MEDICAL POLICY

POLICY TITLE	SEMI-IMPLANTABLE AND FULLY IMPLANTABLE MIDDLE EAR HEARING AIDS
POLICY NUMBER	MP 1.130

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**5/1/2024**

I. POLICY

TOP

The Vibrant® Soundbridge® and Maxum® semi-implantable middle ear hearing aids are considered **medically necessary** for adult members when all of the following criteria are met:

- Member has documented moderate-to-severe sensorineural hearing loss; AND
- Member has pure-tone air-conduction threshold levels that fall at or within the limits outlined in Table PG1 (see Policy Guidelines); AND
- Member has a word recognition score of ≥50%, using recorded material; AND
- Member cannot tolerate an ear mold because of a medical condition (including but not limited to recurrent otitis externa and malformation/disorder of the external ear or canal).

All other semi-implantable and fully implantable middle ear hearing aids are considered **not medically necessary**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

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

Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted hearing aids.

Cross-Reference

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO- Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

TOP

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 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 and aural atresia).

SEMI- AND FULLY IMPLANTABLE MIDDLE EAR HEARING AIDS

Semi-implantable and fully implantable middle ear hearing aids are an alternative 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 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. In order to prevent feedback, the intact ossicular chain must be disarticulated, resulting in a new conductive hearing loss on top of baseline sensorineural dysfunction. In the event of device failure or explanation for non-use, an additional reconstructive procedure would be required to re-establish baseline hearing function.

REGULATORY STATUS

Two semi-implantable devices were approved by the U.S. Food and Drug Administration (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.

IV. RATIONALE

TOP

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 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. Due to input from this society, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

TOP

HEARING AID is any device that does not produce as its output an electrical signal that directly stimulates the auditory nerve. Examples of hearing aids are devices that produce air-conducted sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window. Devices such as cochlear implants, which produce as their output an electrical signal that directly stimulates the auditory nerve, are not considered to be hearing aids.

OSSICLE refers to any small bone, especially one of the three bones of the ear.

SENSORINEURAL HEARING LOSS refers to a form of hearing loss in which sound is conducted normally through the external and middle ear but a defect in the inner ear or auditory nerve results in hearing loss. The loss is measured in decibels and may be described as mild, moderate, severe, or profound.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
S2230	V5095	69799						

ICD-10-CM Diagnosis Code	Description
H60	Various disorders associated with otitis externa
H61	Various disorders of the external ear

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ICD-10-CM Diagnosis Code	Description
H62	Various disorder of external ear in diseases classified elsewhere
H90.3	Sensorineural hearing loss, bilateral
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.5	Unspecified sensorineural hearing loss
H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side
Q16.0	Congenital absence of (ear) auricle
Q16.1	Congenital absence, atresia and stricture of auditory canal (external)

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 1.130	**8/20/2020 Consensus review.** Policy Statement unchanged. Coding checked no changes. References reviewed, updated. Product variation statement updated.
	3/8/2021 Consensus review. Policy statement unchanged. References reviewed and updated.

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	6/28/2022 Major review. Policy is now MN with criteria. Updated FEP, Background, Rationale, Coding table, and references.
	2/14/2023: Administrative update. Language updated in coding table to reflect that codes are MN.
	7/13/2023 Consensus review. Updated references. No changes to coding.
	1/19/2024 Administrative update. Clinical benefit added.

Top