Medicare Medical Policy

Bone-Anchored Hearing Aids

MEDICARE MEDICAL POLICY NUMBER: 399

Effective Date: 1/1/2024

Last Review Date: 11/2023

Next Annual Review: 8/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes:

- This policy **only** applies to bone-anchored hearing aids (BAHAs; also known as osseointegrated implants).
- It does **not** apply to the following hearing devices:
  - Cochlear or auditory brainstem implants, which are addressed in a separate medical policy (see Policy Cross References)
  - Bone conduction or air conduction type hearing aids, which may be member benefit exclusions (see IMPORTANT NOTE below).
- State mandates do not apply to Medicare Advantage plans.

Service	Medicare Guidelines
IMPORTANT NOTE: According to Medicare, hearing aids are amplifying devices to compensate for impaired hearing and include both **air conduction** and **bone conduction** hearing devices. These devices are excluded from Traditional (Original) Medicare coverage and may only be eligible for Medicare Advantage coverage if a supplemental hearing benefit exists. However, cochlear implants, auditory brainstem implants, and osseointegrated implants (also known as bone-anchored hearing aids or BAHA devices) are considered separate from this exclusion, as Medicare considers these devices to be prosthetics.	
Bone-Anchored Hearing Aids – Initial Provision	Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §100 - Hearing Aids and Auditory Implants I. BAHA devices may be considered **medically necessary** for Medicare plan members when: A. The device is implantable, intended to replace the function of the middle ear. B. The guidelines of the CMS coverage manual above are met (1 or 2): 1. Hearing aids are medically inappropriate; ***or***

	2. Hearing aids cannot be used due to a congenital malformation, chronic disease, severe sensorineural hearing loss or surgery; C. The device is approved by the Food and Drug Administration (FDA); and D. The device is used in accordance with the FDA approved indications. II. BAHA devices with no implantable components (e.g., external sound processor for an auditory osseointegrated device used without osseointegration, body-worn, such as a headband or other means of external attachment [L8692]) are considered **not medically necessary** based on the Medicare definition.
Replacement and Upgrades	Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices, A. General **NOTE:** I. Replacement of existing **non-**functioning BAHA devices or components may be **medically necessary** when **all** of the following are met (a-c): a. The BAHA device met coverage criteria for the initial placement; and b. Medicare's prosthetic replacement requirements in the above manual are met (e.g., irreparable change in condition of device or component, etc.); and c. The device or required component is not under manufacturer warranty. II. Replacement or upgrades of existing **functioning** BAHA implants or components may be **medically necessary** if **both** of the following are met (a and b): a. The BAHA device met coverage criteria for the initial placement; and b. The implant is no longer providing therapeutic benefit due to a change in the physiological condition of the member. III. Replacement or upgrades (e.g., conversion to a next generation model, upgrades to smaller profile external components, or switching from a body worn sound processor to a behind-the-ear model) of existing **functioning** BAHA implants or components are **not medically necessary** because they are considered a "convenience" if the replacement criteria above are not met. *See "Policy Guidelines" below*
Accessories	• Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.3 - Coverage of Supplies and Accessories

	• Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §90 - Payment for Additional Expenses for Deluxe Features **NOTE:** I. According to Chapter 15 of the Medicare Benefit Policy Manual, supplies or accessories used directly with a BAHA implant device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device may be **medically necessary** when the base item meets medically necessary requirements. II. According to Chapter 20 of the Medicare Claims Processing Manual, supplies or accessories that are not necessary for the functioning of the device (e.g., cell phone adapters, telecoils, carrying cases, keychain wallets, or car charger adapters), supplies and accessories for non-covered devices, as well as accessories and upgrades to accommodate personal convenience or deluxe items are **not covered** under Medicare.
Removal	• Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare **NOTE:** I. According to Chapter 16 of the Medicare Benefit Policy Manual, removal of an implanted device may be **medically necessary** when required "required to treat a condition or complication that arises" (e.g., infection). This applies to both non-covered devices or devices which did not meet medical necessity criteria when initially provided.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Cochlear Implants and Auditory Brainstem Implants, MP189

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

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- All relevant medical records, including history and physical examination, specifically documentation as to why other hearing aids cannot be used or would not be medically appropriate

MEDICARE GENERAL COVERAGE POSITION

Non-Covered Hearing Aids Under Original Medicare
Hearing aids are statutorily excluded under Original Medicare.[1] Specifically, Medicare excludes:

- **Air conduction** devices (provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound); and
- **Bone conduction** devices (provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles). This includes semi-implantable bone conduction hearing devices (CPT 69710).
- **Hearing assistive technologies** (HAT) or **Assistive Listening Devices** (ALDs) (HCPCS V5268-V5274, V5281-V5290), which are devices used 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. The primary purpose of an ALD is to amplify sound.

All of these devices are excluded from Traditional (Original) Medicare coverage. They may only be covered for Medicare Advantage members ***if*** the member has a supplemental hearing benefit that allows the type of hearing aid requested. Not all Medicare Advantage products include a supplemental hearing benefit, so each individual member's benefits would need to be confirmed for the above types of hearing aid options.

Potentially Covered Hearing Aids Under Original Medicare

Under Medicare, prosthetic devices are items "which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ."[2] Therefore, because cochlear, auditory brainstem, and osseointegrated implants "produce perception of sound by **replacing the function of the middle ear, cochlea or auditory nerve,**" these devices are considered prosthetic devices and as such, are eligible for potential coverage by Medicare.[1]

DEFINITIONS

Bone-Anchored Hearing Aid (BAHAs)

Percutaneous bone–anchored hearing aids (BAHA), also referred to as osseointegrated implants, are "devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer."[1]

INITIAL IMPLANTATION, REPLACEMENT AND UPGRADES

Initial Implant

While not detailed, Medicare does indicate coverage may be available for BAHA devices (osseointegrated implants) "only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery."[1]

Replacement

Because osseointegrated implants fall under the Medicare Benefit Category of "Prosthetic Devices," replacement of medically necessary implants is subject to Medicare rules for prosthetic device replacement. Specifically, documentation must demonstrate the following:

1) The initial provision of the implant device met coverage criteria; and
2) Either:
   a) A change in physiological condition of the member and their current device does not adequately provide the necessary therapeutic benefit; or
   b) There is an irreparable change in the condition of the device or part of the device; and
3) There is no warranty provision provided by the manufacturer to either replace or repair the current device.[3]

Upgrades

Items which provide features *beyond* what is necessary to support the body member would fall under the category of an "upgrade." Upgrades include "excess components" to a prosthetic or orthotic device (e.g., a feature, an accessory, or a service) that are in addition to, or more extensive and/or more expensive than, the item that is reasonable and necessary under Medicare's coverage requirements.[4] In addition, in order to be considered for coverage, Medicare requires the requested item to be both medically necessary and reasonable. This includes determining if there is a "less costly alternative" which can provide the necessary therapeutic benefit for the individual.[5]

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage (*Medicare Benefit Policy Manual, Chapter 14 - Medical Devices*), the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

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.

Devices with no implantable components would not be eligible for Medicare coverage as a BAHA device, based on the Medicare definition.[1] This would include, but may not be limited to, an external sound processor for an auditory osseointegrated device used without osseointegration, body-worn, including a headband or other means of external attachment (L8692).

NOTES:

- Cochlear implants are addressed in a separate medical policy (see Cross References).
- The devices discussed above may not be a fully comprehensive list. 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.
- Only items which meet Medicare's requirements to be considered a "prosthetic" would be eligible for coverage as a BAHA device. That means the device must be implanted in the skull and must replace the function of the middle ear to provide mechanical energy to the cochlea via a mechanical transducer.

BILLING GUIDELINES AND CODING

GENERAL

Medicare has provided billing guidance for osseointegrated devices in the past, but with the development and implementation of new HCPCS codes in the years since, some of this billing and coding information is outdated.[6,7]

CODES*		
CPT	69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor

	69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
	69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
	69719	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	L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
	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 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 code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- 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. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §100 - Hearing Aids and Auditory Implants
2. CMS. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices
3. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty
4. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §120 - DME MACs - Billing Procedures Related To Advanced Beneficiary Notice (ABN) Upgrades
5. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 - Definition of Durable Medical Equipment, C. Necessary and Reasonable, 2. Reasonableness of the Equipment
6. Medicare MLN Article MM4038, *Auditory Osseointegrated and Auditory Brainstem Devices*; Dated: November 18, 2005; Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/JA4038.pdf. [Cited 6/7/2023]
7. Medicare Transmittal 39, Change Request 4038. Dated: November 18, 2005; https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R39BP.pdf. [Cited 6/7/2023]

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
11/2023 1/2024	New Medicare Advantage medical policy Q1 2024 code updates