

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



**EFFECTIVE DATE:** 10|01|2015  
**POLICY LAST UPDATED:** 12|06|2016

### 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

Moderate-to-severe sensorineural hearing loss is often treated with external acoustic hearing aids, while 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 detect sound and transduce signals directly to the ossicles in the middle ear, and have been used as an alternative to external acoustic hearing aids.

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 ( $\geq 80$  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. Conductive hearing loss may be treated with acoustic or bone conduction hearing aids when surgical or

medical interventions are unable to correct hearing loss. However, these hearing aids may not be acceptable to patients, either due to issues related to anatomic fit, sound quality, or personal preference. In some cases, external acoustic hearing aids cannot be used due to external ear pathologies (eg, otitis externa). 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 have Food and Drug Administration (FDA) approval: the Vibrant Soundbridge (MED-EL Corp.) and the Maxum System (Ototronix). 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 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.

### **Fully implantable middle ear hearing aid:**

One fully implantable middle ear hearing aid has FDA approval: the Esteem Implantable Hearing System (Envoy Medical). Similar to the semi-implantable devices, the fully implantable device consists of a sensor, a sound processor, and a driver connected to the ossicles. The sensor detects vibrations of the tympanic membrane and transforms the vibrations into electrical signals that are processed by the sound processor. The processor transduces these signals via 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 into electrical signals that are delivered to the stapes by another piezoelectric transducer, the driver.

The evidence for semi-implantable and fully implantable middle ear hearing aids in individuals who have hearing loss is insufficient to determine the effects of the technology on health outcomes. Therefore, semi- and 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, January 2017

Provider Update, August 2015

Provider Update, July 2015

Provider Update, April 2014

Provider Update, March 2013

Provider Update, February 2012

Provider Update, April 2011

## **REFERENCES**

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