BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy #: 169
Category: Surgery

Latest Review Date: March 2021
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **semi-implantable middle ear hearing aid** for moderate to severe sensorineural hearing loss as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **fully implantable middle ear hearing aid (e.g. Esteem® implantable hearing system)** as a **non-covered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Moderate-to-severe sensorineural hearing loss is often treated with external acoustic hearing aids, while conductive hearing loss may be treated with acoustic or bone conduction hearing aids when surgical or medical interventions are unable to correct hearing loss. Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic hearing aids.

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 (ASLHA) has defined the degree of hearing loss based on pure-tone average (PTA) 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 (AC) 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 may not be able to 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 have been developed as an alternative to external acoustic hearing aids. Two semi-implantable devices have Food and Drug Administration (FDA) approval, the Vibrant Soundbridge (MED-EL Corporation, Durham, NC) and the Maxum System (Ototronix, Houston, TX). 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 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 (Envoy Medical Corp., St. Paul, MN). Similar to the semi-implantable devices, the fully implantable device consists of a sensor, a sound processor, and a driver which is 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 to electrical signals that are delivered to the stapes by another piezoelectric transducer, the driver.

KEY POINTS:

This evidence review is updated regularly with searches of the MEDLINE database. The most recent literature review covers the period through January 7, 2021.

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 limited data suggest implantable middle ear hearing aids may provide marginal improvement in hearing compared to 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-implantable device must be associated with clinically significant improvement in various hearing parameters compared to external hearing aids. While safety concerns appear to be minimal, only a limited number of patients have been included in the clinical trials, and few have completed more than 1 year of follow-up. Given the small number of patients and the limited safety data, risks cannot be adequately evaluated and compared with the marginal improvement in hearing. Studies on 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 in these patients cannot be made, and further study with longer term follow-up is needed. 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.

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 states:

> "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. Preventative Services Task Force Recommendations
Not applicable.

KEY WORDS:
Sensorineural hearing loss, semi-implantable middle ear hearing aid, acoustic hearing aid, Vibrant® Soundbridge™, SOUNDTEC® Direct System, Esteem®, Esteem® implantable hearing system, Carina® Fully Implantable Hearing Device , Maxum System(Ototronix)

APPROVED BY GOVERNING BODIES:
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."

In 2010, the Esteem® Implantable Hearing System (Envoy Medical, St. Paul, MN), a fully implantable middle ear hearing aid, was approved by the 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."

Another fully implantable middle ear hearing aid, the Carina® Fully Implantable Hearing Device, is in development (Otologics, now Cochlear), but does not have the FDA approval. Phase 1 and 2 trials have been conducted in the United States under investigational device exemptions.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

69799	Unlisted procedure, middle ear

HCPCS codes:

S2230	Implantation of magnetic component of semi-implantable
V5095	Semi-implantable middle ear hearing prosthesis

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POLICY HISTORY:

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