



Medical Coverage Policy

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Hearing Aids

Table of Contents

Overview 2

Coverage Policy..... 2

Health Equity Considerations..... 4

General Background 5

Medicare Coverage Determinations 17

Coding Information..... 17

References 21

Revision Details 29

Related Coverage Resources

- [Cochlear and Auditory Brainstem Implants](#)
- [Otoplasty and External Ear Reconstruction](#)
- [Prosthetic Devices](#)

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will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses hearing aid devices, including air conduction, bone conduction, and middle ear devices. Hearing aids are devices that amplify and deliver speech and other sounds at levels equivalent to that of normal speech and conversation and are used by individuals with hearing loss.

Coverage Policy

Hearing aid devices include:

- air conduction devices
- middle ear devices
- bone conduction devices

Coverage for hearing aid devices (including all of the above) varies across plans. Refer to the customer's benefit plan document for coverage details.

If coverage for U.S. Food and Drug Administration (FDA)-approved hearing aid devices is available, the following conditions of coverage apply.

An FDA approved hearing aid device (per device-specific criteria below) is considered medically necessary for ANY of the following:

- conductive hearing loss unresponsive to medical or surgical interventions
- sensorineural hearing loss
- mixed hearing loss

When ONE of the above medical necessity criteria for an FDA approved hearing aid device has been met, ANY of the following FDA approved hearing aid devices used to amplify sound, including advanced signal processing technologies (e.g., digital signal processing, directional microphones, multiple channels, multiple memories) is considered medically necessary.

Air Conduction Hearing Aids

ANY of the following air conduction FDA approved hearing aid devices is considered medically necessary for the treatment of mild to profound hearing loss:

- behind the ear (BTE) device
- in the ear (ITE) device
- in the ear canal (ITC) device
- completely in the canal (CIC) device
- contralateral routing of sound (CROS) device, for single-sided hearing loss (i.e., bone conduction on the hearing side is normal)

Partially Implantable Bone Conduction Hearing Aids

A partially implantable middle ear FDA approved hearing aid device (e.g., Vibrant Soundbridge, Maxum™) is considered medically necessary when ALL of the following criteria are met:

- age 18 or older
- moderate to severe sensorineural hearing loss
- evidence of a medical condition precluding use of an air conduction aid
- absence of middle ear disease

Bone Conduction Hearing Aids

EITHER of the following bone conduction hearing aid devices is considered medically necessary

- unilateral percutaneous U.S. Food and Drug Administration (FDA)-approved bone-anchored hearing aid (BAHA) device with abutment (e.g., Ponto Systems, Cochlear® Baha Connect System), or magnetic coupling (e.g., Baha® Attract, Sophono® Systems, Bonebridge, Cochlear Osia, Cochlear Osia 2) for an individual with conductive or mixed hearing loss
- bilateral percutaneous U.S. Food and Drug Administration (FDA)-approved bone-anchored hearing aid (BAHA) device with abutment (e.g., Ponto Systems, Cochlear® Baha Connect System), or magnetic coupling (e.g., Baha® Attract, Sophono® Systems, Bonebridge, Cochlear Osia, Cochlear Osia 2) for an individual with symmetrical conductive or mixed hearing loss (i.e., difference of < 15 dB HL each side at individual frequencies or < 10 dB HL difference of pure tone average measured at frequencies of 500, 1000, 2000, and 3000 Hz between ears)

WHEN ALL of the following criteria are met:

- use of a conventional device is precluded by EITHER of the following:
 - malformations of the external or middle ear (e.g., microtic ears, congenital atresia, small ear canals, tumor)
 - conditions involving chronic middle ear drainage (e.g., dermatitis, severe chronic otitis media)
- EITHER of the following:
 - pure tone average bone conduction threshold of up to 65 dB HL (decibel hearing level) with average measured at 500, 1000, 2000, and 3000 Hz, for the percutaneous device with abutment
 - pure tone average bone conduction threshold of up to 55 dB HL with average measured at 500, 1000, 2000, and 3000 Hz for the magnetic coupling device
- speech discrimination score of better than 60% in the indicated ear
- ANY of the following conditions:
 - documentation of chronic ear infection/inflammation
 - congenital or surgically induced ear malformations of the external or middle ear canal
 - tumors of the external canal and/or tympanic cavity
 - conditions that contraindicate an air conduction hearing aid

A unilateral percutaneous U.S. Food and Drug Administration (FDA)-approved bone-anchored hearing aid (BAHA) device with abutment (e.g., Ponto Systems, Cochlear® Baha Connect System), or magnetic coupling (e.g., Baha® Attract, Sophono® Systems, Bonebridge, Osia System, Osia 2 System) is considered medically necessary as an alternative to an air conduction CROS device for an individual with single-sided deafness

(i.e., unilateral sensorineural hearing loss > 100 dB HL) and normal hearing in the other ear (e.g., pure tone average ≤ 20 dB HL, measured at 500 Hz, 1000, 2000, 3000 Hz).

Batteries

Initial and replacement batteries (V5266, L8621, L8622, L8623, L8624) that are specifically designed to provide a power supply to a medically necessary hearing aid device are considered medically necessary.

NOTE: Off-the-shelf batteries are generally considered not medically necessary, regardless of whether coverage is available for hearing aid devices, because they are not primarily medical in nature.

Repair and/or Replacement

Repair and/or replacement of a medically necessary hearing aid device not under warranty are considered medically necessary as follows:

- Repair, when the currently used device is no longer functioning adequately, inadequate function of the item interferes with activities of daily living, and repair is expected to make the equipment fully functional (as defined by the manufacturer).
- Replacement, when the currently used device is no longer functioning adequately and has been determined to be non-repairable.

Experimental, Investigational Or Unproven

EACH of the following hearing aid devices is considered experimental, investigational or unproven:

- fully implantable middle ear hearing aid (e.g., Esteem®)
- non-implantable, intraoral bone conduction hearing aid (e.g., SoundBite™ Hearing System)

Not Medically Necessary

A personal sound amplification product (PSAP) is considered not medically necessary because a PSAP is not intended to aid individuals with or to compensate for impaired hearing.

Health Equity Considerations

The U.S. Department of Health and Human Services in conjunction with the Office of Disease Prevention and Health Promotion sets health goals for the nation every 10 years with the most recent being Healthy People 2030. One objective is to increase the proportion of adults with hearing loss who use a hearing aid. The baseline data revealed 24.4 percent of adults aged 18 years and over with hearing loss used a hearing aid in 2018. The target goal is to increase hearing aid use to 26.4 percent (Healthy People 2030).

According to the National Institutes of Health's National Institute of Deafness and Other Communication Disorders (NIDCD) (2024), age is the strongest predictor of hearing loss among adults aged 20–69 years, with the greatest amount of hearing loss in the 60–69 age group. Men are almost twice as likely as women to have hearing loss among adults aged 20–69 years. Non-Hispanic white adults are more likely to have hearing loss than adults in other racial/ethnic groups. Non-Hispanic black adults have the lowest prevalence of hearing loss among adults aged 20–69 years (Hoffman, et al., 2016). Based on calculations performed by the National Institute of Deafness and Other Communication Disorders (NIDCD) Epidemiology and Statistics Program using data from the 1999-2010 National Health and Nutrition Examination Survey (NHANES), about 2%

of adults aged 45–54 years have disabling hearing loss. The rate of loss increases to 8.5% for adults aged 55–to 64, almost 25% of those aged 65–74 years and 50% of those who are 75 years and older have disabling hearing loss. According to NIDCD Epidemiology and Statistics Program (based on December 2015 Census Bureau estimates of the noninstitutionalized U.S. population) about 28.8 million U.S. adults could benefit from using hearing aids. Among adults aged 70 years and older with hearing loss who could benefit from hearing aids, fewer than one in three (30%) have ever used them. Even fewer adults aged 20–69 (approximately 16%) who could benefit from wearing hearing aids have ever used them (based on calculations by NIDCD Epidemiology and Statistics Program staff using data collected by (1) the National Health Interview Survey [NHIS] annually for number of persons who have ever used a hearing aid [numerator], and (2) periodic NHANES hearing exams for representative samples of the U.S. adult and older adult population [denominator]; these statistics are also used for tracking Healthy People 2010 and 2020 objectives).

Arnold et al. (2019), reported hearing aid use among U.S. adults of Hispanic/Latino backgrounds is lower than that of the general U.S. population. The biggest barrier was current access to health insurance. Lesser factors include low acculturation, language and economic barriers, and cultural aspects.

General Background

Hearing impairment is the consequence of sensorineural and/or conductive malfunctions of the ear. Hearing loss may be congenital or secondary to trauma, use of ototoxic medication or disease. The three basic types of hearing loss, which can be unilateral or bilateral, include conductive, sensorineural and mixed. Conductive hearing loss involves the outer and middle ear and is due to mechanical or physical blockage of sound. It can result from a blockage of wax, a punctured eardrum, birth defects, ear infections, or heredity. Usually, conductive hearing loss can be corrected medically or surgically. Sensorineural or “nerve” hearing loss involves damage to the inner ear (hair cells within the cochlea) or the eighth cranial nerve (i.e., auditory nerve). It can be caused by aging, prenatal or birth-related problems, viral or bacterial infections, heredity, trauma, exposure to loud noises, the use of certain drugs, fluid build-up in the middle ear, or a benign tumor in the inner ear of the auditory nerve. Only rarely can sensorineural hearing loss be medically or surgically corrected. It is the type of hearing loss that is most commonly managed with a hearing aid. Mixed hearing loss is conductive hearing loss coupled with sensorineural hearing loss.

Hearing loss is measured on a scale based on the threshold of hearing. Audiometric testing is used to measure the frequency and hearing level of an individual. Frequency is measured in hertz (Hz) which are cycles per second. The range of frequencies tested is 125 Hz to 8000 Hz. The intensity or loudness of the sound is measured in decibels (dB) which range from -10 dB to 120 dB. A summary of the audiogram for each ear is the pure-tone average (PTA) of thresholds measured at specific frequencies. A traditional PTA measure is the speech frequency average of thresholds at 500, 1000, and 2000 Hz. Normal speech and conversation occur at 40–60 dB within a frequency range of 500–3000 Hz. Hearing loss severity is classified as follows (American Speech-Language-Hearing Association [ASHA], 2024b; National Institute on Deafness and Other Communication Disorders [NIDCD], 2011):

- **Mild:** 26–40 dB HL
- **Moderate:** 41–70 dB HL
- **Severe:** 71–90 dB HL
- **Profound:** ≥ 91 dB HL

Audiometric testing is also used to measure speech discrimination which indicates the ability to hear and understand speech at typical conversational levels. It also indicates how well speech is perceived if the presentation level is increased; this predicts the potential benefits of amplification. Speech discrimination, or word recognition ability, is scored as a percentage that represents how well a list of words can be repeated. In the presence of hearing loss, a word discrimination of > 80% indicates that a hearing aid may be useful. A hearing aid device is not beneficial for those with poor word discrimination (i.e., < 60%).

A measure used for describing auditory function is the speech-recognition threshold (SRT). That is the lowest intensity level at which a score of approximately 50% correct is obtained on a task of recognizing spondee words (2-syllable words or phrases that have equal stress on each syllable) (Haddad, et al. 2020).

Hearing aids are described by the U.S. Food and Drug Administration (FDA) as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing" (FDA, 2022). A hearing aid is also called an electroacoustic device because it takes an acoustical signal, such as speech, and converts it to an electric signal before the amplification stage. Through amplification, hearing aids increase the audibility of sounds, including speech for hearing impaired listeners. All hearing aids include a microphone, an output receiver, a battery with its connectors, and some way to control the electronic circuit for converting the acoustic signal to an electronic signal before the amplification stage.

Although hearing aids provide amplification to sound, the manner by which they process or control incoming signals may differ. Presently, hearing aids fall into three categories:

1. Analog hearing aids provide constant analysis and modification of the incoming signal.
2. Digitally programmable hearing aids use analog processing and programming of the hearing aid response characteristics into digital memory, with digital control of the analog circuit.
3. True digital devices use digital signal processing (DSP). DSP differs from traditional analog and digital/hybrid systems, in that the incoming acoustic signal is first converted to a string of digits, after which a DSP scheme (i.e., complex mathematical algorithm) is applied.

Analog hearing aids provide the most basic type of technology to supply quality amplification to a wide range of hearing losses. This type of device is designed based on particular frequency response from an audiogram. Digitally programmable devices have a microchip and may allow greater flexibility for amplification needs and capability. A computer is used to program the device for different listening situations, depending on the individual hearing loss profile, speech understanding, and range of tolerance for louder sounds. Digital signal processing devices are digitally programmable hearing aids that utilize digitalized sound processing to convert sound waves into digital signals. These devices are self-adjusting and allow even more flexibility in programming the hearing aid so that the sound it transmits more specifically matches the hearing loss. DSP aids function by analyzing the incoming sound. The digital aid then determines whether the sound is speech or noise and converts this information to numbers. The resultant digitized numbers are then manipulated according to algorithm instructions, reconverted to an analog form (i.e., sound waves), and delivered to the ears without producing the types of distortion often associated with analog technology hearing aids. DSP aids may be considered an advanced signal processing technology.

Hearing aids can be further categorized as air conduction hearing aids, bone conduction hearing aids and middle ear hearing aids. Air conduction devices are the treatment of choice for sensorineural hearing loss, mixed hearing loss or conductive hearing loss not responsive to

medical or surgical correction. Middle ear hearing aids are only indicated for sensorineural hearing loss and until recently were available only as semi-implantable devices. In March of 2010, the FDA granted premarket approval for a fully implantable middle ear hearing aid. Bone conduction devices are primarily indicated for conductive hearing loss, mixed hearing loss and unilateral sensorineural hearing loss (e.g., single-sided deafness). Single-sided deafness is generally defined as a condition in which an individual has non-functioning hearing in one ear and receives no clinical benefit from amplification in that ear and has normal audiometric function in the contralateral ear.

Air Conduction Hearing Aids

Air conduction hearing aids allow sound to travel along the normal physiological route through the external ear canal and middle ear. Air conduction hearing aids are designed for placement in one of several locations:

- **Behind the ear (BTE):** This type of hearing aid fits behind the ear and carries sound to the ear through a custom ear mold. Hearing aids that are attached to eyeglasses are a type of behind-the-ear hearing aid. They are useful for mild-to-severe hearing loss.
- **In the ear (ITE):** These hearing aids are custom-made to fit in the outer ear. Wires cannot be seen because they are inside the aid. They are useful for mild to moderate hearing loss.
- **In the ear canal (ITC):** This type of hearing aid is custom-made to fit in the ear canal. There are no wires or tubes. These hearing aids are almost impossible to see. They help people with all but the most severe hearing loss.
- **Completely in the canal (CIC):** This type of hearing aid fits almost entirely in the canal. Due to the small size, the numbers of output/response controls are limited. Deep placement precludes use of a directional microphone. Amount of gain is sufficient for no more than moderate hearing loss.

Contralateral routing of signal (CROS): This type of hearing aid is designed for persons with no usable hearing in one ear and normal hearing or minimal hearing loss in the other ear. A microphone is located on the impaired side and sound is transmitted to the good ear via an open ear mold. The microphone and receiver may be coupled by a wire that runs around the back of the neck (or through the glasses), or the signal may be transmitted wirelessly over a radio frequency.

U.S. Food and Drug Administration (FDA): Air conduction hearing aids are Class I devices regulated by the FDA. Class I devices are subject to the least regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices.

The FDA defines a personal sound amplification product (PSAP) as “an electronic product that is intended for non-hearing-impaired consumers to amplify sounds in certain environments, such as for hunting or other recreational activities, and is not intended to aid persons with or compensate for impaired hearing” (FDA, 2022). PSAPs are not considered medical devices by the FDA (FDA, 2022). In August 2022, the FDA issued a guidance document on the regulatory requirements for hearing aid devices and personal sound amplification products (PSAP) to provide clarity for consumers regarding these devices. The guidance describes hearing aids, PSAPs, their intended use and the regulatory requirements. Per the FDA, “PSAPs are not intended to diagnose, treat, cure, mitigate, or prevent disease and are not intended to affect the structure or function of the body”. Additional examples given by the FDA (2022) of situations in which PSAPs may be used

include bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations).

Bone Conduction Hearing Aids

For some people, the use of a conventional air-conduction hearing device is precluded by medical conditions, such as chronic ear drainage. Under such circumstances, users may consider an alternative device, such as a bone conduction hearing aid. Bone conduction devices are primarily indicated for conductive hearing loss and mixed hearing loss. With this system, a bone conduction receiver is placed on the mastoid and held in position by a headband, an abutment, or a magnet. These devices transmit sound vibrations to the inner ear by direct bone conduction through the skull. More energy is required to stimulate the ear by bone conduction than by air conduction; consequently, this device can be used only with milder hearing losses. The frequency response of the bone conduction aid is not as good as with the more traditional systems. Bone conduction hearing aids may be appropriate when air conduction hearing aids do not fulfill the amplification needs for conductive hearing losses. Such cases may include atretic (i.e., no ear canal opening) or microtic ears, chronic middle ear drainage, mastoid cavity problems, and abnormally small ear canals. Due to the variability in quality of the sound and problems in maintaining proper placement, these aids are considered only when more traditional hearing aids are not acceptable.

U.S. Food and Drug Administration (FDA): Bone conduction hearing aids, including bone-anchored hearing aids, are FDA approved as Class II devices.

Percutaneous Bone Anchored Hearing Aid (BAHA)/Bone Anchored Hearing Device (BAHD) (i.e., with Abutment): The BAHA devices are FDA-approved as a bone-anchored, bone conduction hearing aid and, according to the FDA and manufacturer are indicated for patients over five years of age (FDA 510(k) K984162, 1999; BAHA, Entific Medical Systems, 2002–2004). These devices are also referred to as auditory osseointegrated implant systems. The bone anchored hearing aid or hearing device consists of a titanium implant anchored in the mastoid, a skin-penetrating abutment, and a sound processor. The sound processor transforms sound into mechanical vibrations that are transmitted through the abutment and implant to the skull. This direct transmission of mechanical energy is 10 to 15 dB more efficient than sound transmission via skin and underlying tissues with conventional bone conduction. Indications for the device have broadened since the initial approval and are FDA approved for unilateral or bilateral mixed or conductive hearing loss, and for unilateral sensorineural hearing loss. According to the FDA approval for unilateral sensorineural hearing loss (FDA, 510(k) summary K021837) the Branemark Bone Anchored Hearing Aid (Baha®) was substantially equivalent regarding intended use to air conduction hearing aids with a CROS unit. FDA labeling supports BAHA devices as an alternative to an air conduction CROS device when a CROS device is not tolerated or desired.

In general, a unilateral implant is used for individuals with unilateral conductive or mixed hearing loss and for unilateral sudden sensorineural hearing loss of a profound degree. According to the FDA-approved indications, a bilateral implant is intended for patients with bilaterally symmetric moderate to severe conductive or mixed hearing loss. With symmetrical hearing loss (difference of less than 15 db HL each side at individual frequencies or < 10 dB difference of PTA measured at frequencies of 500 Hz, 1000, 2000, and 3000 between ears) the degree and configuration of hearing loss is the same in both ears (Kerber and Baloh, 2012; FDA, 2012).

With the percutaneous device, the hearing aid transducer is coupled to a titanium screw located in the upper mastoid region on the temporal bone; the screw protrudes through the skin. The difference between the standard bone conduction hearing aid and the bone-anchored hearing aid is direct stimulation of the bone instead of stimulation through the skin. A bone anchored hearing aid transmits sound to the cochlea bypassing any conductive component that may be obstructing

sound (i.e., a bone anchored hearing system can pick up sounds on the deaf side, convert them into sound vibrations, and transfer them to the healthy ear via the skull bone).

FDA approved bone anchored hearing aid systems include the Ponto (Oticon Medical, Somerset, NJ) and the Cochlear Baha and Cochlear Baha Connect system (Cochlear Americas, Centennial, CO). The differences are primarily related to the power requirement for use, sound selectivity and adaptability to other accessories. All of the following Sound Processors have received FDA 510(k) clearance: Baha® Divino™, Baha® Intenso™, Baha® BP100™; Baha® Cordelle™ II 65dB Sound Processor, Baha® 5 SuperPower, and the Baha® 6 Max (Cochlear Americas, Centennial, CO). The sound processors are designed for different levels of hearing loss; therefore, the required bone conduction thresholds vary with the type of processor. For example, the Baha Divino utilizes digital sound processing and a built-in directional microphone. This device may be utilized by patients with bone conduction thresholds of 45 dB HL. Patients with unilateral, profound sensorineural hearing loss of the indicated ear with normal contralateral hearing (defined as 20 dB HL air conduction pure tone average) may also benefit from this device. The more powerful bone conduction systems (e.g., utilizing the Baha® 5 SuperPower processor) are indicated for more severe hearing loss (up to 65 dB HL).

BAHA /BAHD devices are considered an acceptable alternative if air conduction hearing aids are contraindicated. The patients recommended for these devices must either be unable to use conventional air conduction hearing aids or have undergone ossicular replacement surgery because of chronic otitis media, congenital malformation of the middle/external ear, or other acquired malfunctions of the middle or external ear canals which preclude the wearing of a conventional air conduction hearing aid. Patients must be able to maintain the abutment/skin interface of the BAHA, if the percutaneous abutment is used with the direct connect system. Therefore, careful consideration must be given to the patient's psychological, physical, emotional, and developmental capabilities of maintaining hygiene.

For children with congenital malformations, sufficient bone volume and bone quality must be present for a successful fixture implantation. In general, children are more likely to lose a BAHA device due to rough play or because the skull of a child is thin and soft, for the device to become loose. When a child receives a BAHA device a sleeper implant may be inserted which acts as a back-up device. The sleeper implant is a fixture implanted near the primary implant that can be fitted with a sound processor in the event the initial device is lost or becomes loose. Since hearing is important for normal speech development a sleeper implant avoids the need for replacement surgery and prevents any delay in sound processing as a new sound processor can be easily connected to restore hearing. Kiringoda and Lustig (2013) published a meta-analysis of the complications associated with osseointegrated hearing aids and noted that in children the total rate of implant loss ranged from 0.0% to 25%. In some cases, however, the sleeper implant may never be activated. Furthermore, it is possible the sleeper implant can also be affected by factors that contributed to the loss or loosening of the primary device.

Improved patient outcomes and functioning with the use of bone anchored hearing devices have been reported in the published medical literature. Most of the published evidence consists of case series and reviews. However, the evidence supports that the majority of patients preferred the bone anchored hearing device over conventional devices and reported improved speech recognition scores and sound quality (Zeitler, et al., 2012; de Wolf, et al., 2011; Ricci, et al., 2011; Christensen, et al., 2010; House and Kutz, 2010; Linstrom, et al., 2009; House and Kutz, 2007). Several studies have focused on individuals who suffer from single sided deafness (i.e., unilateral sensorineural deafness) while the other ear has normal to near-normal hearing (Zeitler, et al., 2012; Linstrom, et al., 2009; Baguley, et al., 2006; Lin, et al., 2006; Hol, et al., 2005). BAHA devices have not been proven effective in the peer-reviewed published scientific literature to

improve clinical outcomes when used for other conditions, including bilateral sensorineural hearing loss.

Partially Implantable Magnetic BAHA/BAHD (i.e., Abutment-Free): A second type of bone conduction hearing aids without percutaneous abutment that are partially implantable use magnetic coupling. Advantages of magnetic coupling theoretically include improved comfort, no need for abutment or headbands and hearing gain is proposed to be comparable to that of other bone anchored hearing aid devices. These devices pick up sounds through the externally worn microphone and convert the sound signal to electromechanical vibrations, which are then transmitted through the skin to the skull bone and then to the cochlea. Benefits of the devices are influenced by multiple factors including the degree and natural history of an individual's hearing loss, the use of early or updated device audio processors, the speech perception tests used, and the type and optimization of conventional hearing aids.

One device currently available, the Sophono[®] Alpha 2™ System (Sophono, Inc., Boulder, CO), consists of a titanium implant using two magnets for fixation and transmits sound through an externally worn sound processor. In contrast to a percutaneous Baha[®] device, this implant system requires no headband or abutment, no hair follicle removal, and has a faster healing time. In order to promote greater transmission of acoustics between magnets, skin thickness must be reduced to 4-5 mm over the implant when it is surgically placed. The device is indicated when the hearing loss (e.g., PTA measured at 500 Hz, 1000, 2000, and 3000 Hz) is less than 45 dB HL.

The Baha[®] Attract system (Cochlear Americas, Centennial, CO) also uses a magnetic system with a titanium implant and avoids the use of the abutment connection protruding out of the skin. Similar to the FDA-approved indications for the standard Baha device with abutment, requirements for the Baha Attract include the following (FDA, 2013):

- patients aged 5 years and older
- patients who have a conductive or mixed hearing loss and can still benefit from sound amplification
- bilateral fitting - intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss
- patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. single-sided deafness)
- Baha for single-sided deafness (SSD) is also indicated for any patient who is a candidate for an air conduction contralateral routing of signals (AC CR0S) hearing aid, but who for some reason cannot or will not use an AC CR0S

The Bonebridge (Med-EL., Innsbruck, Austria) was FDA 510(k) approved as a Class II device (K183373) in 2019. The System consists of the externally worn audio processor and the internal implant. The external component is comprised of an audio processor (e.g. SAMBA audio processor (AP). The AP attaches to the internal component with a magnet and is powered by a hearing aid battery. Per the FDA approval, the Bonebridge bone conduction hearing implant system is intended for the following 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 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 Bonebridge for SSD is also indicated for any patient who meets the criteria for an air conduction contralateral routing of sound (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS hearing aid.
- Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids." (FDA, 2019)

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 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 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.
- Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids."

Evidence in the peer-reviewed scientific literature evaluating the effectiveness of various partially implantable hearing systems using magnetic coupling consists primarily of case series and cohort studies with small patient populations (n=8-57) (Pla-Gil, et al., 2021; Gawecki, et al., 2020; Goycoolea, et al., 2020; Lau, et al., 2020; Gawecki, et al., 2016; Briggs, et al., 2015; Carr, et al.,

2015; Siegert & Kanderske, 2013; Siegert, 2011). In general, these studies have demonstrated positive results for outcomes of pure-tone average (PTA), speech recognition threshold (SRT), and quality of life (QOL), with improvements of 41% and 56% in the hearing parameters and a wide variation in improvement levels for QOL. Adverse events and complication rates have been comparable to standard BAHAs with abutment.

Dimitriadis et al. (2016) conducted a systematic review of the available evidence (n=10 studies/89 subjects) to evaluate indications, surgical technique, and audiological, clinical and functional outcomes of the Baha Attract. Studies were selected that reported on patients who underwent Baha Attract implantation and were primarily prospective and retrospective cohort studies and case series. Outcomes measured included PTA, speech recognition threshold (SRT), and quality of life scores compared to the unaided condition. Follow-up in studies occurred through three years. On average PTA thresholds were improved by 41 dB HL and speech reception thresholds by 56 dB HL. QOL measured by various tools ranged from 30%-91%. Complications included seroma or hematoma formation (4.4 % of patient), and pain and redness around the implant related to the magnet strength, which was commonly resolved by adjusting the power of the magnet. Limitations of reviewed studies were the observational design and small sample sizes. The authors concluded that functional and audiological results of the Baha Attract are satisfactory thus far with a lower complication rate compared to the skin penetrating Baha devices (Dimitriadis, et al., 2016). These study results support safety and efficacy of the Baha Attract system, but due to the small number of patients, results may not be generalizable.

A limited number of studies in the published peer-reviewed medical literature support the safety and effectiveness of magnetic bone conduction systems. In addition, magnetic and standard BAHAs are fundamentally equivalent with the exception of the processor attachment mechanism. As such, magnetic bone conduction systems are indicated for a subset of individuals who have conductive or mixed (conductive and sensorineural) hearing loss.

Non-surgical BAHA/BAHD: A bone conduction system that does not require surgical implantation has gained FDA approval. The ADHEAR bone conduction system (Med-EL, Innsbruck, Austria) includes an audio processor that can be retained on the head with an adhesive adapter or by a headband situated over the mastoid behind the auricle. The System is intended to be worn during waking hours and removed at night. The adapter is applied on the hairless area behind the ear. The audio processor is connected to the adhesive adapter via the snap connector. The processor detects, processes, amplifies, and transmits sound to the adhesive adapter that transmits vibrations to the mastoid which conducts sounds to the inner ear. The adhesive can be worn for 3–7 days and is water resistant. The processor has four pre-defined settings that can be adjusted with a push button switch (Med-EL, 2024; FDA, 2018).

The ADHEAR System is FDA approved as a Class II hearing aid (K172460) and considered substantially equivalent to legally marketed devices. Per the FDA approval "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 for use include:

- "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."

Non-implantable Intraoral BAHA/BAHD: The FDA has granted 510(k) approval for another type of bone anchored hearing device known as the SoundBite™ Hearing System (K100649, K110831) (Sonitus Medical, Inc., San Mateo, CA). This device is a noninvasive intraoral bone conduction hearing aid and is intended for individuals 18 years of age or older who have moderately severe, severe, or profound sensorineural hearing loss in one ear (i.e., single-sided deafness) and for individuals with conductive hearing loss where the pure tone average bone-conduction hearing threshold is ≥ 25 dB HL. The device functions similar to a bone anchored hearing aid however with the SoundBite System the receiver (place on the non-hearing ear) picks up sound and transmits the sound signal to a transducer. The transducer (placed on the back tooth on the maxillary arch on the side of the normal hearing ear) sends the electromechanical sound signal to the normal cochlea.

Evidence evaluating the use of intraoral bone conduction hearing aid devices is limited in comparison to other hearing aid devices currently available. Published clinical trials are nonrandomized, involve small sample populations, and evaluate short-term outcomes (Gurgel, et al., 2015; Gurgel and Shelton, 2013; Popelka, et al., 2010; Murray, et al., 2011a; Murray, et al., 2011b). The reported outcomes of these few studies do not lead to firm conclusions regarding the safety and efficacy of these devices.

In a prospective cohort study, Gurgel et al. (2015) evaluated the safety and efficacy of an intraoral bone conduction hearing aid (SoundBite device) after 12 months use. Initially the study included 127 subjects; 37 were terminated due to incomplete follow-up (21 stated their drop-out was unrelated to the device, 16 were lost to follow-up). An additional nine subjects withdrew leaving 81 subjects for the analysis. Outcomes were measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire and audiometric testing. The authors reported that APHAB showed a significant improvement in ease of communication, reverberation, background noise, and global hearing score. There were no major adverse events reported. Overall patient satisfaction was high, although only 55.6% of subjects were satisfied with their ability to eat with the transducer in place. The study is limited by lack of control group, subjective outcome measures, and the nine subjects who withdrew from the study secondary to device related problems, as noted by the authors. Additional studies involving large populations and evaluating long-term outcomes are required to support improved clinical outcomes in comparison to other well-established BAHA devices.

Middle Ear Implants (MEIs) - Partially or Fully Implantable Devices

Implantable middle ear hearing aids can be either totally implantable or partially implantable and use either a piezoelectric, electromechanical, or electromechanical based vibration transducer that directly moves inner or middle ear structures. The mechanism by which these devices amplify and transmit sound varies. Implantable middle ear hearing aids differ from other conventional aids in that they convert electric signals into mechanical energy which is coupled directly to the ossicular chain. The critical component of these devices is the transducer. Piezoelectric devices function by passing an electric current through a piezo-ceramic crystal. Piezoelectric transducers are directly coupled to the ossicular chain; electromagnetic units can be placed in approximation to the ossicular chain and provide direct drive capability. Electromagnetic transducers generate a magnetic field using a coil carrying current encoded by a microphone. In contrast to other conventional aids, fully implantable devices are not visible externally and do not require removal for activities such as bathing or swimming.

U.S. Food and Drug Administration (FDA): Middle ear implants are regulated as Class III devices by the FDA. Class III is the most stringent regulatory category for devices and requires premarket approval to ensure safety and effectiveness.

Partially Implantable Device: Partially or semi-implantable electromagnetic devices consist of an external microphone and speech processor with a battery that is located in the external device. The FDA has approved two semi-implantable electromagnetic hearing aids: the Vibrant Soundbridge (P990052) (Med-El, GMBH; Austria) and the Maxum System (P010023), a newer device based on Soundtec® Direct Drive Hearing System (Ototronix, TX). The Maxum system is a hearing implant which includes a small magnetic titanium device (placed in the middle ear on the incus) and the use of a sound processor worn in the ear canal. The implant is placed in the middle ear with a minimally invasive procedure through the ear canal, which requires the separation of the incus and stapes. The magnet is mounted on the stapes, and the incus and stapes are positioned together again. After the canal is healed, a sound processor is worn deeply in the ear canal which uses electromagnetic energy to vibrate the implant, and subsequently the stapes, which directly stimulates the inner ear hair cells in the cochlea. In contrast to the standard hearing aids that use air pressure to transport sound to the middle ear, electromagnetic hearing aids use the periodic attraction and repulsion of two magnetic fields, one from an electromagnet and the other from a static magnet, as a means of vibrating ossicles and transmitting sound to the inner ear.

Electromagnetic hearing aids are an alternative for adults who have moderate to severe sensorineural hearing loss. Both systems operate by similar mechanisms, with slight differences in design (FDA, 2009; FDA, 2001). Each device is approved for adults aged 18 or older who have moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid. It is recommended that the individual have some prior experience with a well-fitting acoustic hearing aid prior to receiving a semi-implantable hearing aid. Electromagnetic hearing aids are contraindicated for subjects who have conductive hearing loss, retrocochlear or central auditory disorders, active middle ear infection, tympanic membrane perforations associated with recurrent middle ear infections, disabling tinnitus, or prior surgery of the middle ear. The manufacturers have issued a warning regarding avoidance of strong magnetic fields, including magnetic resonance imaging (MRI), electrosurgical instrumentation, diathermy, electroconvulsive therapy, positron emission tomography (PET) scans, transcranial ultrasounds, and linear acceleration techniques (Ototronix, 2014; FDA, 2001).

Early published clinical studies evaluating middle ear semi-implantable hearing aids focused on the use of the Soundtec Direct System and the Vibrant Soundbridge semi-implantable devices and involved small numbers of patients (Hough, et al., 2002; Luetje et al., 2002). However, the results of those early trials indicated that the devices are well tolerated and capable of improving thresholds in patients with moderate to severe sensorineural hearing loss. More recent studies in the published peer reviewed scientific literature continue to support safety and efficacy. Furthermore, there is evidence from published clinical trials that suggests when compared to acoustic hearing aids, the semi-implantable devices are relatively safe and can provide significant improvements in functional gain and speech perception.

Fully Implantable Device: The Esteem® (Envoy Medical, Minneapolis, MN), a piezoelectric middle ear hearing aid device, has been approved through the FDA PMA process as a fully implantable hearing device indicated for the treatment of moderate to severe sensorineural hearing loss. The device consists of three implantable components: a sound processor (implanted in the temporal bone behind the outer ear), sensor and driver (implanted in the middle ear). The natural ear is used as a microphone. A sensor senses vibrations from the eardrum and middle ear bones and converts these mechanical vibrations into electric signals, which are then sent to the sound processor, where the signal is amplified and filtered to compensate for the individual's hearing loss. The driver converts the enhanced electrical signal back to vibrations which are then transmitted to the inner ear. The vibrations cause pressure waves in the fluid of the cochlea and the cochlea converts the waves to nerve impulses which are transmitted to the brain where they are interpreted as sound.

The Esteem was FDA PMA approved (P090018) "to alleviate hearing loss in patients by replicating the ossicular chain and providing additional gain. The Esteem is indicated for patients with hearing loss that meet the following criteria: 1) 18 years of age or older; 2) stable bilateral sensorineural hearing loss; 3) moderate to severe sensorineural hearing loss defined by pure tone average (PTA); 4) unaided speech discrimination test score greater than or equal to 40%; 5) normally functioning eustachian tube; 6) normal middle ear anatomy; 7) normal tympanic membrane; 8) adequate space for Esteem implant determined via a high resolution CT scan; and 9) minimum 30 days of experience with appropriately fit hearing aids" (FDA, 2010).

Contraindications include a history of middle ear infections, chronic middle ear disease, Meniere disease, disabling tinnitus or vertigo, fluctuating hearing loss, central auditory disorder, keloid formation, and sensitivity to the component materials of the device. Battery life is dependent on the number of hours used and exposure to average noise level (estimated at 4.5 to 9 years). The initial surgical procedure may take 4–8 hours depending on the surgeon's experience. Replacement requires a surgical procedure and local anesthesia. Risks associated with the Esteem device are similar to those of mastoid operative procedures. Implants that result in limited or no hearing benefit may require a second surgical procedure to correct the problem (Envoy Medical Corp, 2020; Seidman, et al., 2019; Shohet, et al., 2018). A second fully implantable middle ear device, not yet FDA approved and currently under investigation, is the Otologics MET (Middle Ear Transducer) Carina™ (Otologics, Boulder, CO) device (Seidman, et al., 2019).

There is insufficient evidence to support the safety and efficacy of the Esteem device. Studies are primarily in the form of retrospective reviews and case series with small patient populations. Published data supporting long-term safety, efficacy, device durability and improvement in health outcomes is lacking. Clinical trials comparing the outcomes of fully implantable devices to other conventional aids, such as bone conduction or semi-implantable devices are limited and the clinical advantages of this device, which requires a surgical procedure for insertion and battery replacement, have not been established.

Shohet et al. (2018) conducted a prospective multicenter study (n=51) to assess the safety and efficacy of the Esteem totally implanted middle ear device. Subjects who completed the original pivotal trial (n=61) prior to FDA approval were invited to enroll in this post approval study. Primary outcome measures were speech reception threshold (SRT) and word recognition scores at 50 dB (WRS50s). Secondary outcome measures were WRS and subjective hearing results from the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire. Post implantation follow-ups occurred for five years, and implant-aided audiometric measurements were made annually from years 1–5. Five-year data was available on 49 subjects. Compared to the baseline aided (BLA) condition, SRT scores improved significantly at every annual follow-up ($p < 0.01$) up to year five. Through the four-year follow-up, the WRS50s improved from 64%–79%. At five years postimplant, 46/49 subjects had improved pure tone averages (PTA) and 36/49 had an improved WRS compared to baseline unaided (BLU) hearing. A total of 34/49 had improved PTA and 28/49 had improved WRS compared to BLA. The greatest benefit from the implant over the hearing aid was at 2,000 Hz. At the 5-year follow-up, WRS improved by $17.0\% \pm 4.2\%$ compared to the BLA. APHAB scores were improved in most subscales at every annual follow-up. There were 15 adverse events (e.g., distortion, facial tingling, incision pain and soreness) in 11 subjects. Three serious adverse events in three subjects, including two surgical wound dehiscence events, were reported. Three devices were explanted, and five devices required revisions. Bone conduction scores were assessed to ensure that there was no significant decline in residual cochlear function. The scores had improved significantly by 3.7 dB at the 5-year follow-up ($p = 0.024$). Average battery life was 4.9 years. Limitations of the study include the small patient population and lack of a control group. The author's noted that one potential reason why the implant performed better than hearing aids is that subjects were tested at baseline with their own hearing aid, and in some

cases, the subject's own hearing aid was either not of the optimal configuration or not optimally fitted.

Preliminary data evaluating the fully implantable Esteem middle ear device consisted of a feasibility trial (n=7), case series (n=6), and a trial (n=57) that was part of the FDA PMA process. Chen et al. (2004) published the results of a feasibility study (n=7) that demonstrated the device had potential benefit for subjects with mild to severe sensorineural hearing loss. Barbara et al. (2009) evaluated the use of the Esteem 2[®] device and remarked primarily on aspects regarding the surgical procedure. The authors noted the surgical procedure was complex, the duration differed among patients, and required interruption of the ossicular chain resulting in unaidable hearing until activation of the device following surgery. Once the device was activated, hearing was restored. According to the FDA PMA application study results, the Esteem implant had a 5% revision rate prior to the four-month follow-up visit due to fibrotic tissue growth/interference, and no revisions between the four and 10 month follow-up. The Esteem implant procedure had no significant effect on cochlear function stability as measured by bone conduction. Regarding effectiveness, the Esteem was statistically superior to the pre-implant hearing aid in Speech Reception Threshold and Word Recognition Scores. The type of pre-implant hearing aid varied among subjects and included: behind the ear (BTE), in the ear (ITE), in the ear canal (ITC), completely in the canal (CIC). In addition, Esteem outcomes were better than or equal to the pre-implant hearing aid condition in several other standard audiological measures, including Abbreviated Profile of Hearing Aid Benefit and the hearing in noise test as measured by QuickSIN. As part of the PMA process, the FDA is requiring two post approval studies. Facial paralysis developed in seven percent of the FDA PMA study participants and 42 percent developed taste disturbance. Both events resolved during the one-year study period.

Earlier studies (Gerard, et al, 2012; Barbara, et al., 2011; Shohet, et al., 2011; Memari, et al., 2011; Kraus, et al., 2011) consisted of small patient populations with short-term follow-ups. One group of authors reported that at 12-month follow-up the Esteem resulted in improvements in functional gain and word recognition scores in a subset of individuals (n=5) who were part of the initial FDA PMA trial with profound hearing loss (Shohet, et al., 2011). Memari et al. (2011) reported the results of a prospective nonrandomized controlled clinical trial (n=10) that involved subjects with moderate to severe sensorineural hearing loss who received the Esteem device. Each subject served as their own control. The average follow-up period was 29.4 month. One device was explanted as a result of low hearing gain and facial weakness and one subject had a revision due to excessive bone growth after insertion. Based on preoperative and postoperative comparisons, all but one subject had an overall average hearing gain compared to conventional device with improvement in subjective hearing quality. Barbara et al. (2011) reported the results of a group of 27 subjects who received the Esteem. The authors compared results of hearing and quality of life between individuals with moderate bilateral sensorineural hearing loss and severe. There was a high degree of satisfaction among participants overall and air conduction thresholds and mean speech reception scores improved. The authors noted that implantation of the Esteem may be considered an alternative for individuals with severe sensorineural hearing loss for which other challenging interventions such as cochlear implantation could be considered. Kraus et al. (2011) reported the 12-month results of a phase 2 FDA trial following insertion of the Esteem device in 57 subjects. Reported results demonstrated that speech reception thresholds (SRT), word recognition scores (WRS) and pure tone averages improved. The authors acknowledged that the results were statistically superior to best-fit hearing aids for both SRT and WRS ($p \leq .001$).

Advanced Signal Processing Technologies

There is extensive growth in the number of new sound-producing schemes aimed at improved speech recognition, sound quality and comfort. Advanced signal processing technologies such as digital signal processing, directional microphones, multiple channels, and multiple memories have been incorporated into hearing aid devices. Digital signal processing is utilized in many hearing

aids to improve performance. Some of the potential advantages of DSP include flexible gain processing, digital feedback reduction, digital noise reduction and digital speech enhancement. However, in some cases, even the most complex DSP schemes may not be very selective to speech. They generally amplify all environmental sounds within specific frequency ranges. Directional microphones can improve signal-to-noise ratio by reducing input that is not in front of the hearing aid user (i.e., amplifies sounds originating in the front). Combining DSP with directional microphones may further enhance the signal-to-noise ratio. Multiple channels allow different programming for gain and compression and may be useful for digital noise reduction and feedback cancellation. Multiple memories are used to store hearing aid settings designed for particular listening situations and may be controlled with a remote device or automatically. In most cases, advanced signal processing technologies are accompanied by high patient expectations. Nevertheless, despite these improvements, some individuals continue to have problems with background noise, especially the speech of other people talking in their vicinity.

The device of choice is dependent on the severity of hearing loss, the acoustic environment in which the individual functions, and whether or not that individual’s hearing needs are being met. DSP instruments are very sophisticated and offer advantages and options not available in standard technology. The choice of selecting advanced signal processing technologies (i.e., DSP, directional microphones, multiple channels, multiple memories) versus the standard analog device is a decision that needs to be made by the patient in concert with a trained health professional (physician or audiologist).

Professional Societies/Organizations

A revised 2021 position statement from the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) states that bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device are considered to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by a qualified otolaryngology-head and neck surgeon. The AAO-HNS notes “These devices are approved by the Food and Drug Administration (FDA) for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and the respective regulatory agencies in countries other than the United States” (AAO-HNS, 2021).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information. (NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Air Conduction Hearing Aids

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
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
V5100	Hearing aid, bilateral, body worn
V5120	Binaural, body
V5130	Binaural, in the ear
V5140	Binaural, behind the ear
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)
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
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
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
V5264	Ear mold/insert, not disposable, any type
V5265	Ear mold/insert, disposable, any type
V5267	Hearing aid or assistive listening device/supplies/accessories, not otherwise specified

HCPCS Codes	Description
V5275	Ear impression, each

Partially Implantable Bone Conduction Hearing Aids

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
69799	Unlisted procedure, middle ear

HCPCS Codes	Description
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis

Bone Conduction Hearing Aids

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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
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

HCPCS Codes	Description
L8690	Auditory osseointegrated device, includes all internal and external components
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment

Batteries

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
V5266	Battery for use in hearing device
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
L8623	Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each

Repair and/or Replacement

Considered Medically Necessary, when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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
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
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
69399 [†]	Unlisted procedure, external ear

†Note: Considered Medically Necessary when used to represent removal and replacement of an abutment only and when criteria in the applicable policy statements listed above are met.

HCPCS Codes	Description
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8693	Auditory osseointegrated device abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each
L9900 ^{††}	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code
V5014	Repair/modification of a hearing aid

†† Note: Considered Medically Necessary when used to represent the replacement auditory osseointegrated device headband only and when criteria in the applicable policy statements listed above are met.

Experimental, Investigational, Unproven when used to report a fully implantable middle ear hearing aid device (e.g., Esteem®), or a non-implantable intraoral bone anchored hearing aid device (e.g., Soundbite™ Hearing System):

CPT®* Codes	Description
69799	Unlisted procedure, middle ear

HCPCS Codes	Description
L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code
V5298	Hearing aid, not otherwise classified

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	No policy statement changes.	5/15/2024

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