FEP 7.01.84 Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Effective Date: July 15, 2018

Related Policies:
7.01.83 Auditory Brainstem Implant

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

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.

FDA 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 system 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]

POLICY STATEMENT

Semi-implantable and fully implantable middle ear hearing aids are considered **not medically necessary**.

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 PG1.

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

Table PG1. 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) who have 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 dB) to severe (71-90 dB) sensorineural hearing loss defined by pure-tone average
- Unaided speech discrimination test score ≥40%
- 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

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 concerns 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 5 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

The American Academy of Otolaryngology – Head and Neck Surgery issued a position statement on implantable hearing devices, most recently updated in 2016, which stated[43]:

> "The American Academy of Otolaryngology-Head and Neck Surgery considers active middle ear implants as appropriate treatment for adults with moderate to severe hearing loss when performed by a qualified otolaryngologist-head and neck surgeon. Based on available literature demonstrating that clinically selected adults receive substantial benefit, implanting active middle ear implants is accepted medical practice in those who benefit from amplification but are unable to benefit from the amplification provided by conventional hearing aids. Use of active middle ear implants, which have been Food and Drug Administration (FDA)-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency…."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

No national coverage determination has been published. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage.[44] However, devices producing the "perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss, or surgery." The benefit manual does not specifically refer to semi- or fully implantable hearing aids as prosthetic devices.

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POLICY HISTORY

Date	Action	Description
June 2012	New Policy	Semi-implantable and fully implantable middle ear hearing aids are considered **not medically necessary**
June 2013	Update Policy	Policy updated with literature review. References 10, 12, 15, 23-28 added; policy statement unchanged.
June 2014	Update Policy	Policy updated with literature review, adding references 16-19 & 22. Policy statement was unchanged.
June 2015	Update Policy	Policy updated with literature review, adding references 1, 7, 22-25, 31, and 40-41. Policy statements unchanged.
September 2016	Update Policy	Policy updated with literature review; references 6 and 10-11 added; outdated references removed. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; references 1, 6-7, 41, and 43 added. Policy statement unchanged.