Corporate Medical Policy

Semi-Implantable and Fully Implantable Middle Ear Hearing Aid

File Name: semi_implantable_and_fully_implantable_middle_ear_hearing_aid
Origination: 8/2010
Last Review: 2/2024

Description of Procedure or Service

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). Sound amplification using an air-conduction hearing aid can provide benefit to individuals 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.

Individuals with moderate-to-severe sensorineural hearing loss are typically fitted with externally-worn, conventional acoustic hearing aids. Conductive and mixed 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 users, either due to issues related to anatomic fit, recurrent ear infections, sound quality, or personal preference. In some cases, external acoustic hearing aids cannot be used due to external ear pathologies (eg, otitis externa).

Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic and bone conduction hearing aids. These hearing aids detect sound and transduce signals directly to the middle ear ossicles.

Regulatory Status

Two semi-implantable devices received approval by the U.S. Food and Drug Administration (FDA), the Vibrant Soundbridge and the Maxum system. The FDA labeling approved for both devices states that they 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."

The devices consist of 3 components: a magnetic component that is implanted onto the ossicles of the middle ear, a receiver, and a sound processor. The Vibrant Soundbridge device is implanted subcutaneously behind the ear while the processor is worn externally on the scalp over the receiver unit and is held in place by a magnet. The Maxum System device is placed in the user's ear canal with the processor resting over the external ear. In general, the sound processor of both devices 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 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 middle ear ossicles to directly stimulate the cochlea resulting in hearing sensation.

The Esteem Implantable Hearing System is a fully implantable middle ear hearing aid that received FDA approval in March 2010. The 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." The fully implantable device consists of a sensor, a sound processor, and a driver connected to the ossicles. Unlike the Soundbridge and Maxum systems, the Esteem uses piezoelectric components instead of electromagnetic components. In the Esteem, the sensor, placed at the head of the incus, detects vibrations of the tympanic membrane/malleus/incus triad and transforms the vibrations into electrical signals that are processed by the sound processor. The driver then transfers these vibrations to the inner ear, stimulating the cochlea, which results in hearing sensation.

An additional fully implantable middle ear hearing aid, the Carina® Fully Implantable Hearing Device was under 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.

Related Policies:
Implantable Bone Conduction Hearing Aids
Cochlear Implant

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Semi-implantable and fully implantable middle ear hearing aids are considered investigational for all indications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When semi-implantable and fully implantable middle ear hearing aids are covered

Not applicable.

When semi-implantable and fully implantable middle ear hearing aids are not covered

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 recipient selection criteria:

- Pure-tone air-conduction threshold levels that fall at or within the limits outlined below
  - 30-65 dB at 0.5 kHz
  - 40-75 dB at 1 kHz
  - 45-80 dB at both 1.5 kHz and 2 kHz
  - 50-85 dB at both 3 kHz and 4 kHz
- 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.

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 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 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.

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 Food and Drug Administration, systematic reviews, and a number of observational series. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The data suggest 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 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 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *69799, S2230, V5095*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 11/12/2009

Vibrant Soundbridge. FDA Summary of Safety and Effectiveness. Available online at: www.fda.gov/cdrh/pdf/p990052.html.

Esteem Implantable Hearing System. FDA Summary of Safety and Effectiveness: Available online at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P090018.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 4/14/2011

Medical Director review June 2011

Specialty Matched Consultant Advisory Panel – 2/29/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 4/12/2012

Specialty Matched Consultant Advisory Panel – 2/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 3/14/2013

Specialty Matched Consultant Advisory Panel – 2/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 3/13/2014

Specialty Matched Consultant Advisory Panel – 2/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 3/12/2015

Specialty Matched Consultant Advisory Panel – 2/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 2/11/2016

Specialty Matched Consultant Advisory Panel – 2/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 2/9/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 2/8/2018

Specialty Matched Consultant Advisory Panel – 2/2018

Specialty Matched Consultant Advisory Panel – 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 2/14/2019

Specialty Matched Consultant Advisory Panel – 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 2/13/2020

Specialty Matched Consultant Advisory Panel – 2/2021

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.84, 2/11/2021

Specialty Matched Consultant Advisory Panel – 2/2022

Specialty Matched Consultant Advisory Panel – 2/2023

Uhler K, Anderson MC, Jenkins HA. Long-Term Outcome Data in Patients following One Year's Use of a Fully Implantable Active Middle Ear Implant. Audiol Neurootol. 2016; 21(2): 105-12. PMID 27031589

Specialty Matched Consultant Advisory Panel – 2/2024

Medical Director Review- 2/2024

Policy Implementation/Update Information

10/12/10	New policy issued. Semi-implantable middle ear hearing aids for patients with moderate to severe sensorineural hearing loss are considered investigational. BCBSNC does not provide coverage for investigational services or procedures. (adn)
3/15/11	Specialty Matched Consultant Advisory Panel review 2/23/11. No changes to policy statement or coverage criteria. (adn)
7/1/11	Policy name changed from Semi-Implantable Middle Ear Hearing Aid to Semi-Implantable and Fully Implantable Middle Ear Hearing Aid. Description section updated to include information related to Fully Implantable Middle Ear Hearing Aids. Policy Statement revised to read: Semi-implantable and fully implantable middle ear hearing aids are considered investigational. Rationale in the Policy Guidelines section and References updated. (adn)
3/20/12	Specialty Matched Consultant Advisory Panel review 2/29/12. Policy Guidelines updated. (sk)
3/12/13	Reference added. Specialty Matched Consultant Advisory Panel review 2/20/13. No change to policy statement. (sk)
5/28/13	Reference added. Policy guidelines updated. Medical Director review. No change to policy statement. (sk)
4/15/14	Specialty Matched Consultant Advisory Panel review 2/25/14. No change to policy statement. (sk)
5/27/14	Reference added. Medical Director review. No change to policy statement. (sk)
3/10/15	Specialty Matched Consultant Advisory Panel review 2/25/15. (sk)
4/28/15	Reference added. (sk)
4/1/16	Specialty Matched Consultant Advisory Panel review 2/24/16. Code 69799 added to Billing/Coding section. (sk)

4/29/16 Reference added. (sk)

3/31/17 Specialty Matched Consultant Advisory Panel review 2/22/17. (sk)

6/30/17 Reference added. (sk)

3/9/18 Reference added. Specialty Matched Consultant Advisory Panel review 2/28/2018. (sk)

3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/19. (sk)

5/14/19 Reference added. (sk)

3/10/20 Specialty Matched Consultant Advisory Panel review 2/19/2020. (sk)

8/25/20 Reference added. (sk)

4/20/21 Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)

3/8/22 Reference added. Specialty Matched Consultant Advisory Panel review 2/16/2022. (sk)

3/7/23 Specialty Matched Consultant Advisory Panel review 2/15/2023. (sk)

3/20/24 Updated Description, Regulatory Status, Policy Guidelines, and References. No change to policy intent. Specialty Matched Consultant Review 2/2024. Medical Director review 2/2024. (ldh)