

Protocol

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

(70184)

Medical Benefit		Effective Date: 04/01/13	Next Review Date: 11/19
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, 11/17, 11/18	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With hearing loss	Interventions of interest are: <ul style="list-style-type: none">• Semi-implantable middle ear hearing aids	Comparators of interest are: <ul style="list-style-type: none">• External hearing aid	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Functional outcomes• Quality of life• Treatment-related morbidity
Individuals: <ul style="list-style-type: none">• With hearing loss	Interventions of interest are: <ul style="list-style-type: none">• Fully implantable middle ear hearing aids	Comparators of interest are: <ul style="list-style-type: none">• External hearing aid	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Functional outcomes• Quality of life• Treatment-related morbidity

DESCRIPTION

Moderate-to-severe sensorineural hearing loss is often treated with external acoustic hearing aids, while conductive hearing loss can be treated with acoustic or bone-conduction hearing aids when surgical or medical interventions do not 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.

SUMMARY OF EVIDENCE

For individuals who have hearing loss who receive semi-implantable or fully implantable middle ear hearing aids, the evidence includes the single-arm interventional studies submitted to the FDA, systematic reviews, and a number of observational series. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The data have suggested implantable middle ear hearing aids may provide some 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- and fully implantable device must be associated with clinically significant improvement in various hearing parameters compared with external hearing aids. While safety con-

cerns appear to be minimal, only a limited number of patients have been included in the clinical trials, and with a median duration of follow-up less than five years. Studies of patients with conductive or mixed hearing loss and aural atresia, when external acoustic hearing aids are not an option, have also demonstrated a hearing benefit with semi-implantable middle ear 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 are limited. 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 that fall at or within the limits outlined in Table 1.
- 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

Table 1: Pure-Tone Air-Conduction Threshold Levels

Limits	Frequency, kHz					
	0.5	1	1.5	2	3	4
Lower limit	30	40	45	45	50	50
Upper limit	65	75	80	80	85	85

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 (40-70 decibels) to severe (71-90 decibels) sensorineural hearing loss defined by pure tone average
- Unaided speech discrimination test score 40% or higher
- Normally functioning eustachian tube
- Normal middle ear anatomy
- Normal tympanic membrane
- Adequate space for Esteem implant determined via high resolution computed tomography scan

- Minimum 30 days of experience with appropriately fit hearing aids.

BACKGROUND

HEARING LOSS

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 detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥ 80 dB).

Treatment

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 the 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- and Fully Implantable Middle Ear Hearing Aids

Semi-implantable and fully implantable middle ear hearing aids are alternatives to external acoustic hearing aids. Two semi-implantable devices have Food and Drug Administration (FDA) approval: the Vibrant Soundbridge and the Maxum System. The devices consist of three components: a magnet 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 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 FDA approval: the Esteem Implantable Hearing System. 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 delivered to the stapes by another piezoelectric transducer (the driver).

REGULATORY STATUS

Two semi-implantable devices were approved by the FDA through the premarket approval process: the Vibrant® Soundbridge™ (MED-EL Corp.) in 2000 and the Direct System™ (Soundtec) in 2001. The Soundtec sys-

tem was discontinued by the manufacturer Ototronix in 2004 due to performance issues; it was re-released in 2009 under the name Maxum™ System. Approved FDA labeling for both 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 2010, the Esteem® Implantable Hearing System (Envoy Medical, St. Paul, MN), a fully implantable middle ear hearing aid, was approved by FDA through the premarket approval process. 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, is in development (Otologics, now Cochlear), but does not have FDA approval. Phase 1 and 2 trials have been conducted in the United States under investigational device exemptions.¹

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.

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