DEFINITION

A hearing aid is a regulated medical device that aims to improve hearing by manipulating sound to make it more intelligible. Hearing aids cannot in and of themselves correct or cure hearing loss; as such they are better characterized as acoustic utilities intended to make sounds more accessible.

The most common type of hearing aid is termed an “air conduction” hearing aid. It earns its name by virtue of its function to amplify sounds through a small speaker and send them to the ear through the air. The air conduction devices are the simplest in design and are subject to the least federal regulation as medical devices. They also present the least potential for harm to the user.

There are also “bone conduction” hearing aids: they work by transmitting sound through the bones of the skull to the ear to create vibrations that are interpreted by the brain as sounds. A recent advancement is the implantable hearing aid, which is completely internal and sends sound pressure waves through the cochlear fluid and cranial nerves as interpretable sound to the brain.

There are multiple clinical means of evaluating hearing loss amenable to treatment by hearing aids. Among them are perceptive criteria of diminished social interactivity, and impairment of daily activities or occupation by the person suffering hearing loss. Another popular qualitative measure is the speech recognition threshold (SRT). SRT is defined as the sound pressure level at which 50 percent of speech is identified correctly.

Chief among quantitative measures of hearing loss is pure tone audiometry— a commonly performed test which measures threshold hearing levels in a controlled, quiet condition such as a closed, noise-abated booth and compares them to a theoretical normally-hearing person. Conventional audiometry tests frequencies between 250 hertz (Hz) and 8 kHz, whereas high frequency audiometry tests in the region of 8 kHz-20 kHz. Pure-tone average (PTA) is the average of hearing sensitivity spot-checked at 500, 1000, and 2000 Hz.
COVERAGE CRITERIA

A hearing aid for covered persons is medically necessary when all the following criteria are met:

- Moderate to profound hearing loss ≥41 dB in the poorer ear\(^1\)
- SRT <50 percent of speech identified correctly\(^2\)
- The hearing aid and all related services must be prescribed and performed by a licensed healthcare provider (e.g., audiologist or otologist).
- The hearing aid must be dispensed by a licensed medical equipment provider.

A hearing aid is not currently considered medically necessary or is considered experimental / investigational in the following instances:

- There is a limit for covered persons of one (1) medically appropriate hearing aid per hearing impaired ear every thirty-six (36) months.
- Coverage may be subject to prior approval and is subject to all applicable copayments, coinsurance, deductibles, and out-of-pocket limits, for one (1) hearing aid per hearing impaired ear every thirty-six (36) months.
- Coverage does not extend to routine hearing tests or screenings (other than the screening of a newborn in the hospital), audiograms and audiometric services unless related to the diagnosis or management of a specific illness or traumatic injury.
- Coverage does not include bone anchored hearing aids. (Covered in a separate criteria policy)
- Coverage does not extend to the cost of implantable hearing aids. Covered in a separate criteria policy)
- Coverage does not extend to any hearing aid having convenience or luxury features
- Coverage does not extend to the cost of a hearing aid under this benefit if such a claim was paid under any insurance policy in the past thirty-six (36) months.

MEDICAL BACKGROUND

The medical evidence supporting treatment of hearing loss with a hearing aid is substantial and convincing.

Johnson, et al. conducted a systematic review on behalf of the American Academy of Audiology (AAAu) to weigh the medical evidence regarding benefits derived from the use of amplification by adults with untreated sensorineural hearing loss (SNHL).\(^3\) The authors found unaddressed hearing loss is associated with chronic health-care conditions, isolation, loneliness, and reduced quality of life in adult hearing aid wearers with bilateral average pure-tone thresholds ≤45 dB hearing level (HL) at 500, 1000, 2000, and 4000 Hz. The bulk of the subjects were middle-aged to elderly patients using hearing aids of various styles and circuitry. Results from all of the studies indicated positive benefits from amplification for patients with SNHL.

Cherko, et al. reported in a systematic review the effects of age-related hearing loss on cognition and quality of life in the elderly, and evaluated the efficacy of interventions for hearing loss.\(^4\) The authors acknowledged there is a large body of medical evidence associating hearing loss with detriment to physical and mental health, cognition, independence, social interaction and quality of life. Hearing aids and cochlear implants showed beneficial effects in restoring communicative ability in the elderly and subsequently improved quality of life. Furthermore,
much of the benefit seen was comparable to that seen in similarly-treated younger adults.

Kitterick, Smith et al. conducted a systematic review and meta-analysis to assess the medical evidence for the use of hearing instruments in adults with a unilateral severe to profound SNHL. Studies were included that assessed the impact of any form of hearing instrument, including devices that reroute signals between the ears (contralateral routing of signals or CROS, a type of hearing aid that takes sound from the ear with poorer hearing and transmits it to the ear with better hearing). The authors also compared different devices with placebo or the unaided condition, and measured outcomes in terms of speech perception, spatial listening, or quality of life. The meta-analysis identified statistically significant benefits to speech perception for devices that rerouted the speech signals of interest from the worse ear to the better ear using either air or bone conduction (mean benefit, 2.5 dB). However, these devices also degraded speech understanding significantly and to a similar extent (mean deficit, 3.1 dB). Evidence for the relative efficacy of different devices was sparse but a statistically significant advantage was observed for rerouting speech signals using abutment-mounted bone conduction devices when compared with outcomes after preoperative trials of air conduction devices when speech and noise were colocated (mean benefit, 1.5 dB). Patients reported significant improvements in hearing-related quality of life (HRQoL) with both rerouting devices and following cochlear implantation.

Kitterick, Lucas et al. evaluated unilateral severe-to-profound hearing loss, or single-sided deafness (SSD), in a systematic review of the medical literature which examined the impact of hearing-assistive devices on HRQoL. A meta-analysis of disease-specific measures suggested that hearing-assistive devices have a small-to-medium impact on HRQoL.

Ng, et al. synthesized current medical evidence to identify the determinants of hearing-aid adoption and use among the elderly in a systematic review of twenty-two articles that found four audiological determinants that impact the adoption and use of hearing aids:

- Severity of hearing loss
- Type of hearing aid
- Background noise acceptance
- Insertion gain.

Among seven non-audiological determinants of hearing-aid adoption and use were self-perceived hearing problems, expectation, demographics, group consultation, support from significant others, self-perceived benefit, and satisfaction.

Sereda, et al. queried United Kingdom (U.K.) clinicians on the medical criteria for hearing aid candidacy and best clinical practice in fitting hearing aids specifically for mild hearing loss with and without tinnitus. For patients with mild hearing loss, the greatest priority was given by clinicians to patient-centered criteria for fitting hearing aids: hearing difficulties, motivation to wear hearing aids, and impact of hearing loss on quality of life. Objective measures were given a lower priority (i.e., degree of hearing loss and shape of the audiogram).

A systematic review from the Canadian Agency for Drugs and Technologies in Health (CADTH) points out that while pure-tone audiometry is the most commonly used test for hearing loss there are situations where background noise is a more impactful factor than threshold hearing levels. CADTH recommended that functional tests of hearing (such as SRT) be a part of clinical investigation of hearing loss; however, the body stopped short of acknowledging that these tests translate into benefit in terms of improved job performance or sociability gain.
The United States (U.S.) Preventive Services Task Force (USPTF) has promulgated guidelines on the evaluation of hearing loss and the efficacy of hearing aid treatment:10

“Before a person receives a hearing aid, diagnosis of objective hearing loss should be confirmed with a pure-tone audiogram. Fair evidence from studies in highly selected populations shows that hearing aids can improve self-reported hearing, communication, and social functioning for some adults with age-related hearing loss.

Finding objective hearing loss indicates eligibility for a hearing aid but does not convincingly identify persons who will find the devices helpful and wearable and will use them. One subgroup analysis of a randomized, controlled trial found that in older adults who did not have self-perceived hearing loss at study entry, screening and receipt of a free hearing aid did not increase use after one year compared with an unscreened control group (and overall use was low, at 0 percent to 1.6 percent). However, health-related quality of life is improved for some adults with moderate to severe hearing loss who use hearing aids compared with those who do not.”

Chou, et al. writing on behalf of the USPTF evaluated the potential benefit of screening for hearing loss in adults age 50 years and older and found that screening for hearing loss was associated with increased hearing aid use at 1 year, but screening was not associated with improvement in hearing-related function.11 The authors concluded that additional research is needed to understand effects of screening compared with no screening on health outcomes, and to confirm benefits of treatment under conditions likely to be encountered in most primary care settings.

The U.S. Veterans Administration (VA) provides limited hearing aid benefits to America’s military veterans.12 The VA provides hearing aids to the following:

- Those with any compensable service-connected disability
- Former Prisoners of War
- Purple Heart recipients
- Those in receipt of benefits under Title 38 United States Code (U.S.C.) 1151.
- Those in receipt of an increased pension based on being rated permanently housebound or in need of regular aid and attendance.
- Those with hearing impairment resulting from diseases or the existence of another medical condition for which the Veteran is receiving care or services from VA, or which resulted from treatment of that medical condition
- Those with significant functional or cognitive impairment evidenced by deficiencies in the ability to perform activities of daily living, but not including normally occurring hearing impairments. Note: Veterans with normally occurring hearing impairments that interfere with their medical care are eligible for hearing aids.
- Those who have hearing impairment severe enough that it interferes with their ability to participate actively in their own medical treatment.
- Veterans who have a service-connected hearing disability that contributes to a loss of communication ability. However, hearing aids are to be provided only as needed for the service-connected hearing disability. Nonservice-connected (NSC) Veterans are eligible for hearing aids on the basis of medical need. All such Veterans (including Medal of Honor recipients who do not have entitling conditions or circumstances and catastrophically
disabled Veterans) must receive a hearing evaluation by a state-licensed audiologist prior to
determining eligibility for hearing aids to establish medical justification for provision of these
deVICES. These Veterans must meet the following criteria for eligibility based on medical
need:
- Be enrolled at VA medical facility where they receive their health care; and
- Have hearing loss that interferes with or restricts communication to the extent
that it affects their active participation in the provision of health care services as
determined by an audiologist or an eye care practitioner or provider.

REGULATORY INFORMATION

Kentucky – 334.020 Requirement of license or permit.13

“No person shall engage in the sale or practice of fitting hearing instruments or display a sign or
in any other way advertise or represent himself as a person who practices the sale or fitting of
hearing instruments unless he holds an unsuspended, unrevoked license issued by the board
pursuant to KRS 334.080, or unless he holds a current, unsuspended, unrevoked apprentice
permit pursuant to KRS 334.090”.

A health benefit plan shall provide coverage, subject to all applicable copayments, coinsurance, deductibles, and
out-of-pocket limits. The Hearing Aid and all related services must be
prescribed by an Audiologist and dispensed by a licensed Audiologist or hearing instrument
specialist for Covered Persons for one (1) medically appropriate Hearing Aid per hearing
impaired ear every thirty-six (36) months, as determined by the Plan.

A health benefit plan shall not be required to pay a claim filed by its insured for payment of
the cost of a hearing aid under the coverage required if less than three (3) years prior to the
date of the claim its insured filed a claim for payment of the cost of a hearing aid under the
required coverage and the claim was paid by any health benefit plan.

Indiana – Medicare Advantage plans may provide some services that Medicare doesn't usually
cover, such as routine physicals and foot care, dental care, eye exams, prescriptions, hearing
aids, and other preventive services.15

Medicare HMOs may provide some services that Medicare doesn't usually cover, such as
routine physicals and foot care, dental care, eye exams, prescriptions, hearing aids, and other preventive services.15

Tennessee – No legislative mandates were found for coverage of hearing aid for treatment of
hearing loss.16

Baptist Health Plan Coverage Guidelines are created to provide members and providers with
peer-reviewed, current medical information.

State and federal laws/mandates and contract language have priority over Coverage Guidelines
and must be taken into consideration before eligibility for coverage is determined.

Ordinary hearing aids are Class I regulated medical devices under federal Food and Drug
321(h) explicitly prohibits any state requirement that is “different from, or in addition to, any
requirement applicable” to regulated medical devices which relates "to the safety and
effectiveness of the device.”17
Further to these rules the FDA requires a medical examination in order to obtain a hearing aid; although

“. . . federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician.”

The FDA has established federal rules governing hearing aid sales, and addressed various requests by state authorities for exemptions from federal preemption, granting some and denying others. The following Kentucky medical device requirement was denied an exemption from preemption under section 521(b) of the act: Kentucky Revised Statutes, section 334.200(1).

The FDA currently considers personal sound amplification products (PSAPs) to be devices for use by those without hearing loss, and therefore, at the present time, the FDA does not regulate PSAPs as hearing aids. Examples include the iPhone-linked earpiece to amplify phone calls, stream music and environmental sounds; an earpiece engineered to help detect various musical tones while composing, and directional microphones aimed to help isolate voices from background noise.

Baptist Health Plan Coverage Guidelines may or may not mirror Centers for Medicare & Medicaid Services benefits or coverage offered by any other health insurance company.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

### COVERAGE DETAIL

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REFERENCES


**SEARCH TERMS**

- Audiogram
- Audiometry
- Hearing aid
- Hearing level
- Hearing loss
- Personal sound amplification products (PSAPs)
- Pure-tone average
- Sensorineural hearing loss
- Speech recognition threshold