MASSACHUSETTS

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Medical Policy

Semi-Implantable and Fully Implantable Middle Ear Hearing Aid

Table of Contents

Policy Number: 480

BCBSA Reference Number: 7.01.84 (For Plans internal use only)
NCD/LCD: NA

Related Policies

- Auditory Brainstem Implant, #481
- Cochlear Implant, #478
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids, #479

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

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

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes
There is no specific CPT code for this service.

HCPCS Codes

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

Description
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 (eg, 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 the U.S. Food and Drug Administration (FDA) approval: the Vibrant Soundbridge and the Maxum System. The devices consist of 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 the 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).

Summary

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.

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 U.S. 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 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 that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2017	Annual policy review. New references added.
3/2016	Annual policy review. New references added.
5/2015	Annual policy review. New references added.
5/2014	Annual policy review. New references added.
5/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
12/2011	Annual policy review. No changes to policy statements.
5/2010	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.

3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
5/2008	Annual policy review. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2007	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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