

Health Plan of Washington

BENEFIT COVERAGE GUIDELINE – 1.01.528 Hearing Aids (Excludes Implantable Devices)

Effective Date:	Feb. 1, 2025	RELATED POLICIES/GUIDELINES:
Last Revised:	Jan. 14, 2025	7.01.83 Auditory Brainstem Implant
Replaces:	N/A	7.01.84 Semi-Implantable and Fully Implantable Middle Hearing Aids
		7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids
		7.01.586 Cochlear Implant

Select a hyperlink below to be directed to that section.

COVERAGE GUIDELINES | DOCUMENTATION REQUIREMENTS | CODING RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

A hearing aid is a small device that fits in or on the ear. It is worn to help people who have lost hearing sense by making sounds louder so they can be heard. Hearing aids are only covered when the member has a specific benefit. This policy explains when hearing aids would be covered if the member has a hearing aid benefit.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Coverage Guidelines

If benefits for a hearing aid are available, the following criteria apply.

Equipment	Medical Necessity
Hearing aids	Hearing aids that meet the FDA regulatory requirements and
	are dispensed as prescription hearing aids may be considered

Equipment	Medical Necessity
	 medically necessary for a moderate hearing loss of 40 to 60 dB (based on pure tone average bone-conduction detection threshold) for any of the following: Conductive hearing loss (external and middle ear blockage/damage/disease) that is unresponsive to medical/surgical interventions OR Sensorineural hearing loss (inner ear cilia are damaged) OR Mixed hearing loss (combination of conduction hearing loss and sensorineural hearing loss) Traditional hearing aids are externally worn microphones that amplify sound to the ear through an ear mold that fits in the ear canal (see Definition of Terms). Selection of the hearing aid is based on the results from a complete work-up performed by a hearing professional that includes skilled hearing tests and assessment along with fitting the chosen device.
	The hearing aid dispensed should meet the hearing requirements of the member in the environments and under the conditions where enhanced hearing is needed.
	Note: This policy does not address semi-implantable/fully implantable or bone anchored hearing devices (see Related Policies).
Hearing Hardware covered under the Hearing Care benefit	 To receive your hearing hardware benefit: You must be examined by a licensed physician (MD or DO) or audiologist (CCC-A or CCCMSPA) before obtaining hearing aids You must purchase a hearing aid device
	 Benefits are then provided for the following: Hearing aids (monaural or binaural) prescribed as a result of an exam Ear molds

Equipment	Medical Necessity
	The hearing aid instruments
	Hearing aid rental while the primary unit is being repaired
	• The initial batteries, cords, and other necessary ancillary
	equipment
	• A warranty, when provided by the manufacturer
	• A follow-up consultation within 30 days following delivery of
	the hearing aids with either the prescribing physician or
	audiologist
	• Repairs, servicing, and alteration of hearing aid equipment
	purchased under this benefit

Equipment	Investigational	
Hearing Aids	Hearing aids that are investigational include but are not	
	limited to:	
	• Non-implantable intraoral (in the mouth) bone conduction	
	hearing aids (e.g., SoundBite Hearing System)	

Equipment	Non-Covered	
FDA cleared OTC hearing aids	Over-the-counter, FDA cleared hearing aids, available without a prescription or an examination by a hearing professional, are not covered, including the Hearing Aid Feature software used with compatible Apple AirPods Pro.	
OTC hearing assistive devices/personal sound amplification products (PSAPs)	Over-the-counter hearing assistive devices/personal sound amplification products (PSAPs) available without a prescription are not covered (e.g., NewEar, Pocketalker, TV Ears and others).	
Hearing Hardware not covered under the Hearing Care benefit	 The Hearing Hardware benefit doesn't cover the following: Batteries or other ancillary equipment other than that obtained upon purchase of the hearing aids 	

Requirement	Coverage Guidelines
Documentation	Documentation must include ALL of the following information:

Requirement	Coverage Guidelines
	Written prescription from the examining physician/licensed
	healthcare provider within the past 6 months
	AND
	• A complete audiology evaluation within the past 6 months
	AND
	• Explanation of audiometric test data/results that demonstrates
	the member's hearing loss & need for a hearing aid
	AND
	• History of prior use or current use of a hearing aid (not
	applicable if the member has never had a hearing aid)
	AND
	• Recommendation for the type of hearing aid technology that is
	appropriate for the member
	AND
	• Follow up plan for assessing the effectiveness/outcome of
	using a hearing aid - a trial period may be needed to test the
	usability of a specific hearing aid model/type

Coding

Code	Description
СРТ	
92550	Tympanometry and reflex threshold measurements
92551	Screening test, pure tone, air only
92552	Pure tone audiometry (threshold); air only
92553	Pure tone audiometry (threshold); air and bone
92555	Speech audiometry threshold;
92556	Speech audiometry threshold; with speech recognition
0208T	Pure tone audiometry (threshold), automated; air only
0209T	Pure tone audiometry (threshold), automated; air and bone
0210T	Speech audiometry threshold, automated;

Code	Description
0211T	Speech audiometry threshold, automated; with speech recognition
0212T	Comprehensive audiometry threshold evaluation and speech recognition (0209T, 0211T combined), automated
HCPCS	
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
V5120-V5267	Hearing aids, services and accessories
V5298	Hearing aid, not otherwise classified

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Related Information

Definition of Terms

Audiometric testing: Diagnostic tests that evaluate the ability to hear sounds. The intensity (loudness) of sound is measured in decibels. The tone (speed of sound wave vibrations) is measured in cycles per second. The standard battery of hearing tests varies depending on whether the individual is an infant, child, or adult.

Conductive hearing loss occurs when sound is not conducted effectively through the outer ear canal and the small bones of the middle ear to the inner ear. This condition makes it hard to hear soft sounds. This type of hearing loss can generally be corrected medically or surgically.

Contralateral Routing-of-Signals (CROS) hearing aids capture sound from the ear with hearing loss and transmit it to the ear with better hearing. CROS hearing aids are used in individuals with single sided deafness to replicate the experience of natural hearing in both ears.

Decibel (dB) is a unit used to measure the intensity or loudness of a sound. (The degree of hearing loss is based on how loud sounds need to be for an individual to hear them. dB HL describes an individual's hearing loss in decibels).

Hearing impairment (deafness/hearing loss): A reduction in the ability to perceive sound that is classified as mild, moderate, severe, or profound.

Mixed hearing loss occurs when conductive hearing loss occurs in combination with a sensorineural hearing loss indicating there is damage in the outer or middle ear and in the inner ear (cochlea) or auditory nerve.

Pure-tone average (PTA) is the average of an individual's hearing level in each ear calculated at various frequencies (the pitch of the sound).

Sensorineural hearing loss occurs when there is damage to the sensitive hair cells (cilia) inside the inner ear (cochlea), or to the auditory nerve. This type of hearing loss cannot be medically or surgically corrected and is the most common type of permanent hearing loss.

Traditional hearing aid: A non-implanted, non-disposable on-ear or in-ear device that is FDAapproved and dispensed only by prescription.

Exclusions and Limitations

Hearing aids are specifically excluded under many benefit plans (see Scope).

When hearing aid benefits exist in a health plan, limitations may include a dollar maximum and/or frequency of benefit availability (e.g., once every 36 months or once every 48 months).

Washington Mandate

For non-grandfathered group health plans other than small group health plans issued or renewed on or after January 1, 2024, a health carrier shall include coverage for hearing instruments, including bone conduction hearing devices. This section does not include coverage of over-the-counter hearing instruments. Includes a dollar maximum and frequency of benefit availability. More information can be found at the following link: https://app.leg.wa.gov/RCW/default.aspx?cite=48.43.135&pdf=true Accessed December 12, **Note**: This state statue is applicable to fully-insured members. Self-funded groups may or may not elect to provide similar provisions to their contract. Please check the member contract for benefits and administer accordingly.

Benefit Application

Coverage is determined by the member-specific contract and applicable laws that may require coverage for a specific service. Benefits are subject to all terms and limitations in the member contract. Please contact Customer Service with any questions about this benefit.

Evidence Review

Background

Degree of Hearing Loss

Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral (one ear) or bilateral (both ears). The American Speech - Language - Hearing Association (ASHA) has defined the degree of hearing loss based on pure-tone average (PTA). The PTA is the average air-conduction threshold for 1000 and 2000 Hz, and 3000 Hz measured with an earphone. Normal hearing is the detection of sound at or below 20 decibels (dB).¹

The degree of hearing loss based on PTA detection thresholds is defined as:

- Mild hearing loss (20 to 40 dB)
- Moderate hearing loss (40 to 60 dB)
- Severe hearing loss (60 to 80 dB)
- Profound hearing loss (greater or equal to 80 dB)

Hearing Instrument/Aids

A hearing aid is an electronic device used to help members with a hearing impairment by providing sound amplification through the use of a microphone, amplifier and receiver.

Members with moderate to severe sensorineural hearing loss are usually fit with acoustic hearing aids that are worn externally. An air-conduction (AC) hearing aid can benefit members with sensorineural, conductive, or mixed hearing loss. Contralateral routing of signal (CROS) is a system in which a microphone on the affected side transmits a signal to an air-conduction hearing aid on the normal or less affected side.²⁻⁴ Hearing aids that are marketed for use by the public should have approval from the U.S. Food and Drug Administration (FDA).

Hearing Aid Styles

There are two hearing aid styles:²⁻⁴

- The body level instrument/aid (worn on the body) is not commonly prescribed and yet may be used for individuals, including infants, whose ears are too small to hold a behind the ear aid.
- The ear level instrument/aid (worn on and/or in the ear) is categorized by where on the ear the device is worn:
 - Behind the ear (BTE)
 - Completely in the canal (CIC)
 - In the canal (ITC)
 - In the ear (ITE)

The receiver that fits in the ear canal for all hearing aids requires a mold and is custom-fitted to the individual.

Hearing Aid Types

There are three types of hearing aids:²⁻⁴

 Analog hearing aids convert sound waves that are amplified as an electrical signal in proportion to the sound signal. They have a few adjustment options for the audiologist to fine-tune the instrument to meet the member's amplification needs. Analog aids are a relatively inexpensive option. However, analog hearing aids are being replaced by digital technology.

- Digital hearing aids convert sound waves into numerical codes before amplifying them, similar to binary computer code. This technology is more flexible with options for fine tuning the hearing aid to the member's hearing needs by the audiologist and user.
- Digital hybrid hearing aids have both analog technology for sound processing and digital technology for programming. Hybrid aids offer more options for the audiologist and user to adjust the "channels" to meet a variety of listening environments.

There are many brands of hearing aids available. This link includes a comprehensive guide to hearing aids.: https://www.hearingtracker.com/hearing-aids, last updated September 24, 2024, accessed December 12, 2024.

Accessories

Telephone adapters are not covered.

Batteries and cords often are not covered.

Benefits for the following are often included in the hearing aid benefit limits or may not be covered:

- Ear molds
- Hearing aid dispensing fees
- Hearing aid fittings

Over-the-Counter Hearing/Listening Assistive Devices

Over-the-counter hearing assistive devices/personal sound amplification products (PSAPs) available without a prescription are not covered. These include but are not limited to the following:

- Cyberscience Amplifier
- NewEar
- Pocketalker
- TV Ears

Repair/Replacement

Benefits for hearing aid repair/replacement services are often included in the hearing aid benefit limits or may not be covered (see Scope).

Medicare National Coverage

Hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from coverage.⁶

Regulatory Status

Air conduction hearing aids that are intended to compensate for hearing loss are regulated by the US Food and Drug Administration (FDA). The FDA does not consider sound amplifiers to be medical devices when labeled for recreational or other use by individuals with normal hearing. However, certain safety regulations related to sound output levels still apply to these products.⁵

In October of 2022, the FDA issued a final rule establishing a new category of over-the-counter hearing aids for those 18 years of age and older through 510(k) premarket notification. This ruling permits individuals with mild to moderate hearing loss to purchase hearing aids directly from stores or online retailers without a prescription or a professional hearing assessment. The device Class II classification name: self-fitting air-conduction hearing aid, over the counter.

FDA Product Code: QUH.

In September of 2024, the FDA issued a De Novo classification DEN 230081 for Hearing Aid Feature (HAF) into Class II under the generic name air-conduction hearing aid software. With the following indications for use: "The Hearing Aid Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Hearing Aid Feature utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use."

FDA Product Code: SCR.

References

- 1. American Speech-Language-Hearing Association (1988). Determining threshold level for speech [guidelines]. Available online at: https://www.asha.org/policy/gl1988-00008/. Accessed December 12, 2024.
- National Institute on Deafness and Other Communication Disorders (NIDCD). Hearing Aids, NIH Pub. No. 99-4340. Last Updated October 11, 2022. Available online at: http://www.nidcd.nih.gov/health/hearing/pages/hearingaid.aspx Accessed December 12, 2024.
- Yetter CJ. A hearing aid primer. WROCC outreach site at Western Oregon University. Available online at: http://eric.ed.gov/?id=ED543736 Accessed December 12, 2024.
- Davis, C.D., Atcherson, S.R., & Johnson, M.L. Demystifying hearing assistance technology: A guide for service providers and consumers. 2007. Available online at: https://dcmp.org/public_content/learn/static-assets/472_demystifying-hearingassistive-technology.pdf Accessed December 12, , 2024.
- U.S. Food and Drug Administration. Home health and consumer devices. Hearing aids. Last updated 1/12/2023. Available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/H earingAids/default.htm Accessed December 12, 2024.
- Medicare Policy Benefit Manual. Chapter 16 General Exclusions from Coverage, section 100 Hearing Aids and Auditory Implants Rev. 198. Effective 11/06/14. Available online at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c16.pdf. Accessed December 12, 2024.
- Smith C, Wilber LA, Cavitt K. PSAPs vs hearing aids: An electroacoustic analysis of performance and fitting capabilities. Hearing Review. 2016;23(7):18-24. Available at: http://www.hearingreview.com/2016/06/psaps-vs-hearing-aids-electroacousticanalysis-performance-fitting-capabilities/ Accessed December 12, , 2024.
- 8. Weber, PC. Hearing amplification in adults. In: UpToDate, Deschler DG (Ed). Last update Ocober 8, 2024. UpToDate, Waltham, MA. Accessed December 12, 2024.
- National Institute of Deafness and Other Communication Disorders. (NIDCD). National Institutes of Health (NIH) Pub. No. 21-DC-8172. Over-the-Counter Hearing Aids. Bethesda, MD. U.S. Department of Health and Human Services. Last updated June 13, 2024. Available at URL: https://www.nidcd.nih.gov/health/over-counter-hearing-aids. Accessed December 12, 2024.
- U.S. Food and Drug Administration (FDA). Federal Register. Medical devices; ear, nose, and throat devices; establishing overthe-counter hearing aids. A rule by the Food and Drug Administration. Published 8/17/2022. Effective date: 10/17/2022. Silver Spring, MD. FDA. Available at URL: https://www.federalregister.gov/documents/2022/08/17/2022-17230/medicaldevices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids. Accessed December 12, 2024.
- U.S. Food and Drug Administration (FDA). Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products. Guidance for Industry and Food and Drug Administration Staff. Document Issued on August 17, 2022. Silver Spring, MD. FDA. Available at URL. https://www.fda.gov/media/87330/download. Accessed December 12, 2024.
- U.S. Food and Drug Administration (FDA). Hearing aids and personal sound amplification products: what to know. Current as of 1/12/2023. Available at URL: https://www.fda.gov/consumers/consumer-updates/hearing-aids-and-personal-soundamplification-products-what-know. Accessed January 12, 2023.
- U.S. Food and Drug Administration. FDA News Release. FDA finalized historic ruling enabling access to over-the-counter hearing aids for millions of Americans. Released August 16, 2022. Silver Spring, MD. FDA. Available at URL: https://www.fda.gov/news-events/press-announcements/fda-finalizes-historic-rule-enabling-access-over-counterhearing-aids-millions-americans. Accessed December 12, 2024.

14. U.S. Food and Drug Administration. OTC Hearing Aids: What You Should Know. May 3, 2023. Available online at URL:

. Accessed December 12, 2024

15. U.S. Food and Drug Administration. FDA News Release. FDA Authorizes First Over-the-Counter Hearing Aid Software. Released September 12, 2024. Silver Springs, MD, FDA. Available at URL:

. Accessed December 12, 2024.

 U.S. Food and Drug Administration Center for Devices and Radiological Health (CDRH). De Novo Classification Decision Summary for Hearing Aid Feature, (Apple Inc., Cupertino, CA) No. DEN230081. Silver Spring, MD. Available at URL: . Accessed December 12, 2024.

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Date	Comments	
03/10/14	New policy. Non-implanted traditional hearing aids that are FDA-approved and dispensed by prescription may be considered medically necessary for a moderate hearing loss when criteria are met.	
01/28/15	Annual Review. Policy reviewed. Added Definition of Terms to Policy Guidelines. Benefit Application now includes reference and hyperlink to Oregon specific laws about coverage of non-implantable, non-disposable hearing aids. Reference 5 added; others renumbered. Policy statement unchanged. ICD-9 and ICD-10 codes removed from policy; these are not utilized in adjudication of the policy.	
01/12/16	Annual Review. Policy reviewed; no change to the policy statement.	
02/01/17	Annual Review, approved January 10, 2017. Policy reviewed through November 2016, references added. Policy statements unchanged. Policy moved to new format.	
02/01/18	Annual Review, approved January 9, 2018. Policy reviewed. No change to the policy statement.	
02/01/19	Annual Review, approved January 4, 2019. Policy reviewed. References updated. No change to policy statement.	
03/01/20	Annual Review, approved February 4, 2020. Guideline reviewed. Guideline statement unchanged.	
02/01/21	Annual Review, approved January 6, 2021.Benefit coverage guideline reviewed. Guideline statement unchanged.	
02/01/22	Annual Review, approved January 24, 2022. Reference added and updated. Guideline statement unchanged.	
06/01/22	Interim Review, approved May 9, 2022. Added covered and non-covered Hearing Hardware benefits for clarification.	
02/01/23	Updated Related Policies. 7.01.03 is replaced by 7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids	
03/01/23	Annual Review, approved February 14, 2023. Benefit coverage guideline reviewed. Added guideline statement that over-the-counter, FDA cleared hearing aids, available	

Date	Comments
	without a prescription or an examination by a hearing professional, are not covered. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/15/23	Updated Related Policies. 7.01.05 is replaced with 7.01.586 Cochlear Implant.
01/01/24	Interim Review, approved December 11, 2023. Added information regarding WA Mandate effective 1/1/2024 to Related Information.
03/01/24	Interim Review, approved February 12, 2024. Corrected policy criterion statement to read "Hearing aids that meet the FDA regulatory requirements and dispensed as prescription hearing aids" from "FDA-approved hearing aids".
02/01/25	Annual Review, approved January 14, 2025. Policy reviewed. References added and updated. Added to the following policy statement: Over-the-counter, FDA cleared hearing aids, available without a prescription or an examination by a hearing professional, are not covered, "including the Hearing Aid Feature software used with compatible Apple AirPods Pro".

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.