head Neck Surg. Dec 2004; 131(6): 904-16. PMID 15577788
- Gerard JM, Thill MP, Chantrain G, et al. Esteem 2 middle ear implant: our experience. Audiol Neurootol. 2012; 17(4): 267-74. PMID 22627489
- Kam AC, Sung JK, Yu JK, et al. Clinical evaluation of a fully implantable hearing device in six patients with mixed and sensorineural hearing loss: our experience. Clin Otolaryngol. Jun 2012; 37(3): 240-4. PMID 22708943
- Monini S, Biagini M, Atturo F, et al. Esteem(R) middle ear device versus conventional hearing aids for rehabilitation of bilateral sensorineural hearing loss. Eur Arch Otorhinolaryngol. Jul 2013; 270(7): 2027-33. PMID 23143506
- Tsang WS, Yu JK, Wong TK, et al. Vibrant Soundbridge system: application of the stapes coupling technique. J Laryngol Otol. Jan 2013; 127(1): 58-62. PMID 23218176
- Savas VA, Gunduz B, Karamert R, et al. Comparison of Carina active middle-ear implant with conventional hearing aids for mixed hearing loss. J Laryngol Otol. Apr 2016; 130(4): 340-3. PMID 26991874
- Barbara M, Volpini L, Monini S. Delayed facial nerve palsy after surgery for the Esteem((R)) fully implantable middle ear hearing device. Acta Otolaryngol. Apr 2014; 134(4): 429-32. PMID 24433055
- Zwartenkot JW, Mulder JJ, Snik AF, et al. Active Middle Ear Implantation: Long-term Medical and Technical Follow-up, Implant Survival, and Complications. Otol Neurotol. Jun 2016; 37(5): 513-9. PMID 27023016
- American Academy of Otolaryngology - Head and Neck Surgery. Position Statement: Active Middle Ear Implants. 2021; https://www.entnet.org/resource/position-statement-active-middle-ear-implants/#:~:text=The%20American%20Academy%20of%20Otolaryngology,otolaryngologist%2Dhead%20and%20neck%20surgeon
- Centers for Medicare & Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage. 2014; https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c16.pdf
- Gurgel RK, Curtis SH, Shelton C. A novel intraoral bone conduction hearing prosthesis: one-year safety and efficacy study. Otol Neurotol. 2015 Jan;36(1):106-10.
- Moore BC, Popelka GR. Preliminary comparison of bone-anchored hearing instruments and a dental device as treatments for unilateral hearing loss. Int J Audiol. 2013 Jul 17.Nicholson N, Christensen L, Dornhoffer J, et al. Verification of speech spectrum audibility for pediatric baha softband users with craniofacial anomalies. Cleft Palate Craniofac J. 2011 Jan;48(1):56-65.
- Hampton T, Milinis K, Whitehall E, et al. Association of Bone Conduction Devices for Single-Sided Sensorineural Deafness With Quality of Life: A Systematic Review and Meta-analysis. JAMA Otolaryngol Head Neck Surg. 2022;148(1):35–42. doi:10.1001/jamaoto.2021.2769. Available at:

https://jamanetwork.com/journals/jamaotolaryngology/article-abstract/2785101?resultClick=1
- American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Bone Conduction Hearing Devices. April 21, 2021. Available at URL address: http://www.entnet.org/content/position-statement-bone-conduction-hearing-devices

POLICY HISTORY		
Date	**Reason**	**Action**
August 2022	Annual Review	Policy Revised
September 2021	Interim Review	Policy Revised
August 2021	Annual Review	Policy Revised
August 2020	Annual Review	Policy Revised
June 2020	Interim Review	Policy Revised
August 2019	Annual Review	Policy Revised
August 2018	Annual Review	Policy Revised
March 2018	Interim Review	Policy Revised
December 2017	Interim Review	Policy Revised
August 2017	Annual Review	Policy Revised
June 2017	Interim Review	Policy Revised
November 2016	Interim Review	Policy Revised
February 2016	Annual Review	Policy Revised
April 2015		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
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