BlueCross BlueShield of North Carolina

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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 CAP Review: 2/2014
Next CAP Review: 2/2015
Last Review: 2/2014

Description of Procedure or Service

Patients with moderate to severe sensorineural hearing loss are typically fitted with external acoustic hearing aids. However, these hearing aids may not be acceptable to patients, either due to issues related to anatomic fit, sound quality, or personal preference. Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic hearing aids.

Two semi-implantable devices received approval by the U.S. Food and Drug Administration (FDA), the Vibrant® Soundbridge™, approved in August 2000, and the Soundtec® Direct System™, approved in September 2001. The Soundtec was discontinued by the manufacturer Ototronix, LLC in 2004 due to performance issues; it was rereleased in 2009 under the name 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 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 Soundtec (Maxum System) device is placed in the user's ear canal with the processor resting 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 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.

The Esteem® Implantable Hearing System by Envoy Medical Corporation 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." This device uses 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.

Related Policies:

- Implantable Bone Conduction Hearing Aid
- 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.***

Semi-Implantable and Fully Implantable Middle Ear Hearing Aid

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

The limited data suggest semi-implantable middle ear hearing aids may provide marginal improvement in hearing compared to conventional external acoustic hearing aids. However, given the safety and effectiveness of external acoustic hearing aids and the increased risks inherent in a surgical procedure, an 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 were included in the clinical trials, and few have completed more than 1 year of follow-up. With 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. There is a lack of adequate safety data in broader patient populations over a longer period of time.

The available evidence for use of fully implantable middle ear hearing aids is insufficient to demonstrate long-term improvement in net health outcome. Concerns exist about adverse events with these devices.

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

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the Category Search on the Medical Policy search page.

Applicable service codes: *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

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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.