



Bone-Anchored Hearing Aids Clinical Coverage Criteria

Description

A bone conduction hearing aid works by transmitting sound through the mastoid bone to the inner ear (cochlea), bypassing the outer and middle ear. Hearing through bone conduction is helpful for people with conductive or mixed hearing loss that cannot be corrected surgically, and for people with chronic, severe middle ear infection.

Surgical and nonsurgical bone conduction hearing aids are available. Surgical bone conduction hearing aids can be classified broadly into percutaneous and transcutaneous devices based on the presence or absence of a skin-penetrating abutment. Transcutaneous devices can be further classified into active and passive implants. There are several different manufacturers of surgically implanted bone conduction hearing aids on the market today. Surgically implanted bone conduction hearing aids are also known as bone-anchored hearing aids or osseointegrated implants. Bone-anchored hearing aids have both internal and external components.

Percutaneous bone-anchored hearing aids

A percutaneous bone-anchored hearing aid has an external sound processing component that sends vibration waves to the internal component through a titanium abutment screw (post) which penetrates the skin and joins the external and internal components. This allows direct vibration transmission to the cochlea via the skull which bypasses the skin and subcutaneous tissue.

Transcutaneous bone-conduction hearing aids

There are two types of semi-implantable transcutaneous devices, active (i.e., direct drive) and passive (i.e., skin drive). The active transcutaneous bone conduction hearing aids use an implanted transducer to send vibrations to the bone. The implanted components and the external sound processor are joined by retention magnets. As the internal device is responsible for generating mechanical forces against the skull, skin attenuation does not occur. In the passive transcutaneous bone conduction hearing aids, a titanium implant is placed directly in the skull in the same manner as the percutaneous devices. A magnet is attached to the titanium implant and the skin is closed, avoiding a percutaneous component. The external device is retained via attraction to the internal magnet and vibrates in response to sound inputs. Passive transcutaneous devices rely on vibratory signal delivery through the skin and are subject to signal attenuation up to 20 dB, especially at high frequencies (Ellsperman et al., 2017). Both types of transcutaneous bone conduction implants leave the skin intact and avoid adverse skin reactions that are associated with a percutaneous bone anchored implant.

Nonsurgical bone conduction hearing aids

Nonsurgical bone conduction hearing aids are worn with a headband or may be attached directly to the skin with adhesive. The BAHA Headband (also known as Softband), the Cochlear Baha SoundArc and the Adhear System (Med-El) are examples of nonsurgical, non-invasive devices that are used to hold a bone conduction hearing aid in contact with the skin. The bone conduction hearing aid vibrates in response to sound and transmits vibratory signals through the intact skin and soft tissue to the skull, leading to bone conduction hearing. Nonsurgical, non-invasive bone conduction hearing aids and devices used to hold bone conduction hearing aids in contact with the skin are outside of the scope of this policy.

Policy

This Policy applies to the following Fallon Health products:

- Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- MassHealth ACO
- NaviCare HMO SNP
- NaviCare SCO
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care

Bone-anchored hearing aids prior authorization.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for bone-anchored hearing aids, also known as osseointegrated implants. Medicare does not have a National Coverage Determination (NCD) for bone-anchored hearing aids. National Government Services, Inc. does not have a Local Coverage Determinations (LCD) for bone anchored hearing aids (MCD search 01/18/2024).

CMS has determined that osseointegrated implants are not subject to the hearing aid exclusion (see 42 C.F.R. § 411.15(d)(2)(ii)).

The scope of the hearing aid exclusion encompasses all types of air conduction hearing aids that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound and bone conduction hearing aids that provide mechanical stimulation of the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles. Devices not subject to the hearing aid exclusion include devices that produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve.

The Medicare Benefit Policy Manual (Chapter 16, Section 100) additionally states that, "*Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.*" Osseointegrated implants, i.e., devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer are prosthetic devices.

Coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, therefore, Fallon Health Clinical Coverage Criteria are applicable.

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Medical Necessity Guidelines for bone-anchored hearing aids (MassHealth website search 01/18/2024), therefore the Plan's Clinical Coverage Criteria are applicable.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Effective June 1, 2024, Fallon Health will use InterQual® criteria when making medical necessity determinations for bone-anchored hearing aids for plan members 5 years of age or older.

For coverage criteria for initial placement, refer to the InterQual criteria in effect on the date of service:

- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Anchored Hearing Device
- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Conduction Hearing Device
- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Anchored Hearing Device (Pediatric)
- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Conduction Hearing Device (Pediatric)

For coverage criteria for internal or external component replacement, refer to the InterQual criteria in effect on the date of service:

- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Conduction Hearing Device Internal Component Replacement
- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Conduction Hearing Device External Component Replacement
- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Conduction Hearing Device Internal Component Replacement (Pediatric)
- InterQual® CP:Procedures, Hearing Device, Bone Anchored or Bone Conduction, Bone Conduction Hearing Device External Component Replacement (Pediatric)

See below for **Sound Processor Specifications**.

Fallon Health makes InterQual criteria available to the public through the transparency tool on our website, effective January 1, 2024.

Requests for bone-anchored hearing aids for plan members < 5 years of age will be reviewed on an individual case-by-case basis.

Nonsurgical, non-invasive bone conduction hearing aids and devices used to hold these hearing aids in contact with the skin, such as the BAHA Headband (also known as Softband), the Cochlear Baha SoundArc and the Adhear System (Med-El) are outside of the scope of this policy.

Currently there are several FDA-approved bone-anchored hearing aids marketed in the U.S. Despite many similarities in these devices, there are important features that distinguish them from one another. Coverage for bone-anchored hearing aids is premised upon the use of an FDA-approved device in accordance with its FDA-approved indications.

Sound Processor Specifications

1. Percutaneous bone anchored hearing aids

a. Cochlear Baha® Connect System (Cochlear)

For patients 5 years of age and older who have a conductive or mixed hearing loss and can still benefit from sound amplification, the pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the Baha 5 sound processor (K142907), 55 db HL for use with the Baha 5 Power sound processor (K161123) and Baha 6 Max sound processors (K202048), and 65 db HL for use with the Baha 5 SuperPower (K153245) sound processor .

Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.

b. Ponto (Oticon Medical AB)

For patients 5 years of age and older who have a conductive or mixed hearing loss and can still benefit from sound amplification, the pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the Ponto 3 (K161671), Ponto 4 (K190540) and Ponto 5 Mini (K211640) sound processors, 55 db HL for use with the Ponto 3 Power (K161671) sound processor, and 65 db HL for use with the Ponto 3 SuperPower (K161671) and Ponto 5 SuperPower (K213733) Sound Processors.

Symmetrical bone-conduction thresholds are defined as less than 10 dB on average measured at 0.5, 1, 2 and 4 kHz, or less than 15 dB at individual frequencies.

2. Passive transcutaneous bone-anchored hearing aids

a. Baha® Attract System (Cochlear)

For patients 5 years of age and older who have a conductive or mixed hearing loss and can still benefit from sound amplification, the pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the Baha 5 sound processor (K142907), 55 db HL for use with the Baha 5 Power (K161123) and Baha 6 Max (K202048) sound processors, and 65 db HL for use with the Baha 5 Super Power (K153245) Sound Processor.

Symmetrical bone-conductive thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15dB difference at individual frequencies.

b. Alpha 2 MPO (formerly SOPHONO) (Medtronic)

For patients 5 years of age and older who have a conductive or mixed hearing loss and can still benefit from sound amplification, the pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the Sophono (K153391) Sound Processor.

Symmetrical bone-conductive thresholds are defined as less than 10 dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

3. Active transcutaneous bone-anchored hearing aids

a. Cochlear Osia 2 System (Cochlear)

For patients 12 years of age or older who have a conductive or mixed hearing loss and still can benefit from sound amplification, the pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL (K220922).

Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.

b. BoneBridge (Med-El)

For patients 12 years of age or older who have a conductive or mixed hearing loss and still can benefit from sound amplification, the pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL (K200504).

Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.

Exclusions

- Any use of bone-anchored hearing aids other than outlined above.
- Semi-implantable hearing aids (also known as middle-ear implants) in which the hearing aid is surgically implanted in the middle ear.
- A BAHA “sleeper fixture” or other accessories which are not medically necessary.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

The following codes are for implantation of an osseointegrated implant. These devices treat hearing loss through surgical placement of an abutment or device into the skull that facilitates transduction of acoustic energy to be received by the better-hearing inner ear or both inner ears when the implant is coupled to a speech processor and vibratory element. This coupling may occur in a percutaneous or transcutaneous fashion (Source: AMA CPT Manual).

Code	Description
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
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

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.
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
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, 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

Bone Anchored Hearing Aids

Note: L8690 is Medicare OPPS Status Indicator “N” (packaged, not paid separately). L8692 is OPPS Status Indicator “E” (statutorily excluded). Replacement sound processors (L8691) are paid under the DME benefit.

Regarding Cochlear Osia 2 System and Osia 2 Sound Processor, CMS declined to issue a separate HCPCS code. Though the mechanism of action with comparable devices may differ, the vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear) is the same. CMS did not find any new evidence in the HCPCS Level II application to establish a significant therapeutic distinction. CMS, as an agency, continues to believe that our decision in the 2022 OPPS Final Rule remains accurate. As such, existing HCPCS Level II code L8690, "Auditory osseointegrated device, includes all internal and external components" describes the Cochlear™ Osia® 2 System. The Osia 2 System meets the criteria to be considered a prosthetic device as it is an osseointegrated implant in the skull bone that provides mechanical energy to the cochlea via a mechanical transducer per §411.15(d)(2)(i). As such, it is not subject to the hearing aid exclusion at §411.15(d)(1). The current Medicare policy and prior established benefit category determination for code L8690 apply to this item.¹

Bone-anchored hearing aids are considered prosthetic devices, not hearing aids.

L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, 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

¹ <https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-2-2022-non-drug-and-non-biological-items-and-services.pdf>.

L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each
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References

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Policy history

Origination date: 05/22/2007

Review/Approval(s): Technology Assessment Subcommittee: 03/27/2007, 05/22/2007, 05/07/2009
 Technology Assessment Committee: 10/09/2007, 09/30/2009, 03/26/2013, 05/28/2014 (Removed hearing aid benefit as part of criteria, updated template, references updated) 06/03/2015 (BAHA product names removed, updated references) 05/26/2016 (updated references), 05/24/2017 (updated references), 05/15/2018 (annual review, no updates), 05/22/2019 (added code L8692, updated references); 06/22/2021 (annual review; updated references; 06/15/2021: Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section; 03/15/2022

(updated coding), 02/27/2024 (annual review, adopted InterQual criteria, added section for Sound Processor Specifications, updated coding).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.