

Bone-Conduction and Bone-Anchored Hearing Aid (BAHA) Implantation, Replacement, and Upgrades

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Hearing aids are amplifying devices that compensate for impaired hearing. They can be categorized into one of the following types:

- Air conduction (AC) devices – AC hearing devices provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound.
- Bone conduction (BC) devices – BC hearing 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.
 - External bone-conduction hearing aids function by transmitting sound waves through the bone to the ossicles of the middle ear.
 - Bone-anchored hearing aid (BAHA) systems, also known as osseointegrated devices, are surgically implanted hearing devices. They are founded on the process of “osseointegration” through which living tissue integrates with titanium

in the implant over a period of 3 to 6 months. This allows amplified and processed sound to be conducted via the skull bone directly to the cochlea. The lack of intervening skin permits the transmission of vibrations at a lower energy level than required for external bone-conduction hearing aids.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: Some devices may be referred to as Cochlear™ Baha® systems or Cochlear osseointegrated implants, reflecting the manufacturer’s name. These devices should not be confused with cochlear implants, which are addressed in a separate Medicare Advantage medical policy (see Cross References).

Procedure(s): CMS Coverage Manuals and National Coverage Determinations (NCDs)

Initial placement

**Medicare Benefit Policy Manual
Chapter 16 - General Exclusions From Coverage**

*See Section 100 in the following link:
[§100 - Hearing Aids and Auditory Implants](#)*

This Medicare Benefit Policy Manual states “hearing aids” are “amplifying devices that compensate for impaired hearing,” and that such devices are excluded from Medicare coverage. The manual adds that the classification of “hearing aids” includes air and bone conduction devices.

However, the manual includes a provision for “devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve,” stating these devices are payable by Medicare as prosthetic devices. The manual specifically includes osseointegrated implants as devices that may be payable as prosthetics. *When hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery, **implanted osseointegrated devices** may be considered medically necessary.*

Replacement or upgrade

Prosthetic devices “replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.”⁽¹⁾ The *Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, [§100 - Hearing Aids and Auditory Implants](#)* states osseointegrated implants are considered “prosthetic” devices. Therefore, in addition to the criteria from §100, the same rules for the replacement of prosthetics would also apply to the replacement of osseointegrated implants.

Medicare Benefit Policy Manual, Pub. No. 100-02
Chapter 15 - Covered Medical and Other Health Services

See Section 120, Subsection A, in the following link:

[§120 - Prosthetic Devices, Subsections A. General and D. Supplies, Repairs, Adjustments, and Replacement](#)

““The coverage of prosthetic devices includes replacement of and repairs to such devices as explained in subsection D.

“...Payment may be made for the replacement of a prosthetic device that is an artificial limb, or replacement part of a device if the ordering physician determines that the replacement device or part is necessary because of any of the following:

1. A change in the physiological condition of the patient;
2. An irreparable change in the condition of the device, or in a part of the device; or
3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.”

See Section 110.2 in the following link:

[§110.2 - Repairs, Maintenance, Replacement, and Delivery, Subsection C. Replacement](#)

IMPORTANT NOTE: Consistent with Medicare coverage guidelines, documentation must support §100 of Chapter 16 of the Medicare Benefit Policy Manual **AND:**

- (1) The device needs replacement (i.e., the device has gone bad or has sustained irreparable damage), **or**
- (2) The member’s physiological condition has changed to a level where the device is no longer adequate for their needs.

Additional Notes:

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- Coverage would not be considered reasonable or necessary if the request is for an upgrade to obtain newer technology for the member's convenience in the absence of other medically necessary circumstances. The reason for replacement needs to be sufficiently documented (i.e., device or component no longer functional, damaged due to an accident, etc.).
 - Requests for the replacement of an osseointegrated implant will take into consideration the "reasonable useful lifetime" of the equipment or device. Under this Medicare manual, this in no case can be less than five (5) years.
 - Finally, requests for the replacement of properly functioning equipment for the sole purpose of allowing the member to obtain an upgrade to newer technology may be denied as not medically necessary.
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POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Description of treatment (i.e., initial implant, a replacement, or upgrade);
- Name and manufacturer of the device being used;
- Clinical documentation must support why hearing aids are medically inappropriate or why they cannot be utilized (i.e., congenital malformations, chronic disease, severe sensorineural hearing loss or surgery, etc.).
- If the request is for a replacement or an upgrade, include the following information:
 - Does the device still function properly?
 - If not, provide information regarding whether or not the device is still under manufacturer warranty;
 - If so, provide medical reasons for the replacement (i.e., documentation of changes in patient condition, etc.).

REGULATORY STATUS

DEVICE	MANUFACTURER	FDA APPROVAL
Baha® system* <i>(Initially approved under the trade name Branemark Bone-Anchored Hearing Aid [BAHA™] by Entific Medical Systems, Inc.)</i>	Cochlear™	For use in children aged 5 years and older, and in adults, for the following indications: <ul style="list-style-type: none">• 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:		

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

Baha® 5 Sound Processor	Cochlear™	For use with the Baha auditory osseointegrated implant (hearing aid) systems (such as the Baha® Connect system)
Baha® 5 SuperPower Sound Processor		
Baha® 5 Power Sound Processor		
Baha® Softband™	Cochlear™	Yes For use in children under the age of 5 years

***Note:** These devices may be referred to as Cochlear™ Baha® systems or Cochlear osseointegrated implants, reflecting the manufacturer’s name. These devices are bone conduction hearing aids and should not be confused with cochlear implants which are prostheses that replace a damaged or absent cochlea in the inner ear. Cochlear implants are addressed in a separate Medicare Advantage medical policy (see Cross References).

Subsequent **bone conduction hearing systems** which share similar indications as the Cochlear™ Baha® devices:

OBC Bone Anchored Hearing Aid System™	Oticon Medical	Yes
Sophono® (S) (predicate device was Otomag [Sophono])	Cochlear™	Yes
Ponto	Oticon Medical	Yes To be used with the Oticon or BAHA devices.
Ponto Pro, Ponto Plus, Ponto Plus Power, Ponto 3, Ponto 3 Power or Ponto 3 SuperPower processors	Oticon Medical	Yes

The following **partially implantable magnetic bone conduction** devices:

Sophono® (M) (predicate device was Otomag Alpha [Sophono])	Cochlear™	Yes
Sophono™ Alpha 2 MPO™	Medtronic	Yes
Baha® Attract	Cochlear™	Yes
BoneBridge™ partially implantable bone-conduction hearing aid	MedEl	No

CROSS REFERENCES

None

REFERENCES

1. CMS [Provider Inquiry Assistance Download](#) dated 11/18/2005, related to MLN Matters Article MM4038; *Auditory Osseointegrated and Auditory Brainstem Devices*.
2. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, [§40.4 - Items Covered Under Warranty](#) (payment for devices replaced under a warranty)

CODING

NOTE: CPT code 69710 is a Medicare Status N code, and therefore, is non-covered by Medicare and Medicare Advantage.

The following CPT codes describe semi-implantable bone conduction hearing aids:

Codes	Number	Description
CPT	69710*	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone (<i>Non-covered by Medicare</i>)
*The Audiant™ bone conductor is a type of electromagnetic bone conduction hearing device. While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.		
	69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone.
	69714**	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
	69715**	; with mastoidectomy
	69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
	69718	; with mastoidectomy
**These codes describe <i>implantation</i> of the Baha®, Ponto™, and similar devices.		
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 (<i>Non-covered by Medicare</i>)

Codes	Number	Description
	L8693	Auditory osseointegrated device abutment, any length, replacement only
	L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each

***These codes describe the Baha®, Ponto™, and similar devices.

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.