United Healthcare Community Plan

UnitedHealthcare® Community Plan
Medical Policy

Hearing Aids and Devices Including Wearable, Bone-Anchored, and Semi-Implantable (for Tennessee Only)

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Ü Instructions for Use

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Related Policies
- Cochlear Implants (for Tennessee Only)
- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Tennessee Only)

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

This policy only applies to individuals under 21 years of age. (TennCare Rules 1200-13-13)

Wearable air-conduction Hearing Aids required for the correction of a Hearing Impairment are proven and medically necessary.

When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, the following are proven and medically necessary for hearing loss in an individual who is not a candidate for an air-conduction Hearing Aid:
- Bilateral fully or partially implantable bone-anchored Hearing Aids for Conductive or Mixed Hearing Loss in both ears
- Bilateral or unilateral bone conduction Hearing Aids utilizing a headband or adhesive (without osseointegration)
- Semi-implantable electromagnetic Hearing Aid for Sensorineural Hearing Loss
- Unilateral fully or partially implantable bone-anchored Hearing Aids for Conductive or Mixed Hearing Loss in one or both ears
- Unilateral fully or partially implantable bone-anchored Hearing Aids for Sensorineural Hearing Loss in one ear

The following are unproven and not medically necessary for treating hearing loss due to insufficient evidence of efficacy:
- Intraoral bone conduction Hearing Aids
- Laser or light-based Hearing Aids
- Totally implanted middle ear hearing systems

Note: Equipment Upgrades

- A change in the member's medical condition and equipment needs requires the same criteria as a new request
- Equipment upgrades are equivalent to a new service

Definitions

Conductive Hearing Loss: Occurs when sound is not conducted efficiently through the outer ear canal to the eardrum and the tiny bones (ossicles) of the middle ear. Conductive Hearing Loss usually involves a reduction in sound level or the ability to hear faint sounds. This type of hearing loss can often be corrected medically or surgically.

Degree of Hearing Loss:

Degree of Hearing Loss	Range (dbHL = decibels hearing level)
Normal Hearing	-10 to15 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

(ASHA, Type, Degree, and Configuration of Hearing Loss; Clark, 1981)

Frequency Modulated Systems (Auditory Trainers): A wireless connection to the listener's amplification system.

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.

Hearing Impairment: A reduction in the ability to perceive sound which may range from slight to complete deafness.

Mixed Hearing Loss: Occurs when a Conductive Hearing Loss occurs in combination with a Sensorineural Hearing Loss (SNHL). In other words, there may be damage in the outer or middle ear and in the inner ear (cochlea) or auditory nerve.

Sensorineural Hearing Loss (SNHL): Occurs when there is damage to the inner ear (cochlea), or to the nerve pathways from the inner ear to the brain. Most of the time, SNHL cannot be medically or surgically corrected. This is the most common type of permanent hearing loss.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Fitting and Testing of Hearing Aids	
92590	Hearing aid examination and selection; monaural
92591	Hearing aid examination and selection; binaural

CPT Code	Description
Fitting and Testing of Hearing Aids	
92592	Hearing aid check; monaural
92593	Hearing aid check; binaural
92594	Electroacoustic evaluation for hearing aid; monaural
92595	Electroacoustic evaluation for hearing aid; binaural
Semi-Implantable Electromagnetic Hearing Aids (SEHA)	
69799	Unlisted procedure, middle ear
Bone Anchored Hearing Aids (BAHA)	
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 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

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HCPCS Code	Description
Fitting and Testing of Hearing Aids	
S0618	Audiometry for hearing aid evaluation to determine the level and degree of hearing loss
V5010	Assessment for hearing aid
V5011	Fitting/orientation/checking of hearing aid
V5014	Repair/modification of a hearing aid
V5020	Conformity Evaluation
V5264	Ear mold/insert, not disposable, any type
V5265	Ear mold/insert, disposable, any type
V5275	Ear impression, each
Semi-Implantable Electromagnetic Hearing Aids (SEHA)	
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis
Bone Anchored Hearing Aids (BAHA)	
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8693	Auditory osseointegrated device abutment, any length, replacement only

HCPCS Code	Description
Bone Anchored Hearing Aids (BAHA)	
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each
Wearable Hearing Aids	
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
V5030	Hearing aid, monaural, body worn, air conduction
V5040	Hearing aid, monaural, body worn, bone conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5070	Glasses, air conduction
V5080	Glasses, bone conduction
V5100	Hearing aid, bilateral, body worn
V5120	Binaural, body
V5130	Binaural, in the ear
V5140	Binaural, behind the ear
V5150	Binaural, glasses
V5171	Hearing aid, contralateral routing device, monaural, in the ear (ITE)
V5172	Hearing aid, contralateral routing device, monaural, in the canal (ITC)
V5181	Hearing aid, contralateral routing device, monaural, behind the ear (BTE)
V5190	Hearing aid, contralateral routing, monaural, glasses
V5211	Hearing aid, contralateral routing system, binaural, ITE/ITE
V5212	Hearing aid, contralateral routing system, binaural, ITE/ITC
V5213	Hearing aid, contralateral routing system, binaural, ITE/BTE
V5214	Hearing aid, contralateral routing system, binaural, ITC/ITC
V5215	Hearing aid, contralateral routing system, binaural, ITC/BTE
V5221	Hearing aid, contralateral routing system, binaural, BTE/BTE
V5230	Hearing aid, contralateral routing system, binaural, glasses
V5242	Hearing aid, analog, monaural, CIC (completely in the ear canal)
V5243	Hearing aid, analog, monaural, ITC (in the canal)
V5244	Hearing aid, digitally programmable analog, monaural, CIC
V5245	Hearing aid, digitally programmable, analog, monaural, ITC
V5246	Hearing aid, digitally programmable analog, monaural, ITE (in the ear)
V5247	Hearing aid, digitally programmable analog, monaural, BTE (behind the ear)
V5248	Hearing aid, analog, binaural, CIC
V5249	Hearing aid, analog, binaural, ITC
V5250	Hearing aid, digitally programmable analog, binaural, CIC
V5251	Hearing aid, digitally programmable analog, binaural, ITC
V5252	Hearing aid, digitally programmable, binaural, ITE
V5253	Hearing aid, digitally programmable, binaural, BTE
V5254	Hearing aid, digital, monaural, CIC
V5255	Hearing aid, digital, monaural, ITC
V5256	Hearing aid, digital, monaural, ITE

HCPCS Code	Description
Wearable Hearing Aids	
V5257	Hearing aid, digital, monaural, BTE
V5258	Hearing aid, digital, binaural, CIC
V5259	Hearing aid, digital, binaural, ITC
V5260	Hearing aid, digital, binaural, ITE
V5261	Hearing aid, digital, binaural, BTE
V5262	Hearing aid, disposable, any type, monaural
V5263	Hearing aid, disposable, any type, binaural
V5267	Hearing Aid or assistive listening device/supplies/accessories, not otherwise specified (**Note**: For plans that cover hearing aids, this code requires manual review to determine what the item is before a coverage determination can be made.)
V5298	Hearing aid, not otherwise classified

Description of Services

Wearable Air-Conduction Hearing Aids (ACHA)

Hearing Aids are electronic amplifying devices designed to bring sound more effectively into the ear to aid people who have a Hearing Impairment. A Hearing Aid consists of a microphone that picks up the sound, amplifier that makes the sound louder, receiver or loudspeaker that delivers the amplified sound into the ear canal, and batteries that power the electronic part. Wearable Hearing Aids, including air-conduction Hearing Aids (ACHAs) are the standard treatment for hearing loss that cannot be medically or surgically corrected.

Non-Implantable Bone Conduction Hearing Aids Utilizing a Headband or Adhesive

While Conductive Hearing Loss can often be treated with ACHAs, in some cases (e.g., those resulting from the congenital malformation of the external ear canal, pinna and middle ear structures) the use of ACHAs is not possible. In these cases, a standard non-implantable bone conduction Hearing Aid (BCHA) may be required. These bone conduction or bone-anchored Hearing Aids may be held in place by a headband or adhesive, with the amplified vibrational sound transmitted transcutaneous to the bones of the skull for transmission to the cochlea. In this application there is no implantation surgery; rather, the sound processor is attached firmly to the head using either a hard or soft headband or adhesive, and the amplified vibrational sound is transmitted transcutaneous to the bones of the skull for transmission to the cochlea. Children may use a headband or adhesive until their temporal bone is mature enough for implantation of a bone anchored Hearing Aid. For adults, a headband or adhesive is often used to determine whether they might benefit from bone anchored implant systems.

Semi-Implantable Electromagnetic Hearing Aids (SEHA)

Semi-implantable electromagnetic Hearing Aids use the periodic attraction and repulsion of two magnetic fields, one electromagnetic and the other static magnetic, to cause vibration of the ossicles and transmission of sound to the inner ear. When the external sound processor receives sound, it is transformed into electrical signals, which are then amplified and transmitted to a magnetic device that is surgically implanted into the middle ear. The implant's vibrations directly drive the ossicles' movement, producing amplified sound perception. By mimicking the natural vibrations of the ossicular chain, an enhanced signal is sent to the cochlea, resulting in a clearer sound that can be increased without the volume amplification required by ACHAs. In addition, since the air pressure on each side of the sound processor is the same, the wearer does not experience the feeling of occlusion that is common with standard Hearing Aids. Currently, there are three commercially available semi-implantable electromagnetic hearing devices: 1) the Vibrant® Soundbridge™ System (Symphonix Devices Inc.; later acquired by Med-El GmbH), 2) the Maxum™ System (Ototronix) that was originally called the Soundtec Direct System, and 3) the Middle Ear Transducer (MET) Ossicular Stimulator System (Otologics LLC). The Soundtec Direct device was voluntarily removed from the market in 2004 while the manufacturer attempted to eliminate a rattling sound some individuals experienced, primarily when the sound processor was not used. The Maxum System represents an upgrade over the Soundtec Direct System. The two systems use the same technology and components, although the designs differ.

Semi-implantable electromagnetic Hearing Aids are classified by the U.S. Food and Drug Administration (FDA) as Hearing Aids.

Bone Anchored Hearing Aids

Bone anchored Hearing Aids are surgically implantable systems to treat hearing loss through bone conduction. The devices convert sound waves into mechanical vibration that is conducted to the inner ear through direct contact with the skull. An implantable bone- anchored or implantable bone conduction Hearing Aid is an alternative to a wearable Hearing Aid. These can be classified into percutaneous and transcutaneous devices based on the presence or absence of a skin-penetrating abutment.

The fully implantable bone-anchored hearing aid is a percutaneous BCHA involving the surgical implantation of a titanium screw into the mastoid process of the skull (osseointegration). In contrast to traditional BCHAs, bone-anchored Hearing Aids transmit sound vibrations directly to the skull instead through the skin. After a waiting period to allow for complete osseointegration, a sound processor is linked to the skull through an abutment attached to the osseointegrated screw.

Partially implantable transcutaneous bone conduction Hearing Aids using magnetic coupling or magnetic attraction such as the Sophono® Otomag Alpha 1 System and the Sophono Alpha 2 MPO™ Magnetic Bone Conduction Hearing System (Medtronic, formerly Sophono, Inc.), the BAHA® Attract System (Cochlear® Corporation), the Bonebridge™ (MED-EL), and the Osia Systems (Cochlear Americas) feature completely subdermal magnetic implants and do not require an abutment. Rather, the external sound processor is attracted by the magnetic implant and rests on top of the skin.

Bone-anchored Hearing Aids are classified by the FDA as Hearing Aids.

Intraoral Bone Conduction Hearing Aids

The SoundBite™ Hearing System is a non-surgical intraoral bone conduction Hearing Aid that was developed for individuals with single-sided deafness. It consists of a behind the ear device (which houses the receiver, wireless transmitter, and microphone) and a removable, custom-fit oral retainer-like device. According to the manufacturer, the device allows sound to travel via the teeth, through the bones, to both cochleae, bypassing the middle and outer ear. As of January 1, 2015, Sonitus Medical, Inc. is no longer manufacturing the Soundbite Hearing System. There is no new information concerning production of this or a similar device.

Laser or Light-Based Hearing Aids

Laser or light-based Hearing Aids such as the Earlens Contact Hearing Device (CHD) uses light to transmit sound, unlike traditional Hearing Aids that simply amplify air-conducted sound. The Earlens CHD consists of 2 components: a light-based behind-the-ear (BTE) sound processor; and a removable, custom-made tympanic membrane transducer, which is non-surgically placed deep in the ear canal. The BTE processor uses a microphone and a digital signal processor to pick up sound and convert it to infrared light. Light pulses are transmitted to the transducer and are converted into vibrations that are directly applied to the tympanic membrane and perceived as sound. The Earlens CHD was cleared by the FDA via the de novo regulatory pathway. The de novo process provides a pathway to classify low- to moderate-risk devices for which general controls or general and special controls provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

Totally Implanted Middle Ear Hearing Systems

Totally implantable middle ear hearing systems are also being evaluated in individuals with hearing loss. The Esteem prosthetic hearing restoration device (Envoy Medical Corporation) is totally implanted behind the outer ear and in the middle ear. Unlike other Hearing Aids, the Esteem device does not use a microphone or a speaker. Three implanted components comprise the system: a sound processor, a sensor and a driver that converts electrical signals transmitted by the sound processor to the inner ear, where they are perceived as sound. The device is powered with a maintenance-free battery that may last up to nine years and requires no recharging. The Carina Fully Implantable Hearing Device (Cochlear, Ltd) is another totally implantable active middle ear device that was in development in the United States by Otologics, LLC but did not receive FDA approval. In September of 2012, Cochlear, Ltd, an Australian based company, purchased the hearing related assets of Otologics LLC.

Clinical Evidence

Wearable Hearing Aids (Including Non-Implantable Bone Conduction Hearing Aids Utilizing a Headband)

Air Conduction Hearing Aids

In a Cochrane review, Ferguson et al. (2017) evaluated the effects of hearing aids for mild to moderate hearing loss in adults. Five randomized controlled trials (RCTs) of hearing aids compared to a control (no hearing aids or placebo hearing aids) involving 825 participants were included in the review. The authors concluded that the available evidence concurs that hearing aids are effective at improving hearing-specific health-related quality of life, general health-related quality of life and listening ability in adults with mild to moderate hearing loss. The authors indicted that the evidence is compatible with the widespread provision of hearing aids as the first-line clinical management in those who seek help for hearing difficulties. According to the authors, greater consistency is needed in the choice of outcome measures used to assess benefits from hearing aids.

Non-Implantable Bone Conduction Hearing Aids Utilizing a Headband or Adhesive

Liu et al. (2022) study had three primary objectives: to detect the hearing benefits of a bone conduction device (BCD) on speech perception and subjective satisfaction in children with unilateral microtia and atresia (UMA); to compare characteristics of sound localization in children with congenital UMA and children with normal hearing (NH), as well as acquired unilateral conductive hearing loss (UCHL); to investigate whether the use of BCD would be detrimental to the original sound localization of children with UMA and reveal predictive factors for the improvement of sound localization accuracy after using a BCD. Hearing benefits were evaluated by the word recognition score (WRS), speech reception threshold, the international outcome inventory for hearing aids (IOI-HA), and the Speech, Spatial, and Qualities of Hearing Test for Parent (SSQ-P). Sound localization was measured using broadband noise stimuli randomly played from seven loudspeakers at different stimulus levels [65-, 70-, and 75-dB sound pressure levels (SPLs)]. The average unaided WRS and speech-to-noise ratio (SNR) for UMA patients was 18.27 ±14.63 % and -5 ±1.18 dB SPL, and the average aided WRS and SNR conspicuously changed to 85.45 ±7.38 % and -7.73 ±1.42 dB SPL, respectively. The mean IOI-HA score was 4.57 ±0.73. Compared to the unaided condition, the mean SSQ-P score in each domain improved from 7.08 ±2.5, 4.86 ±2.27, and 6.59 ±1.4 to 8.72 ±0.95, 7.61 ±1.52, and 8.55 ±1.09, respectively. In the sound localization test, some children with UMA were able to detect sound sources quite well and the sound localization abilities did not deteriorate with the non-surgical BCD. Although there were limitations within the study, the authors conclude that for children with UMA, the BCD provided a positive benefit on speech recognition and high satisfaction without worsening their sound localization abilities. It is an effective and safe answer for the early hearing intervention of these patients.

Skarzynski et al. (2019) conducted a comparative prospective study to assess whether the ADHEAR system can achieve similar audiological performances in users of passive transcutaneous BC implants or not. Also, they measured the audiological outcomes in comparison to that of a BCD on a softband in patients with conductive hearing loss who are not using any hearing device. Ten subjects with conductive hearing loss (CHL) were evaluated with the ADHEAR, 5 of these were users of a passive bone conduction implant (Baha Attract with Baha4) and 5 received a Baha4 on a softband for test purposes at a tertiary referral center. Results showed that users of the passive bone conduction implant received comparable hearing benefit with the ADHEAR. The mean aided thresholds in sound field measurements and speech understanding in quiet and noise were similar, when subjects were evaluated either with the ADHEAR or the passive bone conduction implant. The audiological outcomes for the non-implanted group were also comparable between the ADHEAR and the bone conduction hearing device using the softband. The authors determined that the ADHEAR system seemed to be an appropriate alternative for individuals with CHL but who cannot or do not want to undergo surgery for a passive bone conduction device.

Urík et al. (2019) in a pilot study, reported the first experience of the ADHEAR device involving 17 subjects aged between 3 months and 10 years, 11 children with conductive hearing loss (CHL) and 6 children with unilateral sensorineural hearing loss (SNHL). Subjects were tested at baseline and after 8 weeks of device use. The analysis showed the average value of hearing threshold in sound field in the group of children with CHL supported 20.23 (±16.84) dB HL with the device and 33.52 (±27.27) dB HL for those not using the ADHEAR device, which is a statistically significant gain ($p = 0.008$). The average value of speech audiometry was 23.45 (±14.45) dB HL with the ADHEAR device and 37.27 (±26.65) dB HL without the device, which is a statistically significant gain ($p = 0.012$). The average value of speech audiometry with bubble noise was 30.55 (±10.03) dB HL with the ADHEAR device and 45.45 (±18.41) dB HL without the device, which is a statistically significant gain ($p = 0.008$). The authors concluded that new non-adhesive hearing aid for bone conduction in children which is very well tolerated and brings a good benefit for pediatric patients without any concomitant aesthetic and other complications.

Wang et al. (2018) evaluated in a retrospective cohort study the auditory development and hearing improvement in patients with bilateral microtia-atresia using softband and implanted bone-anchored hearing devices. The subjects were divided into two groups: the softband group (40 infants, 3 months to 2 years old, Ponto Softband) and the implanted group (6 patients, 6-28 years old, Ponto). The Infant-Toddler Meaning Auditory Integration Scale was used to evaluate auditory development at baseline and after 3, 6, 12, and 24 months, and visual reinforcement audiometry was used to assess the auditory threshold in the softband group. In the implanted group, bone-anchored hearing devices were implanted combined with the auricular reconstruction surgery. Auditory threshold and speech discrimination scores of the patients with implants were measured under the unaided softband and implanted conditions. Total Infant-Toddler Meaning Auditory Integration Scale scores in the softband group were lower than standard scores initially but improved significantly and approached normal levels gradually with time. The authors concluded that the use of softband bone-anchored hearing devices is effective for auditory development and hearing improvement in infants with bilateral microtia-atresia. According to the authors, wearing softband bone-anchored hearing devices before auricle reconstruction and combining bone-anchored hearing device implantation with auricular reconstruction surgery may be the optimal clinical choice for these patients, and results in more significant hearing improvement and minimal surgical and anesthetic injury.

Ramakrishnan et al. (2011) retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in a case series of 109 children and young adults. Criteria for the selection of the implanted device or the Softband were not described; however, the authors did note an uneven distribution by mean age, gender, and syndromic co-morbidity. The authors conclude that this population benefits from bone-anchored and Softband-held conductive hearing aids based on mean scores.

Nicholson et al. (2011) determined the benefit of the BAHA Softband for infants and children with bilateral conductive hearing loss; and verified the audibility of the speech spectrum for octave frequencies 500 through 4000 Hz in a case series. Twenty-five children aged 6 months to 18 years with craniofacial disorders and bilateral conductive hearing loss participated in the study. Participants were consistent, full-time unilateral BAHA users with the BAHA Compact bone-conduction amplifier coupled to the head via the Softband. Results revealed an improvement in sound field thresholds with BAHA amplification for the four octave frequencies. Percentages of thresholds meeting target levels were significant at all frequencies, exceeding the 80% criterion. According to the investigators, this study demonstrates the benefit of the BAHA in providing audibility of the speech spectrum for infants and children with bilateral congenital conductive hearing loss.

Semi-Implantable Electromagnetic Hearing Aids

Bruchhage et al. (2017) conducted a systematic review to determine the efficacy/effectiveness and patient satisfaction with the Vibrant Soundbridge (VSB) active middle ear implant in the treatment of mild to severe Sensorineural hearing loss (SNHL). A search of electronic databases, investigating the safety and effectiveness of the VSB in SNHL plus medical condition resulted in 24 studies meeting inclusion criteria. Data was searched on safety, efficacy, and economical outcomes with the VSB. Safety-oriented outcomes included complication/adverse event rates, damage to the middle/inner ear, revision surgery/explant rate/device failure and mortality. Efficacy outcomes were divided into audiological outcomes, including hearing thresholds, functional gain, speech perception in quiet and noise, speech recognition thresholds, real ear insertion gain, and subjective outcomes determined by questionnaires and patient-oriented scales. Data related to quality of life (QALY, ICER) were considered under economical outcomes. The authors concluded that VSB turns out to be a highly reliable and a safe device which significantly improves perception of speech in noisy situations with a high sound quality. In addition, the subjective benefit of the VSB was found to be mostly significant in all studies. Additionally, implantation with the VSB proved to be a justified health care intervention.

Butler et al. (2013) conducted a systematic review to evaluate the effectiveness of the active middle-ear implant in patients with sensorineural hearing loss, compared with external hearing aids. Fourteen comparative studies were included. Nine studies reported on the primary outcome of functional gain: one found that the middle-ear implant was significantly better than external hearing aids, while another found that external hearing aids were generally significantly better than middle-ear implants. Six of the seven remaining studies found that middle-ear implants were better than external hearing aids, although generally no clinically significant difference (i.e., ≥ 10 dB) was seen. The authors concluded that the active middle-ear implant appears to be as effective as the external hearing aid in improving hearing outcomes in patients with sensorineural hearing loss.

Implantable Bone-Anchored Hearing Aids (BAHA)

Fully Implantable Bone-Anchored Hearing Aids

Liu et al. (2017) systematically reviewed the literature on the audiological and/or quality of life benefits of a bone conduction hearing aid (BCHA) in children (age < 18 years) with congenital unilateral conductive or sensorineural deafness. Eight studies were included in the review. Four studies examined the audiological outcomes associated with bone conduction hearing aid implantation. There was a consistent gain in speech reception thresholds and speech discrimination, especially in noisy environments. Results pertaining to sound localization was inconsistent. The studies that examined quality of life measures reported a high usage rate of BCHAs among children. Quality of life improvements are reported with suggested benefit in the subdomain of learning. The authors concluded that given the potential benefits of a BCHA, along with the fact that it can be safely trialed using a headband, it is reasonable to trial a BCHA in children with congenital unilateral deafness. If the trial offers audiological and/or quality of life benefits for the individual child, then BCHA implantation can be considered.

In a systematic review, Kim et al. (2017) analyzed the capabilities of bone-anchored hearing aids (BAHAs) in the context of single-sided deafness (SSD) and evaluated the efficacy of BAHAs in improving speech recognition in noisy conditions, sound localization, and subjective outcomes. A systematic search was undertaken until August 2015 by two independent reviewers, with disagreements resolved by consensus. Among 286 references, 14 studies were analyzed that used both subjective and objective indicators to assess the capabilities of a total of 296 patients. Study comparators included other interventions, normal control groups, or unaided hearing groups. Although there was "no benefit" of BAHA implantation for sound localization, BAHAs certainly improved subjects' speech discrimination in noisy circumstances. In the six studies that dealt with sound localization, no significant difference was found after the implantation. 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.], an improvement in the quality of life was noted. According to the authors, 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.

Bilateral Fitting of Bone-Anchored Hearing Aids (BAHA)

Janssen et al. (2012) systematically reviewed the outcomes of bilateral versus unilateral bone-anchored hearing aids (BAHA) for individuals with bilateral permanent conductive hearing loss (CHL). 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 the criteria for data extraction and analysis. All 11 studies were observational. In most studies, comparisons between unilateral and bilateral BAHA were intra-subject. Bilateral BAHA provided audiologic benefit compared to unilateral BAHA [improved thresholds for tones (2 studies), speech in quiet (5 studies) and in noise (3 studies), and improved localization/lateralization (3 studies)] and patients perceived subjective benefit from bilateral BAHA (3 studies). Disadvantages of bilateral BAHAs included listening in noise in some conditions (3 studies) and presumed increase in adverse event risk.

Colquitt et al. (2011) performed a systematic review to assess the clinical effectiveness of BAHAs for people with bilateral hearing impairment. Nineteen electronic resources were searched from inception to November 2009. Twelve studies were included. Studies suggested audiological benefits of BAHAs when compared with bone-conduction hearing aids or no aiding. A mixed pattern of results was seen when BAHAs were compared to air-conduction hearing aids. Improvements in quality of life with BAHAs were found by a hearing-specific instrument but not generic quality of life measures. Issues such as improvement of discharging ears and length of time the aid can be worn were not adequately addressed by the studies. Studies demonstrated some benefits of bilateral BAHAs. The authors concluded that the available evidence is weak. As such, caution is indicated in the interpretation of presently available data. However, based on the available evidence, BAHAs appear to be a reasonable treatment option for people with bilateral conductive or mixed hearing loss. Further research into the benefits of BAHAs, including quality of life, is required to reduce the uncertainty.

Partially Implantable Bone-Anchored Hearing Aids with Magnetic Coupling

Magele et al. (2019) conducted a systematic review and meta-analysis to assess the current literature on the safety, efficacy, and subjective benefit after implantation with an active transcutaneous bone conduction hearing device. The literature was screened and extracted by two reviewers independently. Inclusion criteria included participants of any age, gender, or ethnicity, unilateral or bilateral mixed or conductive hearing loss or single-sided deafness who had active transcutaneous bone conduction devices. 39 citations reporting on pre- and postoperative audiological results, speech performance in quiet and in noise, localization testing as well as subjective outcomes were included in this systematic review. Functional gain as well as word recognition score outcomes could be further investigated via meta-analysis. All outcomes reported and summarized reflect beneficial audiological performance and high patient satisfaction, accompanied with a low complications rate (minor event incidence rate: 9.9 person-years; major incidence rate: 148.9 person-years) for the indications of conductive and mixed hearing loss as well as in individuals suffering from single-sided deafness for all age groups of subjects who had active transcutaneous bone conduction hearing device implantation. The study was limited to cohort studies and case-control studies. Also, this was limited to one active transcutaneous bone conduction hearing device since this is the only available at this time. The device's transcutaneous technology results in a minor event incidence rate of one in 9.9 person-years and a major incidence rate of one in 148.9 person-years. Based on the audiological outcomes, high patient satisfaction as well as the low complication rate, the authors recommend the active transcutaneous bone conduction hearing device as a safe and effective treatment for patients suffering from hearing loss within the device's indication criteria (conductive and/or mixed hearing loss or single-sided deafness).

Cooper and McDonald (2017) systematically reviewed the literature on currently available passive transcutaneous bone conduction hearing implants (pTCBI) with regard to complications, audiological outcomes, and quality-of-life scores. All identified English-language articles reporting on the implantation of currently available pTCBIs and their complications. Both pediatric and adult patients were included. No limitation was placed on study design or level of evidence. Twenty-six articles were included in the review. Most of these articles were small retrospective case series. Four hundred eighty-two pTCBIs have been reported in the literature. Major complications including skin breakdown, wound dehiscence, hematoma, seroma, and inability to use the device occurred in 5.2% of patients. Minor complications including pain and self-resolving erythema at the implant site occurred in 13.1% of the patients. The weighted mean pure-tone average gain of the two included devices was 28.4 ±2.1dB and the mean speech reception threshold gain was 32.9 ±3.9dB. Favorable quality-of-life scores have been shown with pTCBIs. The authors concluded that pTCBIs are a viable alternative to percutaneous devices in a carefully selected group of patients. According to the authors, these devices have shown good audiological outcomes, low morbidity, and high patient satisfaction. The authors stated that the study has several limitations. As a systematic review, it is limited by the methodology of the individual articles included. There is heterogeneity across studies regarding the follow-up period, measured audiological and quality-of-life outcomes, and reporting of complications. Considerable heterogeneity was shown statistically in calculating the mean pure-tone average (PTA) and speech reception threshold (SRT) gains. This was partially mitigated by the use of a random effects model in the analysis. There is no validated scale of soft tissue complications arising from transcutaneous devices. As such, it is difficult to define which minor complications such as erythema or implant site pain are clinically significant. Although there is high frequency attenuation through soft tissue, lower rates of postoperative complications and the aesthetics of a transcutaneous hearing device may outweigh this limitation which can also be mitigated through careful patient selection.

In a prospective case series, Dimitriadis et al. (2017) assessed outcomes with a novel passive transcutaneous bone conduction device (t-BCD). One hundred five patients were implanted with the BAHA Attract. Numbness superior to the incision was commonly noticed. Four patients (3.8%) developed skin tenderness and redness that settled with conservative measures. Among those patients who had a conversion from a percutaneous Bone Conduction Hearing Device (BCHD) to the t-BCD (n = 15), 1 (0.9%) developed seroma and 2 (1.9%) developed skin dehiscence at the edge of the implant magnet. Significant improvement in Client Oriented Scale of Improvement and Glasgow Benefit Inventory scores with a global satisfaction of 84% and 77.4% was observed for those previously aided and unaided respectively, with use of the device. A 22% improvement in Speech, Spatial and Qualities of Hearing scale (SSQ-12) mean score was observed in the pediatric population. The authors concluded that the t-BCD is a good solution for hearing rehabilitation in carefully selected patients.

Dimitriadis et al. (2016) conducted a systematic review of the indications, surgical technique and audiological, clinical, and functional outcomes of the BAHA Attract which is a transcutaneous bone conduction hearing aid device. Ten studies and 89 reported cases were included in the review. The vast majority of implanted patients were satisfied with the aesthetics of the device scoring highly at the Abbreviated Profile of Hearing Aid Benefit, Glasgow Benefit Inventory and Client Oriented Scale of Improvement. Overall, hearing outcomes, tested by various means including speech in noise, free field hearing testing and word discrimination scores showed a significant improvement. Complications included seroma or hematoma formation, numbness around the area of the flap, swelling and detachment of the sound processor from the external magnet. The authors concluded that the functional and audiological results presented so far in the literature have been satisfactory and the complication rate is low compared to the skin penetrating Bone Conduction Devices. According to the authors, further robust trials are needed to study the long-term outcomes and any adverse effects.

Rigato et al. (2016) conducted an early observational study to compare transcutaneous bone conduction implant (BCI) and bone-anchored hearing aid (BAHA) groups of patients over several audiometric measurements, including speech audiometry and warble tones thresholds with and without the device. Additionally, questionnaires were used to assess the general health condition, benefit, and satisfaction level of patients. Six patients wearing BCI, and six BAHA users were included in the study with a matched-pairs design. No statistically significant difference was detected in any of the audiological measurements. The outcome of patient-related measurements was slightly superior for BCI in all subscales. According to the authors, these results confirm the initial hypothesis of the study: the BCI seems to be capable of providing as good rehabilitation as percutaneous devices for indicated patients.

Intraoral Bone Conduction Hearing Aid

There is insufficient quality evidence to support the use of intraoral bone conduction hearing aids to treat hearing loss. The quality of the studies was low due to small study populations, short follow-up, and lack of randomization and appropriate control groups.

In a prospective cases series, Gurgel et al. (2015) assessed the safety and efficacy of an intraoral bone conduction (IOBC) hearing prosthesis (SoundBite) after 12 months of use. At the end of 6 months and 12 months, patients were asked to complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire and SSD questionnaire in addition to audiometric testing. Eighty-one patients aged 18 years or older with single-sided deafness (SSD) completed the study. Hearing thresholds remained the same throughout the study. APHAB results showed a significant benefit in categories of ease of communication, reverberation, background noise, and global score. The SSD questionnaire showed a high satisfaction among participants, with 93.8% of patients likely to recommend the IOBC. Dissatisfaction was highest with regard to patient's ability to eat with device, with only 55.6% satisfied. No serious adverse events were reported during the study. The authors concluded that the IOBC is a safe and effective alternative to percutaneous osseointegrated hearing implants for patients with SSD. Patient satisfaction and improved hearing benefit are observed after 1 year of using the device. According to the authors, the IOBC significantly benefitted patients in APHAB categories of ease of communication, reverberation, background noise, and the overall global hearing score. The authors stated that the in-the-mouth transducer is the least-liked feature for some patients, particularly with regard to eating; however, the majority of patients are willing to deal with the size of the device for the hearing benefit gained. The lack of a control group limits the validity of the results of this study. Author reported study limitations include the following: 1) Despite the APHAB being a well-validated way to assess the benefit of hearing prosthesis, the questionnaire responses are subjective and subject to bias. 2) When comparisons were made between the 6- and 12-month APHAB results, 65 and 80 patients filled out the two questionnaires, respectively. The 6-month visit was not a required follow-up time, which explains the difference in participation. The study results have some potential to be skewed because of the differential participation at the two time points, but the 6- and 12-month APHAB results were very similar, with no statistically significant differences. 3) A selection bias is also possible in those patients who were willing to participate in the study as well as providers who have incorporated the IOBC into their practice. These patients and providers may feel more strongly for or against the device than more objective users. 4) More than 90% of patients responded that they preferred the device compared with no device and would likely recommend the device. This percentage may be artificially high because nine subjects withdrew from the study secondary to device-related problems and did not complete the evaluation.

Moore and Popelka (2013) compared the effectiveness of two types of treatment for unilateral hearing loss (UHL), bone-anchored hearing instruments (BAHI) and a dental device (SoundBite). Nine adult BAHI wearers with UHL were included in the study. Either BAHI or SoundBite were worn for 30 days, and then the devices were swapped, and the second device was worn for 30 days. Measures included unaided and aided sound-field thresholds, sound localization, and perception of speech in babble. The APHAB questionnaire was administered for each trial period. Both devices gave benefits for localization after 30 days, but there was no difference between devices. Speech perception was better for both devices than for unaided listening when the target speech came from the poorer hearing side or in front, and the interfering babble came from the better-hearing side. There was no consistent difference between devices. APHAB scores were better for SoundBite than for BAHI. The authors concluded that speech perception and sound localization were similar for the two types of devices, but the SoundBite led to lower aided thresholds and better APHAB scores than the BAHI. The significance of this study is limited by small sample size, which could have limited the ability to detect clinically significant differences, and short follow-up period.

Laser or Light-Based Hearing Aids

The evidence assessing the effectiveness of laser or light-based hearing aids is limited. Well-designed studies with concurrent control groups are required to demonstrate the safety and benefits of these devices.

Arbogast et al. (2019) evaluated the benefit of extended high-frequency amplification in a real-world use scenario, with a device that restores audibility for frequencies up to 10 kHz. A total of 78 participants (149 ears) with mild to moderately severe sensorineural hearing loss completed one of two studies conducted across eight clinical sites. Participants were fitted with a light-driven contact hearing aid (the Earlens system) that directly drives the tympanic membrane, allowing extended high-frequency output and amplification with minimal acoustic feedback. Participants wore the devices for an extended period. Prescribed versus adjusted output and gain, frequency-specific FG, and self-perceived benefit assessed with the Abbreviated Profile of Hearing Aid Benefit, and a custom questionnaire were documented. Abbreviated Profile of Hearing Aid Benefit results revealed a significant improvement in communication relative to unaided listening, averaging 28 to 32 percentage points for the background noise, reverberation, and ease of communication subscales. Relative to participants' own hearing aids, the subscales ease of communication and aversiveness showed small but significant improvements for Earlens ranging from 6 to 7 percentage points. For the custom satisfaction questionnaire, most participants rated the Earlens system as better than their own hearing aids in most situations. The investigators concluded that the results of the two studies show that the Earlens system can provide the gains and output levels prescribed by the CAM2 fitting method over the whole frequency range up to 10kHz for participants with a wide range of hearing losses. The current two clinical trials have the limitation that they were not blinded, so the satisfaction measures may have been affected by placebo effects or biases. The lack of a concurrent comparison group is another weakness of this study.

In a single-arm, open-label investigational-device clinical trial, Gantz et al. (2017) evaluated the safety and effectiveness of the light-driven contact hearing aid to support FDA clearance. The trial included 43 subjects (86 ears) with mild-to-severe bilateral sensorineural hearing impairment. The intervention was treatment of the hearing impairment using amplification provided by the Earlens contact hearing aid (CHA) for a duration of 120 days. The primary safety endpoint was a determination of "no change" (PTA4 < 10 dB) in residual unaided hearing at the 120-day measurement interval. The results for the 86 ears in the study determined a mean change of -0.40 dB in PTA4, indicating no change in residual hearing. There was no serious device- or procedure-related adverse events, or unanticipated adverse events. Word recognition aided with the Earlens improved significantly over the unaided performance, by 35% rationalized arcsine units on average. Mean functional gain was 31 dB across 2 to 10 kHz. The average speech-recognition threshold improvement over the unaided case for the Hearing in Noise Test was 0.75 dB and 3.14 dB for the omnidirectional and directional microphone modes, respectively. The authors concluded that the safety and effectiveness data supported a de novo 510(k) submission that received clearance from the FDA. According to the authors, future studies should perform careful comparisons between other devices and the CHA, to establish whether the broad-spectrum amplification of the CHA provides additional benefits over those devices in terms of sound quality and speech understanding.

Totally Implanted Middle Ear Hearing Systems

There is insufficient quality evidence demonstrating the efficacy of totally implanted middle ear hearing systems for treating hearing loss. Well-designed studies with concurrent control groups are required to demonstrate the safety and benefits of these devices.

Shohet et al. (2018) conducted a prospective, multicenter case series to provide long-term hearing outcome measures of a totally implantable hearing system (implant) and compare to the baseline unaided (BLU) and baseline aided (BLA) conditions, and to discuss relevant safety measures. Fifty-one subjects with mild to severe sensorineural hearing loss were implanted between 2008 and 2009 and enrolled in this post-market approval study in the setting of private and hospital-based practices. Forty-nine of these subjects completed the 5-year study, which included annual follow-ups. Primary effectiveness endpoints were speech reception threshold (SRT) and word recognition scores at 50 dB (WRS50s). Secondary effectiveness endpoints were WRSs and the Abbreviated Profile of Hearing Aid Benefit (APHAB) scores. Adverse Device Effects (ADEs) and Serious Adverse Device Effects (SADEs) reported during the study period and a comparison of bone conduction scores were submitted as safety measures. The results showed that compared to the BLA condition, SRT scores were improved at every annual follow-up; WRS50s were better in 49%, and the same in 41% at the 5-year follow-up; WRSs were improved by 17% at the 5-year follow-up; and APHAB scores were improved in most subscales at every annual follow-up. There were three SADEs in three subjects and 15 ADEs in 11 subjects. Bone conduction scores increased by 3.7 dB at the 5-year follow-up. Average battery life was 4.9 years. The authors concluded that the implant compared favorably to the subjects' hearing aid throughout the 5-year period in all of the areas measured and was found to be safe. Further research with randomized controlled trials is needed to validate these findings. The findings are limited by the lack of comparison group.

Barbara et al. (2018) evaluated the long-term benefits of a totally implantable active middle ear implant (AMEI) that has been used in a single implanting center for over 10 years. Forty-one subjects who underwent implantation with an Esteem AMEI during a 10-years period were evaluated on the auditory benefits, as derived from pure tone and speech audiometry tests. The analysis included a comparison with a conventional hearing aid, the problematics related to the battery duration and surgical replacement and, finally, the complication rate. Over 80% of the implanted subjects maintained over time a satisfactory auditory gain, ranging from 10 to over 30 dB in respect to the unaided situation, as mean at 0.5, 1, 2 and 4 kHz. In more than 60% of them, an improvement has also been found at 4 and 8 kHz. Battery duration varied according to the severity of the hearing loss and to the daily use of the device. No major post-operative complications were recorded, while explanation was necessary in five subjects, although none for device failure. The authors concluded that the Esteem can be considered a reliable device for rehabilitation of sensorineural hearing loss in alternative to conventional hearing aids. The findings of this study need to be validated by well-designed controlled studies with larger sample sizes.

In a systematic review, Pulcherio et al. (2014) reviewed the outcomes of the fully implantable middle ear devices (MEDs) Carina and Esteem for treatment of hearing loss. Twenty-two studies and two literature reviews in English directly demonstrating the results of Carina and Esteem were included in the review. There was a total of 244 patients ranging from 18 to 88 years. One hundred and 10 patients were implanted with Carina and with 134 Esteem. There were registered 92 males and 67 females. Five studies provided no information about patients' age or gender. From the data available, the follow-up ranged from 2 to 29.4 months. The comparison of the results about word recognition is difficult as there was no standardization of measurement. The results were obtained from various sound intensities and different frequencies. The studies included in the review showed improvement of sound field threshold from unaided to aided conditions with a fully implantable middle ear device. However, there were conflicting results among the different studies regarding functional gain. Some of the studies had no statistical significance and some studies reported a functional gain but with a limited benefit on frequencies above 3 kHz. According to the authors, the use of fully implantable MEDs is promising for those dissatisfied with their current conventional air-conduction hearing aids. The authors concluded that due to the relatively few publications available and small sample sizes, one must be careful in extrapolating these results to a broader population. Additionally, none of these studies represented level high levels of evidence (i.e., randomized controlled trials) or controlled studies.

Klein et al. (2012) conducted a review to examine the safety and effectiveness of fully implantable middle ear devices in the treatment of hearing loss. Thirty articles were selected for full review, of which, 7 articles on the Esteem (n = 105 patients) and 13 on the Carina (n = 68 patients) met the study's eligibility criteria. Because of heterogeneity across studies, meta-analysis was not performed, and comparisons were made by structured review. Complication rates with the Esteem were higher than with the Carina. The most common adverse effects with the Esteem were chorda tympani nerve damage or taste disturbance, occurring in 30 percent of patients. Facial weakness was also reported in eight percent of the patients and was permanent in two patients. Seven explants and five revision surgeries were reported with the Esteem device. Device failure was common with the Carina, predominately related to charging difficulties. For both devices, clinically significant improvements in functional gain, speech reception, and speech recognition over the unaided condition were found. According to the authors, most of the studies included in the review were quasi-experimental pre-post comparisons of aided and unaided conditions. In addition, the studies had significant limitations including lack of a control group, and no strict inclusion and exclusion criteria.

Clinical Practice Guidelines

American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)

The AAO-HNS 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 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 FDA in the United States and other similar regulatory agencies in countries other than the United States (AAO-HNS, Active Middle Ear Implants Position Statement 2016).

The AAO-HNS considers bone conduction hearing devices (BCHD) as appropriate, and in some cases preferred, for the treatment of conductive and mixed hearing loss. BCHD may also be indicated in select patients with single-sided deafness. BCHD include semi-implantable bone conduction devices utilizing either a percutaneous or transcutaneous attachment, as well as bone conduction oral appliances and scalp-worn devices. The recommendation for BCHD should be determined by a qualified otolaryngology-head and neck surgeon. These devices are approved by the 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. (AAO-HNS, Bone Conduction Hearing Devices Position Statement 2016, Revised 2021).

Ontario Health Technology (OHT)

Following a systematic review of the literature, the Ontario Health Technology Advisory Committee (2020) recommendations for patients with conductive or mixed hearing loss stated that bone-conduction implants when compared with no intervention are likely to result in a large improvement in hearing thresholds, improve speech perception in noise and improve hearing-specific quality of life. In comparison to no treatment, bone-conduction implants for patients with single-sided deafness who are contraindicated for cochlear implantation, it is likely to result in a large improvement in hearing thresholds, improve speech perception in noise and improve hearing-specific quality of life; however, it is not likely to improve sound localization.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Semi-Implantable Electromagnetic Hearing Aid

Two semi-implantable, electromagnetic, direct-drive, middle ear hearing devices have received FDA approval.

Vibrant® received FDA approval on August 31, 2000. According to the FDA, Vibrant Soundbridge is utilized for providing a useful level of sound perception to individuals via mechanical stimulation of the ossicles.

According to the professional labeling information on the FDA website, the selection criteria for Vibrant Soundbridge include the following:

- Adults aged 18 or older
- Audiologic results consistent with moderate to severe sensorineural hearing loss
- Pure tone air conduction threshold levels within the following ranges:
  - 500 Hz: 30-65 dB
  - 1000 Hz: 40-75 dB
  - 1500 Hz: 45-80 dB
  - 2000 Hz: 45-80 dB
  - 3000 Hz: 50-85 dB
  - 4000 Hz: 50-85 dB
- Word recognition score of 50% or better using recorded material
- Normal middle ear anatomy
- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device

Refer to the following website for more information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p990052. (Accessed September 14, 2023)

Maxum Hearing Implant® was approved by the FDA on September 7, 2001. This device was manufactured initially under the name Soundtec Direct System by Ototronix and is currently manufactured under the name Maxum Hearing Implant®. According to the professional labeling information on the FDA website, the selection criteria for Maxum Hearing Implant® include the following:

- Adults aged 18 or older
- Audiologic results consistent with moderate to severe sensorineural hearing loss
- Patients with a desire for an alternative to an acoustic hearing device
- Patients should have experience with appropriately fit hearing aids

Refer to the following website for more information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p010023s013.
(Accessed September 14, 2023)

Bone-Anchored Hearing Aids

Fully Implantable Bone Anchored Hearing Aids

In 1995, the FDA granted clearance to Nobelpharm USA to market the Branemark Bone-Anchored Hearing Aid (BAHA) System. Note: since 1995, the device was acquired by Entific Medical Systems and then in 2005, it was acquired by Cochlear Corp. The device is indicated for adult patients with malformations of the external ear, chronically draining ear, a pure tone threshold hearing loss of ≥ 45 decibels (dB), and/or inability or unwillingness to use an air conduction hearing aid. In 1999, this clearance was extended for use in children 5 years of age or older. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/K984162.pdf. (Accessed September 14, 2023)

The indications for the BAHA System have broadened since the initial FDA clearance. In 2001, the BAHA system was cleared for bilateral implantation. For bilateral implantation of bone-anchored hearing aids, patients must have moderate to severe bilateral symmetrical conductive hearing loss (defined as less than 10 dB difference in average or less than 15 dB in bone-conduction thresholds at 500, 1000, 2000, and 4000 Hz) or mixed hearing loss with average bone conduction thresholds better than 45 dB hearing loss.

In 2002, the BAHA system was cleared for single sided deafness (SSD) or unilateral sensorineural hearing loss. According to the FDA, the use of BAHA hearing aid for SSD is intended to improve speech recognition. The SSD indication for BAHA hearing aid is intended for patients who suffer from unilateral sensorineural deafness on one ear while the other ear has normal hearing. Normal hearing is defined as PTA AC threshold equal to or better than 20dB measured at 0.5, 1,2 and 3 kHz. BAHA for SSD is also indicated for patients who are indicated for an AC Contra-lateral Routing of Signals (CROS) but who for some reason cannot or will not use an AC CROS. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf2/k021837.pdf. (Accessed September 14, 2023)

BAHA System models include the following:
- BAHA BP100 (2009). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf
- BAHA Cordelle II . Refer to the following websites for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080363.pdf
  - https://www.accessdata.fda.gov/cdrh_docs/pdf/K992872.pdf
- BAHA Intenso (2008). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf8/K081606.pdf
- BAHA Divino (2004). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf4/K042017.pdf
- BAHA auditory osseointegrated implant system using model B31300 implant and model BA300 abutment (2010). Refer to the following website for more information:
  - http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100360.pdf

(Accessed September 14, 2023)

In November 2008, the OBC Bone Anchored Hearing Aid System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf8/k082108.pdf.
(Accessed September 14, 2023)

In September 2012, the Ponto Bone Anchored Hearing System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121228.pdf. (Accessed September 14, 2023)

In August 2021, the Ponto 5 Mini (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. Refer to the following website for more information: K211640.pdf (fda.gov). (Accessed September 14, 2023)

Other bone anchored hearing aid devices have also been cleared by the FDA. Refer to the following website for more information (use product code LXB or MAH): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 14, 2023)

Partially Implantable Bone-Anchored Hearing Aids or Devices

The partially implanted Otomag Alpha 1 (M) Bone Conduction Hearing System (Sophono, Inc.) received FDA clearance in May 2011 as a bone conduction hearing aid. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Sofiband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing loss, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz.)
- Bilateral fitting is applicable for most patients having a symmetrically conduction or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average, measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2, and 3 kHz)

Refer to the following websites for more information about FDA clearances for Sophono hearing systems:

- http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102199.pdf
- http://www.accessdata.fda.gov/cdrh_docs/pdf15/K153391.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K132189
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K123962

(Accessed September 14, 2023)

The Cochlear Baha Attract System (Cochlear Americas, Centennial, CO) received FDA clearance on November 7, 2013. The Cochlear Baha Attract is intended for the following patients and indications for use:

- Patients aged 5 and older
- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB3 HL for use with the BP1 00 sound processor, and 55 dB HL for use with the BP1IO0 sound processor
- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss
- Symmetrical bone-conductive thresholds are defined as less than a 10 dB3 average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15dB difference at individual frequencies
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e., Single-sided deafness: SSD). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20d13 HL
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CR08) hearing aid, but who for some reason cannot or will not use an AC CR08

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf13/K131240.pdf. (Accessed September 14, 2023).

The Bonebridge (MED-EL), a transcutaneous bone-conduction hearing device was cleared by the FDA via the de novo regulatory pathway on July 20, 2018. The de novo process provides a pathway to classify low- to moderate-risk devices for which general controls or general and special controls provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. The Bonebridge bone conduction hearing implant system is intended for the following patients and indications:

- Patients 12 years of age or older
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5,1, 2, and 3 kHz) should be better than or equal to 45 dB HL

- Bilateral fitting of the Bonebridge is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear [i.e., single-sided deafness (SSD)]. The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz)
- The Bonebridge for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS
- Before receiving the device it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids

The FDA subsequently granted 510(k) marketing clearance (K183373) for the Bonebridge in March 2019. Refer to the following websites for more information:
- https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170009.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K183373

(Accessed September 14, 2023)

In 2019, Cochlear's Osia System and Cochlear's™ Osia 2 System (Cochlear Americas, Englewood, CO) were FDA 510(k) approved as Class II devices (K190589, K191921) as active implantable bone conduction hearing systems. Both the Osia System and the Osia 2 System are made up of several components. The Osia Implant (OSI100) consists of a receiver/stimulator and an actuator (vibrator) which is surgically implanted on the skull bone. The Osia 2 Implant (OSI200) consists of a receiver/coil and an actuator/stimulator (vibrator) which is also surgically implanted on the skull bone. The external component of the Osia System is a sound processor, worn off-the-ear, which picks up the sound from the environment, and sends, after processing, the information to the implant via a transcutaneous inductive link. This link is also referred to as a radiofrequency (RF) link. Each Osia System or Osia 2 System is configured to meet an individual's hearing needs, using dedicated fitting software. The Osia System and Osia 2 System use a Piezo Power™ transducer that sits within the OSI100/OSI200 Implant. The transducer is positioned under the skin to send sound to the cochlea. The OSI100/OSI200 Implant is positioned on top of the bone, connected to the BI300 Implant (in the same manner as that used in Baha® Connect/Attract), and osseointegrated into the bone; this gives an important single point of transmission for sound. The system has a fitting range of 55 dB SNHL. Per the FDA, both the Osia System and the Osia® 2 System are intended for the following patients and indications:
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL
- Bilateral fitting of either the Osia System or the Osia® 2 System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz)
- The Osia System and the Osia® 2 System for SSD are also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. Page 9 of 23 Medical Coverage Policy: 0093
- Prior to receiving the device it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids"

The FDA subsequently granted 510(k) marketing clearance for the Class II devices (K190589, K191921) for the Oasis in November 2019. Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191921.pdf. (Accessed September 14, 2023)

Non-Implantable Bone-Conduction Hearing Aids

In 2000, the FDA cleared the BAHA headband. The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms. Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K002913. (Accessed September 18, 2023)

In 2009, the FDA cleared the Cochlear Baha BP100 sound processor that is intended for use with the Baha auditory osseointegrated implant (for children aged 5 and older, or adults), or with the Baha Headband or Baha Softband (no age limitations) for the following patients and indications:

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL
- Bilateral fitting of the BP100 is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e., single-sided deafness or "SSD"). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to .20 dB HL
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090720.pdf. (Accessed September 18, 2023)

The BAHA SoundArc received FDA clearance on June 7, 2017. The BAHA SoundArc is intended for patients who cannot or choose not to have an implant for the following indications for use:

- Patients of any age who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the BP100, Baha 4 and Baha 5 sound processors, 55 dB HL for use with the BP110 Power and Baha 5 Power sound processors, and better than or equal to 65 dB HL for use with the Cordelle II and Baha 5 SuperPower Sound Processors
- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conductive thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1,2, and 3 kHz), or less than a 15dB difference at individual frequencies
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e., Single sided deafness: SSDTM). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS

Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171088.pdf. (Accessed September 18, 2023)

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 transcutaneous to the cochlea via the bones of the skull. In 2002, the Baha® Softband™ was cleared for marketing by the FDA for use in children younger than 5 years.

In May 2010, the FDA cleared the Otomag Alpha 1(S) Sound Processor for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz)
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10OdB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear who for some reason will not or cannot use an AC CR05. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB H-IL (measured at 0.5, 1, 2 and 3 kl-z)

Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100193.pdf. (Accessed September 18, 2023)

In April 2018, the ADHEAR System was cleared by the FDA for marketing thru the 510K process.

The ADHEAR system is intended to treat patients of all ages with conductive hearing loss or single-sided deafness via bone conduction. The ADHEAR system is a non-invasive bone conduction hearing device which is retained on the patient's head with an elastic headband or an adhesive adapter that is placed behind the auricle.
Indications:

- Unilateral or bilateral conductive hearing loss, either chronic or temporary
- The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 25 dB HL
- Single-sided deafness (i.e. unilateral profound sensorineural deafness) with normal hearing on the contralateral side
- Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL

Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172460.pdf. (Accessed August 21, 2023)

Other non-implantable bone anchored hearing aid devices have also been cleared by the FDA. Refer to the following website for more information (use product code LXB): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 21, 2023)

Totally Implanted Middle Ear Hearing System

The Esteem® prosthetic hearing restoration device has been approved by the FDA. Refer to the following websites for more information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P090018
- https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090018c.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090018b.pdf

(Accessed August 21, 2023)

Intraoral Bone Conduction Hearing Aid

The SoundBite Hearing System received FDA clearance in 2011. Refer to the following websites for more information:

- http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100649.pdf
- http://www.accessdata.fda.gov/cdrh_docs/pdf11/K110831.pdf

(Accessed August 21, 2023)

Laser or Light-Based Contact Hearing Aid

The FDA has cleared the Earlens Contact Hearing Device via the de novo regulatory pathway. Refer to the following websites for more information:

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN150002
- http://www.accessdata.fda.gov/cdrh_docs/pdf15/DEN150002.pdf

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Policy History/Revision Information

Date	Summary of Changes
04/01/2024	**Applicable Codes** ***Bone Anchored Hearing Aids (BAHA)*** • Revised description for CPT code 69719 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information • Archived previous policy version CS052TN.P

Instructions for Use

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