



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Hearing Aids

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Hyperlink to Related Coverage Policies

- Aural Rehabilitation
- Cochlear and Auditory Brainstem Implants
- Facial Protheses, External
- Otoplasty/Ear Reconstruction

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. 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 group 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. Proprietary information of CIGNA. Copyright ©2008 CIGNA

Coverage Policy

Hearing aids 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 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 the following devices, including advanced signal processing technologies (e.g., digital signal processing, directional microphones, multiple channels, multiple memories) when one of the above medical necessity criteria for the hearing aid has been met:

- air conduction devices for the treatment of mild to profound hearing loss:

- **behind the ear (BTE)** devices, for cases of mild to profound hearing loss
 - **in the ear (ITE)** devices, for cases of mild to moderate hearing loss
 - **in the ear canal (ITC)** devices, for all but the most severe hearing loss
 - **completely in the canal (CIC)** devices, for mild to moderate hearing loss
 - **on the body hearing aid** devices, for severe/profound hearing loss
 - **contralateral routing of sound (CROS)** devices, for cases of single-sided hearing loss
- **middle ear implant devices 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
 - **bone conduction devices when use of a conventional device is precluded by a medical condition (this list may not be all-inclusive):**
 - microtic ears
 - small ear canals
 - conditions involving chronic middle ear drainage
 - **bone-anchored hearing aids (BAHAs) for patients with ALL of the following:**
 - pure tone average bone conduction threshold of up to 70 dBHL (decibel hearing loss)
 - 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 activity
 - conditions that contraindicate an air conduction hearing aid

CIGNA covers repair and/or replacement of a medically necessary hearing aid as follows:

- Repair is covered when the currently used device is no longer functioning adequately and repair is expected to make the equipment fully functional.
- Replacement is covered when the currently used device is no longer functioning adequately and has been determined to be non-repairable.

General Background

Hearing loss occurs with a frequency of about one in one thousand newborns and is also a prevalent, but not necessarily an inevitable, feature of the aging process. According to the National Institute on Deafness and Other Communication Disorders (NIDCD), hearing loss affects 17 in 1000 children under the age of 18. Incidence increases with age: 314 out of 1000 people over the age of 65 have hearing loss, as do 40–50% of people over the age of 75. Approximately 28 million people in the U.S. suffer from hearing impairment. Many of the patients have unilateral severe to profound sensorineural hearing loss or conductive hearing loss that is not correctable with surgery or with the use of traditional hearing aids. (House, Kutz, 2007).

The three basic types of hearing loss are 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 (cochlea) or the eighth cranial 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. Mixed hearing loss is conductive hearing loss coupled with sensorineural hearing loss.

Normal speech and conversation occurs at 40–60 dB (decibels) within a frequency range of 500–3000 Hz (Hertz). Severity of hearing loss is defined as follows:

Mild	26–40 dBHL
Moderate	41–70 dBHL
Severe	71–90 dBHL
Profound	≥ 91 dBHL

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. Sensorineural hearing loss can affect selective portions of a person's range of hearing. Therefore, the degree of hearing loss and the specific pitches (frequencies) affected will vary from person to person. Even in instances where the pattern of the loss is the same, the degree of sound clarity may vary from person to person or may differ between ears in an individual. As a result, individuals suffering from sensorineural hearing loss often require hearing aids tailored to the specific sensitivity and pattern of their hearing loss.

The goal of hearing aid use is to amplify and deliver speech and other sounds at levels equivalent to that of normal speech and conversation. Many factors are considered when selecting a hearing aid, including the patient's degree of hearing loss, work setting or profession, motivation and acceptance of the hearing loss. Acceptance of a hearing aid depends on the degree and type of hearing loss, acceptance of hearing loss, motivation regarding use of the aid and level of expectation.

The U.S. Food and Drug Administration (FDA), for the purposes of labeling, has described a hearing aid 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). All standard hearing aids are amplification devices that have elements in common. 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).

The American National Standards Institute (ANSI) has developed a standard so that different hearing aids can be compared across clinics. The standard requires that electroacoustic properties be measured in either an anechoic (i.e., echoless) chamber or a specially designed test box containing absorbent material sufficient to reduce background noises. The three most important characteristics associated with the ANSI standard continue to be:

- **Gain:** The amount of amplification the hearing aid provides. Gain is usually measured in decibels (dB).
- **Frequency response:** The amount of gain a hearing instrument provides across a range of frequency regions. Gain is usually provided only in frequency regions where hearing loss is present.
- **Saturation sound pressure level (SDPL):** The loudest sound the hearing instrument can produce, regardless of the incoming signal or the amount of gain. The hearing aid should be set so that it never becomes uncomfortably loud or damaging to the ear (Joint Committee on Infant Hearing [JCIH], 1994).

Types of Hearing Aids

Although standard 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.

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, 2005). 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).

Conventional Hearing Aids

Conventional hearing aids can be divided into air conduction hearing aids, bone conduction hearing aids and middle ear implants (i.e., semi-implantable devices). 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 implant devices are only indicated for sensorineural hearing loss. Bone conduction devices are primarily indicated for conductive hearing loss and mixed hearing loss.

Air Conduction Devices: Air conduction devices 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.
- **On the body:** This type of hearing aid is appropriate for severe hearing loss. A larger microphone, amplifier and battery are enclosed in a case and worn on the body. The case is connected by a wire to an ear receiver that is attached to an ear mold (FDA, 2001).
- **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. Class I devices are subject to General Controls, which include establishment registration, medical device listing, manufacturing devices in accordance with good manufacturing practices, and labeling in accordance with labeling regulations and submission of premarket notification.

Bone Conduction Devices: For some people, the use of a conventional amplification device is precluded by medical conditions. 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, Chicchis, Bess, 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 include microtic ears, chronic drainage for middle ear 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. Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls which may include special labeling requirements, mandatory performance standards and postmarket surveillance.

Bone-Anchored Hearing Aids (BAHAs): 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 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.

In this 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. The BAHA device transmits sound to the cochlea bypassing any conductive component that may be obstructing sound. There are several BAHA models available: the Baha Divino™, BAHA® Classic 300, BAHA® Compact, and the BAHA® Cordelle (Entific Medical Systems, Goteberg, Sweden). 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 Classic and Compact are suitable for people with conductive or mixed hearing loss and a maximum bone conduction threshold of 45 dB. The Cordelle is indicated for more severe hearing loss, with an average bone threshold of approximately 70 dB. The patients recommended for this device 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. Therefore, careful consideration must be given to the patient's psychological, physical, emotional and developmental capabilities of maintaining hygiene. For children and patients with congenital malformations, sufficient bone volume and bone quality must be present for a successful fixture implantation.

Improved patient outcomes and functioning with the use of BAHA devices have been reported in the published medical literature. Snik et al. (1995) compared the BAHA device with conventional bone conduction devices and reported improved speech recognition scores with the BAHA device. Wazen et al. (1998) reported improved speech reception threshold and patient satisfaction with use of the BAHA device.

A scientific literature review was conducted by the Medical Advisory Secretariat (MAS), Ontario Ministry of Health and Long Term Care (2002) currently known as the Ontario Medical Health Technology Advisory Committee (OMHTAC). The authors reported on the safety and efficacy of the BAHA in their review; they indicated that BAHAs have been safely implanted in adults and children with success rates of 90% and higher in most studies. In addition, they stated that BAHAs significantly improved the free field and sound field thresholds, as well as speech discrimination, for former users of bone conduction hearing aids. The outcomes were ambiguous for former users of air conduction aids (OMHTAC, 2002). Hayes conducted a technology assessment to evaluate the safety and efficacy of the BAHA device for moderate to severe conductive or mixed hearing loss (Hayes, 2005a). The authors evaluated evidence from the published peer-reviewed literature and concluded the evidence from several prospective studies and some retrospective reviews suggests that BAHAs can provide significant improvements in functional gain, speech perception, and hearing ability in various listening situations, compared to air conduction hearing aids for some patients with moderate to severe conductive hearing loss. BAHA use was also associated with improvements in language development in young children.

House and Kutz (2007) reported the results of a retrospective case review consisting of 149 patients who underwent implantation with a BAHA device over a consecutive four-year period of time to determine the incidence of complications. Sensorineural hearing loss was present in 127 patients, and the remaining 22 patients had a conductive hearing loss. The authors noted significant complications were uncommon after implantation. The most common complication was skin overgrowing the abutment (n=11); other complications included extrusion of the fixture (n=5) and local irritation (n=2).

The published scientific literature contains no randomized controlled trials, and most of the studies reviewed are case series. However, the evidence supports that a majority of patients preferred the BAHA device over conventional devices and reported improved speech recognition scores and sound quality.

Middle Ear Implants (MEIs): The FDA has approved two semi-implantable electromagnetic hearing aids: the Vibrant Soundbridge (manufactured by Symphonix Inc., of San Jose, CA) and Soundtec® Direct Drive Hearing System (manufactured by Soundtec, Inc., Oklahoma City, OK). 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).

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. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Premarket approval is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

Hough and associates (2002) presented to the FDA the results of a multicenter phase II clinical trial comparing the use of the Soundtec Direct System with an optimally fitted air conduction hearing aid in subjects with bilateral, moderate to moderately severe sensorineural hearing impairment. The authors evaluated 103 patients in the trial to assess safety and efficacy of the Soundtec system. Compared to an optimally fitted hearing aid, the Soundtec resulted in an increase in functional gain in speech frequencies, and increases in speech discrimination and patient satisfaction.

Luetje et al. (2002) reported similar findings in a Phase III clinical trial conducted for the Vibrant Soundbridge device. In this prospective, multicenter study, 53 adults with moderate to severe sensorineural hearing loss had middle ear devices implanted and were evaluated at four or more intervals after implantation. The authors reported improvements in functional gain and patient satisfaction, with occlusion and feedback virtually eliminated. Aided speech recognition was comparable, and residual hearing was unchanged. The authors concluded that the Vibrant Soundbridge was safe and effective for the treatment of moderate to severe sensorineural hearing loss.

HAYES conducted a technology assessment evaluating the safety and efficacy of semi-implantable electromagnetic hearing aids and concluded that there is limited 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, speech perception, and hearing ability in various listening situations for some adults with moderate to severe sensorineural hearing loss (Hayes, 2005b). Hayes further reported additional studies are required to evaluate long-term safety and efficacy of the implants and to define appropriate patient selection criteria, as one study reported conflicting data.

Most of the recent published clinical studies for middle ear implantable hearing aids focused on the use of the Soundtec Direct System and the Vibrant Soundbridge and involves small numbers of patients. No randomization or blinding was noted. However, the evidence reported to the FDA does indicate that these devices are well tolerated and capable of improving thresholds in some patients.

Summary

The basic types of hearing loss are sensorineural, conductive or mixed. A variety of microphones, amplifiers and receivers may be used in the hearing aid, depending on the type and degree of hearing loss. 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. Conventional hearing aids can be divided into air conduction hearing aids, bone conduction hearing aids and middle ear implants (i.e., semi-implantable devices). 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

implant devices are only indicated for sensorineural hearing loss. Bone conduction devices 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. Patients should be counseled regarding selection and appropriate expectations when using a hearing aid device.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

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

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
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy

HCPCS Codes	Description
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, replacement
V5014	Repair/modification of a hearing aid
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
V5095	Semi-implantable middle ear hearing prosthesis
V5100	Hearing aide, bilateral, body worn
V5120	Binaural; body
V5130	Binaural body; in the ear
V5140	Binaural body; behind the ear
V5170	Hearing aid, CROS ;in the ear
V5180	Hearing aid, CROS; behind the ear
V5210	Hearing aid, bicros; in the ear
V5220	Hearing aid, bicros; behind the ear
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
V5266	Battery for use in hearing device
V5267	Hearing aid supplies/accessories
V5275	Ear impression, each
V5298	Hearing aid, not otherwise classified

ICD-9-CM Diagnosis Codes	Description
382.9	Unspecified otitis media
387.0 – 387.9	Otosclerosis
388.12	Noise-induced hearing loss
388.2	Unspecified sudden hearing loss
389.00 – 389.9	Hearing Loss
744.00 – 744.09	Congenital anomalies of ear causing impairment of hearing
744.23	Microtia
	Multiple/Varied

***Current Procedural Terminology (CPT®) ©2007 American Medical Association: Chicago, IL.**

References

1. AAA hearing aid batteries & hearing accessories [product information]. Hearing USA. 2002. Accessed April 3, 2008. Available at URL address: <http://www.hearingusa.com/>
2. American Speech Language and Hearing Association. Hearing Aids. ©1997-2008 American Speech-Language-Hearing Association. Accessed April 3, 2008. Available at URL address: http://www.asha.org/public/hearing/treatment/hearing_aids.htm
3. Arlinger S, Billermark E, Oberg M, Lunner T, Hellgren J. Clinical trial of a digital hearing aid. Scand Audiol. 1998;27(1):51-61.
4. BAHA® - a difference patients can hear [product information]. Entific Medical Systems. Updated 2002-2004. Accessed March 29, 2007. Available at URL address: <http://www.entific.com/aboutBAHA.asp>
5. Bance M, Abel SM, Papsin BC, Wade P, Vendramini J. A comparison of the audiometric performance of bone anchored hearing aids and air conduction hearing aids. Otol Neurotol. 2002 Nov;23(6):912-9.

6. Baguley DM, Bird J, Humphriss RL, Prevost AT. The evidence base for the application of contralateral bone anchored hearing aids in acquired unilateral sensorineural hearing loss in adults. *Clin Otolaryngol*. 2006 Feb;31(1):6-14
7. Bergeron F. Bone-anchored hearing aids. Montreal: Agence d'Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS) 2006. Accessed April 4, 2008. Available at URL address: <http://www.aetmis.gouv.qc.ca/site/download.php?f=0c0b7b64123cca3dfcffda4457982115>
8. Bille M, Jensen AM, Kjoerbol V, Sibelle P, Nielson H. Clinical study of a digital vs an analogue hearing aid. *Scand Audiol*. 1999;28(2):127-35.
9. Blackmore KJ, Kernohan MD, Davison T, Johnson IJ. Bone-anchored hearing aid modified with directional microphone: do patients benefit? *J Laryngol Otol*. 2007 Mar 26;:1-4 [Epub ahead of print].
10. Carlson DL, Reeh HL. Pediatric audiology. In: Bailey BJ, Calhoun KH, Healy GB, Pillsbury HC III, Johnson JT, Tardy ME Jr, et al., editors. *Head and neck surgery—otolaryngology*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2001. Ch. 91.
11. Centers for Medicare and Medicaid (CMS). Medicare benefit policy manual. Chapter 16 General Exclusions From Coverage. 100 Hearing aids and auditory implants. Accessed April 3, 2008. Available at URL address: <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?itemID=CMS012673>
12. D'Angelo WR, Bolia RS, Mishler PJ, Morris LJ. Effects of CIC hearing aids on auditory localization listener with normal hearing. *J Speech Lang Hear Res*. 2001;44(6):1209-14.
13. Davids T, Gordon KA, Clutton D, Papsin BC. Bone-anchored hearing aids in infants and children younger than 5 years. *Arch Otolaryngol Head Neck Surg*. 2007 Jan;133(1):51-5.
14. Della Santina CC, Lustig LR. Surgically implantable hearing aids. In : Cummings CW, Flint PW, Haughey BH, Robbins KT, Thomas JR, Harker LA, et al., editors. *Cummings: Otolaryngology: Head & Neck Surgery*, 4th ed., Copyright © 2005. CH 157.
15. Duthie EH, Katz PR, editors. *Practice of geriatrics*. 3rd ed. Philadelphia, PA: W.B. Saunders Company; 1998. p. 454-5.
16. Edwards B. The future of hearing aid technology. *Trends Amplif*. 2007 Mar;11(1):31-45.
17. FDA approves new implanted hearing device [FDA talk paper]. Rockville, MD: U.S. Food and Drug Administration (FDA). 2000 Oct. Accessed April 3, 2008. Available at URL address: <http://www.fda.gov/bbs/topics/ANSWERS/ANS01049.html>
18. Frye GJ. Testing digital and analog hearing instruments: processing time delays and phase measurements. *The Hearing Review*. 2001 Oct. Accessed April 3, 2008. Available at URL address: http://www.hr-hpr.com/issues/articles/2001-10_03.asp
19. Frye GJ. Testing digital hearing instruments: the basics. *The Hearing Review*. 2000 Aug.
20. Guidelines for hearing detection and intervention programs. Boys Town National Research Hospital, Joint Committee on Infant Hearing (JCIH). Omaha, NE: The Hospital; 2002.
21. Hakansson BE, Carlsson PU, Tjellstrom A, Liden G. The bone-anchored hearing aid: principal design and audiometric results. *Ear Nose Throat J*. 1994 Sep;73(9):670-5.

22. Hall JW III, Antonelli. Assessment of peripheral and central auditory function. In: Bailey BJ, Calhoun KH, Healy GB, Pillsbury HC III, Johnson JT, Tardy ME Jr, et al., editors. Head and neck surgery—otolaryngology. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2001. Ch. 132.
23. HAYES Medical Technology Directory™. Bone-anchored Hearing Aids. Lansdale, PA: HAYES, Inc.; © 2007 Winifred S. Hayes, Inc. 2005a June. Updated search November 2006, November 2007.
24. HAYES Medical Technology Directory™. Semi-Implantable Electromagnetic Hearing Aids. Lansdale, PA: HAYES, Inc.; © 2007 Winifred S. Hayes, Inc. First published May 28, 2002. Reviewed, updated and retitled May 18, 2005b. Updated search May 2006, May 2007.
25. Hearing aid devices; professional and patient labeling. In: U.S. Food and Drug Administration (FDA). Code of federal regulations; title 21, vol. 8; subchapter H (medical devices); part 801 (labeling); subpart H (special requirements for specific devices); sec. 801.421. Revised 2007 Apr. Accessed April 3, 2008. Available at URL address:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=801.420>
26. Hearing Aids, selecting hearing aids for children; programmable hearing aids. Boys Town National Research Hospital. Omaha, NE: The Hospital; 2002.
27. Hearing loss. In: Beers MH, Jones TV, Berkwitz M, Kaplan JL, Porter R, editors. Merck manual of geriatrics. Sec. 15, ch. 128: Accessed April 3, 2008. Available at URL address:
http://www.merck.com/mrkshared/mm_geriatrics/sec15/ch128.jsp
28. Homer JJ, Roberts AC, Wengraf CL. In-the-ear aids within auricular prostheses. J Laryngol Otol. 2001;115(12):998-1000.
29. Hough DA, Matthews P, Hough JV. Bone conduction Implants for amplification: comparison of results. J Ear Nose Throat. 1997;(12):857-65.
30. Hough JV, Matthews P, Wood MW, Dyer RK Jr. Middle ear electromagnetic semi-implantable hearing device: results of the phase II SOUNDTEC direct system clinical trial. Otol Neurotol. 2002 Nov;23(6):895-903.
31. House JW, Kutz JW Jr. Bone-anchored hearing aids: incidence and management of postoperative complications. Otol Neurotol. 2007 Feb;28(2):213-7.
32. How your hearing works. Hearing USA. 2001. Accessed April 3, 2008. Available at URL address:
<http://www.hearingusa.com/hearingcare.htm#How%20Your%20Hearing%20Works>
33. Koch DB, Staller S, Jaax K, Martin E. Bioengineering solutions for hearing loss and related disorders. Otolaryngol Clin North Am. 2005 Apr;38(2):255-72.
34. Kunst SJ, Leijendeckers JM, Mylanus EA, Hol MK, Snik AF, Cremers CW. Bone-anchored hearing aid system application for unilateral congenital conductive hearing impairment: audiometric results. Otol Neurotol. 2008 Jan;29(1):2-7.
35. Levitt H. A historical perspective on digital hearing AIDS: how digital technology has changed modern hearing AIDS. Trends Amplif. 2007 Mar;11(1):7-24.
36. Luetje CM, Brackman D, Balkany TJ, Maw J, Baker RS, Kelsall D, et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: A prospective controlled multicenter study. Otolaryngol Head Neck Surg. 2002;126(2):97-107.
37. Maddison I. Ear structure and function. 1994 Nov. Revised 1998 Jul. London South Bank University website. Accessed April 3, 2008. Available at URL address:
http://myweb.lsbu.ac.uk/dirt/museum/ear_ct.html

38. Mills JH, Weber PC. Anatomy and physiology of hearing. In: Bailey BJ, Calhoun KH, Healy GB, Pillsbury HC III, Johnson JT, Tardy ME Jr, et al., editors. Head and neck surgery—otolaryngology. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2001. Ch. 129.
39. Moore BC, Stone MA, Alcantara JI. Comparison of the electroacoustic characteristics of five hearing aids. *Br J Audiology*. 2001 Oct 1;35(5):307-25.
40. Mueller G, Bentler R. Brief guide to modern hearing instrument technology. Hearing solutions, Hearing instruments. Better hearing Institute. Accessed April 3, 2008. Available at URL address: http://www.betterhearing.org/hearing_solutions/hearingInstrumentsGuide.cfm
41. National Institute on Deafness and other Communication Disorders [testimony/report]. United States Department of Health and Human Services, National Institutes of Health. 1997 Feb. Accessed April 3, 2008. Available at URL address: <http://www.nidcd.nih.gov/health/hearing/hearingaid.asp>
42. Negri S, Bernath O, Hauser R. Bone conduction implants: Xomed Audiant Bone Conductor VS BAHA. *J Ear Nose Throat*. 1997;76(6):394-6.
43. New device approval: Soundtec[®] Direct Drive Hearing System – P010023 [CDRH consumer information]. Rockville, MD: United States Food and Drug Administration (FDA), Center for Devices and Radiological Health; 2001 Sep 7. Accessed April 3, 2008. Available at URL address: <http://www.fda.gov/cdrh/mda/docs/p010023.html>
44. New device approval: Vibrant Soundbridge – P990052 [CDRH consumer information]. Rockville, MD: United States Food and Drug Administration (FDA), Center for Devices and Radiological Health; 2000 Aug 31. Accessed April 3, 2008. Available at URL address: <http://www.fda.gov/cdrh/mda/docs/p990052.html>
45. 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; 2002 Sep. Accessed April 3, 2008. Available at URL address: http://www.health.gov.on.ca/english/providers/program/ohtac/tech/reviews/sum_baha_090102.html
46. Palmer CV, Ortmann A. Hearing loss and hearing aids. *Neurol Clin*. 2005 Aug;23(3):901-18,viii.
47. Plyler PN, Lowery KJ, Hamby HM, Trine TD. The objective and subjective evaluation of multichannel expansion in wide dynamic range compression hearing instruments. *J Speech Lang Hear Res*. 2007 Feb;50(1):15-24.
48. Principles on infant hearing: background, roles and responsibilities, future directions. Boys Town National Research Hospital, Joint Committee on Infant Hearing (JCIH). Omaha, NE: The Hospital; 2002.
49. Principles on infant hearing loss. Boys Town National Research Hospital, Joint Committee on Infant Hearing (JCIH). Omaha, NE: The Hospital; 2002.
50. Prinz I, Nubel K, Gross M. Digital vs. analog hearing aids in children. Is there a method for making an objective comparison possible? *HNO*. 2002 Sep 1;50(9):844-9.
51. Priwin C, Jonsson R, Hultcrantz M, Granstrom G. BAHA in children and adolescents with unilateral or bilateral conductive hearing loss: a study of outcome. *Int J Pediatr Otorhinolaryngol*. 2007 Jan;71(1):135-45. Epub 2006 Nov 7.
52. Ricketts TA. Digital hearing aids: current "state of the art". American Speech Language and Hearing Association. ©1997-2008 American Speech-Language-Hearing Association. Accessed April 3, 2008. Available at URL address: http://www.asha.org/public/hearing/treatment/digital_aid.htm

53. Ricketts TA, Chicchis AR, Bess FH. Hearing aids and assistive listening devices. In: Bailey BJ, Calhoun KH, Healy GB, Pillsbury HC III, Johnson JT, Tardy ME Jr, et al., editors. Head and neck surgery—otolaryngology. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2001. Ch. 155.
54. Sandlin RE. Digital hearing aids: hype, hoax or hope. Audiology Online.com. Accessed March 29, 2007. Available at URL address: http://audiologyonline.com/articles/arc_disp.asp?id=293&catid=1
55. Schmuziger N, Schimmann F, àWengen D, Patscheke J, Probst R. Long-term assessment after implantation of the Vibrant Soundbridge device. Otol Neurotol. 2006 Feb;27(2):183-8.
56. Smeeth L, Fletcher AE, Ng ES, Stirling S, Nunes M, Breeze E, et al. Reduced hearing, ownership, and use of hearing aids in elderly people in the UK. Lancet. 2002;359(9316):1466-70.
57. Snik AF, Mylanus EA, Cremers CW. Implantable electronic otologic devices: state of the art; the bone anchored hearing aid, a solution for previously unresolved otologic problems. Otolaryngol Clin North Am. 2001 Apr;34(2)337-64.
58. Snik AF, Mylanus EA, Cremers CW. The bone-anchored hearing aid compared with conventional hearing aids: audiologic results and the patients' opinions. Otolaryngol Clin North Am. 1995 Feb;28(1):73-83.
59. Sound advice on hearing aids. Washington, DC: Federal Trade Commission (FTC); 1998 May. © Copyright 1999-2008 JLCOM Publishing Co., L.L.C. Accessed April 3, 2008. Available at URL address: <http://www.lawpublish.com/ftchear.html>
60. Statistics about hearing disorders, ear infections, and deafness. Bethesda, MD: National Institute on Deafness and Other Communication Disorders (NIDCD), National Institutes of Health (NIH). Updated 4/2/08. Accessed April 3, 2008. Available at URL address: <http://www.nidcd.nih.gov/health/statistics/hearing.asp>
61. Straight talk about hearing loss and hearing aids. Rockville, MD: U.S. Food and Drug Administration (FDA), Dept. of Health and Human Services; 1999 Oct. Accessed April 3, 2008. Available at URL address: <http://www.fda.gov/opacom/lowlit/hearaid.html>
62. Taylor RS, Paisley S, Davis A. Systematic review of the clinical and cost effectiveness of digital hearing aids. Br J Audiology. 2001 Oct 1;35(5):271-88.
63. Taylor RS, Paisley S. The clinical and cost effectiveness of advances in hearing aid technology [report to the National Institute of Clinical Excellence (NICE)]. Updated 2000 Jun 14. Accessed March 29, 2007. Available at URL address: http://www.nice.org.uk/pdf/hearing_hta_report.pdf
64. United States Food and Drug Administration (FDA). Summary of Safety and Effectiveness. 510(k) summary. K992872. (Cordelle II System). November 24, 1999. Accessed April 3, 2008. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=117923>
65. United States Food and Drug Administration (FDA). Summary of Safety and Effectiveness. 510(k) K011438. (Bilateral fitting of BAHAs device) July 23, 2001. Accessed April 3, 2008. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=4501>
66. United States Food and Drug Administration (FDA). Summary of Safety and Effectiveness. 510(k) summary. K021837 (Single-sided sensorineural deafness). August 30, 2002. Accessed April 3, 2008. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=8407>
67. United States Food and Drug Administration (FDA). Summary of Safety and Effectiveness (Initial clearance, BAHAs). 510(k) summary. K955713. August 9, 1996. Accessed April 3, 2008. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=103548>

68. United States Food and Drug Administration (FDA). Summary of Safety and Effectiveness. 510(k) summary. K984162 (Pediatric clearance, BAHA) June 1999. Accessed April 3, 2008. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=115207>
69. Wade PS, Halik JJ, Wegerer JP, Vosu LK. Ten year experience with percutaneous bone-anchored hearing aids. J Otolarygol. 2002 Apr;31(2):80-4.
70. Wazen JJ, Caruso M, Tjellstrom A. Long-term results with the titanium bone-anchored hearing aid: the U.S. experience. Am J Otolaryngol. 1998 Nov;19(6):737-41.
71. Wood SA, Lutman ME. Relative benefits of linear analogue and advanced digital hearing aids_Int J Audiol. 2004 Mar;43(3):144-55.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	0093	Hearing Aids
Great-West Healthcare	7/28/2006	04.236.02	Bone-Anchored hearing Aid

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.