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

EFFECTIVE DATE: 06|01|2010
POLICY LAST UPDATED: 02|04|2014

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

Prior authorization review is required for the removal of the device for BlueCHiP for Medicare members and recommended for Commercial products.

POLICY STATEMENT

Blue CHiP for Medicare and Commercial

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.**

Removal of a fully implantable or semi-implantable middle ear hearing aid is covered when performed as a result of a complication such as infection.

MEDICAL CRITERIA

Approval for removal or repair of a semi-implantable or fully implantable middle ear hearing aid due to complications such as infection would require submission and review of proper clinical documentation.

BACKGROUND

External acoustic hearing aids 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: a magnetic component that is implanted onto the ossicles of the middle ear, a receiver, and 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

The following code will be covered under the member's surgical benefit and **preauthorization is required for BlueCHiP for Medicare members and recommended for Commercial products:**

69711

*The Audiant™ bone conductor is a type of electromagnetic bone conduction hearing device. While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.

The following codes are **not medically necessary:**

69710, S2230

RELATED POLICIES

Cochlear Implants
Hearing Aid Mandate

PUBLISHED

Provider Update	Apr 2014
Provider Update	Mar 2013
Provider Update	Feb 2012
Provider Update	Apr 2011
Provider Update	Nov 2009
Provider Update	Jul 2008
Policy Update	Jul 2007

REFERENCES

1. Vibrant Soundbridge. FDA Summary of Safety and Effectiveness. Available online at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p990052. Last accessed March 8, 2012.

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.

4. 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 2003; 24(3):427-36.

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.

6. 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 2002; 23(6):895-903.

7. Silverstein H, Atkins J, Thompson JH, Jr. et al. Experience with the SOUNDTEC implantable hearing aid. Otol Neurotol 2005; 26(2):211-7.

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.

9. Beltrame AM, Martini A, Prosser S et al. Coupling the Vibrant Soundbridge to cochlea round window: auditory results in patients with mixed hearing loss. Otol Neurotol 2009; 30(2):194-201.

10. Gunduz B, Atas A, Bayazit YA et al. Functional outcomes of Vibrant Soundbridge applied on the middle ear windows in comparison with conventional hearing aids. Acta Otolaryngol 2012; 132(12):1306-10.