Anthem

Clinical UM Guideline

Subject: Air Conduction Hearing Aids
Guideline #: CG-DME-37
Status: Reviewed

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Description

This document addresses the use of air conduction hearing aids in the treatment of individuals with hearing loss.

Note: Please see the following documents related to other treatments and devices for the treatment of hearing loss:

- CG-SURG-81 Cochlear Implants and Auditory Brainstem Implants
- CG-SURG-82 Bone-Anchored and Bone Conduction Hearing Aids
- SURG.00084 Implantable Middle Ear Hearing Aids

Note: Benefit language supersedes this document. Hearing aids are not a covered benefit under all member contracts/certificates. Please see the text in the footnote of this document regarding Federal and State mandates and applicable benefit plan contract language, as contract terms, conditions and limitations of coverage within these documents may specifically address the topic of hearing aids.

Clinical Indications

Medically Necessary:

Air conduction hearing aid devices are considered **medically necessary** for the treatment of hearing loss when **ALL** of the following criteria are met (A and B):

A. The hearing loss is due to one of the following etiologies:
    1. Sensorineural hearing loss; **or**
    2. Mixed hearing loss; **or**
    3. Conductive hearing loss which has been:
        a. unresponsive to medical interventions;**and**
        b. unresponsive to surgical interventions or not amenable to surgical correction;**and**
B. The degree of hearing loss is confirmed by audiometry or other age-appropriate testing to be greater than or equal to 26 decibels (dB).

Binaural air conduction hearing aids are considered**medically necessary** when BOTH of the following criteria are met (A and B):

A. Both ears meet the criteria listed above in A and B;**and**
B. Binaural testing shows improved speech recognition using bilateral devices.

Air conduction hearing aid devices with advanced technology models and features (for example, in-the-ear and in-the-ear-canal models with digital signal processing, directional microphones, multiple channels/memories) are considered **medically necessary** when the technology enhancement is needed to improve the hearing quality for the wearer.

Replacement of an air conduction hearing aid device that is out of warranty and no longer functioning adequately to support activities of daily living is considered **medically necessary** when the device is malfunctioning and cannot be refurbished or repaired sufficiently to resume its original functionality.

Not Medically Necessary:

Air conduction hearing aid devices are considered **not medically necessary** when the above criteria are not met.

Air conduction hearing aid devices with advanced technology models and feature enhancements (for example, in-the-ear and in-the-ear-canal models with digital signal processing, directional microphones, multiple channels/memories) are considered **not medically necessary** when provided solely for the convenience of the wearer or to improve his/her cosmetic appearance.

Replacement of a currently functional air conduction hearing aid device that is still under warranty for the sole purpose of obtaining a device with updated technology, (commonly referred to as an "upgrade"), is considered **not medically necessary** unless the new updated device will provide a significant functional advantage over the device that was originally issued.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
V5030	Hearing aid, monaural, body worn, air conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5070	Glasses, air conduction
V5100	Hearing aid, bilateral, body worn
V5120	Binaural, body
V5130	Binaural, in the ear
V5140	Binaural, behind the ear

V5150	Binaural, glasses
V5242	Hearing aid, analog, monaural, CIC (completely in 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

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

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). Air conduction hearing aids are considered Class I devices by the FDA due to simplicity of design and minimal potential for harm to the user. In 2022, in order to provide reasonable assurance of the safety and effectiveness of over-the-counter (OTC) hearing aids, the Center for Devices and Radiological Health of the FDA established a new regulatory category for OTC hearing aids and is also amending regulatory controls for prescription hearing aids as follows:

> The Food and Drug Administration (FDA, we, or the Agency) is establishing a regulatory category for over-the-counter (OTC) hearing aids and making related amendments to update the regulatory framework for hearing aids. Specifically, we define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with the new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that will become obsolete as a result of changes to the hearing aid requirements. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health (FDA, 2022).
>
> For hearing aids that have been legally offered for sale prior to October 17, 2022, including hearing aids that already have a 510(k) clearance, compliance with the new or revised requirements must be achieved by April 14, 2023.
>
> For hearing aids that have not been offered for sale prior to October 17, 2022, or have been offered for sale but are required to submit a new 510(k) due to changes unrelated to this rule, compliance with the new or revised requirements applicable to the hearing aid, and obtaining 510(k) clearance if applicable, must be achieved before marketing the device on or after October 17, 2022.

Externally worn air conduction hearing aid devices, which are also referred to as acoustic hearing aids, are widely accepted for use by individuals with mild to profound sensorineural hearing loss. Hearing loss can be tested by a variety of different modalities, but the most common and reliable method is pure-tone audiometry, which is then rated on a scale based on the threshold of hearing ability. Severe to profound sensorineural hearing loss is defined by the American Academy of Otolaryngology-Head and Neck Surgery Foundation as a bilateral hearing threshold of 70 decibels (dB) or greater PTA (that is, pure-tone air-conduction average) at 500, 1000, and 2000 Hz. In infants 12 to 24 months of age, thresholds of 90 dB or greater at 1000 Hz. is considered profound hearing loss and, in children 24 months to 17 years, severe to profound bilateral hearing loss is considered to be thresholds greater than 70 dB. Moderate to profound hearing loss is defined by the Centers for Medicare and Medicaid (CMS) as, “Test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition.” Benefit from acoustic hearing aids for adults is defined as a score of 50% or greater on the Bamford-Kowal-Bench (BKB) Sentence testing at a sound intensity of 70 dB. In very young children aged 2 years and under, accurate assessment of hearing level and functional communication is difficult to confirm. However, adequate benefit from acoustic hearing aids in children is generally demonstrated by speech, language and listening skills that are considered appropriate to the child’s age, developmental stage, and cognitive ability.

According to the American Speech Language Hearing Association (ASLHA), the following classification system is commonly used to demonstrate the degree of hearing loss:
Degree of hearing loss by range in dB:
Normal – (-)10 to 15 dB;
Slight – 16 to 25 dB;
Mild – 26 to 40 dB;
Moderate – 41 to 55 dB;
Moderately severe – 56 to 70 dB;
Severe – 71 to 90 dB;
Profound – 91+dB (ASLHA, 2015).

The ASLHA provided the following additional information regarding hearing loss:

> The configuration, or shape, of the hearing loss refers to the degree and pattern of hearing loss across frequencies (tones) as illustrated in a graph called an audiogram. For example, a hearing loss that only affects the high tones would be described as a high-frequency loss. Its configuration would show good hearing in the low tones and poor hearing in the high tones. On the other hand, if only the low frequencies were affected, the configuration would show poorer hearing for low tones and better hearing for high tones. Some hearing loss configurations are flat, indicating the same amount of hearing loss for low and high tones (ASLHA, 2015).

All types of hearing aids work by providing amplification of sound but they function in different ways. The air conduction (acoustic) hearing aid is the standard treatment for sensorineural hearing loss, mixed hearing loss and for conductive hearing loss that has been unresponsive to medical and surgical treatment. These devices are available in a variety of models which are primarily designed for external use either behind-the-ear or custom-made models for in-the-ear or in-the-ear canal. Advances in technology have introduced enhancements in functionality beyond the basic analog models, such as digital signal processing, directional microphones and devices with multiple channels and memories. These features are intended to improve performance, noise reduction and the speech of the hearing aid recipient. Despite these improvements in technology, some users continue to struggle with the audio quality of conventional hearing aids that is related to background noise and the conflicting effects on sound quality due to others speaking in close proximity to the hearing aid wearer (Ricketts, 2001).

In a Cochrane review, Schilder and colleagues (2017) compared the effects of bilateral and unilateral hearing aids in adults with a bilateral hearing impairment. Four randomized controlled trials, including 209 participants aged 23-85 with varying types and degrees of sensorineural hearing loss, compared the fitting of 2-ear versus 1-ear- hearing aids, with both ears being eligible for hearing aids. The primary measured outcomes were participant preference for bilateral or unilateral aids, hearing-specific health-related quality of life, and adverse effects (for example, pain or ear infection). Secondary outcomes were hearing aids usage, generic health-related quality of life, listening ability, and audiometric benefit measured as binaural loudness summation. All the studies included the use of hearing aids for a period of 8 weeks or longer before questions on preference were asked. Three of the studies were published in the 1990s. The fourth study was published in 2011. Only the most recent study (2011) used hearing aids incorporating technology comparable to currently available aids. Furthermore, only 1 primary outcome (participant preference) was reported in all studies. The percentages of participants that preferred bilateral hearing aids were 54% (51 out of 94 participants), 39% (22 out of 56), 55% (16 out of 29) and 77% (23 out of 30). The other outcomes were not reported. Due to the very low quality of the evidence, the authors concluded that they cannot confirm whether people with hearing loss prefer 1 hearing aid or 2, and whether hearing-specific health-related quality of life, or any of other outcomes, were better with bilateral versus unilateral hearing aids.

Another Cochrane review by Ferguson (2017), examined the effects that hearing aids have on everyday life in adults aged 69-83 years old with mild to moderate hearing loss. The primary measured outcomes were ability to take part in everyday situations, general health-related quality of life, the ability to listen to other people, and adverse effects such as pain or over-exposure to noise. The five studies reviewed, ranged from 6 weeks to 6 months, and included 825 adults with mild to moderate hearing loss who were randomly assigned to three groups; hearing aids, no hearing aids, or placebo hearing aids. The results showed that the hearing aid group had greater hearing-specific health-related quality of life associated with participation in daily life, as measured using the Hearing Handicap Inventory for the Elderly (HHIE scale range) (moderate-quality evidence). There was also a beneficial effect of hearing aids on general health-related quality of life in 568 participants (moderate-quality evidence). Additionally, there was a beneficial effect of hearing aids on listening ability in 534 participants (moderate-quality evidence). Adverse effects were measured in only 1 study (48 participants), and none were reported. The authors concluded that hearing aids improve the ability of adults with mild to moderate hearing loss to take part in everyday life, their general quality of life, and their ability to listen to other people, thus hearing aids are an effective clinical intervention.

DeSousa and colleagues (2022), reported a single center, randomized controlled trial that compared the effectiveness of self-fitting OTC hearing aids with remote support to a hearing aid fitted using audiologist-fitted best practices. The trial included 64 participants with self-perceived mild to moderate hearing loss who were randomly assigned to either the self-fitting group (n=32) or the audiologist-fitted group (n=32). The groups did not differ in age (mean age 63) or 4-frequency pure tone test average. In the self-fitting group, participants set up the hearing aids using the commercially supplied instructions and a smartphone application. In the audiologist-fitted group, the same hearing aid was fitted according to the National Acoustics Laboratories algorithm, using real-ear verification with hearing aid use instruction. The primary outcome was self-reported hearing aid benefit, measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB). The APHAB is a 24-item self-assessment inventory to rate communication difficulties in different listening situations. Secondary measures were the International Outcome Inventory for Hearing Aids (IOI-HA) and speech recognition in noise. This was measured using speech-in-noise test and a digits-in-noise test. The measurements were completed at baseline, and 2 and 6 weeks following the fitting. No p values were reported, however the results demonstrated that at the 2-week measurement, the self-fitting group had an advantage compared with the audiologist-fitted group on the self-reported APHAB and IOI-HA, but not speech recognition in noise. At the end of the 6-week trial, there were no meaningful differences between the groups on any outcome measures. The authors concluded the short-term outcomes of self-fitting OTC hearing aids for people with mild to moderate hearing loss were comparable to those obtained from audiologist-fitted hearing aids, and that affordable self-fitting OTC hearing aids may be an accessible hearing intervention with outcomes similar to audiologist-fitted hearing aids. Due to the small study size, larger trials are needed to generalize these findings.

The safety and effectiveness of conventional acoustic (air conduction) hearing aids is well established. The decision to use an acoustic (air conduction) hearing aid is best determined by the affected individual in consultation with their treating physician.

Definitions

Analog Hearing Aids: These acoustic hearing aid devices convert sound waves into electrical signals, which are amplified. Analog/adjustable hearing aids are custom built to meet the needs of each user. The aid is programmed by the manufacturer according to the specifications recommended by the audiologist.

Audiometry testing: A method of testing for hearing loss; two modalities utilized are pure tone audiometry and Auditory Steady State Response (ASSR). The severity of hearing loss is measured in frequencies. Pure tone audiometry utilizes measurements of pure tone hearing thresholds in a variety of settings. Hearing thresholds are defined as the lowest decibel hearing level at which responses occur in at least one-half of a series of ascending trials. ASSR is an objective test used for evaluation of hearing ability in children too young for traditional audiometric testing. Results are obtained by measuring brain activity while the person listens to tones of varying frequency (pitch) and intensity (loudness). The results obtained from ASSR testing can be used to estimate the behavioral pure-tone audiogram.

Automated Auditory Brainstem Response (AABR) test: A method of testing newborns for hearing ability; sensors are placed on his/her head to measure brain wave activity in response to sound.

Bamford-Kowal-Bench (BKB) Sentence testing: A speech perception assessment performed on children 6 years of age and older

which consists of multiple lists of 16 sentences. The test may be administered in an open-set format or with a set of picture choices. The child is asked to repeat words that are understood or is directed to point to a picture of the word when heard. This test can also be administered in 4-talker babble. In this format, known as the BKB-SIN (speech-in-noise) test, the level of background noise increases incrementally. Key words in each sentence are marked and the number of correct words is used to calculate an average signal-to-noise ratio where a child can understand 50% of the sentences. The lower the score, the better the child performs.

Binaural Hearing Loss: A term which refers to bilateral hearing loss in both ears; these individuals can be candidates for binaural hearing aid devices (in both ears) when use of two devices helps to improve sound quality, sound localization, speech intelligibility in noisy environments and speech recognition in eligible individuals.

Binaural Loudness Summation (binaural additivity): The physiological effect of sound presented to both ears being perceived as louder than the same signal presented to a single ear.

Conditioned Play Audiometry (CPA) test: A method of hearing test used for children aged 2 to 4 years; the child is asked to perform a simple play activity, such as placing a ring on a peg, when they hear a sound. Older children and adults may be asked to press a button or raise their hand when they hear sounds.

Conductive Hearing Loss: Hearing loss that occurs when sound is conducted inefficiently through the outer ear canal to the eardrum and the small bones (ossicles) of the middle ear. Conductive hearing loss usually involves a reduction in sound level or the ability to hear faint sounds.

Decibel (dB): A unit of measurement indicating the loudness of sound. The intensity relates to how loud or soft a sound is. Sound scales are based on either sound pressure level (dB SPL) or hearing level (dB HL).

Digital Hearing Aids: These acoustic hearing aid devices convert sound waves into numerical codes, similar to the binary code of a computer, before amplifying them. Because the code also includes information about a sound's pitch or loudness, the aid can be specially programmed to amplify some frequencies more than others. 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 afford more flexibility in programming the hearing aid to align with the individual's hearing loss.

Hertz (Hz): A unit of frequency equivalent to 1 cycle per second. Frequency of pitch is measured in Hz. Frequencies of 250-8000 Hz are typically used in audiometric testing because this range represents most of the speech spectrum.

Mixed Hearing Loss: Refers to hearing loss that is both conductive and sensorineural, occurring in one or both ears. This term refers to a condition where conductive hearing loss coexists with sensorineural hearing loss.

Otoacoustic Emissions (OAE) test: A method of testing hearing in newborns; a microphone is placed in the baby's ear through which soft clicking sounds are transmitted, and a computer then records the inner ear's response to the sounds.

Pure-tone average (PTA): The average of hearing sensitivity (that is, the minimum volume that the person hears) calculated at multiple frequencies (perceived by pitch), typically within the range of 0.25 to 8 kHz (kilohertz).

Pure tone threshold audiometry: The measurement of an individual's hearing sensitivity for calibrated pure tones; includes manual air-conduction measurements at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz (125 Hz under some circumstances) plus bone-conduction measurements at intervals from 250 Hz to 4000 Hz and at 3000 Hz as needed (ASHA, 2005). Pure tone thresholds (PTTs) are the faintest tones or softest sound (lowest intensity) a person can hear at least 50% of the time; PTT is measured in dB

Sensorineural Hearing Loss (SNHL): A permanent hearing loss related to the sensory or neural structures responsible for hearing that involves a reduction in sound level or ability to hear faint sounds; this disorder affects speech understanding or the ability to hear clearly; the involved structures include, but are not limited to, the cochlea and the acoustic nerve. In most cases, SNHL cannot be medically or surgically corrected. This is the most common type of permanent hearing loss.

Visual Reinforcement Audiometry (VRA) test: A method of testing hearing in infants over 6 months of age; a series of sounds are transmitted through earphones. The child is asked to turn toward the sound, then he/she is rewarded with an entertaining visual image.

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2. 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):1209-1214.
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Government Agency, Medical Society, and Other Authoritative Publications:

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Hearing Aids, Acoustic
Hearing Aids, Air Conduction
Hearing Aids, Binaural

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated the Discussion, Definitions, and References sections.
Reviewed	11/10/2022	MPTAC review. Updated the Discussion, Definitions, Index and References sections.
Reviewed	11/11/2021	MPTAC review. Updated References section.
Reviewed	11/05/2020	MPTAC review. Updated References section. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Updated References section.
Reviewed	11/08/2018	MPTAC review. References were updated.
Reviewed	11/02/2017	MPTAC review. The document header wording was updated from "Current Effective Date" to "Publish Date." References were updated.
Revised	11/03/2016	MPTAC review. Updated the formatting in the Clinical Indications section. The criterion for conductive hearing loss was clarified to indicate when unresponsive to medical interventions and unresponsive to surgical interventions or not amenable to surgical correction would meet medical necessity. A new statement was added for binaural hearing aids as medically necessary when criteria are met. The Definitions and References were updated.
New	11/05/2015	MPTAC review. Initial guideline development.