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

EFFECTIVE DATE: 06|01|2015
POLICY LAST UPDATED: 05|19|2015

OVERVIEW
Patients with moderate to severe sensorineural 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.

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and 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.

MEDICAL CRITERIA
Not applicable

BACKGROUND
External acoustic hearing aids may not be acceptable to patients, either due to issues related to anatomic fit, sound quality, or personal preference. 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:
A semi-implantable middle ear hearing aid has been developed as an alternative to external acoustic hearing aids. In these devices, 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 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. FDA-approved labeling states that these devices are intended for use in adults over the age of 18, with a moderate-to-severe sensorineural hearing loss who desire an alternative to an acoustic hearing aid. This device consists of 3 components: 1) a magnetic component that is implanted onto the ossicles of the middle ear; 2) a receiver; and 3) a sound processor. Depending on the design, the device may be implanted subcutaneously behind the ear and held in place by a magnet; or placed in the user's ear canal with the processors resting over the external ear.

The limited literature currently available does not provide support for the use of semi-implantable middle ear hearing aids. Because of the lack of efficacy, this procedure is considered not medically necessary.

Fully implantable middle ear hearing aid:
The Esteem® Implantable Hearing System by Envoy Medical Corporation 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 limited literature currently available does not provide support for the use of fully implantable middle ear hearing aids. Because of the lack of efficacy, this procedure is considered not medically necessary.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable surgical benefit.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are not medically necessary:

69710
S2230

RELATED POLICIES

Cochlear Implants
Hearing Aid Mandate
Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, July 2015
Provider Update, April 2014
Provider Update, March 2013
Provider Update, February 2012
Provider Update, April 2011
Provider Update, November 2009
Provider Update, July 2008

REFERENCES

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2. Soundtec Direct System. FDA Summary of Safety and Effectiveness. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf/P010023b.pdf. Last accessed March 8, 2012

3. 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 2002; 126(2):97-107.

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5. 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 2010; 31(9):1369-75.

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8. Truy E, Philibert B, Vesson JF et al. Vibrant soundbridge versus conventional hearing aid in sensorineural high-frequency hearing loss: a prospective study. Otol Neurotol 2008; 29(5):684-7.

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