Hearing Aids

Number: 0612

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Air conduction hearing aids are considered medically necessary when the following criteria are met:

I. hearing thresholds 40 decibels (dB) HL or greater at 500, 1000, 2000, 3000, or 4000 hertz (Hz); or
II. hearing thresholds 26 dB HL or greater at three of these frequencies; or
III. speech recognition less than 94 percent.

Aetna considers implantable hearing aids (e.g., the Esteem implantable hearing system and the Carina prosthesis) and semi-implantable hearing aids (e.g., the Maxum system and the Vibrant Soundbridge) medically necessary for members who have moderate-to-severe sensorineural hearing impairment and can not tolerate an ear mold because of medical conditions (such as auricular atresia or severe chronic otitis externa).

Aetna considers implantable hearing aids and semi-implantable hearing aids experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

Policy History

Last Review 06/22/2017
Effective: 05/03/2002
Next Review: 06/21/2018

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Aetna considers the use of free-floating piezoelectric microphone in an implantable hearing aid experimental and investigational because the effectiveness of this approach has not been established.

**Note:** Most Aetna benefit plans exclude coverage of hearing aids. Any applicable benefit plan exclusions and limitations for coverage of hearing aids would apply to air conduction hearing aids, implantable hearing aids and semi-implantable hearing aids. Please check benefit plan descriptions for details.

See also **CPB 0403 - Bone-Anchored Hearing Aid.**

**Background**

Implantable hearing systems (middle ear implants), in which all components are inserted within an individual, are purported to be an alternative to the traditional over the ear hearing aid. Examples of totally implantable hearing systems include, but may not be limited to, Esteem totally implantable hearing system and Carina fully implantable hearing device.

Partially implantable or semi implantable electromagnetic hearing aids, also called bone conduction hearing aids, create an electromagnetic field that vibrates and stimulates the ossicles, sending signals to the cochlea. Examples of semi-implantable electromagnetic hearing aids include, but may not be limited to, Vibrant soundbridge system, Maxum system, Otomag alpha 1(M) bone conduction hearing system and Semi-Implantable middle ear transducer (MET) ossicular stimulator system.

**Vibrant Soundbridge:**

According to the manufacturer, the Vibrant Soundbridge is not a cochlear implant, but an implantable alternative to an external hearing aid for adults who have moderate-to-severe sensorineural hearing loss. Unlike the cochlear implant, the Vibrant Soundbridge is not a prosthetic replacement for the ear; rather, the Vibrant Soundbridge acts as a hearing aid in amplifying sounds, and like a hearing aid, is indicated for persons with sensorineural hearing loss.
The Vibrant Soundbridge consists of 2 components: (i) an internally implanted Floating Mass Transducer (FMT) and (ii) an externally worn Audio Processor (AP). The AP picks up sound from the environment and transmits that sound across the skin to the implanted receiver. The implanted receiver converts the signal and transmits it to the FMT, which is a transducer that directly vibrates the ossicles by mimicking the natural motion of the ossicular chain, sending an enhanced signal to the fluid-filled inner ear (cochlea). The ossicular motion creates movement in the cochlea stimulating the hair cells, which in turn provide stimuli to the auditory nerve, which are then interpreted by the brain as sound.

Snick et al (2001) explains that "application of the Vibrant Soundbridge involves surgery and is more expensive than the application of conventional hearing aids. Therefore, to justify its use, the results obtained with the Vibrant Soundbridge should be better than those obtained with conventional hearing aids (except in patients with severe chronic otitis externa who can not tolerate an ear mold)."

The manufacturer states that the Vibrant Soundbridge provides superior results to hearing aids. But the clinical data are inconsistent (e.g., Snik and Cremers, 2001) and the Food and Drug Administration (FDA) did not allow the manufacturer (Symphonix) to claim superiority to standard hearing aids in product labeling indications. Rather, the product is indicated for patients who "desire an alternative to an acoustic hearing aid." In clinical studies presented to the FDA, measures of patient's subjective preference for the implant were not matched by clinically significant in objective measures between the implant and conventional hearing aids. FDA's Commissioner concluded that "[t]he results showed that the participants could hear about as well with the implant as with traditional hearing aids."

The Vibrant Soundbridge does offer clinically significant benefit to adult patients who have moderate to severe sensorineural hearing loss and severe chronic otitis externa such that they are unable to be fitted with an ear mold. The Vibrant Soundbridge has not been shown to offer clinically significant benefits to other
patients with sensorineural hearing loss.

In general, an implantable hearing aid consists of a transducer that is coupled to the ossicular chain and electronics. The coupling is of major importance. The Vibrant Soundbridge transducer is fixed to the ossicular chain by means of a special clip that is crimped around the long process of the incus. In addition to crimping, bone cement has been used to optimize the fixation. Snik and Cremers (2004) reported that there was no negative effect of using bone cement; however, there is also no reason to use bone cement in users of the Vibrant Soundbridge on a regular basis.

Implantable hearing aids have been used in persons with auricular atresia. Kiefer and associates (2006) noted that congenital malformations of the auricle are often combined with atresia of the outer ear canal and malformations of the ossicles, representing aesthetic as well as functional deficits. Optimal treatment should therefore address both aspects equally. These investigators described a new approach that combine the reconstruction of the auricle with implantation of an active middle ear hearing aid, stimulating the round window membrane. A 33-year old man, with bilateral ear microtia, fibrous atresia of the external ear canals and malformation of the ossicles due to Treacher Collins-Franceschetti syndrome was included in the study. In stage I, the cartilage framework of the new auricle, made of autogenous rib cartilage, was fabricated and implanted. During stage II, the auricle was elevated, a retro-auricular sulcus was formed and a Vibrant MED-EL Soundbridge device was implanted. The transducer was coupled to the round window membrane. Both functional as well as aesthetical results were favorable. Aided thresholds were between 15 and 30 dB in the frequency range of 0.75 to 6 kHz, mono-syllabic word understanding at 65 dB SPL increased from 0 to 80 %. The authors concluded that combining aesthetic and functional rehabilitation, autogenous reconstruction of a new auricle together with the implantation of an active middle ear hearing aid, coupled to the round window membrane, is a promising new approach.
Siegert and colleagues (2007) noted that patients with congenital auricular atresia suffer from a conductive hearing loss (HL) with an air-bone gap of 50 to 60 dB. Conventional bone conducting or bone anchored hearing aids are treatment options with several disadvantages and a biophysical limitation of almost no sound attenuation in the skull bone. In a prospective study, these investigators attempted to improve the hearing results of auricular atresia with the use of fully implantable hearing aids (Otologics Fully Implantable Middle Ear Transducer). They were implanted in 5 patients with congenital auricular atresia and their audiological outcome evaluated. After activation and fitting of the devices, patients experienced an improvement of sound-field thresholds up to 50 dB HL. The mean functional gain in a three frequency pure-tone average was approximately 35 dB HL. The authors concluded that this technique appears to provide a completely new dimension for the audiological rehabilitation of patients with severe malformation of the middle ear.

Wollenberg et al (2007) presented 3 cases of unilateral atresia to illustrate a combined approach integrating hearing rehabilitation using the active middle ear implant Vibrant Soundbridge (VSB) into plastic auricular reconstruction. The VSB was attached to the stapes supra-structure via the titanium clip in 2 of these cases and in the 3rd case a sub-facial approach was used to attach it directly to the membrane of the round window. The air-bone gap was reduced to 17 dB, 14 dB and 0.25 dB HL. In free-field speech recognition tests at 65 dB SPL, the patients achieved 100 %, 90 % and 100 % recognition with the activated implant. No post-operative complications such as facial nerve paresis, vertigo or inner ear damage were found. The authors concluded that the integration of active middle ear implants in auricular reconstruction opens up a new approach in complete hearing rehabilitation. The additional implantation of the VSB does not have any negative effect on the healing process or the cosmetic outcome of the auricular reconstruction.

An assessment of the Vibrant Soundbridge and other middle ear implants (MEI) by the Australian Medical Services Advisory Committe (MSAC, 2010) found that "there was a paucity of high level evidence with which to assess the effectiveness of the MEI."
Luers and Huttenbrink (2014) stated that the Vibrant Soundbridge is the world’s most often implanted active middle ear implant or hearing aid. During the last few years, the device indications have expanded from sensorineural hearing loss to conductive and mixed hearing loss. Titanium couplers have led to improved contact of the floating mass transducer with the middle ear structures. The resulting hearing gain is satisfying for most patients, but so far, there is no clear audiologic advantage over conventional hearing aids. The authors concluded that the indications are mainly related to intolerance of conventional hearing aids (e.g., chronic otitis externa), severe mixed hearing loss with a destructed middle ear and certain medical diagnosis (e.g., congenital atresia).

Shohet et al (2011) evaluated the effectiveness of the Envoy Esteem totally implantable hearing device in treating profound high-frequency sensorineural hearing loss (PHFSNHL). A total of 5 patients with PHFSNHL participated in a prospective, multi-center, non-randomized Food and Drug Administration clinical trial. Main outcome measures included speech reception threshold and word recognition scores (WRS) at 50 dB HL presentation level. Pre-operative speech reception threshold improved from an unaided 65 dB and aiding 48 dB average to 26 dB with the Esteem at 12 months; WRS at 50 dB scores improved from an unaided 10 % and aided 23 % average to 78 % post-operatively. The authors concluded that the Esteem totally implantable middle ear hearing device provided appreciable functional gain and improvement in WRS to rehabilitate hearing in patients with PHFSNHL.

The FDA classifies the Vibrant Soundbridge as a surgically implanted hearing device intended to help adults with moderate-to-severe nerve hearing loss. It is used as an alternative to traditional hearing aids, adults with a moderate-to-severe sensorineural hearing loss may choose this device. Adults who choose this device should have already tried using appropriately fit hearing aids. 

[http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm089772.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm089772.htm)

**Totally Implantable Hearing Device:**

The Esteem Totally Implantable Hearing System by Envoy Medical Corporation (St. Paul, MN) is a fully implantable system that uses piezoelectric transducers. It uses the eardrum as the microphone. The mechanical signal is detected by a piezoelectric transducer at the head of the incus (the sensor) and converted to an electrical signal that is amplified, filtered, and converted back to a vibratory signal. The processed vibratory signal is then delivered by another piezoelectric transducer (the driver) to the stapes capitulum (Altuna Mariezcurrena et al, 2008). The Esteem hearing implant is different from all other microphone-based hearing devices (e.g., hearing aids, other middle ear implants or cochlear implants) because it uses the eardrum to process the incoming sound and thus preserves a natural way of hearing. The Esteem is implanted under the skin behind the ear and in the middle ear space, and therefore invisible.

In a prospective, single-subject, repeated-measures, multi-center, phase I clinical study, Chen and colleagues (2004) evaluated safety and functionality of the Envoy System, a totally implantable middle ear hearing system for sensorineural loss. Data collected included Abbreviated Profile of Hearing Aid Benefit, bone conduction threshold, speech reception threshold, functional gain, word recognition, and adverse events. Testing was performed unaided, with the patient's best-fit hearing aid, and post-device activation at 2 (trial endpoint) and 4 months. Five of 7 patients at the 2-month post-activation period had working systems. All 5 patients perceived benefit increases with the
Envoy System over their best-fit hearing aid, including communication in high background noise levels. Word recognition was improved over hearing aids. Functional gain and speech reception thresholds were similar for the Envoy device and hearing aids. The authors concluded that the feasibility trial has shown the Envoy device can safely sense and drive the ossicular chain.

Barbara et al (2009) evaluated the benefits of a totally implantable middle ear device, the Esteem 2 (Envoy Medical), in subjects affected by moderate-to-severe sensorineural hearing loss as measured through pure tone audiometry testing carried out during the different post-operative fitting sessions. A total of 6 patients were included in this study. Selection was carried out via pre-operative audiometric tests and thorough counseling, which considered information on previous experience with conventional hearing aids as well as each patient's motivation to undergo a surgical application. Specific surgical training is needed to accommodate routine surgical steps along with less familiar steps, such as placement of cement material and overall fixation of the system. The surgical procedure took a long time, but a reduced duration was recorded in the last procedure compared with the first one. The implantation process induced a deterioration in hearing thresholds, which fully recovered after activation of the device. A post-operative hearing gain could be measured in all 3 patients: in this regard, the perceived quality of sound was shown to be better than could be expected by the measurable hearing gain.

In March 2010, the FDA approved the Esteem, an implantable hearing system, for the treatment of patients with moderate-to-severe sensorineural hearing loss. The Esteem system consists of external testing and programming instruments and 3 implantable components: (i) a sound processor, (ii) a sensor, and (iii) a driver. The sensor senses vibrations from the eardrum and middle ear bones and converts these mechanical vibrations into electrical signals, which are then transmit to the sound processor, which amplifies and filters the signal to compensate for the individual patient's hearing loss. The driver converts the enhanced electrical signal back to vibrations, which are then transmitted
into the inner ear where they are perceived as sound. The system is designed to alleviate the effects of hearing loss in patients aged 18 years and older. Other criteria for implanting the Esteem entail a normally functioning Eustachian tube, normal middle ear anatomy, as well as stable bilateral sensorineural hearing loss. In a multi-center clinical study of Esteem versus pre-implant hearing aids, 93% of Esteem recipients scored equal to or better than their pre-implant hearing aids on a speech intelligibility test; 7% scored less than with their pre-implant hearing aids, and 56% scored better than with their pre-implant hearing aids. There are some side effects associated with the implantation of the device -- 7% of participants experienced facial paralysis, and 42% experienced taste disturbance. The majority of these side effects resolved during the 1-year study period.

Bittencourt et al (2014) noted that the complaints associated with the use of conventional amplifying hearing aids prompted research at several centers worldwide that ultimately led to the development of implantable devices for aural rehabilitation. These investigators reviewed the history, indications, and surgical aspects of the implantable middle ear hearing devices. Semi-implantable hearing aids (e.g., the Vibrant Soundbridge system and the Maxum system), as well as fully implantable hearing aids (e.g., the 4th-generation of Carina prosthesis and the Esteem device), have their own peculiarities on candidacy and surgical procedure. The authors concluded that implantable hearing aids, which are currently in the early stages of development, will unquestionably be the major drivers of advancement in otologic practice in the 21st century, improving the quality of life of an increasingly aged population, which will consequently require increased levels of hearing support.

_Free-Floating Piezoelectric Microphone in an Implantable Hearing Aid:_

Einger and colleagues (2016) noted that current hearing aids and implants rely on feedback compensation to prevent instability (e.g., howling), usually in the form of a digital or analogue filter. These researchers investigated the effect of mechanically
stabilizing a piezo-driven mechanical amplifier inserted into the incudo-stapedial joint gap. They examined if this is possible and discerned the advantages and disadvantages of the design. These investigators examined a 10:1 scale model of a prospective implantable hearing aid comprising 1 piezoelectric sensor and 2 independent piezoelectric actuators in a single-titanium housing. As expected, the maximum gain of the device was limited by feedback between sensor input and the output of the primary actuator. The secondary actuator was used to provide a counter force to the recoil of the primary output piezo. This added a virtual mass to the device, effectively reducing feedback in the mechano-acoustic path. The compensation unit (CU) described in this study was driven by a real-time adaptive control algorithm. Using the above approach, these researchers observed an added stable gain of greater than 30 dB, and reported a functional hearing gain of up to 40 dB. Physical and digital feedback compensation can be employed in parallel for best results. The experimental data were backed by computer simulations. The authors concluded that these findings compared favorably with previous studies of a 2-piezo transducer with digital feedback control and showed the potential for the transducer as a hearing aid for high-frequency hearing loss.

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<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
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<td><strong>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</strong></td>
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### HCPCS codes covered if selection criteria are met:

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<th>Code</th>
<th>Description</th>
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<tr>
<td>S2230</td>
<td>Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear</td>
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<tr>
<td>V5030</td>
<td>Hearing aid, monaural, body worn, air conduction</td>
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<tr>
<td>V5070</td>
<td>Glasses, air conduction</td>
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<tr>
<td>V5095</td>
<td>Semi-implantable middle ear hearing prosthesis</td>
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### ICD-10 codes covered if selection criteria are met:

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<th>Code</th>
<th>Description</th>
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<tr>
<td>H90.3</td>
<td>Sensorineural hearing loss and mixed conductive and sensorineural hearing loss</td>
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<tr>
<td>H90.8</td>
<td>Sensorineural hearing loss and mixed conductive and sensorineural hearing loss</td>
</tr>
<tr>
<td>Q16.1</td>
<td>Congenital absence, atresia and stricture of auditory canal (external)</td>
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The above policy is based on the following references:


ear implant recipients using contralateral digital hearing

21. Todt I, Seidl RO, Ernst A. Hearing benefit of patients after
Vibrant Soundbridge implantation. ORL J Otorhinolaryngol

assessment after implantation of the Vibrant Soundbridge

stimulation with an implantable hearing aid (Soundbridge)
combined with autogenous reconstruction of the auricle - a
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of the active middle ear implant Vibrant Soundbridge in

Vibrant Soundbridge device in patients implanted for 5 to 8

versus conventional hearing aid in sensorineural high-

Vibrant Soundbridge device in patients implanted for 5 to 8

29. Linder T, Schlegel C, DeMin N, et al. Active middle ear
implants in patients undergoing subtotal petrosectomy:
New application for the Vibrant Soundbridge device and its
implication for lateral cranium base surgery. Otol Neurotol.

30. Medical Services Advisory Committee (MSAC). Middle ear
implant for sensorineural, conductive and mixed hearing
Canberra, ACT: MSAC; July 2010.

trial results of the Envoy System: A totally implantable


42. Strenger T, Stark T. The application of implantable hearing aids using the Vibrant Soundbridge as an example. HNO. 2012;60(2):169-176; quiz 176-178.


53. Department of Veteran's Affairs, Veterans Health


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0612 Hearing Aids

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania  revised 08/25/2017