

Origination: 06/23/08	Revised: 12/18/23	Annual Review: 11/12/24
Line of Business: Commercial Only \Box QHP/Exchange Only \Box Medicare Only \Box		
Commercial & QHP/Exchange 🛛 Commercial, QHP/Exchange, & Medicare 🗆		

Purpose:

To provide cochlear implant, bone anchored hearing aids, and auditory brainstem implant guidelines for Population Health and Provider Alliances associates to reference when making benefit determinations.

Additional Information

- Bone-anchored hearing aids (BAHA) are used for conductive and sensorineural hearing loss. It consists of a titanium screw/mounting post that is surgically implanted in the skull behind the ear and a sound processor that includes a Class D amplifier to amplify, process, and transmit sound to the mounting post and effect bone conduction hearing.
- Cochlear implant is an electronic device that bypasses damaged structures in the inner ear and directly stimulates the auditory nerve. Cochlear implants are only recommended after the patient has tried the most powerful and most appropriately fitted hearing aids and has not shown sufficient benefit from hearing aids.
- Auditory brainstem implant (ABI) is a modification of the cochlear implant, in which the electrode array is placed directly into the brain. The FDA has approved a device for use in Members who have developed tumors on both auditory nerves.
- SoundBite is a piezioelectric device that attaches to the teeth and is connected to a hearing aid. It is not bone anchored and non-invasive but still employs bone conduction sound generation that allows good reproducibility and quality of sound.

Coverage Guidelines as allowed by Member's contractual benefits

1. Auditory Brainstem Implant

• Covered for Members 12 years of age or older who have lost both auditory nerves due to disease (e.g., Neurofibromatosis or von Recklinghausen's disease).

2. Cochlear Implant

For Adults:

• Uniaural (monaural) or Binaural (Bilateral) cochlear implantation is covered for pre- or postlinguistic, sensorineural, moderate-to-profound Bilateral hearing impairment that meet *both* of the following criteria:



- Member has severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz; and
- Member has limited benefit from appropriately fitted hearing aids as defined by test scores of 40 % correct or less in best-aided listening condition on open-set sentence cognition.

For Children (aged 12 months to 18 years old):

- Uniaural (monaural) or Binaural (Bilateral) cochlear implantation is covered for Bilateral sensorineural hearing impairment that meets ALL of the following criteria:
- Member has profound, sensorineural hearing loss determined by a pure tone average of 90 dB or greater at 500, 1000 and 2000 Hz, and
- ♦ Member has limited benefit from appropriately fitted hearing aids as demonstrated by the failure to meet age-appropriate auditory milestones in the best-aided condition for young children or score of ≤ 40% correct in the best-aided condition on recorded open-set sentence recognition tests in the best-aided condition for all others, *and*
- ✤ A 3- to 6-month hearing aid trial has been documented unless there is radiological evidence of cochlear ossification.

For both Adults and Children:

• Replacement of a cochlear implant and/or its external components is covered when the existing device cannot be repaired or when replacement is required because a change in the member's condition makes the present unit non-functional and improvement is expected with a replacement unit.

Cochlear hybrid implants (i.e. Cochlear^{$^{\text{M}}$} Nucleus[®] Hybrid^{$^{\text{M}}$} Implant System) are unproven and not medically necessary for hearing loss. There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of cochlear hybrid implants in the management of patients with severe hearing loss. Published evidence has shown that there is a potential risk of low frequency hearing loss as a result of cochlear hybrid implant surgery.

3. Bone Anchored Hearing Aid

- Bone-anchored hearing aids (BAHA) or temporal bone stimulators are covered for Members with a Unilateral conductive or mixed conductive and sensorineural hearing loss as evidenced by:
- ◆ Pure tone average bone conduction threshold of up to 70 dB; and
- ✤ Speech discrimination score greater than 60%.



- And who have any of the following conditions:
 - Congenital or surgically induced malformations of the external ear canal or middle ear (such as aural atresia); or
 - Tumors of the external ear canal and/or tympanic cavity; *or*
 - Severe chronic external otitis or otitis media; or
 - Hearing loss secondary to otosclerosis in persons who cannot undergo stapedectomy.
 or
 - Dermatitis of the external ear, including hypersensitivity reactions to ear molds used in air conduction hearing aids; or
 - Other conditions in which an air-conduction hearing aid is contraindicated.

4. SoundBite

- SoundBite device (mouth and earpieces) are covered for Members with a unilateral conductive or mixed conductive and sensorineural hearing loss as evidenced by:
 - ◆ Pure tone average bone conduction threshold of up to 70 dB; and
 - ✤ Speech discriminations score greater than 60%.
- And who have any of the following conditions:
 - Congenital or surgically induced malformations of the external ear canal or middle ear (such as aural atresia); or
 - Tumors of the external ear canal and/or tympanic cavity; or
 - Severe chronic external otitis or otitis media; or
 - Hearing loss secondary to otosclerosis in persons who cannot undergo stapedectomy. or
 - Dermatitis of the external ear, including hypersensitivity reactions to ear molds used in air conduction hearing aids; or
 - Other conditions in which an air-conduction hearing aid is contraindicated.

Exclusion Criterion

Any other conditions or indications not specifically listed above are considered experimental and investigational.

<u>References</u>:

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- 20. U.S. Food and Drug Administration (FDA). Branemark Bone Anchored Hearing Aid (BAHA). Summary of Safety and Effectiveness. 510(k) No. K021837. Rockville, MD: FDA; June 1, 2002.
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- 22. Hayes Technology review. Cochlear implantation. December 9, 2007.
- 23. SoundBite AvMed MTAC determination at 10/24/13 meeting.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.