Medical Coverage Policy

Fully Implantable and Semi-Implantable Middle Ear Hearing Aid

☐ Device/Equipment  ☐ Drug  ☐ Medical  ☑ Surgery  ☐ Test  ☐ Other

Effective Date: 05/17/2007  Policy Last Updated: 12/6/2011

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

This policy addresses implantable and semi-implantable bone conduction hearing aids.

Description:
Patients with moderate to severe sensorineural hearing loss are typically fitted with external acoustic hearing aids. Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic hearing aids.

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.

Semi-implantable middle ear hearing aid:

A semi-implantable middle ear hearing aid has been developed as an alternative to external acoustic hearing aids. In these devices, 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. FDA approved labeling states that these devices are intended for use in adults over the age of 18, with a moderate to severe sensorineural hearing loss who desire an alternative to an acoustic hearing aid. This device consists of 3 components: a magnetic component that is implanted onto the ossicles of the middle ear, a receiver, and a sound processor. Depending on the design, the device may be implanted subcutaneously behind the ear and held in place by a magnet; or placed in the user’s ear canal with the processors resting over the external ear.

Fully-implantable middle ear hearing aid:
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.

Due to the lack of adequate safety data in broader patient populations over a longer period of time, semi-implantable middle ear hearing aids are not medically necessary. The impact on net health outcome cannot be determined.

The available evidence for use of fully implantable middle ear hearing aids is preliminary and thus insufficient to demonstrate long-term improvement in net health outcome. Concerns exist about adverse events with these devices. Therefore, fully implantable middle ear hearing aids are considered not medically necessary.

Medical Criteria:
Implantable and semi-implantable middle ear hearing aids are considered not medically necessary because the impact on net health outcome cannot be determined.

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Prospective medical review is required for the removal or repair of the device for BlueCHiP for Medicare members and recommended for all other BCBSRI products.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable surgical benefit.

Coding:
The following code will be covered under the member's surgical benefit and preauthorization is needed:
69711*
*The Audiant™ bone conductor is a type of electromagnetic bone conduction hearing device. While this product is no longer actively marketed, patients with existing Audiant devices may require replacement, removal, or repair.

The following code is not covered:
69710 *

The following code is not covered:
S2230 Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear

Also Known As:
Auditory Osseointegrated and Auditory Brainstem Devices
BAHA (Branemark bone anchored hearing aid)
BAHA Divino® device
Nucleus® Freedom™
Semi-implantable hearing aid
Audiant™

Related Topics:
Cochlear Implants
Hearing Aid Mandate

Published
Policy Update, July 2007
Provider Update, July 2008
Provider Update, November 2009
Provider Update, April 2011
Provider Update, February 2012

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