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, (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

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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.

**Note: Bilateral Cochlear Implantation:**

- The Nationally Covered Indications specified by Medicare’s National Coverage Determination for Cochlear Implantation (50.3), define coverage of cochlear implantation only for those individuals who demonstrate limited benefit from amplification, and who meet all other coverage criteria. The Nationally Noncovered Indications define those who do not meet all coverage criteria as ineligible for Medicare coverage of cochlear implantation.

- For those individuals who have already had unilateral cochlear implantation, coverage for an implant in the second ear would generally be excluded unless the hearing test scores of the implanted ear after the implant are still less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Without hearing scores in the implanted ear after the implant testing below this threshold, that individual would no longer have bilateral moderate to-profound sensorineural hearing impairment that cannot be intensified; the National Noncovered Indication would apply for the second implant for bilateral implants.

b. 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. Examples include:

a) Bone anchored hearing aid (BAHA) in accordance with the FDA approved indications.

**FDA Indications for Use:** The use of BAHA hearing aid for single sided deafness (SSD) is intended to improve speech recognition. The SSD indication for BAHA hearing aid is intended for patients who suffer from unilateral sensorineural deafness on one ear while the other ear has normal hearing. Normal hearing is defined as PTA AC threshold equal to or better than 20dB measured at 0.5, 1, 2 and 3 kHz. BAHA for SSD is also indicated for patients who are indicated for an AC Contra-lateral Routing Of Signals (CROS) but who for some reason cannot or will not use an AC CROS. (Refer to the FDA 510(k) Summary for BAHA at http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080363.pdf.)
b) Middle ear implants (MEI)

Notes:

2. 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).

3. Hearing aids and auditory implants that do not meet the criteria in 1 or 2 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.)

4. Tinnitus masking and tinnitus maskers are not covered. See the NCD for Tinnitus Masking (50.6).

5. Oxygen to treat hearing loss is not covered. See the NCD for Oxygen Treatment of Inner Ear/Carbon Therapy (50.5).

6. Transtympanic Micropressure
- Medicare does not have a National Coverage Determination (NCD) for transtympanic micropressure.
- Local Coverage Determinations (LCDs) do not exist at this time.
- For coverage guidelines, refer to the UHC Medical Policy for Transtympanic Micropressure.
- Committee approval date: September 7, 2010
- CMS website accessed July 21, 2010

Also see Hearing Screening and Audiologist Services Coverage Summary.

II. DEFINITIONS

1. 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.

2. 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.

3. Tinnitus Masker: A device designed to be worn like a behind-the-ear hearing aid by persons seeking relief from tinnitus. Tinnitus is the perception of noise in the ear and/or head area. The masker produces external sounds to distract the person from the tinnitus. By producing an external sound a few decibels above the person's audible threshold, tinnitus masking is thought to provide sufficient distraction from subjective idiopathic tinnitus to alleviate the discomfort.
and debilitation associated with endogenous sounds within the ear and/or head area.

4. **Oxygen (95 percent) and Carbon Dioxide (5 percent) To Treat Hearing Loss**: Inhalation therapy for inner ear disease, such as endolymphatic hydrops and fluctuant hearing loss, is not reasonable and necessary. The therapeutic benefit deriving from this procedure is highly questionable.

## III. REFERENCES

1. See above

## IV. REVISION HISTORY

09/07/2010 Policy updated to include guidelines for Transtympanic Micropresssure; also added a statement that some members may have supplemental benefits for hearing aids.