Subject: Hearing Aids

Table of Contents

Coverage Policy .................................................. 1
General Background ........................................... 3
Coding/Billing Information ................................. 11
References ........................................................ 14

In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. 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. Proprietary information of Cigna. Copyright ©2016 Cigna

Coverage Policy

Hearing aid devices include:

- air conduction aids
- bone conduction aids
- middle ear hearing aid devices

Hearing aid devices (including all of the above) are specifically excluded under many benefit plans. In addition, coverage for hearing aids may be governed by federal and/or state mandates. Coverage for advanced signal processing technologies (e.g., digital signal processing, directional microphones, multiple channels, and multiple memories) may vary depending on benefit plan language and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for a hearing aid is available, the following conditions of coverage apply.

Cigna covers a hearing aid device as medically necessary for ANY of the following:

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

Cigna covers ANY of the following hearing aid devices used to amplify sound, including advanced signal processing technologies (e.g., digital signal processing, directional microphones, multiple...
channels, multiple memories) as medically necessary when ONE of the above medical necessity criteria for the hearing aid device has been met:

- **air conduction hearing aid device for the treatment of mild to profound hearing loss:**
  - **behind the ear (BTE)** device, for mild to profound hearing loss
  - **in the ear (ITE)** device, for mild to moderate hearing loss
  - **in the ear canal (ITC)** device, for mild to moderate hearing loss
  - **completely in the canal (CIC)** device, for mild to moderate hearing loss
  - **contralateral routing of sound (CROS)** device, for single-sided hearing loss (i.e., bone conduction on the hearing side is normal)

- **semi-implantable middle ear hearing aid device (e.g., Vibrant Soundbridge, Maxum™)** 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 aid device when 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)

- **unilateral percutaneous bone-anchored hearing aid (BAHA) device for an individual with conductive or mixed hearing loss and ALL of the following:**
  - pure tone average bone conduction threshold of up to 70 dBHL (decibel hearing level) with average measured at 500, 1000, 2000, and 3000 Hz
  - speech discrimination score of better than 60%
  - 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
  - normal hearing on the contralateral side (e.g., pure tone average ≤ 20 dBHL, measured at 500 Hz, 1000, 2000, 3000 Hz)

- **bilateral percutaneous bone-anchored hearing aid (BAHA) devices for an individual with symmetrical conductive or mixed hearing loss (i.e., difference of < 15 dBHL each side at individual frequencies or < 10 dBHL difference of pure tone average measured at frequencies of 500, 1000, 2000, and 3000 Hz between ears) and all of the following:**
  - pure tone average bone conduction threshold of up to 70 dBHL with average measured at 500, 1000, 2000, and 3000 Hz
  - speech discrimination score of better than 60%
  - 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
• unilateral percutaneous bone-anchored hearing aid (BAHA) device as an alternative to an air conduction CROS device for an individual with single-sided deafness (i.e., unilateral sensorineural hearing loss > 100 dBHL) and normal hearing in the other ear

REPAIR AND REPLACEMENT
Cigna covers repair and/or replacement of a medically necessary hearing aid device as follows:

• Repair is covered 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 is covered when the currently used device is no longer functioning adequately and has been determined to be non-repairable.

NOT COVERED
Cigna does not cover ANY of the following hearing aid devices, because each is considered experimental, investigational or unproven:

• fully implantable middle ear hearing aid (e.g., Esteem)
• partially implantable magnetic bone conduction hearing aid (e.g., Sophono® Alpha 2™ System, Cochlear™ BAHA® 4 Attract)
• non-implantable, intraoral bone conduction hearing aid (e.g., SoundBite™ Hearing System)

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 otoxic 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 or that involves 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. The standard PTA measurement is the average of four frequency thresholds at 500, 1000, and 2000 Hz. Normal speech and conversation occur at 40–60 dB (decibels) within a frequency range of 500–3000 Hz (Hertz). Hearing loss severity is classified as follows (American Speech and Language Association, 2015; National Institute on Deafness and Other Communication Disorders [NIDCD], 2015):

<table>
<thead>
<tr>
<th>Level</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>26–40 dBHL</td>
</tr>
<tr>
<td>Moderate</td>
<td>41–70 dBHL</td>
</tr>
<tr>
<td>Severe</td>
<td>71–90 dBHL</td>
</tr>
<tr>
<td>Profound</td>
<td>≥ 91 dBHL</td>
</tr>
</tbody>
</table>

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. 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 compensation for, impaired hearing" (FDA, 2001). 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 (Ricketts, et al., 2001).

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 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 where an individual has non-functioning hearing in one ear and receives no clinical benefit from amplification in that ear, with the contralateral ear possessing normal audiometric function.

Air Conduction Hearing Aid
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 worst 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 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.

**Bone Conduction Hearing Aid**

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 must consider an alternative device, such as a bone conduction aid. With this system, a bone conduction receiver is placed on the mastoid and held in position by a headband and a small wire that connects the bone oscillator to a BTE hearing aid. Bone conduction devices stimulate the cochlea in the same way as during bone conduction threshold assessments. 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 (Ricketts, et al., 2001). 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 labeled Class II devices.

**Percutaneous Bone Anchored Hearing Aid (BAHA)/Bone Anchored Hearing Device (BAHD)**

The BAHA devices are FDA-approved, bone-anchored, bone conduction hearing aids and, according to the FDA and manufacturer, they are specifically indicated for patients over five years of age (FDA 510(k) K984162, 1999; BAHA, Entific Medical Systems, 2002–2004). 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. They are also referred to as auditory osseointegrated implant systems. Indications for the device have broadened since the initial FDA approval. The devices have been successfully used 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 BAHA device 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. The most powerful BAHA sound processor can compensate for a sensorineural loss of up to 65 dBA.

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 dBHL at individual frequencies or < 10dB 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, Baloh, 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 device 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).

There are several BAHA models available for use. The differences are primarily related to the power requirement for use, sound selectivity and adaptability to other accessories. All of the following devices have received 510(k) clearance from the FDA: Baha® Divino™, Baha® Intenso™, Baha® BP100™, BAHA 4 Sound Processor, BAHA 5 Sound Processor; and the Baha® Cordelle™ II 65dB Sound Processor(Cochlear Americas, Englewood, CO) in addition to Ponto Bone Anchored Hearing System (Oticon Medical Ab, Sweden).

Required bone conduction thresholds vary with the type of device. 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. 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 Cordelle is indicated for more severe hearing loss, with an average bone threshold of up to 70 dB.

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 a majority of patients preferred the bone anchored hearing device over conventional devices and reported improved speech recognition scores and sound quality (Snik, et al., 1995; Wazen, et al., 1998; Ontario Medical Health Technology Advisory Committee (OMHTAC), 2002; House and Kutz, 2007; Linstrom, et el., 2009; Christensen, et al., 2010; House, et al., 2010; Ricci, et al., 2011; de Wolf, et al., 2011; Zeitzer, et al., 2012). Several studies have focused on individuals who suffer from single sided deafness (i.e., unilateral sensorineural deafness) in one ear while the other ear has normal to near-normal hearing (Hol, et al., 2005; Baguley, et al., 2006; Lin, et al., 2006; Linstrom, et al., 2009; Zeitler, et al., 2012). 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 Bone Conduction System:** Bone conduction hearing aids without percutaneous abutment that are partially implantable and use magnetic coupling are being developed and investigated. Advantages of magnetic coupling theoretically include improved comfort, no need for abutment or headbands and hearing gain comparable to that of other BAHA 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 (Hayes, 2011; 2015).

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 dBHL. Another device, the BAHA® 4 Attract system (Cochlear Americas, Englewood, CO) also uses a magnetic system and avoids the use of the abutment connection protruding out of the skin.

Evidence in the peer-reviewed scientific literature evaluating the effectiveness of partially implantable hearing devices using magnetic coupling is limited to preliminary trials evaluating safety and efficacy (Gawęcki, et al., 2016; Briggs, et al., 2015; Carr, et al., 2015; Siegert & Kanderske, 2013; Siegert, 2011). A majority of the available evidence involves small sample populations and evaluates short term outcomes. Additional studies with large populations and long-term follow-up are needed to support improvement of hearing and safety with the use of this type of device.

Nonimplantable Baha: The FDA has granted 510(k) approval for another type of bone anchored hearing device known as the SoundBite™ Hearing System (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 nonhearing 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, 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.

A Technology Brief published by Hayes reviewed the available evidence (n=5 studies/111 subjects) on the SoundBite Hearing System used to treat unilateral hearing loss. The review included prospective, nonrandomized, controlled un-blinded studies (n=2 studies), cohort studies (n=2 studies) and a single prospective, randomized crossover study. Follow-up in these studies ranged from one to six months. Outcomes related to aided and unaided hearing were evaluated. The device was found to be associated with few minor medical or dental complications (e.g., mouth irritation). Study results indicated that the SoundBite improved hearing scores compared with nonuse of a hearing device. However the evidence was found to be insufficient and of poor quality, with limitations that included small sample size, short-term follow-up, and a lack of comparisons with other hearing devices. It was summarized that additional well-designed comparative studies are needed and that definitive conclusions regarding safety and efficacy of the device cannot be made at this time (Hayes, 2014; 2015).

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. In the authors opinion the intraoral bone conduction device was safe and effective for the treatment of unilateral sensorineural hearing loss. 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)**

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.

**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) and a sensor and driver (implanted in the middle ear). The device uses the natural ear 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; the cochlea converts the waves to nerve impulses and transmits them to the brain where they are interpreted as sound. According to the manufacturer, the Esteem hearing device is intended for use by adults 18 years of age or older, with mild to severe sensorineural hearing loss, speech discrimination score of >40%, normally functioning Eustachian tube, normal middle ear anatomy and adequate space for the implant. Battery life is dependent on the number of hours used and exposure to average noise level (estimated at 4.5 to 9 years); replacement requires a surgical procedure and local anesthesia. Risks associated with the Esteem device are similar to those of mastoid operative procedures and those that result in limited or no hearing benefit and may require a second surgical procedure to correct. 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.

Preliminary data evaluating the fully implantable Esteem middle ear device consist of a feasibility trial (n=7), case series (n=6), and a trial (n=57) that was part of the FDA PMA process, in addition to published reviews. 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 2nd 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 BTE, ITE, ITC, 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.
Semi-Implantable Device:

Semi-implantable 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 devices: the Esteem and the Memari. Both devices are designed for individuals with moderate to severe sensorineural hearing loss and require a surgical procedure for insertion. However, clinical trials have shown that outcomes of fully implantable devices to other conventional aids, such as bone conduction or semi-implantable devices, have not been established. Post-approval studies are currently being conducted. Furthermore, 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.
electromagnetic hearing aids: the Vibrant Soundbridge (Med-El, GMBH; Austria) and the Maxum System, 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, 2002a; FDA, 2002b). Each device is approved for adults age 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 (FDA, 2002a; FDA 2002b).

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 indicate 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.

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. Edwards (2007) reported that in 2005, 93% of hearing aids sold in the United States contained digital signal processing technology, and more than half of those included directional microphones. 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 (Ricketts, 2001). 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. Data suggests that 25% of people who own hearing aids do not wear them due to this problem (Ricketts, et al., 2001).

The instrument 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 many advantages and options not available in standard technology. The evidence base comparing digital to analog hearing aids is small, of poor quality and inconsistent. Some authors have reported there are no statistically significant differences in outcomes when comparing the use of digital signal processing
devices to analog devices (Taylor, et al., 2001; Moore, et al., 2001; Bille, et al., 1999). Few authors have reported some evidence for advantages of digital aids compared to analog; however, the average differences are not large. Wood and Lutman (2004) compared linear analog and advanced digital hearing aids (DSP) in 100 first-time hearing aid users with mild to moderate sensorineural hearing loss in a single-blind randomized crossover trial. The authors reported that speech recognition in noise was significantly better with digital aids at a raised level of 75dB, and that user satisfaction and preference was higher when compared to analog aids. Arlinger et al. (1998) evaluated 33 patients using a digital signal processing aid (i.e., Oticon DigiFocus), in subjects who had previous experience with modern analog aids, in a one-month clinical trial, and reported that most patients preferred the digital aid over their analog aid (n=23); six preferred their own aid, and four stated there was no difference. 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).

Use Outside of the US: Hearing aids are available in several countries other than the United States; device availability, regulatory guidance, and criteria for coverage vary according to the available health service options for each country.

Summary
Evidence in the published scientific literature supports the safety and effectiveness of hearing aid devices for a subset of individuals with hearing loss. 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 aid devices are only indicated for sensorineural hearing loss. There is sufficient evidence to support safety and efficacy of semi-implantable middle ear devices; data evaluating fully implantable middle ear hearing aids and long-term clinical outcomes are lacking. Furthermore, fully implantable middle ear hearing aids require a surgical procedure for insertion and battery replacement, posing additional risk in comparison to other devices. Bone conduction hearing aids are primarily indicated for conductive hearing loss and mixed hearing loss, although some bone-anchored hearing aid (BAHA) devices may also be utilized for patients with unilateral sensorineural hearing loss. Safety and efficacy of partially implanted BAHA devices or intraoral BAHA devices has not been established in the medical literature. Advanced signal processing technologies such as digital signal processing devices, multiple channels or bands, and/or multiple microphones may enhance the function of the device in various listening situations.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Air and Bone Conduction Devices

Covered when medically necessary, if coverage for hearing aid devices is available under the plan:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V5030</td>
<td>Hearing aid, monaural; body worn, air conduction</td>
</tr>
<tr>
<td>V5040</td>
<td>Hearing aid, monaural; body worn, bone conduction</td>
</tr>
<tr>
<td>V5050</td>
<td>Hearing aid, monaural; in the ear</td>
</tr>
<tr>
<td>V5060</td>
<td>Hearing aid, monaural; behind the ear</td>
</tr>
<tr>
<td>V5100</td>
<td>Hearing aide, bilateral, body worn</td>
</tr>
<tr>
<td>V5120</td>
<td>Binaural; body</td>
</tr>
<tr>
<td>V5130</td>
<td>Binaural body; in the ear</td>
</tr>
<tr>
<td>V5140</td>
<td>Binaural body; behind the ear</td>
</tr>
<tr>
<td>V5170</td>
<td>Hearing aid, CROS; in the ear</td>
</tr>
<tr>
<td>V5180</td>
<td>Hearing aid, CROS; behind the ear</td>
</tr>
<tr>
<td>V5210</td>
<td>Hearing aid, bicros; in the ear</td>
</tr>
<tr>
<td>V5220</td>
<td>Hearing aid, bicros; behind the ear</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>V5242</td>
<td>Hearing aid, analog, monaural, cic (completely in the ear canal)</td>
</tr>
<tr>
<td>V5243</td>
<td>Hearing aid, analog, monaural, itc (in the canal)</td>
</tr>
<tr>
<td>V5244</td>
<td>Hearing aid, digitally programmable analog, monaural, cic</td>
</tr>
<tr>
<td>V5245</td>
<td>Hearing aid, digitally programmable, analog, monaural, itc</td>
</tr>
<tr>
<td>V5246</td>
<td>Hearing aid, digitally programmable analog, monaural, ite (in the ear)</td>
</tr>
<tr>
<td>V5247</td>
<td>Hearing aid, digitally programmable analog, monaural, bte (behind the ear)</td>
</tr>
<tr>
<td>V5248</td>
<td>Hearing aid, analog, binaural, cic</td>
</tr>
<tr>
<td>V5249</td>
<td>Hearing aid, analog, binaural, itc</td>
</tr>
<tr>
<td>V5250</td>
<td>Hearing aid, digitally programmable analog, binaural, cic</td>
</tr>
<tr>
<td>V5251</td>
<td>Hearing aid, digitally programmable analog, binaural, itc</td>
</tr>
<tr>
<td>V5252</td>
<td>Hearing aid, digitally programmable, binaural, ite</td>
</tr>
<tr>
<td>V5253</td>
<td>Hearing aid, digitally programmable, binaural, bte</td>
</tr>
<tr>
<td>V5254</td>
<td>Hearing aid, digital, monaural, cic</td>
</tr>
<tr>
<td>V5255</td>
<td>Hearing aid, digital, monaural, itc</td>
</tr>
<tr>
<td>V5256</td>
<td>Hearing aid, digital, monaural, ite</td>
</tr>
<tr>
<td>V5257</td>
<td>Hearing aid, digital, monaural, bte</td>
</tr>
<tr>
<td>V5258</td>
<td>Hearing aid, digital, binaural, cic</td>
</tr>
<tr>
<td>V5259</td>
<td>Hearing aid, digital, binaural, itc</td>
</tr>
<tr>
<td>V5260</td>
<td>Hearing aid, digital, binaural, ite</td>
</tr>
<tr>
<td>V5261</td>
<td>Hearing aid, digital, binaural, bte</td>
</tr>
<tr>
<td>V5262</td>
<td>Hearing aid, disposable, any type, monaural</td>
</tr>
<tr>
<td>V5263</td>
<td>Hearing aid, disposable, any type, binaural</td>
</tr>
<tr>
<td>V5264</td>
<td>Ear mold/insert, not disposable, any type</td>
</tr>
<tr>
<td>V5265</td>
<td>Ear mold/insert, disposable, any type</td>
</tr>
<tr>
<td>V5266</td>
<td>Battery for use in hearing device</td>
</tr>
<tr>
<td>V5267</td>
<td>Hearing aid supplies/accessories</td>
</tr>
<tr>
<td>V5275</td>
<td>Ear impression, each</td>
</tr>
</tbody>
</table>

**Semi-Implantable Device**

Covered when medically necessary, if coverage for hearing aid devices (e.g., Vibrant Soundbridge, Maxum™) is available under the plan:

<table>
<thead>
<tr>
<th>CPT®* Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69714</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69715</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
</tr>
<tr>
<td>L8692</td>
<td>Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment</td>
</tr>
<tr>
<td>S2230</td>
<td>Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear</td>
</tr>
<tr>
<td>V5095</td>
<td>Semi-implantable middle ear hearing prosthesis</td>
</tr>
</tbody>
</table>
**Bone Anchored Devices**

Covered when medically necessary, if coverage for hearing aid devices is available under the plan and when used to report a bone anchored hearing aid (BAHA) device:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69714</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69715</td>
<td>Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
<tr>
<td>69799</td>
<td>Unlisted procedure, middle ear</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
</tr>
</tbody>
</table>

**Repair/Replacement**

Covered when medically necessary:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
<tr>
<td>69717</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy</td>
</tr>
<tr>
<td>69718</td>
<td>Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy</td>
</tr>
<tr>
<td>69399</td>
<td>Unlisted procedure, external ear</td>
</tr>
</tbody>
</table>

† Note: Covered when used to represent removal and replacement of an abutment only and medical necessity criteria outlined in this Coverage Position are met.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8691</td>
<td>Auditory osseointegrated device, external sound processor, replacement</td>
</tr>
<tr>
<td>L8693</td>
<td>Auditory osseointegrated device abutment, any length, replacement only</td>
</tr>
<tr>
<td>L9900</td>
<td>Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS “L” code</td>
</tr>
<tr>
<td>V5014</td>
<td>Repair/Modification of a hearing aid</td>
</tr>
</tbody>
</table>

†† Note: Covered when used to represent the replacement auditory osseointegrated device headband only and medical necessity criteria outlined in this Coverage Position are met.

Experimental, Investigational, Unproven, Not Covered when used to report a fully implantable middle ear hearing aid device (e.g., Esteem), a partially implantable magnetic bone conduction hearing aid device (e.g., Sophono® Alpha 2® System, Cochlear™ BAHA® 4 Attract), a non-implantable intraoral bone anchored hearing aid device (e.g., Soundbite™ Hearing System):
Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69799</td>
<td>Unlisted procedure, middle ear</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L9900</td>
<td>Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS “L” code</td>
</tr>
<tr>
<td>V5298</td>
<td>Hearing aid, not otherwise classified</td>
</tr>
</tbody>
</table>


References


27. Guidelines for hearing detection and intervention programs. Boys Town National Research Hospital, Joint Committee on Infant Hearing (JCIH). Omaha, NE: The Hospital; 2002.


63. Ontario Medical Health Technology Advisory Committee (OMHTAC). Bone anchored hearing aid [health technology literature review]. Toronto, ON, Canada: Ontario Ministry of Health and Long-Term Care;


68. Principles on infant hearing loss. Boys Town National Research Hospital, Joint Committee on Infant Hearing (JCIH). Omaha, NE: The Hospital; 2002.


The registered marks "Cigna" and the "Tree of Life" logo are owned by Cigna Intellectual Property, Inc., licensed for use by Cigna Corporation and its operating subsidiaries. All products and services are provided by or through such operating subsidiaries and not by Cigna Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, Cigna Health and Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation.