Medical Policy Manual | Surgery, Policy No. 121

Transcutaneous Bone-Conduction and Bone-Anchored Hearing Aids

Effective: June 1, 2025

Next Review: March 2026
Last Review: April 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

External bone-conduction hearing aids function by transmitting sound waves through the bone of the skull to the inner ear.

MEDICAL POLICY CRITERIA

Notes:

- This policy applies *only* to bone-conduction hearing aid systems that are bone anchored (also called bone-anchored hearing aids (BAHAs) or osseointegrated implants) or transcutaneous (non-surgical, secured by a Softband or other method). It does *not* apply to cochlear implants, which are addressed in a separate medical policy (see Cross References), or to intraoral bone-conduction hearing aids.
- Both bone-anchored and transcutaneous bone-conduction systems are hearing aids. There may be specific member benefit language addressing coverage of hearing aids. Any specific contract language supersedes medical policy. Unless otherwise specified, the contract language addressing coverage of hearing aids applies to both bone-conduction hearing aids and externally worn air-conduction hearing aids.

- Oregon HB 4104 Coverage of Hearing Loss Treatments (Oregon Hearing Mandate), effective January 1, 2019, requires coverage of medically necessary hearing aids, including specified replacement supplies, for Oregon members meeting age and educational enrollment requirements. This coverage is detailed in applicable contracts. Note that contract language rather than Criterion IV. may apply for Oregon members meeting the parameters of the Oregon Hearing Mandate.

I. **Unilateral or bilateral transcutaneous bone-conduction or bone-anchored hearing aid(s)** may be considered **medically necessary** as an alternative to air-conduction hearing aid(s) for conductive or mixed hearing loss when all of the following criteria (A.-D.) are met:

   A. Patients who meet any of the following criteria:

      1. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear; or
      2. Chronic external otitis or otitis media; or
      3. Tumors of the external canal and/or tympanic cavity; or
      4. Dermatitis of the external canal.

   B. A bone-conduction pure tone average threshold at 0.5, 1, 2, and 3 kHz no poorer than (i.e. threshold average of 0.5, 1, 2, and 3 kHz no higher than) one of the following (see Policy Guidelines):

      1. 25 dB for ADHEAR; or
      2. 45 dB for OBC, Ponto 3, Ponto 4, BONEBRIDGE, Baha4 and Baha5 devices; or
      3. 55 dB for Ponto 3 Power, BAHA 5 Power, BAHA 6 Max, Osia System (including Osia 2) devices; or
      4. 65 dB for Ponto 3 SuperPower and BAHA 5 SuperPower devices; or
      5. For a device not listed above, average threshold consistent with the device-specific FDA indication.

   C. Meet one of the following age requirements:

      1. 12 years or older for BONEBRIDGE
      2. 5 years or older for all other surgically implanted devices; or
      3. Any age for non-surgically implanted devices; or
      4. For a device not listed above, age consistent with the device-specific FDA indication (See Policy Guidelines).

   D. Patients are to receive either:

      1. A unilateral bone-conduction hearing aid; or
      2. Bilateral bone-conduction hearing aids and have symmetrically conductive or mixed hearing loss (measured without augmentation) as defined by a difference between left- and right-side bone-conduction threshold of less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz (and also 4 kHz for OBC,

Ponto Pro 3, and Otomag Alpha 1 [M]), or less than 15 dB at individual frequencies.

II. **A transcutaneous bone-conduction or bone-anchored hearing aid** may be considered **medically necessary** as an alternative to an air-conduction contralateral routing of signals (CROS) hearing aid in patients five years of age and older with single-sided sensorineural deafness and normal hearing in the other ear.

III. Other uses of transcutaneous bone-conduction or bone-anchored hearing aids, including but not limited to when Criterion I or II is not met and use in patients with bilateral sensorineural hearing loss, are considered **investigational**.

IV. **Implant replacement**, including **replacement parts or upgrades** to existing bone-anchored hearing aids and/or components, may be considered **medically necessary** when components are no longer functional, or for functional devices only in the small subset of patients whose response to existing components is inadequate to the point of interfering with activities of daily living, which would include school and work.

V. **Implant replacement,** including **replacement parts or upgrades** to existing bone-anchored hearing aids and/or components are considered **not medically necessary** when Criterion IV. is not met, including but not limited to when requested for convenience or technology upgrade. Replacement parts or upgrades include, but are not limited to batteries, processors, headbands or Softbands. This criterion may not apply to Oregon members who meet the parameters of the Oregon Hearing Mandate (see applicable contracts for details).

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

HEARING TESTS

Pure tone hearing tests measure the faintest level (hearing threshold) at which a tone can be heard at selected frequencies approximately 50% of the time. Lower thresholds represent better hearing.

Each ear is tested separately. The pure tone average threshold hearing level is calculated separately for each ear by averaging the hearing levels at each frequency. For example, if a patient's bone-conduction hearing threshold in the right ear at frequencies 0.5, 1, 2, and 3 kHz is 20, 20, 30, and 40 dB, respectively, the pure tone average for that ear is (20 + 20 + 30 + 40) divided by 4 = 27.5 dB.

Bone-conduction hearing is necessary for bone conduction hearing aids to provide value. The threshold required depends on the specific device, as listed in the policy criteria and in the FDA approval documentation. For example, given that lower thresholds represent better hearing, a bone-conduction pure tone average threshold of 40 dB would meet the criteria of no poorer than (*no higher than*) 45 dB (e.g. for the Ponto 3 device), while a bone-conduction pure tone average threshold of 50 dB would *not* meet the criteria of no poorer than (*no higher than*) 45 dB, but it would meet the criteria of no poorer than (*no higher than*) 55 dB (e.g. for the Ponto 3 Power device).

FDA APPROVAL

FDA-approved indications can be found by searching by device name in the FDA 510(k) Premarket Notification Database or the De Novo Database and viewing the Summary. Product codes for these devices include LXB, MAH, and PFO.

LIST OF INFORMATION NEEDED FOR REVIEW

SUBMISSION OF DOCUMENTATION

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Audiology test results

CROSS REFERENCES

1. Cochlear Implant, Surgery Policy No. 8

BACKGROUND

Conventional external hearing aids can be generally subdivided into air-conduction hearing aids and bone-conduction hearing aids. Air-conduction hearing aids require the use of ear molds, which may be problematic in patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. In these patients, bone-conduction hearing aids may be an alternative.

External bone-conduction hearing aids historically were closely applied to the temporal bone with either a steel spring over the top of the head or with the use of a spring-loaded arm on a pair of spectacles. These devices may be associated with either pressure headaches or soreness. Partially implantable bone-conduction hearing aids have been investigated as an alternative, and external bone-conduction hearing aids applied with less or no pressure have also become available.

The bone-anchored hearing aid (BAHA) implant systems, also called osseointegrated devices, work by combining a vibrational transducer coupled directly to the skull via a percutaneous abutment that permanently protrudes through the skin from a small titanium implant anchored in the temporal bone. The system is based on the process of “osseointegration” through which living tissue integrates with titanium in the implant over a period of three to six months, allowing amplified and processed sound to be conducted via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing aids.

Baha sound processors can also be used with the Baha® Softband™. With this application there is no implantation surgery. The sound processor is attached to the head using either a hard or soft headband. The band can be adjusted to the individual's head size. The amplified sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. These devices have been suggested as a bridge to bone anchor implantation in young children who are not eligible for the implant due to young age and/or bone strength/thickness not yet adequate. The recently approved ADHEAR device attaches with an adhesive and no headband is required.

Partially implantable magnetic bone conduction hearing systems, also referred to as transcutaneous bone-anchored systems, are an alternative to bone conduction hearing systems connected percutaneously via an abutment. With this technique, acoustic transmission occurs transcutaneously via magnetic coupling of the external sound processor and the internally implanted device components. The bone conduction hearing processor contains a magnet that adheres 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 facilitate greater transmission of acoustics between magnets, skin thickness may be reduced to 4-5 mm over the implant when it is surgically placed.

REGULATORY STATUS

The following *Baha® sound processors, currently marketed by Cochlear™ (formerly called Cochlear™ Americas), have received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for use with the Baha auditory osseointegrated implant (hearing aid) systems (such as the Baha® Connect and Attract systems):

- Baha® 5 Sound Processor
- Baha® 5 SuperPower Sound Processor
- Baha® 5 Power Sound Processor
- Baha® 6 Max Sound Processor

The above devices are currently available from Cochlear™. However, predicate devices include the Baha®4, Cordelle II, Divino®, Intenso™ and BP100™.

*Note: These devices may be referred to as Cochlear™ Baha® systems or Cochlear osseointegrated implants, reflecting the manufacturer’s name. These devices are bone conduction hearing aids and *should not* be confused with cochlear implants which are prostheses that replace a damaged or absent cochlea in the inner ear. Cochlear implants are addressed in a separate medical policy (see Cross References).

The FDA approved the Cochlear™ Baha® system (initially approved under the trade name Branemark Bone-Anchored Hearing Aid [BAHA™] by Entific Medical Systems, Inc.) for use in children aged five years and older, and in adults, for the following indications:

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

Baha sound processors can also be used with the Baha® Softband and Baha® SoundArc. The Baha® Softband received FDA clearance in 2002 for use in children under the age of five years. The Baha® SoundArc received FDA clearance in 2017 for use in people of any age.

Subsequent bone conduction hearing systems (listed below) share similar indications as the Cochlear™ Baha® devices:

- OBC Bone Anchored Hearing Aid System (Oticon Medical)
- Sophono® (S) (Cochlear) (predicate device was Otomag [Sophono])
- Ponto Pro, Ponto Plus, Ponto Plus Power, Ponto 3, Ponto 3 Power, Ponto 3 SuperPower,Ponto 4 and Ponto 5 SuperPower processors (Oticon Medical), to be used with the Oticon or BAHA osseointegrated implant.

The MedEl ADHEAR device, which has no implantable components, received FDA 510(k) clearance with the Contact Mini (audiofon) and BAHA 5 (Cochlear) as predicate devices.

The following partially implantable magnetic bone conduction devices have received FDA 510(k) clearance:

- Sophono® (M) (Cochlear) (predicate device was Otomag Alpha [Sophono])
- Sophono™ Alpha 2 MPO™ (Medtronic)
- Baha® Attract (Cochlear®)

The BoneBridge™ (MedEl) partially implantable bone-conduction hearing aid received FDA approval via the de novo pathway in 2018.

Cochlear™ Osia® System

- The Osia™ (Cochlear) bone-conduction hearing aid received FDA 510(k) approval with BoneBridge™ as the predicate device in July 2019 (K190589). the Osia System is approved for 12 years and older.
- The Cochlear™ Osia™ 2 System received FDA 510(k) approval with Osia™ as the predicate device in November 2019.
- The updated Cochlear™ Osia™ 2 System received FDA 510(k) approval in July 2022 (K220922)
- The Cochlear™ Osia® System replaced the Osia 2 system and received FDA 510 (k) approval in July 2023. The system remains approved for 12 years and older. (K231204)
- In January of 2024, The Cochlear™ Osia® System and received FDA 510(k) approval with the Osia and Osia 2 systems as predicate devices. This change for the Osia System introduces an expanded indication from 12 years of age or older to 5 years of age or older. (K240155).

EVIDENCE SUMMARY

Hearing results of semi-implantable bone-conduction hearing aids may be compared either to 1) external bone-conduction hearing aids in patients with atresias who are unable to use external air-conduction hearing aids, or 2) external air-conduction hearing aids in patients who are unable to tolerate air-conduction hearing aids due to chronic infection. Reported studies have suggested that the bone-anchored hearing aid (BAHA) is associated with improved hearing outcomes compared to external bone-conduction hearing aids and equivalent outcomes compared to conventional air-conduction hearing aids.[1-4] However, given the objectively measured outcomes and the largely invariable natural history of hearing loss in individuals who would be eligible for an implantable bone-conduction device, a within-subjects comparison of hearing before and after device placement may be a reasonable study design.

UNILATERAL DEVICES

Systematic Review

In 2017 Kim conducted a systematic review on the efficacy of BAHAs in single-sided deafness, including 14 studies (n=296 patients). The reviewers reported that in the six studies that dealt with sound localization, no significant difference was found after the implantation. However, twelve studies showed the benefits of BAHAs for speech discrimination in noise. Regarding subjective outcomes of using the prosthesis in patients with SSD (abbreviated profile of hearing aid benefit [APHAB] and the Glasgow hearing aid benefit profile [GHABP], etc.), improvements in quality of life were reported in the majority of studies.

This systematic review has indicated that BAHAs may successfully rehabilitate patients with SSD by alleviating the hearing handicap to a certain degree, which could improve patients' quality of life. This report has presented additional evidence of effective auditory rehabilitation for SSD and will be helpful to clinicians counseling patients regarding treatment options for SSD

In a 2015 Peters published a systematic review of the literature through April 7, 2014 on the use of BAHA devices with contralateral routing of sound systems for single-sided deafness (SSD).[5] Five[6-10] of the six studies that met inclusion criteria were rated as moderate to high directness of evidence and low to moderate risk of bias and, thus, were included in the review. Significant heterogeneity was found in the 91 total patients included. For speech perception in noise there was not consistent improvement with aided hearing over unaided hearing in all environments. All studies reported equal sound localization in the aided and unaided conditions, and quality of life measures were similar for the aided and unaided conditions. Interpretation of these outcomes was limited by the methodological limitations of the included studies, including the lack of RCTs, unclear inclusion criteria, small sample sizes, use in some studies of headband devices which have different bone conduction thresholds in the higher frequencies than implanted devices, clinical heterogeneity of included populations (e.g., duration of deafness, grade of hearing loss), unexplained missing data, and lack of long-term audiometric follow-up. The authors also noted that the lack of recent studies was surprising considering the recent advances in these devices and recommended high-quality studies on the clinical outcome of current devices.

Randomized Controlled Trials

No RCTs of unilateral BAHAs have been published.

Nonrandomized Studies

One retrospective study (Wazen 2021) compared results of BAHA implantation for SSD based on bone-conduction pure tone average (PTA) of the better-hearing ear.[11] Subjects were divided into three groups by bone conduction PTA of the better hearing ear, with the ranges of 0 to 20 dB, 21 to 40 dB, and 41 to 55 dB. All three groups showed statistically significant improvement in bone conduction PTA and quality of life.

Additionally, since publication of the Peters systematic review, the following prospective, interventional studies compared patient satisfaction with transcutaneous BAHA devices to CROS hearing aids for SSD.

Jakob (2021) compared long-term (one-year) results in patients with SSD who chose between a CROS, a BAHA, and a cochlear implant (CI) following a three-week test phase with CROS and a bone-anchored hearing system.[12] At the one-year follow up, study results showed an improvement in speech comprehension when speech was delivered to the deaf ear and noise to the hearing ear for the BAHA ($p=0.008$; median unaided=0%, median 12 m=40.59) and CI ($p<0.001$), but the CROS group had poorer speech comprehension compared to the unaided situation (median unaided=98.58%; median 12 m=64.62%, $p=0.603$). Localization error was significantly reduced in the CI group after 12 months (median unaided 26.36°, median CI 12 m=15.43°; $p<0.001$) compared to the unaided conditions. No differences in localization error were found for the BAHA or CROS groups.

den Besten (2019) 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.[13] No statistically significant difference in audiological outcomes was seen between the two devices ($p>0.05$). At a six-month follow-up after implantation, patients reported numbness (20%) and slight pain/discomfort (38%) associated with the device.

Choi (2019) compared the performance of contralateral routing of signal (CROS)/bilateral routing of signal (BiCROS) and soft-band bone-anchored hearing aid (BAHA) devices in 21 patients with unilateral sensorineural hearing loss.[14] All participants were naïve to hearing devices. Sound localization, speech perception, psychoacoustic performance, and subjective assessments were analyzed. The subjects were assessed with each device and in the unaided condition. Sound localization was not improved in the soft-band BAHA condition and was significantly impaired with the CROS/BiCROS. Both devices significantly improved speech-in-noise perception when targeted to the impaired ear side. With regard to psychoacoustic performance, temporal resolution was significantly decreased with the BAHA compared to the unaided condition and CROS/BiCROS. There were no significant differences reported for preference between devices or subjective assessments of background noise or sound quality.

In 2017, Snapp reported a prospective single-center study of 27 patients with unilateral severe-profound sensorineural hearing loss who had either a CROS (n=13) or transcutaneous BAHA (n=14) device.[15] 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 (GHABP).

Leterme (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.[16] Most patients (72%), after completing trials of both devices, preferred the BAHA device to hearing aid with CROS. Glasgow Benefit Index and Abbreviated Profile of Hearing Aid Benefit (APHAB) scores did not differ significantly between devices. Sixteen of the 18 subjects elected to undergo implantation of a percutaneous BAHA device. In general, hearing improvement with the Baha Softband trial correlated with hearing improvements following device implantation.

BILATERAL DEVICES

Use of bilateral devices has been evaluated in nonrandomized studies of patients with conductive or mixed hearing losses. In general, bilateral BAHAs seem to provide additional objective and subjective benefit compared with unilateral BAHAs.

Systematic Reviews

Heath (2022) conducted a systematic review (SR) of studies that compared outcomes between bilateral and unilateral BAHA for patients with no benefit from conventional hearing aids.[17] A total of 14 articles were included; all studies were retrospective with the exception of one case report, and all studies had a substantial risk of bias. A meta-analysis was not performed, but descriptive comparison found that bilateral BAHA were associated with greater improvement in hearing thresholds, understanding speech, and localization. Unilateral BAHA were more effective when noise was one-sided. All studies reported improvement in quality of life.

A systematic review by the Health Technology Assessment Program was published in 2011 on the use of bone-anchored hearing aids (BAHAs) for bilateral hearing impairment.[18 19]The authors noted that the quality of available studies on the use of BAHAs is weak. No studies with control groups were identified for the review. Cohort pre-post studies and cross-sectional comparative studies demonstrated improvements in hearing with use of BAHAs over conventional bone-conduction hearing aids or unaided hearing. However, whether improvements in hearing with BAHAs are greater than air-conduction hearing aids is uncertain. Additionally, bilateral use of BAHAs improved hearing outcomes in some patients over unilateral use, but the evidence was uncertain. Implant loss was noted to be between 6.1% and 19.4%. The authors noted hearing-specific quality of life improved, but overall quality of life did not differ.

In 2012 Janssen reported similar findings in a systematic review that assessed the outcomes of bilateral versus unilateral BAHA for individuals with bilateral permanent conductive hearing loss (CHL).[20] Their search strategy included studies of all languages published between 1977 and July 2011. Studies were included if subjects of any age had permanent bilateral CHL and bilateral implanted BAHAs. Outcome measures of interest were any subjective or objective audiologic measures, quality of life indicators, or reports of adverse events. Eleven studies met their inclusion criteria. All 11 studies were observational. There were a total of 168 patients in the 11 studies, 155 of whom had BAHAs and 146 of whom had bilateral BAHAs. In most studies, comparisons between unilateral and bilateral BAHA were intra-subject. Patients ranged from 5 to 83 years of age; 46% were male, and 54% were female. Heterogeneity of the methodologies between studies precluded meta-analysis, therefore a qualitative review was performed. Results from three 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 included studies. In general, bilateral BAHA was observed to provide additional objective and subjective benefit compared to unilateral BAHA. For example, the improvement in tone thresholds associated with bilateral BAHA ranged from 2 to 15dB, the improvement in speech recognition patterns ranged from 4 to 5.4dB, and the improvement in the Word Recognition Score ranged from 1 to 8%. However, these results were based on a limited number of small observational studies consisting of heterogeneous patient groups that varied in age, severity of hearing loss, etiology of hearing loss, and previous amplification experience.

Randomized Controlled Trials

No RCTs of bilateral BAHAs have been published.

Nonrandomized Studies

No new studies have been published since the most recent systematic review.

BONE-ANCHORED HEARING AID DEVICES IN CHILDREN UNDER AGE FIVE YEARS

Nonrandomized Studies

The literature on the use of these devices in children consists of a review article and several nonrandomized studies.

The largest series in children under five years identified for this review, described by Amonoo-Kuofi in 2015, which included 24 children identified from a single center's prospectively maintained database.[21] Most patients underwent a 2-stage surgical approach. The largest proportion of patients (52%) received the implant for isolated microtia, followed by Goldenhar syndrome (16%). Following implantation, 13 patients (54%) had grade 2 or 3 local reactions on the Holgers Scale (redness, moistness, and/or granulation tissue) and 7 (29%) had grade 4 local reactions on the Holgers Scale (extensive soft-tissue reaction requiring removal of the abutment). Quality of life scores (Glasgow Children's Benefit Inventory [GCBI]; scoring range, -100 to 100) were obtained in 18 subjects/parents with a finale mean score change of +40 points. Audiologic testing indicated that the average performance of the device fell within the range of normal auditory perception in noisy and quiet environments.

Marsella (2012) reported on their center's experience with pediatric BAHA in all 47 children implanted, seven of which were younger than five years of age.[22] The functional gain was significantly better with BAHA than with conventional bone-conduction hearing aids. There was no significant difference in terms of functional outcome between the seven patients younger than age five and the rest of the patient cohort. Based on these findings, the study authors suggested that implantation of children at an age younger than five years can be conducted safely and effectively in such settings. However, the conclusions from this study were limited by the small number of children younger than five years of age and the limited power to detect a difference between younger and older children.

A 2008 review article noted that for children younger than age five years, other solutions (such as a bone conductor with transcutaneous coupling) should be utilized.[23] This recommendation is in agreement with the FDA clearance of the osseointegration implant only for children five years of age and older, and adults.

McDermott (2008) reported on the role of BAHAs in children with Down syndrome in a retrospective case analysis and postal survey of complication rates and quality of life outcomes for 15 children aged 2 to 15 years.[24] All patients were using their BAHA devices after a follow-up of 14 months. No fixtures were lost, and skin problems were encountered in three patients. All 15 patients had improved social and physical functioning as a result of better hearing.

Davids (2007) at the University of Toronto provided BAHA devices to children less than five years of age for auditory and speech-language development and retrospectively compared surgical outcomes for a study group of 20 children five years or younger and a control group of 20 older children.[25] Children with cortical bone thickness greater than 4 mm underwent a single-stage procedure. The interstage interval for children having 2-stage procedures was significantly longer in the study group to allow implantation in younger patients without increasing surgical or postoperative morbidity. Two traumatic fractures occurred in the study group versus four in the older children. Three younger children required skin site revision. All children were wearing their BAHA devices at the time of writing.

BAHA SOFTBAND AND ADHESIVE HEARING DEVICE USE IN CHILDREN

Nonrandomized Studies

The current evidence consists of small retrospective studies and comparative studies. Externally worn AOD sound processors appears to consistently be beneficial for children under age five years with bilateral aural atresia who are too young to receive an implantable device.[26-28]

A 2014 report compared use of the Softband in 16 children (ages ranging from three months to six years) with bilateral aural atresia to 29 normal-hearing children (ages ranging from eight months to six years).[29] Auditory development was assessed at baseline, six months, and 12 months. The full text of the article was not available and the abstract did not provide data from the normal-hearing children for comparison. The authors concluded that the Softband was a suitable bridge to surgical implantation in infants and young children with bilateral atresia.

Ramakrishnan used the Glasgow Benefit Inventory (GBI) and Listening Situation Questionnaire to report quality of life findings in a retrospective cross-sectional survey administered to parents of 22 children (n=109 total participants), some with skull and congenital/chromosomal abnormalities from inherited syndromes that involve unilateral (hemifocal microsomia) or bilateral hearing impairment (Treacher-Collins Syndrome, n=4 of 22) due to microtia or aural atresia.[30] The youngest child utilizing an externally worn BAHA with Softband was six months of age. Overall, parents reported short-term satisfaction in the mean GBI scores for the children after three months of implanted BAHA or externally worn BAHA with Softband use. Despite the heterogeneous etiology of children in the study population, the authors suggest that the utility of BAHAs for children with syndromes and craniofacial anomalies is poorly recognized, resulting in delays in aid fitting and therefore in early hearing rehabilitation. In such cases, surgical reconstruction of the ear canal and middle-ear defects is not only technically challenging but also plagued by poor results (with a high rate of ear canal restenosis and limited functional hearing benefit). Hence, alternative treatment options such as Softband and BAHA may be of considerable benefit.

In 2010 Christensen reported on a retrospective chart review of 10 children (ages 6 months to 16 years) with bilateral conductive hearing loss.[31] Participants had been initially fit with a traditional bone-conduction hearing aid, then progressed first to the externally worn AOS with the Softband, then to the implanted BAHA. Functional gain was measured at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz for each device. Both the external AOS and the implanted BAHA provided statistically significantly higher functional gain than the conventional BCHAs.

A number of the same authors for the Christensen study also reported the results of a retrospective chart review of 25 children aged 6 months to 18 years with craniofacial disorders and bilateral conductive hearing loss.

It is unknown whether some of the children in the 2010 study were also included in these results. The focus of this study was on functional as measure by comparison of aided (using the Baha Softband) and unaided soundfield audiometric thresholds. Soundfield thresholds were improved with the Baha amplification, with over 80% of the thresholds meeting significant target levels. The authors concluded that this demonstrated the benefit of the Baha for children with bilateral congenital conductive hearing loss.

Hol (2008) evaluated the validity of a BAHA with Softband (fitted unilaterally and bilaterally) in two young children with severe bilateral conductive hearing loss due to CAA.[32] In a small multicenter comparative study, 12 children (including the two children in the Hol, 2005 study) with bilateral CAA with a pure conductive hearing loss of around 60 dB HL were fitted with the BAHA with Softband.[33] These children were retrospectively compared to a reference group of eight children selected from a database of those who had a conventional bone conduction hearing aid for bilateral CAA. The authors reported the mean aided hearing threshold of the children with the BAHA with Softband compared to the reference group was 27 dB HL, ± 6 dB

HL to 25 dB HL ± 6 dB HL, respectively. Further results compared psychological and language development in 5 of the 12 children available from the BAHA with Softband group.

ADVERSE EFFECTS OF BAHAS

Systematic Reviews

Hernández (2021) reported a retrospective chart review the frequency of cutaneous complications due to surgically implanted BAHAs.[34] Of the 88 patients identified (a total of 104 devices) with a minimum of six months of follow-up, 49 (55.7%) developed at least one episode of inflammatory or infectious skin reaction at the surgical incision site (mostly mild in severity), while 47 (53.4%) reported pain at the surgical site unrelated to clinically evident infection at some point during the follow-up.

Schwab (2020) completed a systematic review of adverse events associated with bone-conduction and middle-ear implants.[35] 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, reimplantation, failure to osseointegrate, and minor skin complications.

In 2016, Verheij published a systematic review on complications of tissue preservation surgical techniques with percutaneous BAHA devices including 18 studies with 381 devices.[36] The implantation techniques reported in the studies were as follows: punch method, four studies (81 implants); linear incision technique without soft tissue reduction, 13 studies (288 implants); and Weber technique, one study (12 implants). Indications for surgery were SSD (n=68), sensorineural hearing loss (n=4), mixed hearing loss (n=65), or CHL (n=66). The Holgers classification was used to grade soft tissue reactions (grade 0, no reaction; grade 2, red and moist tissue; grade 3, granulation tissue; grade 4, removal of skin-penetrating implant necessary due to infection). The incidence of Holgers 3 was 2.5% with the punch technique, 5.9% with the linear incision technique, and 0% with the Weber technique. Holgers 4 was reported in one patient implanted with the linear incision technique.

In 2014 Mohamad performed a systematic review focusing on the association between surgical technique and skin complications following BAHA implantation. Thirty randomized controlled trials and retrospective studies were included, which highlighted that the most common surgical techniques identified were full-thickness skin graft, dermatome and linear incision. The investigators reported that dermatome technique is associated with higher rate of skin complications and the use of a linear incision technique is associated with lower skin complications. However, the investigators concluded that the data to support these conclusions in limited and that higher quality studies are needed.[37]

In 2103 Kiringoda reported on a meta-analysis of complications related to BAHA devices. Included in the meta-analysis were 20 studies that evaluated complication in 2134 adult and pediatric patients who received a total of 2310 BAHA devices.[38] The quality of available studies was considered poor and lacking in uniformity. The most common complications related to BAHA devices were minor skin reactions. Holgers Grade 2 to 4 skin reactions were reported to occur from 2.4% to 38.1% in all studies. Zero to 18% of implants failed osseointegration in adult and mixed population studies while 0% to 14.3% failed osseointegration in pediatric population studies. Adult and mixed population studies reported revision surgery was required in 1.7% to 34.5% of cases while pediatric population studies reported required revision surgery in 0.0% to 44.4% of cases. Implant loss occurred in 1.6% to 17.4% in adult and mixed population studies and from 0.0% to 25% in pediatric studies.

Nonrandomized Studies

In 2016, Roplekar 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 one year of follow-up.[39] Twenty-one (24%) patients experienced skin-related complications in the skin flap group (12 skin overgrowths, eight wound infections, one numbness) and three (10%) patients experienced complications in the linear incision group (three wound infections).

Four 2014 retrospective studies reported specific complication rates related to BAHA implants. The rate of skin reaction (e.g., skin overgrowth, inflammation) ranged from 6% to 22%. Implant loss was 10-18% and were spontaneous while others required removal; the primary reasons for implant loss were loss of osseointegration, trauma, and soft tissue reactions or discomfort. In addition, a number of small studies reported the safety outcomes of various techniques for surgically implanting BAHA devices. These included skin flap versus full-thickness skin graft implantation[40], non-skin-thinning technique versus either flap or dermatome implantation[41], and techniques related to implant size[42 43].

Section Summary: Safety and Adverse Events Related to BAHA Devices

The quality of available data for adverse events is generally poor with high heterogeneity. The most frequently reported complication from surgical procedures for BAHA insertion are adverse skin reactions, with an incidence of Holgers grade 2 to 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 improvement in complication rates and severity with newer surgical techniques such as linear incision.

PARTIALLY IMPLANTABLE MAGNETIC BONE CONDUCTION HEARING AIDS

A small body of literature addresses outcomes associated with transcutaneous, partially implantable bone-anchored devices. The majority of studies use a within-subjects comparison of hearing thresholds with and without the device. The indications for partially implantable systems are the same as those for transcutaneous bone-anchored devices.

Systematic Reviews

Key (2024) published a systematic review and meta-analysis examining the functional gain of the transcutaneous Osia hearing device compared to unaided hearing.[44] The study analyzed 14 studies with 15 patient cohorts, totaling 314 subjects. Results showed a pooled overall mean functional gain of 35.0 dB SPL (95% CI 29.12-40.97) for all hearing loss types, with conductive/mixed hearing loss showing a gain of 37.7 dB SPL (95% CI 26.1-49.3). Complication rates were low, with explantation at 0.11% (95% CI 0.00%-1.90%) and wound infection at 1.92% (95% CI 0.00%-6.17%). Limitations included inability to calculate pooled single-sided deafness functional gain due to small patient cohorts, lack of direct comparison studies with other transcutaneous devices, and limited data on frequency-specific gain and patient-reported outcomes measures.

Gutierrez (2024) published a SR comparing quality of life (QOL) outcomes of percutaneous and transcutaneous bone conduction devices (pBCD and tBCD, respectively).[45] A total of 52 articles with 1,469 patients were included. Six hundred eighty-nine patients were implanted with pBCDs, and the remaining 780 were implanted with tBCDs. Average Glasgow Benefit Inventory scores for the tBCD group (33.0, 95% confidence interval [22.7-43.3]) were significantly higher than the pBCD group (30.9 [25.2-36.6]) (Δ2.1 [1.4-2.8], $p < 0.0001$). Mean Glasgow Children's Benefit Inventory scores (Δ3.9 [2.0-5.8], $p = 0.0001$) and mean gain in Abbreviated Profile of Hearing Aid Benefit scores (Δ5.6 [4.8-6.4], $p < 0.0001$) were significantly higher among patients implanted with tBCDs than those implanted with pBCDs. Patients implanted with tBCDs also had significantly higher gains on the Speech (Δ1.1 [0.9-1.3], $p < 0.0001$), Spatial (Δ0.8 [0.7-0.9], $p < 0.0001$), and Qualities of Hearing (Δ1.2 [1.1-1.3], $p < 0.0001$) portions of the Speech, Spatial, and Qualities of Hearing Scale than those implanted with pBCDs. The authors conclude that patients implanted with transcutaneous devices had better QOL outcomes than those implanted with percutaneous devices.

Bezdjian (2017) published a systematic review of noncomparative studies that assessed outcomes and adverse events in patients with Sophono implants.[46] Thirteen articles were assessed for directness of evidence (DoE) and risk of bias (RoB) using predetermined criteria. Of these, eight studies (including 86 patients; 79.1% children) were considered to have high enough quality for data extraction. These studies all had medium or low risk of bias and high directness of evidence. A pooled analysis of all studies showed an average unaided pure tone average of 63.70 dB and an aided pure tone average of 31.60 dB. Four studies reported unaided and aided sound reception thresholds in raw dB scores. A pooled analysis of these studies showed a mean unaided score of 66.90 dB and a mean aided score of 33.34. No intra-operative complications were reported and 29% of patients reported post-operative complications. Of these, three were serious adverse events. No implant loss occurred, except in one patient who requested explantation due to severe headaches. While there were improvements in auditory functions, no statistical analyses were reported.

In 2016, Dimitriadis reported on a systematic review of observational studies of the BAHA Attract device including 10 studies (total n=89 patients; range, 1 to 27 patients).[47] Seventeen (19%) of the patients were children, of whom five 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 postimplantation showed improvement, although statistical comparisons were lacking in some studies.

Randomized Studies

Gawecki (2022) completed a small randomized study that compared patients who received the Osia system (n=4) or the Baha Attract system (n=4) for bilateral mixed hearing loss.[48] After implantation, the mean gain in PTA was 42.8 ± 4.9 dB in the Osia group and 38.8 ± 8.5 dB in the Baha group. Patient ratings of hearing quality were better in the Osia group based on subjective Likert scores of sound loudness, sound distinctness, and hearing of own voice. Patient reported voice quality scores for reverberation were similar in the Osia and Baha groups. Both groups reported improved quality of life based on global Abbreviated Profile of Hearing Aid Benefit scores but there was a numerically larger improvement in the Osia group. Results for the Speech, Spatial and Qualities of Hearing Scale improved in both groups and were slightly better in the Baha group. The authors concluded that larger studies with longer follow-up are needed to evaluate differences in outcomes between these two systems.

Nonrandomized Studies

Brooks (2025) published a retrospective cohort study examining the outcomes of off-label MED-EL Bonebridge implantation in pediatric patients.[49] The study compared two groups: patients under 12 years (20 patients, 25 implants) and patients 12 years and older (17 patients, 23 implants). Results showed that younger patients achieved significantly better post-implantation speech recognition thresholds (median 22.5 dB) compared to older patients (median 35 dB, $p < 0.001$). Both groups demonstrated similar performance on age-appropriate wordlists at 50 dB HL in aided conditions and had comparable low complication rates (9% vs 8%). Operative times were also similar between groups ($p = 0.96$).

Kim (2022) compared the effects of the Osia system with the Baha Attract and Bonebridge systems in 67 patients with CHL or mixed hearing loss or single-sided deafness (SSD).[50] Patients who received the Osia system (n=17) were prospectively recruited and retrospectively compared with patients who received the Baha Attract or Bonebridge systems (n=50). Effective gains in bone conduction threshold at 2 kHz were 11.1 ± 14.9 dB in the Osia group compared to -2.7 ± 12.6 dB in the Baha Attract and Bonebridge group (combined) among patients with CHL or mixed hearing loss (p=0.01). Among patients with SSD, average functional gains at 4 kHz were 37.5 ± 8.9 dB in the Osia group, 21.7 ± 15.7 dB in the Baha Attract group, and 29.0 ± 13.0 dB in the Bonebridge group.

Iseri (2015) described a retrospective, single-center study from Turkey comparing 21 patients treated with a transcutaneous, fully implantable BAHA with 16 patients treated with a percutaneous device (the BAHA Attract).[51] 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 Holger grade 2 skin reactions, and two had stopped using their devices. 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).

There have been other, small nonrandomized studies that have assessed the outcomes of the BAHA Attract device, in comparison with other devices, or in single-center observational studies.[52-54] In addition, one case series of 34 patients has reported on complications of the BAHA attract device, where only three patients reported moderate to severe complications, two of which required removal of the magnet.[55]

In 2015, Denoyelle 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.[56] 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 six-month follow-up, mean aided AC pure-tone audiometry was 33.49 (mean gain, 35.53 dB), with a mean aided sound reception threshold of 38.2 (mean gain, 33.47 dB). The difference in AC pure tone average (PTA) between the Baha Softband and the Sophono device was 0.6 dB (confidence interval upper limit, 4.42 dB), which met the study’s prespecified noninferiority margin. Adverse effects were generally mild, including skin erythema in two patients, which improved by using a weaker magnet, and brief episodes of pain or tingling in three patients.

The Otomag Sophono system has been studied in a number of very small (n=5 to 12) nonrandomized studies in pediatric patients.[52 53 57-63]

Similarly, the Bonebridge partially implantable system has also been studied in a number of small (n=5 to 44) case series, summarized in table 1.[64-70]

Table 1. Case Series Evaluating the Bonebridge Implant

Study	N	Patient Population	Main Hearing Results	Safety Outcomes
Seiwerth (2021)[71]	31	• Seven cases age <16 • 30 unilateral implantations • 1 bilateral implantation	• Mean sound-field threshold improvement at three and six months: 27 and 26 dB • WRS in quiet improved from 11% preoperatively to 74% three months postoperatively • Speech reception threshold in noise improved from -1.01 dB unaided to -2.69 dB best-aided	Not reported
Garcier (2021)[72]	24	• Adults with mixed hearing loss	• Average prosthetic gain in chronic otitis media vs. other etiologies: 43±4.8 dB and 50 ± 7.2, respectively • Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire global score improved: 32 ± 10.2%	No major complications. Local pain on the analogue visual scale was 3.23 ± 3.2 (n = 16 reporting) and manipulation difficulties were 3.1 ± 3.69
Bravo-Torres (2018)[73]	15	• Pediatric patients with bilateral CHL (microtia associated with external auditory canal atresia)	• Aided sound-field threshold improvement: 25.2 dB	Minor feedback (4), broken processors (4), mild skin redness (2) with one-month follow-up
Schmerber (2017)[74]	25	• SSD (n=12) • Bilateral CHL (n=7) • Bilateral mixed HL (n=6)	• SSD, in 5/7 patients speech reception threshold in noise lower with Bonebridge activated • CHL and mixed, average functional gain: 26 dB HL; mean % of speech recognition in quiet improved from 74% unaided to 95% aided	No complications, device failures, revision surgery, or skin injury reported with one year follow-up
Rahne (2015)[69]	11	• SSD (n=6; 1 sensorineural, 3 mixed, 2 conductive)	• Aided sound-field threshold improvement: 33.4 dB • WRS improved from mean of 10% unaided to 87.5% aided	One case of chronic fibrosing mastoiditis

Study	N	Patient Population	Main Hearing Results	Safety Outcomes
		• Bilateral CHL (n=2) • Bilateral mixed HL or mixed/sensorineural (n=3)		requiring mastoidectomy and antrotomy; no other complications
Laske (2015)[70]	9	• Adults with SSD and normal contralateral hearing	• Speech discrimination signal-to-noise improvement for aided vs unaided condition, sound presented to aided ear: 1.7 dB • Positive improvements on quality-of life questions	Not reported
Riss (2014)[64]	24	• Combined HL (n=9) • EAC atresia (n=12) • SSD (n=3)	• Average functional gain: 28.8 dB • Monosyllabic word scores at 65-dB sound pressure increased from 4.6 to 53.7 percentage points	Not reported
Manrique (2014)[65]	5	• Mixed HL (n=4) • SSD (n=1)	• PTA improvement: 35.62 dB (p=0.01) • Disyllabic word discrimination improvement: 20% (p=0.016)	No perioperative complications reported
Ihler (2014)[66]	6	• Mixed HL (n=4) • CHL (n=2)	• PTA functional gain (average, 0.5-4.0 kHz): 34.5 dB • Speech discrimination at 65 dB improvement: o In quiet: 63.3 percentage points o In noise: 37.5 percentage points	Prolonged wound healing in one case
Desmet (2014)[67]	44	• All unilaterally deaf adults	• Statistically significant improvement on APHAB and SHHIA	Not reported

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

Section Summary: Partially Implantable Magnetic BAHA Devices

Studies of transcutaneous, partially implantable BAHAs have typically used a retrospective within-subjects comparison of hearing thresholds with and without the device, although there have been two 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.

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY

In 2021, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) updated its consensus-based position statement on the use of bone conduction hearing devices.[75] It considers bone conduction hearing devices (BCHD) 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. The statement indicates that the procedure should be performed by a qualified otolaryngologist-head and neck surgeon with devices which have been Food and Drug Administration (FDA)-approved, and “should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the Food and Drug Administration in the United States.”

SUMMARY

There is enough research to show that unilateral or bilateral transcutaneous bone-conduction or bone-anchored hearing aid(s) improve net health outcomes when used as an alternative to air-conduction hearing aids in select patients. Clinical guidelines based on research recommend bone conduction hearing devices for the treatment of conductive or mixed hearing loss and single-sided deafness. In addition, a binaural hearing benefit may be provided for patients with single-sided sensorineural deafness by the routing of signals to the hearing ear. Therefore, use of these devices is considered medically necessary for patients who meet the policy criteria.

There is not enough research to show that unilateral or bilateral transcutaneous bone-conduction or bone-anchored hearing aid(s) improve health outcomes for patients who do not meet the policy criteria, including but not limited to patients not meeting the age requirements and patients with bilateral sensorineural hearing loss. In addition, there are no evidence-based clinical practice guidelines that recommend these devices for patients who do not meet the criteria. Therefore, these devices are considered investigational for patients who do not meet the policy criteria.

Implant replacement, including replacement parts or upgrades, may be considered medically necessary only in the small subset of patients whose response to existing components is inadequate to the point of interfering with activities of daily living, which would include school and work; or when components are no longer functional.

Implant replacement, including replacement parts or upgrades to existing bone-anchored hearing aid components (for example, batteries, processor, headband or Softband) are considered not medically necessary when criteria are not met, including when requested for convenience or to upgrade to newer technology when the current components remain functional.

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CODES

NOTE: The following CPT codes describe semi-implantable electromagnetic bone conduction hearing aids:

Codes	Number	Description
CPT	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

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

	69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor **
	69716	Osseointegrated implant insertion with magnetic transcutaneous attachment to a speech processor
	69717	Revision (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
	69719	Revision or 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

Codes	Number	Description
	69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
	69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
	69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
	92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes
	92623	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure)

**These codes describe implantation of the Baha®, Ponto™, and similar devices.

Codes	Number	Description
HCPCS	L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
	L8624	Lithium ion battery for use with cochlear implant device or auditory osseointegrated device speech processor, ear level, replacement each
	L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
	L8690	Auditory osseointegrated device, includes all internal and external components***
	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

***These codes describe the Baha®, Ponto™, and similar devices.

Date of Origin: *July 2003*