Coverage Summary

Hearing Aids, Auditory Implants and Related Procedures

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 11/17/2015

Related Medicare Advantage Reimbursement Policies:
- Cochlear Implantation (NCD 50.3)
- Oxygen Treatment of Inner Ear Carbon Therapy (NCD 50.5)
- Ultrasonic Surgery (NCD 50.8)

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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 is required where applicable.

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I. COVERAGE

Coverage Statement: 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.

Guidelines/Notes:

1. 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.

a. **Cochlear Implants and Auditory Brainstem Implants**

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 criterion 1) or criterion 2) is met:

1) 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

   **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.

2) 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 & 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.


   For payment rules for NCDs requiring CED, see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

**Notes:**

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.

See the CMS Decision Memo for Cochlear Implantation (CAG-00107N). (Accessed November 11, 2015)

**For repair, maintenance and replacement**, refer to #4.d of the DME, Prosthetics, Corrective Appliances/Orthotics and Medical Supplies Coverage Summary.

See the NCD for Cochlear Implantation (50.3). (Accessed November 11, 2015)


b. **Osseointegrated Implants**

Osseointegrated implants are covered, 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. Example include:


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.

Note: For repair, maintenance and replacement, refer to the DME, Prosthetics, Corrective Appliances/Orthotics and Medical Supplies Coverage Summary.


2. Hearing aids and auditory implants that do not meet the criteria in Guidelines #1 above 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.)


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. Example include, but not limited to, totally implanted hearing systems such as the Esteem® Implantable Hearing System.


The Esteem is a totally implantable middle ear hearing device. The Esteem consists of three implantable components, the Sound Processor, the Sensor and the Driver, and external instruments for interrogating, testing and programming the Esteem. Specifically, the Esteem includes the Model 2001 Sound Processor, Sensor Model 7002, Driver Model 7502, Esteem Programmer Model 6001 with Esteem Programmer Software and Wand, Personal Programmer Model 8001, Intraoperative System Analyzer Model 3001, and accessories.

Implantable Components:

1. Sensor: The piezoelectric Sensor tip is attached to the incus bone. The Sensor senses vibrations from the tympanic membrane and malleus/incus and converts these mechanical vibrations into electrical signals that are sent to the Sound Processor.
2. Sound Processor: The Sound Processor, which is implanted in the temporal bone and connected to the Sensor and Driver via leads, receives the electrical signal from the Sensor, amplifies and filters the signal to compensate for the patient's hearing loss profile. The enhanced signal is then sent to the Driver.
3. Driver: The piezoelectric Driver tip is attached to the stapes/incus bone. The Driver converts the enhanced electrical signal received from the Sound Processor back to mechanical energy, i.e. vibrations. The vibrations are transferred to the stapes and delivered as sound waves in the cochlea.

3. 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. See the NCD for Ultrasonic Surgery (50.8). (Accessed November 11, 2015)

4. Oxygen to treat hearing loss is not covered. See the NCD for Oxygen Treatment of Inner Ear/Carbon Therapy (50.5). (Accessed November 11, 2015)
II. DEFINITIONS

**Cochlear Implant Device:** An electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. [NCD for Cochlear Implantation (50.3)](Accessed November 11, 2015)

**Hearing Aids:** 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. [Medicare Benefit Policy Manual, Chapter 16, §100 - Hearing Aids and Auditory Implants](http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf) (Accessed November 11, 2015)

III. REFERENCES

See above

IV. REVISION HISTORY

11/17/2015  Annual review; Guideline 5 [Transtympanic Micropressure (such as Meniett™)] removed; default UnitedHealthcare Medical Policy was retired; procedure no longer in the Prior-Auth list; no LCDs or other Medicare reference found.

04/21/2015  Re-review with the following updates:
- NCD 50.6 Tinnitus Masking was retired. Any reference to this NCD removed from coverage summary.
- Guideline 1.a.2 (Cochlear Implants and Auditory Brainstem Implants)
  - Added reference link to the list of Medicare approved clinical trials.
  - Added reference link to the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf) for payment rules for NCDs requiring CED.
  - Removed all language pertaining to Bilateral Cochlear Implantation.

12/16/2014  Annual review with the following updates:
Guideline 6 (Transtympanic Micropressure) - Added “such as Meniett™” to the section title Definitions
- Cochlear Implant Device: Added reference link to the [NCD for Cochlear Implantation (50.3)]
- Hearing Aids: Added reference link to the [Medicare Benefit Policy Manual, Chapter 16, §100 - Hearing Aids and Auditory Implants]
- Tinnitus Masker: Added reference link to the [NCD for Tinnitus Masking (50.6)]
- Oxygen (95 percent) and Carbon Dioxide (5 percent) To Treat Hearing Loss: Added reference link to the [NCD for Oxygen Treatment of Inner Ear/Carbon Therapy (50.5)]
<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>04/15/2014</td>
<td>Guidelines # 1 (Surgically Implanted Auditory Devices) - added “For repair, maintenance and replacement, refer to #4.d of the DME, Prosthetics, Corrective Appliances/Orthotics and Medical Supplies Coverage Summary.”</td>
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<td>10/24/2013</td>
<td>Annual review; no updates.</td>
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<tr>
<td>10/31/2012</td>
<td>Guidelines #2 updated to include the noncoverage language for Esteem® Implantable Hearing System.</td>
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<tr>
<td>10/13/2011</td>
<td>Guidelines #1.a (Cohlear Implants and Auditory Brainstem) updated to include the notes pertaining to post surgery follow-up and device programming.</td>
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<td>Guidelines #1.b.1 (Bone anchored hearing aid/BAHA) updated to also include the indications for bilateral hearing loss.</td>
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<tr>
<td>09/07/2010</td>
<td>Policy updated to include guidelines for Transtympanic Micropressure; also added a statement that some members may have supplemental benefits for hearing aids.</td>
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