Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Medical Benefit: Effective Date: 04/01/13 | Next Review Date: 11/17
Preauthorization: No | Review Dates: 07/07, 07/08, 05/09, 01/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16

This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: • With hearing loss</td>
<td>Interventions of interest are: • Semi-implantable middle ear hearing aids • Fully implantable middle ear hearing aids</td>
<td>Comparators of interest are: • External hearing aid</td>
<td>Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity</td>
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</tbody>
</table>

Description

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 use as an alternative to external acoustic hearing aids.

Summary of Evidence

The evidence for semi-implantable and fully implantable middle ear hearing aids in individuals who have hearing loss includes the single-arm interventional studies on which the devices’ Food and Drug Administration approvals were based, and a number of observational series. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The limited data suggest implantable middle ear hearing aids may provide marginal improvement in hearing compared with conventional external acoustic hearing aids in patients with sensorineural hearing loss. However, given the safety and effectiveness of external acoustic hearing aids and the increased risks inherent in a surgical procedure, the semi-implantable device must be associated with clinically significant improvement in various hearing parameters compared with external hearing aids. While safety concerns appear to be minimal, only a limited number of patients have been included in the clinical trials, and few have completed more than one year of follow-up. Given small sample sizes and limited safety data, risks cannot be adequately evaluated and compared with the marginal improvement in hearing. Studies of patients with conductive or mixed hearing loss and aural atresia, when external acoustic hearing aids are not an option, have also demonstrated hearing benefit with semi-implantable middle ear hearing aids.
hearing aids. However, these studies are few and limited to small numbers of patients. Therefore, conclusions on the safety and effectiveness of semi-implantable hearing aids in these patients cannot be made, and further study with longer term follow-up is needed. Comparisons of semi-implantable devices with alternative hearing devices such as implantable bone-conduction and bone-anchored hearing aids would also be useful to determine device appropriateness for patients who are unable to use external air-conduction hearing aids. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Semi-implantable and fully implantable middle ear hearing aids are considered **investigational**.

Policy Guidelines

For reference, the package insert of the Vibrant Soundbridge device describes the following patient selection criteria:

- Pure-tone air-conduction threshold levels shall fall at or within the limits outlined in Table 1.

**Table 1: Pure-Tone Air-Conduction Threshold Levels**

<table>
<thead>
<tr>
<th>Frequency, kHz</th>
<th>Lower limit</th>
<th>Upper limit</th>
</tr>
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<tbody>
<tr>
<td>0.5</td>
<td>30</td>
<td>65</td>
</tr>
<tr>
<td>1</td>
<td>40</td>
<td>75</td>
</tr>
<tr>
<td>1.5</td>
<td>45</td>
<td>80</td>
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<tr>
<td>2</td>
<td>45</td>
<td>80</td>
</tr>
<tr>
<td>3</td>
<td>50</td>
<td>85</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
<td>85</td>
</tr>
</tbody>
</table>

- Word recognition score of 50% or better, using recorded material
- Normal middle ear anatomy
- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device

The Maxum System is indicated 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. Before receiving the device, it is recommended that patients have experience with appropriately fitted hearing aids.

The Esteem device is indicated for patients with hearing loss meeting the following criteria:

- 18 years of age or older
- Stable bilateral sensorineural hearing loss
- Moderate (hearing loss between 40 and 70 decibels [dB]) to severe (hearing loss between 71 and 90 dB) sensorineural hearing loss defined by PTA (pure tone average)
- Unaided speech discrimination test score greater than or equal to 40%
- Normally functioning eustachian tube
- Normal middle ear anatomy
- Normal tympanic membrane
- Adequate space for Esteem implant determined via high resolution CT [computed tomography] scan
- Minimum 30 days of experience with appropriately fit hearing aids.
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. 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 (e.g., otitis externa).

Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic hearing aids. Two semi-implantable devices have the United States Food and Drug Administration (FDA) approval: the Vibrant Soundbridge (MED-EL Corp.) and the Maxum System (Ototronix). The devices consist of three 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.

One fully implantable middle ear hearing aid has U.S. 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.

Regulatory Status

Two semi-implantable devices were approved by the U.S. FDA through the premarket approval process: the Vibrant® Soundbridge™ in August 2000 and the Soundtec® Direct System™ in September 2001. The Soundtec was discontinued by the manufacturer Ototronix in 2004 due to performance issues; it was re-released in 2009 under the name Maxum™ System. The FDA labeling approved for both devices states that the devices 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.” FDA product code: MPV.

In March 2010, the Esteem® Implantable Hearing System (Envoy Medical, St. Paul, MN), a fully implantable middle ear hearing aid, was approved by the U.S. FDA through the premarket approval process. U.S. 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.” FDA product code: OAF.

Another fully implantable middle ear hearing aid, the Carina® Fully Implantable Hearing Device, was in development (Otologics, Boulder, CO), but does not have U.S. FDA approval.

Related Protocols
Cochlear Implant
Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References
We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


