Bone-Anchored Hearing Aids

MEDICAL POLICY NUMBER: 398

Effective Date: 1/1/2024

Last Review Date: 11/2023

Next Annual Review: 8/2024

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.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Bone-Anchored Hearing Aids: Guideline Notes 103, 311,446

**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

Notes:

- This policy does not address air conduction, or bone-conduction hearing aids which may be considered medically necessary. See Medical Policy, Hearing Aids, MP261, for further information.
- Member benefit contracts take precedence over medical policy determinations made using this policy.

I. Bone-anchored hearing aids (BAHAs) may be considered **medically necessary** for the treatment of conductive or mixed hearing loss when **both** of the following are met (A.-B.):

A. The patient meets **any one** of the following (1. – 7.):
1. Congenital or surgically induced ear malformations of the external or middle ear canal (for example, atresia); **or**
2. Otosclerosis in patients who cannot undergo stapedectomy or have had failed stapedectomy; **or**
3. Severe chronic external otitis, making use of air conducted aids impossible; **or**
4. Chronic otitis media with draining that makes the use of air conducted aids impossible; **or**
5. Tumors of the external ear canal or tympanic cavity,

6. Dermatitis of the external ear canal, including reactions from ear molds used in air conduction hearing aids; **or**
7. Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid; **AND**

B. The audiologic criteria is met based on the type of hearing loss, limited to **either** of the following (1.-2.):

1. Chronic unilateral or bilateral conductive hearing loss with a pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3, kHz) should be better than or equal to 25 dB HL; **or**
2. Single-sided deafness (i.e., unilateral profound sensorineural deafness) with normal hearing on the contralateral side. (Normal hearing is defined as pure-tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL).

II. Bone-anchored hearing aids (BAHAs) are considered **not medically necessary** for the treatment of hearing loss when the above criteria are not met, including but not limited to use in patients with bilateral sensorineural hearing loss.

Replacements/Upgrades

III. Replacement parts or upgrades to existing BAHAs and/or components (for example, batteries, processor, or headband) are considered **medically necessary** and covered when at least one of the following criteria (A.-B.) is met:

A. There is clinical documentation of quantifiable testing (e.g., pure-tone testing) indicating the patient's auditory response with the existing components is inadequate; **or**
B. One or more of the device components is no longer functional and is no longer under warranty and cannot be repaired.

IV. Replacement parts or upgrades to existing BAHA devices and/or components that are currently functional are considered **not medically necessary**, including but not limited to when requested for convenience or technology upgrade. Replacement parts or upgrades include, but are not limited to batteries, processors, and headbands.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Hearing Aids, MP261
- Cochlear Implants and Auditory Brainstem Implants, MP127

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

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
  - History
  - Physical examination
  - Audiology test results

BACKGROUND

Oregon House Bill 4104: Coverage of Hearing Loss Treatments

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.[1]

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:
  - 18years of age or younger; or
  - 19 to 25 years of age and enrolled in a secondary school or an accredited educational institution.

DEFINITIONS

Bone-Anchored Hearing Aid (BAHAs)

Percutaneous bone–anchored hearing aids (BAHA) are devices that transmit sound vibrations to the inner ear, bypassing the middle ear, via the skull by a skin-penetrating titanium screw implant. BAHA are intended to improve hearing acuity in individuals who have single-sided sensorineural deafness (SSD) and moderate-to-severe conductive or mixed hearing loss who cannot use or are dissatisfied with the level of sound perception or quality of sound provided by standard air conduction hearing aids.

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.

FDA-Approved Bone-Anchored Hearing Aids

Note: The devices discussed below may not be conclusive. Additionally, approved indications and contraindications may change before the policy is annually reviewed. For the most current information of approved devices and supplemental approval order statements, please refer to the U.S. Food and Drug Administration's Premarket Approval (PMA) website. Product codes for these devices include LXB, MAH and PFO.

The following Baha® sound processors, currently marketed by Cochlear™ (formerly called Cochlear™ Americas), have received 510(k) clearance for use with the Baha auditory osseointegrated implant (hearing aid) systems (e.g. Baha® Connect and Attract systems):

- Baha® 5 Sound Processor
- Baha® 5 SuperPower Sound Processor
- Baha® 5 Power Sound Processor
- Baha® 6 Max Sound Processor

Predicate devices include the Baha®4, Cordelle II, Divino®, Intenso™ and BP100™.

The FDA approved the Cochlear™ Baha® system (initially approved under the trade name Branemark Bone-Anchored Hearing Aid [BAHA™] by Entific Medical Systems, Inc.) for use in children aged five years and older, and in adults, for the following indications:

- Patients who have conductive or mixed hearing loss and can still benefit from sound amplification;
- Patients with bilaterally symmetric conductive or mixed hearing loss, may be implanted bilaterally;
- Patients with sensorineural deafness in one ear and normal hearing in the other (i.e., single-sided deafness, SSD);
- Patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who cannot or will not wear an AC CROS device.

Baha sound processors can also be used with the Baha® Softband and Baha® SoundArc. The Baha® Softband received FDA clearance in 2002 for use in children under the age of five years. The Baha® SoundArc received FDA clearance in 2017 for use in people of any age.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of bone-anchored hearing aids as a treatment of hearing loss. Below is a summary of the available evidence identified through May 2023.

Systematic Reviews

- In 2022, Hayes published a health technology assessment on percutaneous bone-anchored hearing aids (BAHAs).[2] Authors identified 11 studies (2 randomized crossover studies, 2 nonrandomized crossover studies, 2 prospective cohort studies, 1 case-control study with normal hearing controls, 1 retrospective cohort study, and 3 pretest/posttest studies) evaluating percutaneous BAHA in patients with hearing loss. Percutaneous BAHA technology was compared with unaided hearing (9 studies), normal hearing (3 studies), contralateral routing of signals hearing aids (CROS) (3 studies) and ACHA (1 study). Results suggested that percutaneous BAHA for the treatment of SSD and conductive or mixed hearing loss does not improve sound localization, but may enhance speech discrimination in specific noisy situations (e.g., when noise is presented to the non-BAHA side of the patient's head) compared with unaided hearing. In addition, patients reported significant improvements with percutaneous BAHA over unaided hearing on the Abbreviated Profile of Hearing Aid Benefit (APHAB) self-assessment questionnaire evaluating hearing aid benefit, which may indicate an improved quality of life. Studies evaluating the Speech, Spatial and Qualities of Hearing Scale (SSQ) and Glasgow Hearing Aid Benefit Profile (GHAPB) questionnaires did not find differences between percutaneous BAHA and unaided hearing. No differences in speech discrimination, sound localization, or self-reported benefit were observed between percutaneous BAHA and CROS across 3 studies. A summary by outcomes follows, with some studies including more than 1 comparison.

  Hayes gave a C rating (potential but unproven benefit) for use of percutaneous bone–anchored hearing aids (BAHA) in adult patients with single-sided sensorineural deafness (SSD) and conductive or mixed hearing loss, who are not able to be fitted with or tolerate traditional air conduction hearing aids (ACHA) or who cannot achieve adequate hearing improvement with ACHA. Hayes gave a D2 rating (insufficient evidence) for use of percutaneous BAHA in children and adolescents 5 years of age or older with SSD and conductive or mixed hearing loss, who are not able to be fitted with or tolerate ACHA or who cannot achieve adequate hearing improvement with ACHA.

- Heath (2022) conducted a systematic review (SR) of studies that compared outcomes between bilateral and unilateral BAHA for patients with no benefit from conventional hearing aids.[17] A total of 14 articles were included; all studies were retrospective with the exception of one case report, and all studies had a substantial risk of bias. A meta-analysis was not performed, but descriptive comparison found that bilateral BAHA were associated with greater improvement in hearing thresholds, understanding speech, and localization. Unilateral BAHA were more effective when noise was one-sided. All studies reported improvement in quality of life.

- In 2017 Kim conducted a systematic review on the efficacy of BAHAs in single-sided deafness, including 14 studies (n=296 patients). The reviewers reported that in the six studies that dealt with sound localization, no significant difference was found after the implantation. However, SUR121 | 7 twelve studies showed the benefits of BAHAs for speech discrimination in noise.

Regarding subjective outcomes of using the prosthesis in patients with SSD (abbreviated profile of hearing aid benefit [APHAB] and the Glasgow hearing aid benefit profile [GHABP], etc.), improvements in quality of life were reported in the majority of studies. This systematic review has indicated that BAHAs may successfully rehabilitate patients with SSD by alleviating the hearing handicap to a certain degree, which could improve patients' quality of life. This report has presented additional evidence of effective auditory rehabilitation for SSD and will be helpful to clinicians counseling patients regarding treatment options for SSD.

- In a 2015 Peters published a systematic review of the literature through April 7, 2014 on the use of BAHA devices with contralateral routing of sound systems for single-sided deafness (SSD).[5] Five[6-10] of the six studies that met inclusion criteria were rated as moderate to high directness of evidence and low to moderate risk of bias and, thus, were included in the review. Significant heterogeneity was found in the 91 total patients included. For speech perception in noise there was not consistent improvement with aided hearing over unaided hearing in all environments. All studies reported equal sound localization in the aided and unaided conditions, and quality of life measures were similar for the aided and unaided conditions. Interpretation of these outcomes was limited by the methodological limitations of the included studies, including the lack of RCTs, unclear inclusion criteria, small sample sizes, use in some studies of headband devices which have different bone conduction thresholds in the higher frequencies than implanted devices, clinical heterogeneity of included populations (e.g., duration of deafness, grade of hearing loss), unexplained missing data, and lack of long-term audiometric follow-up. The authors also noted that the lack of recent studies was surprising considering the recent advances in these devices and recommended high-quality studies on the clinical outcome of current devices.

CLINICAL PRACTICE GUIDELINES

National Institute for Health and Care Excellence (NICE)

In 2018, the NICE released a guideline titled Hearing loss in adults: assessment and management.[3] The guideline recommends that after audiological assessment, adults over the age of 18 may be referred for implanted devices such as the BAHA if it is considered suitable.

EVIDENCE SUMMARY

Evidence is sufficient to support the use of unilateral or bilateral transcutaneous bone-conduction or bone-anchored hearing aid(s) improve net health outcomes in select patients. Peer-reviewed articles and clinical guidelines based on research recommend bone-anchored hearing devices for the treatment of conductive or mixed hearing loss and single-sided deafness. Therefore, use of these devices is considered medically necessary for patients who meet the policy criteria.

BILLING GUIDELINES AND CODING

CODES*

CPT	69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor
	69716	Osseointegrated implant insertion with magnetic transcutaneous attachment to a speech processor
	69717	Revision (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
	69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
	69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor
	69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
	69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
	69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
	69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
	92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes
	92623	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure)
HCPCS	L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
	L8624	Lithium ion battery for use with cochlear implant device or auditory osseointegrated device speech processor, ear level, replacement each
	L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
	L8690	Auditory osseointegrated device, includes all internal and external components
	L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each

	L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
	L8693	Auditory osseointegrated device abutment, any length, replacement only
	L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each

***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.

REFERENCES

1. Oregon House Bill No. 4104. https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2018orlaw0009.pdf. Accessed 7/24/2023.
2. Hayes Inc. Percutaneous Bone-Anchored Hearing Aids. https://evidence.hayesinc.com/report/dir.bone0002. Published 2022. Accessed 6/13/2023.
3. National Institute for Health and Care Excellence. Hearing loss in adults: assessment and management (NG98). https://www.nice.org.uk/guidance/ng98. Published 2018. Accessed 6/13/2023.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
10/2023	New policy.
1/2024	Interim update. Q1 2024 Code Update.