Anthem

Medical Policy

Subject: Implantable Middle Ear Hearing Aids
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Description/Scope

This document addresses the use of semi-implantable and fully implantable middle ear hearing aids for the treatment of moderate to severe sensorineural hearing loss and for all other proposed uses.

Note: Benefit language supersedes this document. Hearing aids are not a covered benefit under all member contracts/certificates. Please see the text in the footnote of this document regarding Federal and State mandates and contract language, as these requirements or documents may specifically address the topic of hearing aids.

Note: Please see the following documents related to the treatment of hearing loss:

- CG-SURG-81 Cochlear Implants and Auditory Brainstem Implants
- CG-SURG-82 Bone-Anchored and Bone Conduction Hearing Aids

Position Statement

Investigational and Not Medically Necessary:

Semi-implantable and fully implantable middle ear hearing aids are considered **investigational and not medically necessary** for all indications.

Rationale

Implantable Middle Ear Hearing Aids

Externally worn acoustic hearing aids are widely accepted for use by individuals with moderate to severe sensorineural hearing loss. Semi-implantable and fully implantable middle ear hearing aids have been proposed as an alternative to an externally worn acoustic hearing aid for select individuals with moderate to severe sensorineural hearing loss.

Semi-Implantable Middle Ear Hearing Aids forBilateral Moderate to Severe Sensorineural Hearing Loss

The efficacy of the semi-implantable middle ear hearing aid was studied by comparing the results of pre- and postimplant audiometric tests and audiologic questionnaires. Additional outcome measures included satisfaction of the subjects with fit and comfort and with the quality and clarity of sound. Individual preference for an implantable middle ear hearing aid compared to an externally worn hearing aid was considered, however, it must be determined to what extent individual preference is based on convenience compared to preference based on improved hearing.

In the early European trials of semi-implantable middle ear hearing aids, the studies included overlapping populations of subjects from many of the same institutions where each subject served as their own control. A feasibility study by Fisch and colleagues (2001) reported detailed steps of the implantation of the Vibrant® Soundbridge™ (VSB) (VIBRANT MED-EL Hearing Technology GMBH, Innsbruck, Austria) direct-drive middle ear hearing aid and evaluated the impact of surgery on residual hearing. A total of 47 subjects had successful implantation, however, the study did not report outcomes in detail, but suggested that implantation was feasible with relatively few surgical complications and little change in severity of hearing impairment. A subsequent multicenter study conducted by Fraysee and colleagues (2001) reported audiometric results for 25 subjects who underwent implantation at several French medical centers. The authors reported that the Soundbridge (model D) semi-implantable middle ear hearing aid provided “significantly superior” functional gain than conventional hearing aids. The VSB implantation procedure did not affect the residual hearing level in the implanted ear, nor did it present any unacceptable risk. The authors concluded that the measurable benefit from VSB in comparison with conventional amplification was demonstrated with regard to the provision of superior usable amplification and greater ease in communication in daily listening environments for the majority of subjects. However, they suggested “A longitudinal study beyond 3 months of the same 25 subjects may help to resolve some of the unanswered questions with regard to the long-term effects and benefits of the VSB for the adults with hearing impairments.”

The U.S. Food and Drug Administration (FDA) premarket approval (PMA) of the Vibrant P/D Soundbridge Systems (VSB) in 2000 was based in part on clinical trials of 53 and 103 participants respectively, who had bilateral moderate to severe sensorineural hearing loss and who were dissatisfied with their existing externally worn acoustic hearing aid. Results of these trials are available in the FDA Summary of Safety and Effectiveness and reported in the following peer-reviewed published literature. Luetje and colleagues (2002) conducted a multicenter, phase III, prospective, single-subject controlled clinical trial evaluating the safety and efficacy of the VSB implant for persons with moderate to severe sensorineural hearing loss. This was the only study of the VSB implant performed in U.S. medical centers; all 54 study subjects were using air conduction hearing aids for 4 hours per day for at least 3 months prior to evaluation for the implant. Principal audiologic outcome measures, before (with the hearing aid in use) and after the implant, were evaluated at 4 or more intervals, following the subjects through 5 months after implantation. Key outcomes were reported as functional gain, speech recognition, and subject self-evaluation of hearing aid effectiveness. While improvement in functional gain, defined as the difference in sound field threshold measured in decibels (dB), was considered modest at 14.1 dB, most subjects (96%) were reported as experiencing a benefit shown by the lack of pure tone average (PTA) changes. No significant difference in word recognition was found in quiet or noisy conditions between the VSB implant and the acoustic hearing aid. The number of subjects with improvement in hearing effectiveness was reported as “significant” across all seven subscales of the Profile of Hearing Aid Performance (PHAP) test. The most significant subject-perceived improvements (n=50) when comparing the VSB implant to the baseline acoustic hearing aid were reported in background noise (53%), reverberation (48%), and reduced cues (39%). General satisfaction with improvement in the overall sound quality of the VSB implant was reported by 94% of the subjects. Limitations of the study include the lack of a randomized control group and subject self-evaluation of hearing effectiveness using a satisfaction scale that was developed by the manufacturer.

In the clinical trial data reported to the FDA, implantation of the VSB resulted in complications among 81 subjects (n=5, feasibility

study; n=54, effectiveness study [Luetje, 2002]; n=22, supplemental safety cohort). The most frequently reported complications included sensation of fullness in the ear (n=18; 22%), transient pain (n=13; 16%), and altered taste sensation (n=7; 8.6%). Most of the complications reported during the clinical trials were temporary. Failure of the implant occurred in 6 subjects (7%), requiring removal and reimplantation. All failures occurred with a version of the implant that is no longer produced by the manufacturer.

Additional data were obtained from subjects implanted with the VSB at 21 tertiary referral and teaching hospitals in France following the FDA approval. Sterkers and colleagues (2003) performed a retrospective survey of audiological data and subjective data from self-assessment scales administered postoperatively to determine the degree of benefit and satisfaction in subjects implanted with the VSB. In the first 125 VSB-implanted subjects, no clinically significant change was observed for residual hearing postoperatively. Most subjects (83%) reported they were either satisfied or very satisfied with the VSB. Speech comprehension in quiet surroundings was reported as significantly improved for implanted subjects versus the preoperative unaided hearing condition. Data analyzed from this measurement, however, is limited in drawing conclusions as different speech test materials were used and analyzed for each of 2 small subgroups, 13 and 37 subjects, respectively. No correlation was observed between subjective reports of satisfaction postoperatively and performance on preoperative objective tests or subject characteristics. Additional limitations of this retrospective study include lack of a randomized control group and the single subject design where each participant served as their own control when reporting subjective data from self-assessment scales.

Schmuziger and colleagues (2006) assessed long-term results with the VSB implant analyzing pre- and post-operative results of audiologic tests. The small study (n=20) involved retrospective chart review with additional subject interview and audiologic testing. Fifteen subjects underwent audiologic testing at follow-up, including pure tone and speech audiometry in silence and noise. The authors concluded that satisfaction with the VSB implant was not superior to conventional hearing aids in subjective and in audiometric terms.

Verhagen and colleagues (2008) retrospectively compared aided speech recognition scores obtained at conversational level (65 dB) in individuals with the VSB implant (n=22), the Otologics Middle Ear Transducer (MET) (Otologics LLC, Boulder, CO) (n=10), conventional hearing aids (behind-the-ears) (n=47), and cochlear implants (CIs) (n=123). In relation to mild hearing loss, the authors concluded that individuals fitted with a VSB middle ear implant do not demonstrate better speech recognition scores than those fitted with conventional hearing aids.

Tysome and colleagues (2010) systematically reviewed 17 studies comparing hearing improvements in middle-ear hearing implants to conventional hearing aids. The authors noted high-quality, long-term studies are not available. They concluded there was sufficient evidence to support the use of middle ear hearing aid implants. They noted hearing gains with middle ear hearing aid implants were comparable to gains with conventional hearing aids and may even improve sound quality and speech perception. Furthermore, they noted the evidence did not demonstrate a decrease in residual hearing. However, the authors recommend that additional study with long-term results is required to compare middle ear hearing implants with conventional hearing aids.

The evidence in the peer-reviewed literature regarding the efficacy and safety of the VSB is inconsistent and the FDA did not allow the manufacturer of the hearing aid to claim superiority to standard hearing aids in product labeling indications. In the data that accompanied the clinical studies presented to the FDA, most subjects were satisfied or very satisfied with the VSB implant (83% to 98%) and 91% reported the hearing aid was beneficial. In one study the expected hearing gains were not achieved in 52% of the subjects (Snik, 2001). In addition, while residual hearing was not affected in most subjects (90% to 96%), in one study residual hearing decreased in 13% of subjects (Luetje, 2002). Most of the study subjects preferred the VSB implant compared to the previously used conventional air conduction hearing aids; however, audiometric parameters such as functional gain and word recognition were not significantly improved for semi-implantable middle ear hearing aids compared to conventional hearing aids in all studies.

Semi-Implantable Middle Ear Hearing Aids for Hearing Loss from Anatomic and other Medical Conditions

The peer-reviewed medical literature consists of small case studies evaluating the safety and effectiveness of VSB implants in individuals with moderate to severe sensorineural hearing impairment who are unable to tolerate an externally worn air conduction hearing aid (ear mold) because of an anatomic or medical condition such as atresia of the external ear or severe chronic otitis externa. Kiefer and colleagues (2006) noted that congenital malformations of the auricle are often combined with atresia of the outer ear canal and malformations of the ossicles, resulting in aesthetic and functional defects. These investigators combined the reconstruction of the auricle with implantation of an active middle ear hearing aid in this single case report of an individual with bilateral ear microtia, fibrous atresia of the external ear canals and malformation of the ossicles due to Treacher-Collins-Franceschetti syndrome. Functional results were reported as favorable, with aided thresholds between 15 dB and 30 dB in the frequency range of 0.75 to 6 kilohertz (kHz), mono-syllabic word understanding at 65 dB sound pressure level (SPL) increased from 0% to 80%. The authors concluded that the combined reconstruction and implantation procedure offered a promising approach to the treatment of congenital malformations of the auricle combined with atresia.

Frenzel and colleagues (2009) prospectively analyzed a consecutive cohort of 7 subjects (mean age, 15) with unilateral osseous aural atresia who underwent plastic auricular reconstruction and placement of a VSB implant. Outcome measurements included audiometric testing, including pure tone thresholds, and speech testing in quiet and noise. The mean threshold with the VSB activated in the free field warble tone audiometry was 23.8 dB hearing level. Mean functional gain was 45.5 dB hearing level. Mean aided free field speech discrimination in quiet was 64% at 50 dB, 99% at 65 dB, and 100% at 80 dB. The authors concluded that VSB implantation was safe and effective and could be implemented in combination with outer ear reconstruction. Conclusions from this small cohort study are limited because it lacked comparison to results achieved by individuals with classic middle ear reconstruction. According to the authors, most of the published data are based on only pure tone audiograms. Concerning speech recognition after atresia repair, the authors' state "long-term stability of the results has to be proven. Further refinements in the surgical technique, signal recording, and signal processing may yield normal hearing for these patients in the future."

Zwartenkot and colleagues (2011) reported on a transcanal approach to implantation of the VSB in 13 adults with chronic external otitis and sensorineural hearing loss. The authors reported the transcanal approach resulted in several postoperative complications over 51 months of follow-up including extrusion of the conducting wire into the ear canal in 5 individuals. After repair of the wire extrusions, 3 individuals experienced repeated extrusion. Therefore, the transcanal approach is not recommended for VSB system implantation in individuals with external otitis.

Additional studies with small sample sizes and short-term follow-ups report results of coupling the VSB system to the cochlea round window for persons with congenital malformation of the outer and middle ear (Colletti, 2011; Mandalla, 2011) and for those with conductive or mixed hearing loss who may not derive benefit from conventional hearing aids (Iwasaki, 2017; Marino, 2013). Colletti and colleagues (2013) reported longer term outcomes on a case series of 50 individuals, aged 2 months to 74 years, with severe conductive or mixed hearing loss due to ossicular chain defects who underwent coupling of the VSB system to the round window. Although improvements were demonstrated in speech perception and pure tone audiometry (in adult subjects) and auditory brainstem response thresholds (in the infants), conclusions drawn from the study are limited due to missing data for many participants (17 of 50) and a lack of comparison to other therapies.

Ernst and colleagues (2016) performed a systematic review that evaluated outcomes in 19 studies (n=294 participants) of VSB system implants, 13 studies (n=666 participants) of bone conduction hearing implants, and 4 studies (n=43 participants) of middle ear surgery plus hearing aid outcomes in the treatment of conductive or mixed hearing loss. There were no studies directly comparing methods. The functional gains with the VSB at 3 months ranged from 12.5 to 43.4 dB hearing loss, averaging 29.6 dB. Significant improvements in speech recognition occurred, although methods of measuring speech differed across studies. In general, the VSB system was reported as safe and effective when compared to no intervention and bone conduction hearing aids. The authors conclude that VSB systems more often provided consistent hearing gain compared to middle ear surgery plus conventional hearing aids. Heterogeneous outcome measures across the studies make it difficult to summarize data.

In 2017, Thomas and colleagues published a retrospective study to assess the safety and effectiveness of coupling a VSB to the short process of the incus in subjects who had congenital aural atresia or acquired meatal fibrosis. A chart review of subjects who met inclusion criteria from January 2009 to January 2016 (n=12) revealed no significant variance between preoperative and postoperative mean unaided air conduction and bone conduction thresholds (p=0.55 and p=0.082, respectively), and no significant difference in postoperative aided thresholds (p=0.053). There were no intraoperative or postoperative complications. While the coupling of a VSB to the short process of the incus had no safety issues in this study, larger randomized controlled trials are needed to validate the benefits.

To date, the VSB system has not received FDA clearance for use in conductive and mixed hearing loss.

Summary

The data in the trials submitted with the FDA-approval application for the VSB implant and the scientific evidence in the peer-reviewed published literature suggests that semi-implantable middle ear hearing aids may provide marginal improvement in hearing compared to conventional externally worn acoustic hearing aids. The clinical significance of the improvement in functional gain, speech perception, and hearing ability in various listening situations is uncertain, although there appears to be a clear preference by users for the VSB implant (Sterkers, 2003). Kahue and colleagues (2014) systematically reviewed the safety and efficacy of the FDA-approved middle ear implant systems then in use for the rehabilitation of sensorineural hearing loss. A total of 17 unique studies satisfied inclusion criteria and were evaluated for variables including functional gain, speech recognition score improvement, audiometric threshold shift following surgery, adverse events, and subject-reported outcome measures. Heterogeneous outcome reporting precluded meta-analysis; however, a structured review was performed using best available data. The authors reported that most studies evaluating the safety and efficacy of middle ear implants are retrospective in nature with limited follow-up. To date, no prospective randomized controlled trial exists comparing contemporary air conduction hearing aid performance and middle ear implant outcomes. Based on available data for persons with sensorineural hearing loss, functional gain and word recognition improvement appear similar between conventional hearing aids and middle ear implants, while subject-perceived outcome measures suggest that middle ear implants provide enhanced sound quality and eliminate occlusion effect.

Given the safety and effectiveness of conventional externally worn acoustic hearing aids, and the increased risks inherent in a surgical procedure, a semi-implantable middle ear hearing aid must be associated with clinically significant improvement in various hearing parameters compared to externally worn hearing aids. While safety concerns appear to be minimal, only a limited number of individuals were included in the clinical trials, and long-term follow-up measures of durability, efficacy and safety have not been reported. Therefore, the scientific evidence does not support the use of a semi-implantable middle ear hearing aid for moderate to severe sensorineural hearing loss and for all other indications.

Fully Implantable Middle Ear Hearing Aids

In a prospective, single-subject, repeated-measures, phase I multicenter U.S. feasibility study, Chen and colleagues (2004) evaluated the safety and functionality of the Envoy® System (St Croix Medical, Minneapolis, MN) (now known as the Esteem®, Envoy Medical Corporation, St. Paul, MN), a fully implantable middle ear hearing system for sensorineural hearing loss. Data was collected for multiple measures, including speech reception threshold, functional gain, word recognition, and adverse events. Testing was performed unaided with the subject's best-fit hearing aid and post-implant activation at 2 (trial endpoint) and 4 months. A total of 5 of 7 subjects at the 2-month postactivation period had working systems. All 5 subjects had perceived an increased benefit 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 implant and hearing aids. A major concern was the number of implant failures, which were three at the 2-month postactivation period. Implant modifications were completed prior to proceeding with the phase II clinical investigations.

Barbara and colleagues (2009) assessed the benefits of a fully implantable middle ear hearing aid, the Esteem 2® (Envoy Medical Corporation, St Paul, MN) in subjects affected by moderate to severe sensorineural hearing loss as measured through pure tone audiometry testing carried out during the different postoperative fitting sessions. A total of 6 subjects were included in this study; selection was carried out via preoperative audiometric tests and thorough counseling, which considered information on previous experience with conventional hearing aids as well as each subject's motivation to undergo a surgical application. The implantation process induced deterioration in hearing thresholds in 3 of the subjects, which fully recovered after activation of the hearing aid. A postoperative hearing gain could be measured in the other 3 subjects; in this regard, the perceived quality of sound was shown to be better than could be expected by the measurable hearing gain. This study is limited by the small size, lack of a randomized control group, and self-reported outcome measures.

The Esteem Implantable Hearing System received FDA approval in March 2010 through the PMA process as a fully implantable middle ear hearing aid "Intended to alleviate hearing loss in patients by replicating the ossicular chain and providing additional gain" in adults 18 years of age or older with stable bilateral sensorineural hearing loss (FDA, 2010). The PMA pivotal clinical trial (Trial 0204), designed as a prospective, multicenter nonrandomized, single-arm study to evaluate safety and effectiveness of the Esteem middle ear implantable (MEI) hearing aid, enrolled 62 subjects who acted as their own controls. A total of 61 subjects were followed out to 1 year. The implant had a 5% revision rate prior to the 4-month follow-up visit due to fibrotic tissue growth/interference and no revisions between the 4- and 10-month follow-up. Efficacy data was reported as statistically superior to the pre-implant hearing in two measures, however, the type of pre-implant hearing aid varied among subjects. Some side effects associated with the implantation of the Esteem MEI included facial paralysis (7%) and taste disturbance (42%). The majority of the side effects reported resolved during the 1-year study period. Kraus and colleagues (2011) reported on the 1-year follow-up results of the phase II FDA trial of the Esteem MEI study. A total of 57 subjects with bilateral, mild to severe sensorineural hearing loss, with discrimination > 40%, were implanted. The Esteem MEIs were activated 2 months postimplant. Hearing results were compared with ipsilateral baseline unaided and baseline aided scores. Speech reception thresholds improved 11.8 dB (± 1.8 dB) from a mean pre-implant aided score of 41.2 dB to 29.4 dB ($p<0.001$). At 12 months, the mean percentage improvement in word recognition scores was 19.8 (± 4.3) from pre-implant aided scores. Of 52 subjects, 32 subjects (62%) had improved, 14 subjects (27%) were the same, and 6 subjects (11%) were worse. The authors reported 133 adverse events/adverse device effects in 52 of 57 (91%) subjects, including 3 cases of facial paresis resolved with medication. Limitations of this study include those related to implantation of the Esteem MEI. A large facial recess is required due to the transducer size. Sacrifice of the chorda tympani nerve (CTN) is necessary in more than 60% of the implant cases.

Functional gain will be limited if the CTN contacts the driver, the transducer vibrates the nerve, and vibrations are sensed by the sensor, thus creating a feedback loop. Additional limitations of this trial include non-blinded audiologists, limitations of computed tomography scanning, and lack of validated tests to measure clarity and fidelity.

Additional studies of small sample populations reporting short-term outcomes are available in the peer-reviewed literature. Barbara and colleagues (2011) reported on the use of the Esteem MEI in a small case series of 21 individuals with severe bilateral sensorineural hearing loss. The authors reported mean hearing threshold levels improved overall from 70 to 48 dB. Limitations of this case series include the reporting of short-term results from a small number of subjects. Shohet and colleagues (2011) reported on the follow-up of a subset of 5 individuals with profound hearing loss who were part of the initial FDA PMA trial. At 12 months, improvements in functional gain and word recognition scores were reported with use of the Esteem MEI. Memari and colleagues (2011) reported the results of a small prospective nonrandomized controlled clinical trial that involved 10 subjects with moderate to severe sensorineural hearing loss who received the Esteem MEI. The average follow-up period was 29.4 months with each subject acting as their own control. In these subjects, 1 Esteem MEI was explanted as a result of low hearing gain and facial weakness and 1 subject had a revision due to excessive bone growth after insertion. Overall average hearing gain and subjective hearing quality was reported by all but 1 subject based on preoperative and postoperative comparisons. Lateral location of facial nerve, sclerotic mastoid air cells and narrow facial recess space appear to be related to postoperative complications. The results of this small study need confirmation in a larger trial.

Gerard and colleagues (2012) reported on clinical outcomes of a small, retrospective MEI implant case series (n=13). A total of 5 minor complications occurred and 3 subjects required revision surgery. Two individuals (15%) suffered major complications and their implants had to be removed 4 months postoperatively because of wound infection. Based on an abbreviated profile of hearing aid benefit (APHAB) questionnaire, 84% of subjects reported satisfaction in addition to improved PTA gain and word recognition scores when compared to previous use with a conventional hearing aid. The authors acknowledge that careful selection of candidates is required and specialized skill and experience is needed to perform the procedure. This study is limited by its small size and retrospective design.

Monini and colleagues (2012) compared the performance of the Esteem MEI to use of a conventional hearing aid in 15 individuals with moderate-to-severe (n=8) or severe-to-profound (n=7) sensorineural hearing loss. The authors reported the Esteem MEI candidates were either unable to wear or had poor results with a conventional hearing aid, or chose the Esteem MEI for aesthetic purposes. Reported outcomes included measurements of speech reception threshold and word recognition scores. Subjective benefit was evaluated by a Client Oriented Scale of Improvement (COSI) questionnaire. Although there were statistically significant differences between unaided and conventional hearing aid use and between unaided and Esteem MEI use, there was no statistically significant difference between the use of conventional hearing aids and the Esteem MEI. Limitations of this study include the small sample of participants, lack of randomization, and lack of statistically significant outcome data to determine if the Esteem MEI offers superior performance when compared to conventional hearing aids for moderate-to severe or severe-to-profound sensorineural hearing loss.

Pulcherio and colleagues (2014) reported results of a systematic review of 22 studies (n=244 subjects) of two fully-implantable middle-ear hearing devices, the FDA-approved Esteem MEI (n=134 subjects) and a fully implantable MEI under development, the Otologics Carina® (n=110 subjects) (Cochlear® Carina® System, UK and Otologics, LLC, Boulder, CO). No randomized controlled trials were identified; most studies included small numbers of participants. The largest series included 57 subjects and 12 series included fewer than 10 subjects. All of the studies showed improvement of sound field threshold from unaided to aided conditions with the fully implantable device, but the magnitude of the improvements varied. Several recent small case series have been published that do not provide significant additional evidence about outcome improvements associated with the Esteem MEI device. Barbara and colleagues (2014) reported on a case series (published since the Pulcherio and colleagues systematic review) where high rates of facial nerve palsies (10 of 34 subjects [29.4%]) occurred and persisted to 3 months of follow-up in 6 of 34 subjects (17.6%) implanted with the Esteem MEI. Overall, studies related to fully implantable middle ear hearing aid devices report on short-term results from a small number of participants and demonstrate insufficient evidence to support the clinical utility of their use.

Shohet and colleagues (2017) reported 5-year hearing outcomes of the Esteem MEI in a prospective, nonrandomized, multicenter post-market approval study conducted in the setting of private and hospital-based practices where each participant acted as their own control. A total of 51 participants with mild to severe sensorineural hearing loss were implanted between 2008 and 2009; 49 participants completed the 5-year study which included annual follow-up visits. The primary efficacy endpoints were speech reception threshold and word recognition scores at 50 dB. Secondary endpoints included adverse device effects, serious adverse device effects, and other parameters. The overall mean speech reception threshold scores demonstrated a significant improvement with implant compared to baseline aided condition through year 5; additionally, a statistically significant mean difference between baseline aided condition and implant speech reception threshold scores was demonstrated at each annual time interval (one-sample t-test; $p<0.01$). A total of 15 adverse device effects were reported by 11 of 51 (22%) participants including, but not limited to, distortions, facial tingling, feedback, incision site soreness or pain, positional vertigo, neck pain, and low performance or reduced performance (that is, reduced speech reception threshold or PTA and functional gain). Three serious adverse device effects were reported in 3 of 51 (6%) participants with two effects related to surgical wound dehiscence (repaired without device removal and complete resolution). Three of 51 participants (5.8%) required device explantation due to development of Meniere disease symptoms, infection, and low implant performance. Five of 51 (9.8%) participants required some type of revision procedure. A limitation of this study includes lack of evaluable data on all 49 participants for every annual follow-up visit. In addition, other implanted individuals (n=10) who declined study enrollment were not asked to specify a reason, resulting in a potential to bias the study conclusions if their performance outcomes were unsatisfactory or they experienced adverse effects of implantation. Finally, as there are no validated instruments for hearing aid lifestyle benefits, reported outcomes are subjective and not quantifiable.

Other Considerations

Zwartenkot and colleagues (2016) reported outcomes from a single-center retrospective cohort study evaluating the long-term medical and technical complications in 94 individuals implanted with either the VSB system, Otologics MET device, or Otologics Carina device. A total of 128 devices were implanted, including 92 VSB devices, 32 MET devices, and 4 Carina devices. During an average 4.4 years of follow-up (range, 1-15 years), 28 participants were considered lost to follow-up, including 7 deaths, 12 explantations, and 6 missed follow-up appointments. During the follow-up period, 36 devices were replaced or explanted (most commonly soon after implantation), with 36% of devices replaced within 18 months of implantation. All four Carina devices had technical difficulties. Twenty (21%) participants had a complication during follow-up, of which 17 were considered serious adverse effects.

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2016) reviewed their position statement on active middle ear implants which was reiterated in 2021 as follows:

> 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.

This statement, however, does not include any data and cites a few weak studies in the peer-reviewed medical literature in support of this recommendation.

Summary

The evidence in the peer-reviewed published literature comparing the Esteem MEI to other conventional hearing aids, such as bone conduction hearing aids is lacking. The available evidence supports short-term safety and utility yet lacks data to support the long-term safety, efficacy, and durability of the Esteem MEI when compared to other conventional hearing aids. Additional studies measuring long-term safety and effectiveness outcomes are required to determine if the implant is superior to conventional hearing aids for those individuals with moderate to severe sensorineural hearing loss. In addition, the implantation requires a surgical procedure for insertion and battery replacement, which is dependent on the number of hours used and exposure to average noise level, estimated at 4.5 to 9 years.

Background/Overview

Hearing loss is described as conductive, sensorineural or mixed, and can be unilateral or bilateral. Sensorineural or "nerve" hearing loss involves damage to the inner ear or the eighth cranial nerve. It can be caused by aging, prenatal or birth-related problems, viral or bacterial infections, heredity, trauma, exposure to loud noises, the use of certain drugs, fluid buildup in the middle ear, or a benign tumor in the inner ear (acoustic neuroma). Since this type of hearing loss can affect selective portions of a person's range of hearing, the degree of hearing loss and the specific pitches affected will vary from person to person. Even in instances where the pattern of the loss is the same, the degree of sound clarity may vary from person to person or may differ between ears in an individual. As a result, individuals suffering from sensorineural hearing loss often require hearing aids tailored to the specific sensitivity and pattern of their hearing loss. Normal speech and conversation occurs at 40-60 dB within a frequency range of 500-3000 Hz. Degree of hearing loss refers to the severity of the loss. Specific numbers are representative of the person's thresholds, or the softest intensity at which sound is perceived. Clark (1981) reported on one of the more commonly used classification systems for designating the degree of hearing loss (ASLHA, 2010) based on PTA detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (≥ 80 dB).

Sound amplification through the use of an air-conduction (AC) hearing aid can provide benefit to individuals with sensorineural, conductive, or mixed hearing loss. Contralateral routing of signal (CROS) 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. The most common type of hearing aid for moderate to severe sensorineural hearing loss is an externally worn acoustic hearing aid, which is placed into the external ear canal and functions to amplify sound. These hearing aids may not be satisfactory to some users, either due to issues related to anatomic fit, sound quality, or personal preference.

Implantable middle ear hearing aids can be either semi-implantable (partially) or fully implantable (totally) and have been developed as an alternative to an externally worn acoustic hearing aid for an individual with moderate to severe sensorineural hearing loss. The devices differ in the use of either a piezoelectric transducer (fully implantable) directly coupled to the ossicular chain, or an electromagnetic-based vibration transducer (semi-implantable) placed in approximation to the ossicular chain. There is a fundamental difference as to how sound is amplified and transmitted (delivered) to the inner ear between a conventional acoustic hearing aid and middle ear hearing aids. An acoustic hearing aid uses air pressure to transport sound to the middle ear while a semi-implantable middle ear hearing aid uses periodic attraction and repulsion of two magnetic fields, one from an electromagnet and the other from a static magnet. Fully implantable middle ear hearing aids, in contrast, function by passing an electric current through a piezo-ceramic crystal and driver that uses the natural ear as a microphone.

Semi-Implantable Middle Ear Hearing Aids

Two semi-implantable middle ear hearing aids have received FDA PMA for use in adults, 18 years of age or older, who have moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid: the Vibrant Soundbridge (VSB) (VIBRANT MED-EL Hearing Technology GMBH, Innsbruck, Austria) and the Maxum® Hearing Implant System (Ototronix, LLC, Houston, TX), released in 2009 and based on the discontinued SOUNDTEC® Direct System™ (SOUNDTEC, Inc., Oklahoma City, OK).

The VSB implant consists of three components: a magnetic component that is surgically implanted subcutaneously behind the ear and onto the ossicles of the middle ear (called the vibrating ossicular prosthesis [VORP]), a receiver, and an externally worn audio/sound processor. The processor is worn externally on the scalp over the receiver unit, held in place by a magnet. The VSB implant receives sound from a microphone, amplifies and processes it according to frequency shaping, and then delivers directly an electrical signal to an electromagnetic coil in the ear canal. This coil produces an electromagnetic field within the middle ear space which stimulates a magnet surgically attached under local anesthesia to the ossicular chain (stapes), causing vibrations of the bones of the middle ear similar to normal hearing.

The Maxum System is placed in the person's ear canal while the processor rests over the external ear. The sound processor receives and amplifies the sound vibrations and transforms the sound pressure into electrical signals that are received by the receiver unit, which then transduces the electrical signals into electromagnetic energy. This electromagnetic energy creates an alternating electromagnetic field with the magnetic component (floating mass transducer) implanted on the ossicles of the middle ear. The 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.

Fully Implantable Middle Ear Hearing Aids

The Esteem MEI is a fully implantable middle ear hearing system that uses piezoelectric transducers along with the natural ear/eardrum as the microphone. According to the FDA's Summary of Safety and Effectiveness Data, the hearing aid consists of three implantable components: a sound processor implanted in the temporal bone behind the outer ear; a sensor; and a driver that is implanted in the middle ear. The piezoelectric sensor tip is attached to the incus bone and senses vibrations from the tympanic membrane and malleus/incus, converting these mechanical vibrations into electrical signals that are sent to the sound processor. The sound processor, which is implanted in the temporal bone and connected to the sensor and driver via leads, receives the electrical signal from the sensor, amplifies and filters the signal to compensate for the person's hearing loss profile; the enhanced signal is then sent to the driver. Finally, the piezoelectric driver tip attached to the stapes/incus bone converts the enhanced electrical signal received from the sound processor back to vibrations which are transferred to the stapes and delivered as sound waves to the cochlea; the cochlea converts the waves to nerve impulses and transmits them to the brain where they are interpreted as sound. In

addition to the intended use by adults with stable moderate to severe bilateral sensorineural hearing loss (defined by PTA), the manufacturer states the Esteem MEI is indicated for persons with an unaided speech discrimination test score ≥ 40%, normally functioning eustachian tube, normal middle ear anatomy, normal tympanic membrane, and adequate space for the implant. The person should also have a minimum of 30 days of experience with appropriately fitted hearing aids.

Summary

There are minimal safety concerns related to externally worn hearing aids. In contrast, a middle ear hearing aid requires a surgical procedure for implantation. Potential risks cited for implantation include a decrease in residual hearing in the implanted ear and infection in the ear and adjacent structures. Major ear surgery may also result in numbness, swelling, or discomfort around the ear, the possibility of facial paresis, neck pain, and disturbance of balance and taste. Therefore, equivalency or proposed improvement in audiologic outcomes associated with implantable middle ear hearing aids must be balanced against the potential risks inherent in a surgical procedure.

Definitions

Abbreviated Profile of Hearing Aid Benefit (APHAB): A questionnaire designed to quantify daily activities related to hearing loss by assessing the reduction of disability with a hearing aid.

Air-conduction hearing aid (ACHA): A conventional hearing aid for hearing loss that cannot be medically or surgically corrected.

Asymmetric hearing loss (AHL): A condition in which hearing in the better ear is not normal, but can be restored using a conventional hearing aid (pure-tone average [PTA] between 30 dB HL and 55–60 dB HL).

Conductive hearing loss: Occurs when sound is not conducted efficiently through the outer ear canal to the eardrum and the small bones (ossicles) of the middle ear; this disorder involves a reduction in sound level or the ability to hear faint sounds.

Congenital aural atresia (CAA): A rare spectrum of congenital deformities present at birth that involves some degree of failure of the development of the external auditory canal; it is commonly accompanied by abnormalities of both the middle ear bones in various degrees, as well as the external ear, including microtia (small ear) or incomplete development of the auricle (the outer projecting portion of the ear).

Decibel (dB): A unit for expressing the loudness of sound. The intensity relates to how loud or soft a sound is. Sound scales are based on either sound pressure level (dB SPL) or hearing level (dB HL).

Decibels hearing level (dB HL): 0 dB HL is the softest sound that can be heard by the average person with normal hearing. It is not the absence of sound, as persons with better than average hearing will have thresholds lower than 0 dB HL (for example, 10 dB HL).

Degree of hearing loss: According to the American Speech-Language-Hearing Association (ASHA, 2018) (Clark, 1981), the degree of hearing loss refers to the severity of an individual's hearing loss range in decibels (dB):

Classification of Hearing Loss	Hearing Threshold
Normal hearing	0 to 20 dB
Mild	21 to 40 dB hearing loss
Moderate	41 to 55 dB hearing loss
Moderately-severe	56 to 70 dB hearing loss
Severe	71 to 90 dB hearing loss
Profound	91 dB or more hearing loss

Hertz (Hz): A unit of frequency equivalent to 1 cycle per second. Frequency of pitch is measured in Hz. Frequencies of 250-8000 Hz are typically used in audiometric testing because this range represents most of the speech spectrum.

Mixed hearing loss: Hearing loss that is both conductive and sensorineural, occurring in one or both ears. This term refers to a condition where conductive hearing loss coexists with sensorineural hearing loss.

Otitis externa: Inflammation or infection of the ear canal.

Piezoelectric: The production of an electric potential when stress is applied.

Pure tone threshold audiometry: The measurement of an individual's hearing sensitivity for calibrated pure tones; includes manual air-conduction measurements at 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz (125 Hz under some circumstances) plus bone-conduction measurements at intervals from 250 Hz to 4000 Hz and at 3000 Hz as needed (ASHA, 2005).

Pure-tone average (PTA): The average of hearing sensitivity (that is, the minimum volume that the person hears) calculated at multiple frequencies (perceived by pitch), typically within the range of 0.25 to 8 kHz (kilohertz).

Pure tone thresholds (PTTs): The faintest tones or softest sound (lowest intensity) a person can hear at least 50% of the time; PTT is measured in dB.

Sensorineural hearing loss (SNHL): A permanent hearing loss related to the sensory or neural structures responsible for hearing that involves a reduction in sound level or ability to hear faint sounds; this disorder affects speech understanding or the ability to hear clearly; the involved structures include, but are not limited to, the cochlea and the acoustic nerve.

Single-sided deafness (SSD): Significant or total hearing loss in one ear; this disorder is sometimes referred to as unilateral sensorineural hearing loss. SSD is defined as a unilateral severe-to-profound deafness (PTA ≥ 70 dB HL), with a contralateral ear that has better, normal or near-normal hearing (PTA ≤ 30 dB HL). SSD may be a result of a congenital unilateral hearing loss, a sudden sensorineural hearing loss, significant head trauma affecting the ear(s), and surgery to treat acoustic neuroma or other tumors of the eighth cranial nerve.

Speech reception threshold: The intensity at which speech is recognized as meaningful symbols; in speech audiometry, it is the dB level at which 50% of spondee words (a bisyllabic word with equivalent stress on each syllable) can be repeated correctly by the subject.

Temporal bone: A bone located on the side of the head that is part of the skull.

Tympanic membrane: The membrane in the ear that vibrates to sound; referred to as the eardrum.

Unilateral hearing loss (UHL): Is generally defined as a condition in which an individual has non-functioning hearing in one ear, receives little or no clinical benefit from amplification in that ear, and has normal or near normal audiometric function in the contralateral ear. UHL includes single-sided deafness (SSD) and asymmetric hearing loss (AHL).

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes or when the code describes a procedure or device indicated in the Position Statement section as investigational and not medically necessary.

CPT

69799	Unlisted procedure, middle ear [when specified as implantation of semi-implantable or fully implantable hearing aid]

HCPCS

S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis

ICD-10 Diagnosis

	All diagnoses

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Reviewed	05/12/2022	MPTAC review. The Rationale, Definitions and References sections were updated.
Reviewed	05/13/2021	MPTAC review. Updated the References and Websites for Additional Information sections.
Reviewed	05/14/2020	MPTAC review. Updated the References and Websites for Additional Information sections.
Reviewed	06/06/2019	MPTAC review. Updated the References section.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated the Rationale, References, and Websites sections.
Reviewed	08/03/2017	MPTAC review. Updated the Rationale and References sections.
Reviewed	08/04/2016	MPTAC review. Updated the Rationale and Reference sections. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. Updated Description, Rationale, Background, Definitions, References, and Websites for Additional Information sections.
Reviewed	08/14/2014	MPTAC review. Updated Rationale, Background, Definitions, References, Websites for Additional Information, and Index sections.
Reviewed	08/08/2013	MPTAC review. Minor format changes throughout document. Updated Rationale, Background, References, and Websites for Additional Information sections.
Reviewed	08/09/2012	MPTAC review. Updated Rationale, References, and Index.
Reviewed	08/18/2011	MPTAC review. Updated Rationale and References. Reformatted Definitions.
Revised	08/19/2010	MPTAC review. Revised subject/title to Implantable Middle Ear Hearing Aids. Revised Position Statement, adding the fully implantable middle ear hearing system as investigational and not medically necessary. Updated Description, Rationale, Discussion, Definitions, Coding, References, and Index.

Reviewed	08/27/2009	MPTAC review. Description and References updated.
Reviewed	08/28/2008	MPTAC review. Position Statement clarified. Rationale, Definitions and References updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	08/23/2007	MPTAC review. Revised document title. Rationale, Background, Definitions and References updated.
Reviewed	09/14/2006	MPTAC review. References updated.
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.		No document	
WellPoint Health Networks, Inc.	09/23/2004	2.03.11	Semi-Implantable Middle Ear Hearing Aids as a Treatment of Hearing Loss

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.