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MEDICAL POLICY – 7.01.84

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

BCBSA Ref. Policy:	7.01.84
Effective Date:	May 1, 2025
Last Revised:	Apr. 7, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

1.01.528	Hearing Aids (Excludes Implantable Devices)
7.01.83	Auditory Brainstem Implant
7.01.547	Implantable Bone Conduction and Bone-Anchored Hearing Aids
7.01.586	Cochlear Implant

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

To hear, sounds waves travel through the outer ear to the eardrum, to the tiny bones of the middle ear, and into inner ear. The structures in the inner ear convert the vibrations into nerve signals that then travel along the auditory nerve to the brain. Typical hearing aids amplify or increase sounds as they are passed through the outer ear and middle ear. Other types of hearing aids can be implanted in the middle ear. These require a sound processor and an internal implant, which is located on one of the bones of the middle ear or the membrane of the inner ear. The processor picks up the sound and transmits the vibrations to the implant. The implant vibrates, which then sends signals to the inner ear. Middle ear implantable and semi-implantable hearing aids are investigational (unproven). Studies to date have been small, and there's not enough information to determine the safety and effectiveness of these types of middle ear hearing aids. More and larger studies are needed.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Investigational
Middle ear hearing aids • **Semi-implantable** • **Fully implantable**	**Semi-implantable and fully implantable middle ear hearing aids are considered investigational (e.g., Vibrant Sound Bridge, Maxum System, and Esteem device)**

Coding

Code	Description
HCPCS	
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear.
V5095	Semi-implantable middle ear hearing prosthesis

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Vibrant Soundbridge

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

- Pure-tone air-conduction threshold levels that fall at or within the limits outlined in **Table 1**.
- Word recognition score of greater or equal to 50%, 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 greater than or equal to 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 individuals have experience with appropriately fitted hearing aids.

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

- 18 years of age or older
- Stable bilateral sensorineural hearing loss
- Moderate (40-70 decibels [dB]) to severe (71-90 dB) sensorineural hearing loss defined by 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 computed tomography scan
- Minimum 30 days of experience with appropriately fit hearing aids.

Consideration of Age

The application of this policy to those 18 years of age or older is based on the US Food and Drug Administration (FDA) labeling. The FDA approval for the 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.

Benefit Application

Benefit/contractual restrictions or exclusions for acoustic hearing aids for moderate-to-severe sensorineural hearing loss may apply.

Evidence Review

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.

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 individuals 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.

Individuals 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 individuals, 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 US Food and Drug Administration (FDA) approval: the Vibrant Soundbridge and the Maxum System. 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 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 that are delivered to the stapes by another piezoelectric transducer (the driver).

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 US Food and Drug Administration, systematic reviews, and a number of observational series. The 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 individuals 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 individuals have been included in the clinical trials, and with a median duration of follow-up less than five years. Studies of individuals 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. However, these studies are few and limited to small numbers of individuals. 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 individuals who are unable to use external air-conduction hearing aids. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in January 2025 did not identify any ongoing or unpublished trials that would likely influence this policy.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion in the remaining sections if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Consensus Statement

An expert consensus statement on bone conduction devices and active middle ear implants in conductive and mixed hearing loss was published in 2022.[47] The statement provides information about patient education and technical aspects of device placement but does not provide clear recommendations regarding the patients who are most likely to benefit from implantable middle ear hearing aids over other devices.

The American Academy of Otolaryngology – Head and Neck Surgery

The American Academy of Otolaryngology – Head and Neck Surgery (2016) issued a position statement on implantable hearing devices, recently updated, which stated[48]:

> 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 FDA-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency…

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.[49] 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.

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]

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History

Date	Comments
04/15/03	Add to Surgery Section - New Policy
06/08/04	Replace Policy - Policy reviewed; no change in policy statement.
06/14/05	Replace Policy - Policy reviewed with literature search; no change in policy statement.
07/11/06	Replace Policy - Policy updated with literature search; reference added; no change in policy statement.
05/13/08	Replace Policy - Policy updated with literature search; no change to the policy statement. Reference added.
01/12/10	Replace Policy - Policy updated with literature search; no change to the policy statement. Reference added.
06/13/11	Replace Policy - Policy updated with literature review, reference numbers 10-14 added, “fully implantable” hearing aid added to policy, title changed to reflect addition, fully

Date	Comments
	implantable device, previously not addressed, is now considered investigational. ICD-10 codes added to policy.
06/26/12	Replace policy. Policy updated with literature review, rationale section reorganized, reference numbers 10-12, 14, 16 and 20 added, policy title changed with the removal of "for moderate to severe sensorineural hearing loss." Policy statement unchanged. HCPCS code L8613 removed, as it does not apply to this policy.
09/28/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014
10/18/12	Update Related Policy – 7.01.03 renumbered to 7.01.547.
05/28/13	Replace policy. Rationale section updated based on a literature review through February 2013; references 10, 12, 15, 23-27 added; others renumbered or removed. Policy statement unchanged.
03/21/14	Update Related Policies. Add 1.01.528.
06/13/14	Annual Review. Policy updated with literature review through February 11, 2014; references 1, 18-20, and 23 added; policy statement unchanged.
05/27/15	Annual Review. Policy updated with literature review through February 2, 2015. References 7, 22-25, 31, and 40-41 added. Policy statement unchanged.
05/01/16	Annual Review, changes approved April 12, 2016. Policy updated with literature review through December 17, 2015; references 6 and 10-11 added; outdated references removed. Policy statement unchanged.
11/08/16	Minor update. Language was added to support that this policy applies to those ages 18 or older to align with FDA-labelling of the devices addressed. No change in policy statements.
05/01/17	Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 1, 6-7, 41, and 43 added. Policy statement unchanged.
10/24/17	Policy moved to new format; no change to policy statements.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through December 2017; no references added; reference 43 updated. Policy statement unchanged.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through January 2019; no references added. Policy statement unchanged. Removed CPT code 69799.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.

Date	Comments
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through December 11, 2019; no references added. Policy statement unchanged.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through January 7, 2021; references added. Policy statements unchanged.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through November 15, 2021; no references added. Policy statements unchanged.
02/01/23	Updated Related Policies. 7.01.03 is replaced by 7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through December 14, 2022; references added. Minor edits to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/15/23	Updated Related Policies. 7.01.05 is replaced with 7.01.586 Cochlear Implant.
05/01/24	Annual Review, approved April 8, 2024. Policy updated with literature review through December 13, 2023; references added. Policy statements unchanged.
05/01/25	Annual Review, approved April 7, 2025. Policy updated with literature review through January 8, 2025; no references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.