Medical Coverage Policy | Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 07|21|2015

OVERVIEW
Patients with hearing loss are typically fitted with external acoustic hearing aids. Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic hearing aids. This policy does not apply to Medicare products as Medicare does not cover hearing aids.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products
Implantable and semi-implantable middle ear hearing aids are considered not medically necessary because the long-term safety and efficacy of this treatment has not been documented in the peer-reviewed medical literature.

Re-insertion of the device after removal is considered not medically necessary.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 decibels (dB). The American Speech Language-Hearing Association has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥80 dB). Sound amplification through the use of an air-conduction hearing aid can provide benefit to patients with sensorineural, conductive, or mixed hearing loss. Contralateral routing of signal is a system in which a microphone on the affected side transmits a signal to an air-conduction hearing aid on the normal or less affected side.

Patients with moderate to severe sensorineural hearing loss are typically fitted with external acoustic hearing aids. However, these hearing aids may not be acceptable to patients, either due to issues related to anatomic fit, sound quality, or personal preference. Conductive hearing loss may be treated with acoustic or bone conduction hearing aids when surgical or medical interventions are unable to correct hearing loss. Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic hearing aids.

Semi-Implantable Middle Ear Hearing Aid
Two semi-implantable devices received approval by U.S. Food and Drug Administration (FDA), the Vibrant® Soundbridge™, approved in August 2000, and the Soundtec® Direct System™, approved in September 2001.

The Soundtec was discontinued by the manufacturer Ototronix in 2004 due to performance issues; it was rereleased in 2009 under the name Maxum™ System. The FDA labeling approved for both devices states that they are "…intended for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid." The devices consist of 3 components: a magnetic component that is implanted onto the ossicles of the middle ear, a receiver, and a sound processor. The Soundbridge device is implanted subcutaneously behind the ear while the processor is worn externally on the scalp over the receiver unit and held in place by a magnet. The Soundtec (Maxum System) device is placed in the user's ear canal while the processor rests over the external ear. In general, the sound processor receives and amplifies the sound vibrations and transforms the sound pressure into electrical signals that are received by the receiver unit. The receiver unit then transduces these electrical signals into electromagnetic energy and creates an alternating electromagnetic field with the magnetic component (floating mass transducer) implanted on the ossicles of the middle ear. This electromagnetic field results in attractive and repulsive forces on the magnetic implant, causing vibration of the bones of the middle ear similar to normal hearing.

Due to limited safety data and the small number of patients included in studies and clinical trials, risks cannot be adequately evaluated and conclusions on the effectiveness of semi-implantable hearing aids cannot be made. Therefore, the use of semi-implantable middle ear hearing aids is considered not medically necessary for all indications.

Fully implantable middle ear hearing aid:
The Esteem® Implantable Hearing System by Envoy Medical is a fully implantable middle ear hearing aid that received FDA approval in March 2010. The FDA-approved labeling for the Esteem hearing implant indicates it is "intended to alleviate hearing loss ... in adults 18 years of age or older with stable bilateral sensorineural hearing loss." This device uses piezoelectric transduction, as opposed to the electromagnetic transduction used in the semi-implantable devices. A piezoelectric transducer, the sensor, is placed at the head of the incus and converts mechanical vibrations detected from the tympanic membrane to electrical signals that are delivered to the stapes by another piezoelectric transducer, the driver.

The available evidence for use of fully implantable middle ear hearing aids is insufficient to demonstrate long-term improvement in net health outcome. Concerns exist about adverse events with these devices. Therefore, fully implantable middle ear hearing aids are considered not medically necessary.

CODING

Commercial Products
The following codes are not medically necessary:
S2230
V5095

RELATED POLICIES

Cochlear Implants
Hearing Aid Mandate

PUBLISHED

Provider Update, August 2015
Provider Update, July 2015
Provider Update, April 2014
Provider Update, March 2013
Provider Update, February 2012
Provider Update, April 2011
Provider Update, November 2009

REFERENCES

1. Ototronix. Important Safety Information. 2014; http://www.ototronix.com/. Accessed January 14, 2015.
2. Vibrant Soundbridge. FDA Summary of Safety and Effectiveness. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p990052. Accessed January 14, 2015.
3. Soundtec Direct System. FDA Summary of Safety and Effectiveness. http://www.accessdata.fda.gov/cdrh_docs/pdf/P010023b.pdf. Accessed January 14, 2015.
4. Luetje CM, Brackman D, Balkany TJ, et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: a prospective controlled multicenter study. Otolaryngol Head Neck Surg. Feb 2002;126(2):97-107. PMID 11870337
5. Sterkers O, Boucarra D, Labassi S, et al. A middle ear implant, the Symphonix Vibrant Soundbridge: retrospective study of the first 125 patients implanted in France. Otol Neurotol. May 2003;24(3):427-436. PMID 12806295
6. Tysome JR, Moorthy R, Lee A, et al. Systematic review of middle ear implants: do they improve hearing as much as conventional hearing AIDS? Otol Neurotol. Dec 2010;31(9):1369-1375. PMID 20479696
7. Butler CL, Thavaneswaran P, Lee IH. Efficacy of the active middle-ear implant in patients with sensorineural hearing loss. J Laryngol Otol. Jul 2013;127 Suppl 2:S8-16. PMID 23790515
8. Hough JV, Matthews P, Wood MW, et al. Middle ear electromagnetic semi-implantable hearing device: results of the phase II SOUNDTEC direct system clinical trial. Otol Neurotol. Nov 2002;23(6):895-903. PMID 12438853
9. Silverstein H, Atkins J, Thompson JH, Jr., et al. Experience with the SOUNDTEC implantable hearing aid. Otol Neurotol. Mar 2005;26(2):211-217. PMID 15793407
10. Truy E, Philibert B, Vesson JF, et al. Vibrant soundbridge versus conventional hearing aid in sensorineural highfrequency hearing loss: a prospective study. Otol Neurotol. Aug 2008;29(5):684-687. PMID 18434928