OVERVIEW
Patients with 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. This policy does not apply to Medicare products as Medicare does not cover hearing aids.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products
Implantable and semi-implantable middle ear hearing aids are considered not medically necessary because the long-term safety and efficacy of this treatment has not been documented in the peer-reviewed medical literature.

Re-insertion of the device after removal is considered not medically necessary.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
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 (PTA) detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥80 dB). 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. However, these hearing aids may not be acceptable to patients, either due to issues related to anatomic fit, sound quality, or personal preference. 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.

Semi-Implantable Middle Ear Hearing Aid
The Soundtec was discontinued by the manufacturer Ototronix 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 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.

Due to limited safety data and the small number of patients included in studies and clinical trials, risks cannot be adequately evaluated and conclusions on the effectiveness of semi-implantable hearing aids cannot be made. Therefore, the use of semi-implantable middle ear hearing aids is considered not medically necessary for all indications.

**Fully implantable middle ear hearing aid:**
The Esteem® Implantable Hearing System by Envoy Medical 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.

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. Therefore, fully implantable middle ear hearing aids are considered not medically necessary.

**CODING**
**Commercial Products**
The following codes are not medically necessary:
S2230
V5095

**RELATED POLICIES**
Cochlear Implants
Hearing Aid Mandate

**PUBLISHED**
Provider Update, August 2015
Provider Update, July 2015
Provider Update, April 2014
Provider Update, March 2013
Provider Update, February 2012
Provider Update, April 2011
Provider Update, November 2009
REFERENCES


