Hearing Aids

MEDICAL POLICY NUMBER: 261

Effective Date: 1/1/2024

Last Review Date: 10/2022

Next Annual Review: 10/2024

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: This medical policy does not address hearing aid assessments which may be considered medically necessary.

I. Air conduction* hearing aid(s) may be considered **medically necessary** when **all** of the following criteria are met:

   A. The hearing aid is prescribed, fitted, and dispensed by a licensed audiologist, hearing aid/instrument specialist, or other Qualified Practitioner; **and**
   B. Hearing loss is not medically or surgically correctable or is refractory to medical or surgical treatments; **and**
   C. One of the following hearing loss qualification criteria are met:
      1. In adult patients (18 years of age or older), pure-tone average loss of 40 decibels (dB) hearing level or greater; **or**
      2. In pediatric patients (less than 18 years of age), pure-tone average loss of 25 dB hearing level or greater.

   *Air Conduction Hearing Aids

   Air conduction hearing aids are defined as any of the following:

   - Behind the ear (BTE) device
   - In the ear (ITE) device
   - In the ear canal (ITC) device
   - Completely in the canal (CIC) device
   - Contralateral routing of sound (CROS) device, for single-sided hearing loss

- Binaural CROS (BiCROS)

II. Bone conduction hearing aid(s) may be considered **medically necessary** when above criterion I. are met and the use of a conventional air conduction hearing aid is precluded by any of the following:

A. Congenital atresia of the ear canal such that it does not exist or cannot accommodate a standard hearing aid; **or**
B. Chronic infection of the middle or outer ear that is exacerbated by a standard hearing aid; **or**
C. Allergic reactions to standard hearing aids; **or**
D. Single-sided deafness as may occur after removal of an acoustic neuroma, from trauma, or from a viral or vascular insult.

III. Repair or replacement of air or bone conduction hearing aid(s) may be considered **medically necessary** when either of the following criteria are met:

A. Hearing aid repair may be covered when the currently used device is no longer functioning adequately and the repair is expected to make the hearing aid fully functional (as defined by the manufacturer); **or**
B. Hearing aid replacement may be covered when both of the following criteria are met:
   1. The currently used device is no longer functioning adequately and has been deemed to be non-repairable; **and**
   2. Documents indicate the replacement is not covered by the manufacturer's warranty or insurance.

IV. Air or bone conduction hearing aids are considered **not medically necessary** when any of the above criteria (I.-III.) are not met.

V. The following hearing aids are considered **not medically necessary** as a treatment of hearing loss:

A. Hearing aids that are surgically placed in the middle ear (e.g. Esteem)
B. Hearing aids placed on the eardrum by a clinician and replaced every three to four months (e.g. Lyric)
C. Over-the-counter hearing aids (e.g., Jabra Enhance™ Plus, Vibe Hearing©)

VI. The following accessories and devices are considered **not medically necessary** as a treatment of hearing loss:

A. Ear plugs
B. Disposable hearing aids

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DEFINITIONS

Oregon House Bill 4104: Coverage of Hearing Loss Treatments[1]

Effective January 1, 2019, the Oregon Hearing Mandate requires coverage of medically necessary hearing aids, including accessories and specified replacement supplies, for Oregon members meeting age and educational requirements.

Pursuant to Oregon House Bill 4104, The Plan shall provide coverage for one hearing aid per hearing impaired ear if:

- Prescribed, fitted, and dispensed by a licensed audiologist with the approval of a licensed physician; and
- Medically necessary for the treatment of hearing loss in an enrollee in the plan who is:
    - 18 years of age or younger; or
    - 19 to 25 years of age and enrolled in a secondary school or an accredited educational institution.

Hearing Assistive Technologies (HAT)

Pursuant to Oregon House Bill 4104 (effective January 1, 2019), the following hearing assistive technologies may be covered at different frequency limits depending on the benefit:[1]

- Bone conduction sound processors
- Hearing Assistive Technology (HAT) systems

Hearing Aid Related Services & Accessories

Pursuant to the Oregon House Bill 4104 (effective January 1, 2019), the following services and accessories are required to be covered as medically necessary.[1] Coverage may be at different frequency limits depending on the requirements of the House Bill. See the bill for complete details.

- Ear molds and replacement ear molds
- Replacement batteries
- Hearing tests
- Hearing aid checks
- Aid testing
- Sound processors

BACKGROUND

Hearing Loss

According to the American Speech-Language Hearing Association (ASHA), hearing loss can be categorized by the area of the auditory system which is damaged:

- A conductive hearing loss happens when sounds cannot get through the outer and middle ear. It may be hard to hear soft sounds. Louder sounds may be muffled.[2]

- Sensorineural hearing loss, or SNHL, happens after inner ear damage. Problems with the nerve pathways from your inner ear to your brain can also cause SNHL. Soft sounds may be hard to hear. Even louder sounds may be unclear or may sound muffled. This is the most common type of permanent hearing loss.[3]

- Sometimes, a conductive hearing loss happens at the same time as a sensorineural hearing loss, or SNHL. This means that there may be damage in the outer or middle ear and in the inner ear or nerve pathway to the brain. This is a mixed hearing loss.[4]

Hearing Aids and Hearing Assistive Technology

Hearing aids and devices are defined as any non-disposable, wearable instrument or device designed to aid or compensate for impaired human hearing and any necessary ear mold, part, attachments or accessory for the instrument or device, except batteries and cords.[1]

Hearing assistive technology (HAT) systems are defined as devices used with or without hearing aids or cochlear implants to improve the ability of a user with hearing loss to hear in various listening situations, such as being located a distance from a speaker, in an environment with competing background noise or in a room with poor acoustics or reverberation.[1]

Over-the-Counter Hearing Aids

In August of 2022, the Food and Drug Administration (FDA) issued a final rule to improve access to hearing aids by establishing a new category of over-the-counter (OTC) hearing aids. OTC hearing aids allow people with mild to moderate hearing impairment to purchase hearing aids directly from stores or online retailers without the need for a medical exam, prescription, or fitting by an audiologist.[5]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of hearing aids and hearing assistive technologies. Below is a summary of the available evidence identified through September 2023.

Systematic Reviews

In 2016, Johnson and colleagues published results from a systematic review which examined the use of hearing aids in patients with mild sensorineural hearing loss.[6] Studies which evaluated adult hearing aid wearers with bilateral average pure-tone thresholds of ≤45 dB HL at 500, 1000, 2000, and 4000 Hz were included for review. Ten articles met inclusion criteria and 5 were suitable for meta-analysis, which demonstrated a small-to-medium effect size of 0.85 (95% confidence intervals = 0.44-1.25) after adjusting for a small publication bias. Overall, authors concluded hearing aids provided an improved benefit to patients with mild sensorineural hearing loss.

In 2017, similar conclusions were reached by Ferguson and colleagues in a Cochrane review regarding the effects of hearing aids for mild to moderate hearing loss in adults.[7] Authors concluded, "The available evidence concurs that hearing aids are effective at improving hearing-specific health-related quality of life, general health-related quality of life and listening ability in adults with mild to moderate hearing loss. The evidence is compatible with the widespread provision of hearing aids as the first-line clinical management in those who seek help for hearing difficulties."

In 2001, Taylor and colleagues published results of a systematic review comparing the clinical and cost effectiveness of digital vs. non-digital (primarily analog) hearing aids.[8] Eight trials were identified which compared digital to non-digital devices (1 randomized controlled trial and 7 randomized cross-over trials). All of the trials were limited by small sample size and poor methodological quality. Overall, no clinical or statistical differences in laboratory scores or user functionality scores were observed between digital and non-digital devices. In addition, no cost-effective studies were identified.

In 2017, Schilder et al. published a Cochrane systematic review of the literature to evaluate bilateral vs. unilateral hearing aids for adults with bilateral hearing loss.[9] Primary outcomes included:

- patient preference for bilateral or unilateral aids,
- hearing-specific health-related quality of life and adverse effects (pain or discomfort in the ear,
- initiation or exacerbation of middle or outer ear infection).

Secondary outcomes included:

- usage of hearing aids (as measured by, for example, data logging or battery consumption),
- generic health-related quality of life,
- listening ability and
- audiometric benefit measured as binaural loudness summation.

Four cross-over randomized trials, with 209 participants, were included in the analysis. Patient ages ranged from 23-85 and included more men than women.

Due to the low-quality of evidence, the data from each of these studies could not be combined. The reviewers noted, "percentage of patients who preferred bilateral hearing aids varied between studies: this was 54% (51 out of 94 participants), 39% (22 out of 56), 55% (16 out of 29) and 77% (23 out of 30), respectively." Due to the considerable variation between studies, the antiquated technology evaluated, no conclusion could be reached regarding the preference of use of bilateral vs. unilateral hearing aids in adult patients with bilateral hearing loss.

Over-the-Counter Hearing Aids

In 2020, Sabin et al. evaluated the self-fitting method of over-the-counter (OTC) hearing aids.[10] Standard practice dictates that hearing aids be fitted by a clinician (e.g., audiologist) who measures an audiogram and uses it to generate hearing targets. The authors compared an alternative method where users select their own hearing parameters in order to self-fit their hearing aids.

Participants were first fitted using best clinical practices (audiogram, verification, fine tuning), then over the course of a month participants either selected their own parameters (self-group; n=38) or used the clinical selected parameters (audiology group; n=37). The gain selected by the self-group was with 1.8 dB overall and 5.6 dB per band of that selected by the audiology group. Participants in the self-group also reported better sound quality, but there was no difference between groups in terms of standard clinical measures of hearing aid benefit or speech perception of noise. The authors concluded that it is possible for users to self-fit hearing aids.

In 2021, Urbanski et al. conducted a dual-aim study to develop and validate fitting methodologies for over-the-counter (OTC) hearing aids.[11] First, the authors aimed to undertake a set of evidence-based preconfigured "presets" for use in the OTC devices and then test the efficacy of the presets relative to best-practice.

A total of 37 older adults with hearing loss used five methods to select their presets (audiogram, self-test, trying, questionnaire, or random assignment). Using a cross over design, each participant completed speech recognition testing and sound quality ratings. The designed presets were found to fit 67.9% of the participants with mild-to-moderate hearing loss. Controlling for hearing thresholds and sound quality ratings, liner mixed-effects models indicated that speech recognition scores for select-by-audiogram, select-by-self-test, and select-by-trying were not statistically different. The authors concluded that the newly developed self-fitting method may provide efficacy comparable to best-practice and could be used in OTC hearing aids.

CLINICAL PRACTICE GUIDELINES

Child and Adolescent Hearing Loss

A review of the current clinical practice guidelines regarding hearing loss in children indicate different specialty organization classify levels of hearing loss differently, with no clear cut-off established for differentiating normal from abnormal hearing loss in children.

American Academy of Audiology: Childhood Hearing Screening Guidelines

In 2011, the American Academy of Audiology (AAA) published evidence-based guidelines regarding hearing screens in children age 6 months through high school.[12] Pure tone screening was recommended starting at age 3 years with a pure tone sweep at 1000, 2000, and 4000 Hz at 20 dB HL. Authors of the AAA guideline note the standard cutoff of 26 dB to differentiate normal from mild hearing loss is an antiquated threshold. The AAA calls in to question the definition of "normal" hearing and indicates that the 26 dB cut-off was established in 1979 by the American Academy of Ophthalmology and Otolaryngology (AAOO) for the purpose of defining who may be eligible to receive workmen's compensation benefits. The AAA authors note this cut-off was not intended to identify children with hearing deficits below the 26 dB cutoff whose deficits may adversely impact early learning and growth.

World Health Organization (WHO)

According to the 2018 WHO factsheet regarding deafness and hearing loss, disabling hearing loss is defined as, "loss greater than 40 decibels (dB) in the better hearing ear in adults and a hearing loss greater than 30 dB in the better hearing ear in children."[13] General hearing loss may be referred to when "(a) person who is not able to hear as well as someone with normal hearing – hearing thresholds of 25 dB or better in both ears." Generally, hearing loss may be mild, moderate, severe, or profound and can affect one or both ears.

Adult Hearing Loss

American Speech-Language Hearing Association (ASHA)

The ASHA general information webpage regarding hearing loss, classifies levels of hearing loss from normal to profound according to range decibels (dB HL) lost:[14]

Degree of hearing loss	**Hearing loss range (dB HL)**
Normal	–10 to 15
Slight	16 to 25
Mild	26 to 40
Moderate	41 to 55
Moderately severe	56 to 70
Severe	71 to 90
Profound	91+
Source: Clark, J. G. (1981). Uses and abuses of hearing loss classification. Asha, 23, 493–500.	

National Institute of Deafness and Other Communication Disorders (NIDCD)

The NIDCD made the following recommendations regarding the level of hearing loss which typically requires the use of a hearing aid:[15]

"For estimating the impact of hearing loss on the person, a pure-tone-average (PTA) more than 25 dB HL generally requires adaptive listening strategies, such as sitting closer to the source of sound. Active treatment, such as hearing aids, is frequently recommended at PTAs greater than 40 dB HL in both ears.

The term "deaf" is generally applied to people with profound bilateral loss (PTAs greater than 90 dB HL)."

It is unclear if the NICDC recommendation, regarding hearing loss levels apply to both adult and pediatric populations.

U.S. Preventive Services Task Force (USPSTF)

A 2011 USPSTF guideline regarding screening for hearing loss in older adults indicated there was good evidence to suggest, "that common screening tests are useful for identifying patients at higher risk for hearing loss.[16] A challenge in understanding diagnostic accuracy is that studies used different thresholds and criteria to define hearing loss. The clinical relevance of detecting mild (25 to 40 dB) hearing loss as it pertains to effectiveness of screening is also uncertain, because the only trial showing benefits of hearing aids enrolled patients with screening-detected hearing loss greater than 40 dB. Relatively simple tests, such as the whispered voice test at 2 feet or single-question screening regarding perceived hearing loss, seem to be nearly as accurate as a more detailed hearing loss questionnaire or a hand-held audiometric device. A negative screening result based on a hand-held audiometric device may be particularly useful for ruling out hearing loss greater than 40 dB. The choice of which screening test to use may depend in part on cost or convenience."

BILLING GUIDELINES AND CODING

- Adjustment of hearing aids is included in the fitting and dispensing fee and is not reimbursable separately.
- Aural rehabilitation therapy is included in the fitting and dispensing fee and is not reimbursable separately.
- Requests for two hearing aids on the same date of service will be reimbursed using binaural (for two ears) codes only.

CODES*		
Hearing Aids and Accessories		
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
	V5070	Glasses, air conduction
	V5080	Glasses, bone conduction
	V5095	Semi-implantable middle ear hearing prosthesis
	V5100	Hearing aid, bilateral, body worn
	V5120	Binaural, body
	V5130	Binaural, in the ear
	V5140	Binaural, behind the ear
	V5150	Binaural, glasses
	V5170	Hearing aid, CROS, in the ear

	V5171	Hearing aid, contralateral routing device, monaural, in the ear (ite)
	V5172	Hearing aid, contralateral routing device, monaural, in the canal (itc)
	V5180	Hearing aid, CROS, behind the ear
	V5181	Hearing aid, contralateral routing device, monaural, behind the ear (bte)
	V5190	Hearing aid, CROS, glasses
	V5210	Hearing aid, BICROS, in the ear
	V5211	Hearing aid, contralateral routing system, binaural, ite/ite
	V5212	Hearing aid, contralateral routing system, binaural, ite/itc
	V5213	Hearing aid, contralateral routing system, binaural, ite/bte
	V5214	Hearing aid, contralateral routing system, binaural, itc/itc
	V5215	Hearing aid, contralateral routing system, binaural, itc/bte
	V5220	Hearing aid, BICROS, behind the ear
	V5221	Hearing aid, contralateral routing system, binaural, bte/bte
	V5230	Hearing aid, BICROS, Glasses
	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
	V5030	Hearing aid, monaural body worn, air conduction
	V5040	Hearing aid, monaural, body worn, bone conduction
Ear Molds		
	V5264	Ear mold/insert, not disposable, any type
	V5265	Ear mold/insert, disposable, any type
Batteries		
	V5266	Battery for use in hearing device
Hearing Assistive Technologies		
	V5268	Assistive listening device, telephone amplifier, any type
	V5269	Assistive listening device, alerting, any type

	V5270	Assistive listening device, television amplifier, any type
	V5271	Assistive listening device, television caption decoder
	V5272	Assistive listening device, TDD
	V5273	Assistive listening device, for use with cochlear implant
	V5274	Assistive listening device, not otherwise specified
	V5281	Assistive listening device, personal FM/DM system, monaural (1 receiver, transmitter, microphone), any type
	V5282	Assistive listening device, personal FM/DM system, binaural (2 receivers, transmitter, microphone), any type
	V5283	Assistive listening device, personal FM/DM neck, loop induction receiver
	V5284	Assistive listening device, personal FM/DM, ear level receiver
	V5285	Assistive listening device, personal FM/DM, direct audio input receiver
	V5286	Assistive listening device, personal Bluetooth FM/DM receiver
	V5287	Assistive listening device, personal FM/DM receiver, not otherwise specified
	V5288	Assistive listening device, personal FM/DM transmitter assistive listening device
	V5289	Assistive listening device, personal FM/DM adapter/boot coupling device for receiver, any type
	V5290	Assistive listening device, transmitter microphone, any type
Other		
	V5267	Hearing aid or assistive listening device/supplies/accessories, not otherwise specified
	V5298	Hearing aid, not otherwise classified
	V5299	Hearing service, miscellaneous (This code should be used only if a more specific code is unavailable.)

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
1/2024	Annual update. Changed denial from “investigational” to “not medically necessary.”