

Bone-Anchored Hearing Aids Clinical Coverage Criteria

Overview

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. A traditional bone-conduction hearing aid requires the use of a bone-conductor or vibrating pad. The vibrating pad is held in place on the mastoid bone by a removable headband. Because of advances in the treatment of outer and middle ear disorders, bone conduction hearing aids are rarely used today.

Also known as osseointegrated implants, a bone-anchored hearing aid (BAHA) is an alternative to a traditional bone conduction hearing aid that eliminates the need for the headband. A BAHA consists of a small titanium fixture, a percutaneous abutment (a screw), and a sound processor (a hearing aid). The titanium fixture is implanted in the mastoid bone during a minor outpatient surgical procedure. Over a period of several months, the titanium fixture bonds with the surrounding tissue; a process known as osseointegration. The osseointegrated titanium fixture and abutment provide secure retention for the sound processor and transmit sound through the bone to the cochlea.

Policy

- This Policy applies to the following Fallon Health products:
- ⊠ Commercial
- Medicare Advantage
- ⊠ MassHealth ACO
- ⊠ NaviCare
- ⊠ PACE

Fallon Health uses guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare guidance classifies 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, as prosthetic devices, therefore, Medicare covers osseointegrated implants, even though Medicare does not cover traditional hearing aids (Medicare Benefit Policy Manual, Chapter 16, Section 100-Hearing Aids and Auditory Implants). Medicare does not have a National Coverage Determination (NCD) for osseointegrated implants. National Government Services, Inc. does not have a Local Coverage Determination (LCD) or Local Coverage Article (LCA) for osseointegrated implants at this time (MCD search 6/15/2021).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

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 are used to determine medical necessity for MassHealth members. Fallon Health Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Bone-anchored hearing aids require prior authorization by Fallon Health.

Fallon Health Clinical Coverage Criteria

The following criteria must be met and supported by the treating provider(s) medical records:

- 1. Patient is 5 years of age or older and is unable to use conventional air conduction hearing aid(s) or undergo surgical repair because of one of the following conditions:
 - Congenital or surgical malformation of the external ear canal or middle ear canal
 - Tumors of the external ear canal and/or tympanic cavity
 - Severe, chronic otitis externa or otitis media
 - Other acquired malfunction of the external ear canal or middle ear canal which precludes the use of a conventional air-conduction hearing aid, such as hypersensitivity to ear molds used in air conduction hearing aids

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.

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.

Note: CPT 69715 and 69718 were deleted on 12/31/2021. To report mastoidectomy performed at the same operative session as osseointegrated implant placement, revision, replacement or removal see 69501-69676.

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
69717	Revision or replacement (including removal of existing device),

osseointegrated implant, skull, with percutaneous attachment to external
speech processor
Revision or replacement (including removal of existing device),
osseointegrated implant, skull; with magnetic transcutaneous attachment
to external speech processor
Removal, osseointegrated implant, skull; with percutaneous attachment
to external speech processor
Removal, osseointegrated implant, skull; with magnetic transcutaneous
attachment to external speech processor
Auditory osseointegrated device, includes all internal and external
components
Auditory osseointegrated device, external sound processor, replacement
only, each
Auditory osseointegrated device, external sound processor, used without
osseointegration, body worn, includes headband or other means of
external attachment
Auditory osseointegrated device abutment, any length, replacement only
Auditory osseointegrated device, transducer/actuator, replacement only,
each

References

- Centers for Medicare & Medicaid Services (CMS), Medicare Benefit Policy Manual Chapter 16, Section 100 - Hearing Aids and Auditory Implants. (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c16.pdf. Accessed 06/15/2021.
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- 12. Steehler MW, Larner SP, Mintz JS, et. al. A Comparison of the Operative Techniques and the Postoperative Complications for Bone-Anchored Hearing Aid Implantation. *Int Arch Otorhinolaryngol.* 2018 Oct;22(4):368-373.
- 13. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Bone Conduction Hearing Devices. Revised 04/13/2021. Available at:

https://www.entnet.org/resource/position-statement-bone-conduction-hearing-devices/. Accessed 06/15/2021.

Policy history

Origination date: Approval(s):	05/22/2007 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; 3-15-2022 updated coding).
	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.