

Hearing Aids, Auditory Implants and Related Procedures

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[Instructions for Use](#)

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Related Medicare Advantage Policy Guidelines
• Cochlear Implantation (NCD 50.3)
• Oxygen Treatment of Inner Ear/Carbon Therapy (NCD 50.5)
• Ultrasonic Surgery (NCD 50.8)

Coverage Guidelines

Cochlear implantation, hearing aids and auditory implants are covered in accordance with Medicare coverage criteria.

Note: Some members have supplemental benefit for hearing aids. Refer to the member’s EOC to determine coverage eligibility for the supplemental hearing aid benefit.

Surgically Implanted Auditory Devices

Surgically implanted auditory devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are covered as prosthetics only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

Cochlear Implants and Auditory Brainstem Implants

For hybrid cochlear implants, refer to the [guidelines](#) below.

Cochlear implants and auditory brainstem implants (i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays) are covered when one of the following is met:

- Bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification for members who meet all of the following selection guidelines:
 - Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment that cannot be intensified with the appropriate hearing (or vibrotactile) aids
 - Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation
 - Freedom from middle ear infection, the cochlear opening is able to accommodate the implant, and freedom from tumors or lesions in the auditory nerve and acoustic areas of the central nervous system
 - No contraindications to surgery
 - The device must be used in accordance with the FDA approved labeling

See the following FDA websites for a current list of indications for each device:

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

(Accessed November 9, 2020)

Note: Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition.

- Member meeting the selection guidelines above (1-5) and hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare and Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.
 - The list of Medicare approved clinical trials is available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Cochlear-Implantation.html>. (Accessed November 9, 2020)
 - For payment rules for NCDs requiring CED, see the Coverage Summary titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

Refer to the [NCD for Cochlear Implantation \(50.3\)](#). (Accessed November 9, 2020)

Also refer to the [Medicare Benefit Policy Manual, Chapter 16, §100 – Hearing Aids and Auditory Implants](#). (Accessed November 9, 2020)

Note: Patients return to the implanting center after 4 to 5 weeks of post-surgery healing to have their speech processor programmed. The patient's age, cognitive skills, and length of deafness are among the factors considered during device programming, which entails selection and fitting of the processing strategy that will be used to translate acoustic stimuli into the electric impulses that will stimulate the auditory nerve. The number of visits needed to accomplish optimum device performance will be influenced by such patient factors as age, previous auditory experience and ability to participate actively in the task. Long-term audiologic follow-up is also necessary as responses to nerve stimulation may change over time. Refer to the CMS [Decision Memo for Cochlear Implantation \(CAG-00107N\)](#). (Accessed November 9, 2020)

For repair, maintenance and replacement, refer to *Repairs, Maintenance and Replacement* section of the Coverage Summary titled [Durable Medical Equipment, Prosthetics, Corrective Appliances/Orthotics and Medical Supplies](#).

Osseointegrated Implants

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 covered. The device must be used in accordance with the FDA approved labeling.

Refer to the following FDA websites for a current list of indications for each device:

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

(Accessed November 9, 2020)

Example includes:

Bone anchored hearing aid (BAHA) in accordance with the FDA approved indications; based on the FDA 510(k) Summary for BAHA; available at http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080363.pdf. (Accessed November 9, 2020)

The Baha Cordelle II sound processor is intended for use with the Baha auditory osseointegrated implant for the following patients and indications:

- Patients 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 3 kHz) should be better than or equal to 65 dB HL.
- Bilateral fitting of the Cordelle II is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. 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.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. single-sided deafness or "SSD"). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

Notes:

- For repair, maintenance and replacement, refer to the Coverage Summary titled [Durable Medical Equipment, Prosthetics, Corrective Appliances/Orthotics and Medical Supplies](#).
- Refer to the [Medicare Benefit Policy Manual, Chapter 16, §100 – Hearing Aids and Auditory Implants](#). (Accessed November 9, 2020)

Hearing Aids and Auditory Implants that are Not Covered

Hearing aids and auditory implants that do not meet the criteria in the [Surgically Implanted Auditory Devices](#) section are not covered.

Note: Some members have supplemental benefit for hearing aids. Refer to the member's EOC to determine coverage eligibility for the supplemental hearing aid benefit.

Hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are not covered.

Section 1862(a)(7) of the Social Security Act states that no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for ... hearing aids or examinations therefore..." This policy is further reiterated at 42 CFR 411.15(d) which specifically states that "hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids" are excluded from coverage.

Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that 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.

Refer to the [Medicare Benefit Policy Manual, Chapter 16, §100 – Hearing Aids and Auditory Implants](#). (Accessed November 9, 2020)

Examples of hearing aids and auditory implants that are not covered include, but are not limited to:

- Totally Implanted Hearing Systems such as the Esteem® Implantable Hearing System
 - Medicare does not have a National Coverage Determination (NCD) for totally implanted hearing systems. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.
 - For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled [Hearing Aids and Devices including Wearable, Bone-Anchored and Semi-Implantable](#).
Note: After searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
- Cochlear Hybrid Implants (For conventional cochlear implant, refer to the [guidelines](#) above)
 - Medicare does not have a National Coverage Determination (NCD) for cochlear hybrid implants. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.
 - For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled [Cochlear Implants](#).
Note: After searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

Ultrasonic Ablative Surgery

Ultrasonic ablative surgery may be covered when required in the treatment of patients with severe and recurrent episodes of vertigo due to Ménière's syndrome. Refer to the [NCD for Ultrasonic Surgery \(50.8\)](#). (Accessed November 9, 2020)

Oxygen to Treat Hearing Loss

Oxygen to treat hearing loss is not covered. Refer to the [NCD for Oxygen Treatment of Inner Ear/Carbon Therapy \(50.5\)](#). (Accessed November 9, 2020)

Also refer to the Coverage Summary titled [Hearing Screening and Audiologist Services](#).

Policy History/Revision Information

Date	Summary of Changes
05/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
11/17/2020	<ul style="list-style-type: none">Routine review; no change to coverage guidelines

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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