IMPLANTABLE/NON-IMPLEMENTABLE HEARING DEVICES AND BONE ANCHORED HEARING AIDS

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**Conditions of Coverage**

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<td>¹Precertification with review by a Medical Director or their Designee is required for placement/provision of implantable hearing devices and bone-anchored hearing aids.</td>
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Implantable/Non-Implantable Hearing Devices and Bone Anchored Hearing Aids:
Clinical Policy (Effective 11/01/2013)

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**COVERAGE RATIONALE**

Coverage for implantable hearing devices and bone-anchored hearing aids is subject to the criteria set forth below.

Note:
- Semi-implantable electromagnetic and bone-anchored hearing aids are hearing aids for the purpose of benefit design.
- See the [US Food and Drug Administration](http://www.fda.gov) section of this policy for additional coverage information.
- For coverage for conventional hearing aids, refer to: Hearing Aids

**Semi-Implantable Electromagnetic Hearing Aid**
The semi-implantable electromagnetic hearing aid is considered medically necessary for treatment of sensorineural hearing loss in a patient who is not a candidate for an air-conduction hearing aid and when used according to U.S. Food and Drug Administration (FDA) approved indications.

**Totally Implanted Hearing Systems**
Totally implanted hearing systems such as the Esteem® prosthetic hearing restoration device are not considered to be medically necessary for the treatment of hearing loss.

There is inadequate evidence demonstrating the efficacy of totally implanted hearing systems for treating deafness. Well designed studies with larger patient populations and longer follow-up are required to demonstrate the safety and benefits of these devices.

**Partially Implantable Bone Conduction Hearing Aid with Magnetic Coupling**
The partially implantable Otomag Bone Conduction Hearing System is unproven for treating hearing loss.

There is limited evidence to support the use of Otomag Bone Conduction Hearing System to treat hearing loss. One observational case series was identified evaluating the Otomag Bone Conduction Hearing System. Additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with this device.

**Implantable Bone-Anchored Hearing Aid (BAHA) for Sensorineural Hearing Loss**

A unilateral implantable bone-anchored hearing aid is considered medically necessary for sensorineural hearing loss in one ear in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.

Unilateral or bilateral implantable bone-anchored hearing aids are considered medically necessary for sensorineural hearing loss in both ears when all of the following criteria are present:

- the poorer ear is not a candidate for an air-conduction hearing aid due to a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60% AND
- the better hearing ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more.

**Implantable Bone-Anchored Hearing Aid (BAHA) for Conductive or Mixed Hearing Loss**

A unilateral implantable bone-anchored hearing aid is considered medically necessary for conductive or mixed hearing loss in one or both ears, in a patient who is not a
candidate for an air-conduction hearing aid and when used according to FDA approved indications.

I. Bilateral implantable bone-anchored hearing aids are considered medically necessary* for conductive or mixed hearing loss in both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications

**Non-Implantable Bone-Anchored or Bone Conduction Hearing Aids**

Bilateral or unilateral bone-anchored hearing aids utilizing a headband (without osseointegration) are considered to be medically necessary* for hearing loss in one or both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.

An intraoral bone conduction hearing aid such as SoundBite™ is unproven for treating hearing loss. There is insufficient evidence to support the use of an intraoral bone conduction hearing aid to treat hearing loss. The quality of the studies was low due to small study populations, short follow-up, and lack of randomization and appropriate control groups. Future studies with larger populations of patients wearing the device for longer periods are needed to evaluate hearing benefits and device safety.

**Additional Information to Support Medical Necessity Review:**

See the U.S. Food and Drug Administration (FDA) section for FDA indications for these hearing devices.

**Benefit Considerations**

Semi-implantable electromagnetic and bone-anchored hearing aids are hearing aids for the purpose of benefit design.

The benefit or exclusion for hearing aids depends on several factors. Please refer to the plan-specific Certificate of Coverage or Summary Plan Description for details.

**Note:** For coverage for conventional hearing aids, please refer to: Hearing Aids

**Background**

Hearing loss can be broadly classified as sensorineural (inner ear), conductive (external and middle ear), or mixed hearing loss. In sensorineural hearing loss, the auditory cranial nerve or part of the bone of the inner ear is defective due to aging, heredity, viral or bacterial infection, and other conditions. Single sided deafness is another term used for unilateral sensorineural deafness. In conductive hearing loss the sound waves’ path through the ear canal, past the ear drum, and into the inner ear is impeded by a physical or mechanical blockage, e.g., a totally blocked ear canal at birth (atresia), tumors in the ear canal, long-term infections of the ear canal (otitis externa) or ear drum (otitis media, tympanic cavity infection), or severe skin problems in the ear canal, such as dermatitis. Mixed hearing loss is a combination of both conditions. The degree of hearing loss is defined as mild [26 to 40 (dB) hearing loss], moderate (41 to 55 dB hearing loss), severe (71 to 90 dB hearing loss), and profound (91 dB or more hearing loss). (ASHA, Type, Degree and Configuration of Hearing Loss; Clark, 1981).

Air-conduction hearing aids (ACHAs) are the standard treatment for hearing loss that cannot be medically or surgically corrected. This technology assessment focuses on the use of semi-implantable electromagnetic hearing and bone-anchored hearing aids as an alternative to ACHAs for the treatment of hearing loss.
Semi-implantable electromagnetic hearing aids use the periodic attraction and repulsion of two magnetic fields, one electromagnetic and the other static magnetic, to cause vibration of the ossicles and transmission of sound to the inner ear. When the external sound processor receives sound, it is transformed into electrical signals, which are then amplified and transmitted to a magnetic device that is surgically implanted into the middle ear. The implant's vibrations directly drive the ossicles' movement, producing amplified sound perception. By mimicking the natural vibrations of the ossicular chain, an enhanced signal is sent to the cochlea, resulting in a clearer sound that can be increased without the volume amplification required by ACHAs. In addition, since the air pressure on each side of the sound processor is the same, the wearer does not experience the feeling of occlusion that is common with standard hearing aids. Currently, there are three commercially available semi-implantable electromagnetic hearing devices: 1) the Vibrant® Soundbridge™ System (Symphonix Devices Inc.; later acquired by Med-El GmbH), 2) the Maxum™ System (Ototronix) that was originally called the Soundtec Direct System, and 3) the Middle Ear Transducer (MET) Ossicular Stimulator System (Otologics LLC). The Soundtec Direct device was voluntarily removed from the market in 2004 while the manufacturer attempted to eliminate a rattling sound some patients experienced, primarily when the sound processor was not used. The Maxum System represents an upgrade over the Soundtec Direct System. The two systems use the same technology and components, although the designs differ. The semi-implantable MET Ossicular Stimulator System is commercially available in Europe for treating moderate to severe SNHL in adults but is not approved by the U.S. Food and Drug Administration (FDA).

While conductive hearing loss can often be treated with ACHAs, in some cases (e.g., those resulting from the congenital malformation of the external ear canal, pinna and middle ear structures) the use of ACHAs is precluded. In these cases, a standard bone conducting hearing aid (BCHA) is required. A bone-anchored hearing aid is an alternative to a standard BCHA. The bone-anchored hearing aid is a percutaneous BCHA involving the surgical implantation of a titanium screw into the mastoid process of the skull (osseointegration). In contrast to traditional BCHAs, bone-anchored hearing aids transmit sound vibrations directly to the skull instead through the skin. After a waiting period to allow for complete osseointegration, a sound processor is linked to the skull through an abutment attached to the osseointegrated screw.

Bone conduction hearing aids are used in very young children with conductive or mixed hearing loss who are not candidates for air conduction hearing aids. Bone conduction hearing aids may be uncomfortable to wear because they are comprised of a bone conduction transducer held in place by a steel springband over the head. A potential alternative to conventional bone conduction hearing aids are bone-anchored hearing aids held in place by a headband. Use of a headband allows the bone-anchored hearing aid to be held against the skin behind the ear. In this application there is no implantation surgery; rather, the sound processor is attached firmly to the head using either a hard or soft headband, and the amplified vibrational sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. Children may use a headband until their temporal bone is mature enough for implantation of a bone anchored hearing aid. For adults, a headband is often used to determine whether they might benefit from bone conduction hearing technology.

Semi-implantable electromagnetic hearing aids and bone-anchored hearing aids are classified by the U.S. Food and Drug Administration (FDA) as hearing aids.

The Otomag Bone Conduction Hearing System is a partially implantable bone conduction hearing aid without a percutaneous abutment. The Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. The principle of these bone conduction hearing aids is a magnetic coupling and acoustic transmission between implanted and external magnets. See the following Web site for more information: http://oto-mag.com/ Accessed June 2012.

Totally implantable hearing systems are also being evaluated in patients with hearing loss. The Esteem prosthetic hearing restoration device (Envoy Medical Corporation) is totally implanted...
behind the outer ear and in the middle ear. Unlike hearing aids, the Esteem device does not use a microphone or a speaker. Three implanted components comprise the system: a sound processor, a sensor and a driver that converts electrical signals transmitted by the sound processor to the inner ear, where they are perceived as sound. The device is powered with a maintenance-free battery that may last up to nine years and requires no recharging. The Carina Fully Implantable Hearing Device (Otologics, LLC) is another totally implantable active middle ear device. This device is currently still in the clinical trial stage and has not yet been cleared for marketing by FDA. The Otologics device differs from the Esteem by using a microphone implanted beneath the skin. Sound is picked up by the microphone and transmitted to a transducer in the middle ear. The transducer vibrates the bones of the middle ear allowing vibrations to enter the cochlea.

The SoundBite™ Hearing System is a non-surgical intraoral bone conduction hearing aid that was developed for individuals with single-sided deafness. It consists of a behind the ear device (which houses the receiver, wireless transmitter, and microphone) and a removable, custom-fit oral retainer-like device. According to the manufacturer, the device allows sound to travel via the teeth, through the bones, to both cochleae, bypassing the middle and outer ear. See the following Web site for more information: http://www.sonitusmedical.com/product/soundbite-in-detail.cfm Accessed June 2012.

CLINICAL EVIDENCE

**Semi-Implantable Electromagnetic Hearing Aids**

According to a Hayes Report (Hayes Directory, Semi-Implantable Electromagnetic Hearing Aids, 2011), data from seven studies and 406 patients indicate that implantation and/or use of the Vibrant Soundbridge System may lead to a change in residual hearing, compared with preimplantation values. This change may be minor when averaged across all tested sound frequencies in entire study cohorts; but varies considerably among different frequencies and patients; and is clinically significant, representing an improvement (negative dB values) or, more often, a decline (positive dB values) in residual hearing, in 3.8% to 24% (mean, 12.8%) of the patients (Fisch et al., 2001; Fraysse et al., 2001; Snik et al., 2001; Leutje et al., 2002; Pok et al., 2010). Several studies demonstrated that use of the Soundbridge device led to significant or substantial improvement in hearing acuity (functional gain) versus unaided hearing (Fraysse et al., 2001; Snik et al., 2001; Pok et al., 2010) or conventional hearing aids (Fraysse et al., 2001; Leutje et al., 2002).

In clinical trial data reported to the U.S. Food and Drug Administration (FDA), the Vibrant Soundbridge resulted in the following complications among 81 patients (5 subjects from a feasibility study, 54 from the effectiveness study, and 22 subjects from a supplemental safety cohort): device failures 6 (7%), transient facial paresis 2 (2%), infections 1 (1%), episodic dizziness 2 (2%), change in residual hearing 2 (2%), fullness sensation in ear, 18 (22%), perforated tympanic membrane 1 (1%), altered taste sensation 7 (8.6%), skin irritation 2 (2%), transient pain 13 (16%), and disconnection of floating mass transducer 1 (1%). See the following Web site for more information: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm089772.htm. (Accessed June 2012). Most complications related to semi-implantable electromagnetic hearing devices during clinical trials were temporary.

Hough et al. (2002) prospectively assessed the safety and efficacy of the Soundtec Direct System, a partially implantable electromagnetic middle ear hearing device. The study included 103 patients with bilateral moderate to moderately severe sensorineural hearing impairment who had worn optimally fit hearing aids for at least 45 days. The results with the use of the SOUNDTEC Direct System compared with an optimally fit hearing aid provided an average 7.9-dB increase in functional gain in the speech frequencies (500-4,000 Hz) and a 9.6 dB gain in high frequencies (2,000, 3,000, and 4,000 Hz). There was a statistically significant average increase of 5.3% in speech discrimination. The mean speech perception in noise test score was improved, but the improvement was not statistically significant.
In a prospective study, Sziklai and Szilvassy (2011) assessed whether an improvement in speech recognition by Vibrant Soundbridge is greater than that by open-fit hearing aids in patients with sloping high frequency sensorineural hearing loss (SNHL). Seven patients aged 21-62 years with sloping high frequency SNHL were recruited into the study. Each patient received a Vibrant Soundbridge middle ear implant and wore an open-fit hearing aid. The authors concluded that there is no significant difference in speech recognition scores obtained with the Vibrant Soundbridge and the open-fit hearing aid. However, the Vibrant Soundbridge may be superior to open-fit hearing aids in improving hearing at high frequencies (4-8 kHz).

Tysome et al. (2010) planned to conduct a systematic review to determine whether middle ear implants (MEIs) improve hearing as much as conventional hearing aids. Seventeen articles met the inclusion criteria of MEI in adults with a sensorineural hearing loss, where hearing outcomes and patient-reported outcome measures (PROMs) compared MEI with conventional hearing aids (CHAs). Study quality assessment included whether ethical approval was gained, the study was prospective, eligibility criteria specified, a power calculation made and appropriate controls, outcome measures, and analysis performed. Middle ear implant outcome analysis included residual hearing, complications, and comparison to CHA in terms of functional gain, speech perception in quiet and in noise, and validated PROM questionnaires. Electromagnetic MEI made up 98% of the implants included in this study. Because significant heterogeneity existed between the interventions (6MEI), comparators (various CHA), and outcome measures of studies (4 languages, 12 tests of speech in quiet and noise, 6 PROM questionnaires), the investigators were unable to pool the results of studies for meta-analysis, and a structured review was done. The authors concluded that the quality of studies was moderate to poor with short follow-up. The evidence supports the use of MEI because, overall, they do not decrease residual hearing, result in a functional gain in hearing comparable to CHA, and may improve perception of speech in noise and sound quality. The authors recommended that publications of long-term results comparing MEI with CHA, reporting a minimum of functional gain, speech perception in quiet and in noise, complications, and a validated PROM to guide the engineering of the new generation of MEI be done in the future.

**Totally Implanted Hearing Systems**

As part of the premarket approval process, the U. S. Food and Drug Administration (FDA) reviewed a pivotal trial that evaluated Esteem versus pre-implant hearing aids. A total of 60 subjects were implanted with the Esteem and acted as their own controls (using hearing aids prior to implanting the Esteem device). Among the 57 patients with follow-up information, the most frequent adverse event was taste disturbance (42%); facial numbness or paralysis was reported in 7%. Severe adverse device effects were reported in six individuals (10.5%); three patients had revision procedures due to limited benefit (not included in the 4 and 10 month evaluations), one had an incision site infection, one had incisions breakdown, and one experienced severe pain and facial weakness. At 4 months the mean decrease in the Speech Reception Threshold was 10.6 dB with 95% confidence interval (CI) of 7.1 to 14.2; at 10 months the mean decrease was 11.4 with 95% CI of 7.7 to 15.2. These changes were considered clinically significant. At 4 months, the Word Recognition Scores were as good as or better in 93% of subjects; however, at 10 months these scores decreased to 88%. As a condition of FDA approval, Envoy Medical must conduct longer-term studies of the device’s safety and effectiveness. See the following Web site for more information: [http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/EarNoseandThroatDevicesPanel/UCM194441.pdf](http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/EarNoseandThroatDevicesPanel/UCM194441.pdf). Accessed June 2012.

The use of a totally implantable hearing system has also been evaluated in several published trials. All of the studies had small sample sizes and short term follow-up. Kraus et al. (2011) assessed the outcomes of the Envoy Esteem Totally Implantable Hearing System as measured by hearing results compared with preimplant baseline unaided (BLU) and best-fit aided conditions (BLA) and determined the safety of the device. The study was a prospective, nonrandomized, multicenter, subject-as-own-control, US Food and Drug Administration (FDA) trial. Fifty-seven subjects with bilateral, mild to severe sensorineural hearing loss, with discrimination greater than 40%, were implanted. Devices were activated 2 months
Implantable/Non-Implantable Hearing Devices and Bone Anchored Hearing Aids: Clinical Policy (Effective 11/01/2013)

Memari et al. (2011) evaluated the safety of totally implantable hearing device implantation, patient's hearing gain, importance of anatomic landmarks, and to describe suitable criteria for patient selection. Via a non-randomized controlled clinical trial, 10 patients with moderate-to-severe sensorineural hearing loss were implanted from 2007 to 2009. Mean follow-up period was 29.4 months. Correlation of pre-operative temporal bone computed tomography (CT) scan anatomy with postoperative outcome was evaluated. The patients' overall average hearing gain were reported to be similar to conventional hearing aids (10-22 dB), but patients reported relatively better subjective sound quality compared with their pre-operative conventional hearing aids. One implanted device was explanted in a patient due to facial weakness and low-hearing gain. Revision surgery was done successfully in another patient secondary to excessive bone growth. According to the investigators, totally implantable hearing device surgery seems to be relatively safe and correct patient selection could lead to good outcomes. Lateral location of facial nerve, sclerotic mastoid air cells and narrow facial recess space seems to be related to postoperative complications. These results need confirmation in a larger trial.

Esteem implantation was carried out in 21 patients with a mild (n = 3), moderate (MHL, n = 9) or severe (SHL, n = 9) degree of sensorineural hearing loss (SNHL). The two latter groups (MHL and SHL) were compared in terms of preoperative versus postoperative pure tone and speech reception thresholds (SRTs). Similarly, they were also compared for the outcome from quality of life (QoL) questionnaires, such as the general Glasgow Benefit Inventory (GBI) and COSI. In the whole sample, mean hearing threshold levels improved from 70 to 48 dB; in the MHL group the mean hearing threshold level improved from 64 to 42 dB; in the SHL group the mean hearing threshold level improved from 82 to 58 dB. GBI and COSI scores were only slightly better in the MHL group than in the SHL group. According to the investigators, the Esteem(®) device proved to offer beneficial results in subjects suffering from high frequency, severe bilateral sensorineural hearing loss (SNHL) and may be considered as an alternative procedure to conventional hearing aids (HAs) or electroacoustic stimulation (EAS) systems (Barbara et al. 2011).

In a retrospective case series, Dontorinis et al. (2010) examined anatomic limitations in implantation of the semi-implantable middle ear transducer (MET) and fully implantable Carina middle ear. The results of the study indicated when dura-meatal distance is greater than 8 mm, implantation of the MET or Carina is a safe procedure. By contrast, in cases with a dura-meatal distance of less than 8 mm, the surgery introduces a high risk of complications. When dura-meatal distance is less than 5 mm, MET or Carina implantation is not recommended.

In a phase III study, Zenner et al. (2004) evaluated the treatment efficacy of an electromechanical middle ear amplifier implant in 20 patients with chronic moderate-to-severe sensorineural hearing loss (SNHL). At 6 months follow-up, 17 patients (89%) demonstrated improved binaural recognition of phonetically balanced monosyllables. Fourteen postoperative patients (74%) attained a perfect score (100%) on this test, compared to 3 preoperative patients (16%). Three patients did not benefit from the implant. The investigators concluded that Treatment of SNHL with a totally implantable hearing system can be an efficient method for those patients unable to wear hearing aids. However, in order to avoid implantation in non-responders, there is a need for more specific audiological indication criteria.

A prospective trial evaluated the use of the Otologics Fully Implantable Middle Ear Transducer in five patients with congenital auricular atresia After activation and fitting of the devices, patients experienced an improvement of sound-field thresholds up to 50 dB HL. The mean functional gain

postimplant. Hearing results were compared with ipsilateral BLU and BLA. Speech reception thresholds (SRTs) improved from BLA of 41.2 dB to 29.4 dB with the Esteem. Word recognition score (WRS) at 50 dB hearing level (HL) improved from BLA of 46.3% to 68.9% with the Esteem. Pure tone averages improved by 27 ± 1 dB. There were no changes in bone conduction. There were 6 serious adverse device effects: 2 wound infections (1 resolved medically, 1 required explantation), 1 delayed facial paralysis that resolved with medication, and 3 revisions due to limited benefit. According to the investigators, phase 2 results at 12 months post implant demonstrated that (1) hearing results with the device are statistically superior to baseline best-fit hearing aids for SRT and WRS and (2) the device is safe.
in a three frequency pure-tone average was approximately 35 dB HL. The investigators concluded that this technique appears to provide a completely new dimension for the audioligic rehabilitation of patients with severe malformation of the middle ear (Siegert, 2007).

Eleven patients were included in a retrospective study that evaluated the totally implantable Carina hearing device. The investigators concluded that additional clinical data studies are needed, including a greater number of patients, to confirm preliminary promising results of this device (Martin, 2009).

Bruschini et al. (2010) evaluated the benefits of the fully implantable Carina in eight adult patients, seven with moderate to severe SNHL and one with mixed hearing loss. All the patients demonstrated improvements in speech perception abilities with the device functioning and reported subjective benefits. Postoperative adverse effects included feedback noise, which resolved with minor fitting adjustments in seven cases, while it required a second surgery to change the microphone position in the other patient. In one case a minimal extrusion of the microphone cable occurred requiring a revision surgery, a device failure occurred in one case, requiring substitution, and one patient decided on explantation of the device owing to psychological problems.

Bruschini et al. (2009) described the surgical and clinical experience with the fully implantable Carina in 5 adults with moderate to severe sensorineural hearing loss. Mean follow-up was 10.2 months of device use. No significant post-operative variation was observed in hearing thresholds, either for air or bone conduction, indicating absence of surgical damage to the cochlea. All patients showed improvements in hearing thresholds and in free field and in speech perception abilities, with the device functioning, moreover, they reported subjective benefits. Problems of feedback noise occurred, which were resolved with minor fitting adjustments in 4 cases, while a second operation was required to change the microphone position in the other patient. The investigators concluded that the Otologics MET Carina is a viable treatment for moderate to severe sensorineural hearing loss and, in selected cases, may represent an alternative to conventional hearing aids.

Barbara et al. (2009) assessed the benefits from implantation of the Esteem hearing device in 6 patients. According to the investigators, the implantation procedure was long in duration, but a reduced duration was recorded in the last procedure compared with the first one. The implantation process induced deterioration in hearing thresholds, which fully recovered after activation of the device. A postoperative hearing gain could be measured in three patients. The investigators concluded that the perceived quality of sound was shown to be better than could be expected by the measurable hearing gain.

Jenkins et al. (2008) assessed the safety of the Otologics fully implantable hearing system after 1 year of use in a Phase I clinical trial of 20 patients. Pure-tone averages and monaural word recognition scores were slightly better for the walk-in-aided condition, whereas the patient benefit scales favored the postoperative implant-aided conditions. At the 12-month data collection point, problems that had been encountered by patients included 1) partial device extrusion (3 patients), necessitating explantation in 2; 2) loss of external communication (2 patients), resulting in 1 explantation; and 3) increased charging times beyond 1.5 hours (7 patients), resulting in 3 explantations and 2 patients not using their device while awaiting explantation. According to the investigators, this phase I trial provided evidence that the fully implantable device can provide sound amplification to sensorineural hearing loss patients, with performance results similar to the patients’ walk-in hearing aids.

Shohet et al. (2011) assessed the efficacy of the Envoy Esteem totally implantable hearing device in treating profound high-frequency sensorineural hearing loss. The prospective, multi-center, nonrandomized Food and Drug Administration clinical trial included 5 patients with profound high-frequency hearing loss. Preoperative speech reception threshold improved from an unaided 65 dB and aided 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% postoperatively. The authors concluded that the Esteem totally implantable middle ear hearing device provides appreciable
functional gain and improvement in WRS to rehabilitate hearing in patients with a profound high-frequency sensorineural hearing loss. Study limitations include non-randomization and small sample size.

A phase I prospective, single-subject, repeated-measures, multicenter study was performed to evaluate the safety and functionality of the Envoy System. Five of 7 patients at the 2-month postactivation period had working systems. The 5 patients with working systems had 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 (Chen, 2004). This study is limited by a small study population.

Implantation of the Esteem has the potential for technical and surgical complications. According to a Hayes report (Hayes Brief, Esteem Totally Implantable Hearing System for Treatment of Moderate to Severe Sensorineural Hearing Loss in Adults, 2012), in the overall study population there were 7 recorded device replacements (6.8%) due to device failure or limited benefit. Additional serious adverse events included wound infections (3%), facial paralysis (2%), and excessive bone growth (1%). The most frequently reported minor adverse event was taste disturbance occurring in 24 of 57 patients in one study (42%). Other transient adverse events included imbalance, facial paralysis/paresis, pain, numbness, middle ear effusion, tinnitus, and headache (Chen et al., 2004; Barbara et al., 2009; Barbara et al., 2011; Kraus et al., 2011; Memari et al., 2011).

An ongoing manufacturer-sponsored clinical trial is registered in the ClinicalTrials.gov database to evaluate the safety and efficacy of the Esteem System in 57 patients with mild to severe sensorineural hearing loss. Primary outcome measures include 1) improvement of the speech threshold of sensitivity for hearing and identifying speech signals as compared with the preimplantation hearing aid; 2) effectiveness in improving speech discrimination as shown by word recognition score at 4 months postactivation; and 3) the incidence of serious adverse device effects, as well as the incidence of device failures and replacements. Interim results of this pivotal study were published by Kraus et al. (2011). At the U.S. Food and Drug Administration’s (FDA’s) request, the study was extended as a post approval study to evaluate long-term outcomes in its 57 patients, new surgeon performance, failure rates, and incidence of delayed fibrosis. Study enrollment began in January 2008 and is estimated to complete in December 2015. See the following Web site for more information; http://www.clinicaltrials.gov/ct2/show/NCT01092910 Accessed June 2012.

Partially Implantable Bone Conduction Hearing Aid with Magnetic Coupling
Siegert (2011) evaluated a partially implantable bone conduction hearing aid without a percutaneous abutment (Otomag Bone Conduction Hearing System). The principle of these bone conduction hearing aids is a magnetic coupling and acoustic transmission between implanted and external magnets. Except for temporary pressure marks in 4% of patients, which healed after careful shimming of the external base plate, there were no other complications. According to the authors, the holding strength of the external components is equivalent to partially implantable hearing aids and cochlea implants and the hearing improvement is similar to other bone conduction hearing aids. The authors found that the comfort and safety of this system is significantly improved compared to conventional or percutaneous bone conduction hearing aids. The lack of a control group limits the validity of the results of this study.

There is insufficient evidence to conclude that the Otomag Bone Conduction Hearing System is beneficial for patients with hearing loss. Additional studies with larger populations and long-term follow-up are needed to evaluate improvement of hearing with this device.

Bone-Anchored Hearing Aids (BAHAs)
The majority of the evidence came from clinical studies at the Nijmegen University Hospital (the Netherlands) and the Birmingham Osseointegration Program (United Kingdom). The outcomes of these studies were reported in several articles with overlapping patient populations and are therefore summarized for each center separately.
The Nijmegen Group: Mylanus et al. (1994), Snik et al. (1995), and Mylanus et al. (1995) reported the results of a prospective intraindividual comparative study that evaluated the bone-anchored hearing aid versus the hearing aid traditionally used by 65 patients. With regard to speech recognition, 62% of patients preferred the bone-anchored hearing aid to their previous hearing aid. Patient preference correlated with speech to noise ratios, which were significantly increased in patients who preferred the bone-anchored hearing aid (-2.5 dB) compared with those who preferred the previous hearing aid (-0.5 dB).

The Birmingham Osseointegration Program: The largest patient group was included in the Birmingham osseointegration program. (McDermott et al., 2002a; Dutt et al., 2002a; Dutt et al., 2002b; McDermott et al., 2002b) The program began in 1988 and by summer 2002 included 351 patients receiving the bone-anchored hearing aid including 242 adults and 109 children. A second prospective study of 84 adult patients aimed at comparing disability, handicap, and benefit of conventional hearing aids versus bone-anchored hearing aid using two instruments, the Glasgow HA benefit profile (GHABP) and the Glasgow HA difference profile (GHADP). (McDermott et al., 2002a) Bone-anchored hearing aid use significantly reduced hearing disability and the patient self-reported benefit and overall satisfaction were improved versus conventional hearing aids.

de Wolf et al. (2011) investigated whether speech perception was better with a bone-anchored hearing aid (BAHA) than with a digital behind-the-ear (BTE) device and whether the crossover point occurs at an air-bone gap of 25 to 30 dB. Experienced unilateral BAHA users with the latest digital BAHA processors were fitted with a powerful BTE with feedback cancellation. After an acclimatization period of 4 weeks, aided thresholds and speech recognition scores were determined and compared to those recorded previously with the BAHA. To obtain patients' opinions, a disability-specific questionnaire was used. Participants comprised 16 subjects with bilateral mixed hearing loss participated. Audiometric and speech recognition data showed similar trends to those described previously, but the crossover point had shifted to an air-bone gap of 30 to 35 dB. In the questionnaire, the BTE was rated higher than the BAHA, except by the patients with an air-bone gap that exceeded an average of 45 dB. The investigators concluded that in patients with mixed hearing loss whose air-bone gap exceeded 35 dB, speech recognition is likely to be better with a BAHA than with a BTE. Therefore, the BAHA should receive greater consideration when mixed hearing loss is combined with a significant air-bone gap, even when there are no contraindications for BTEs.

Bouhabel et al. (2012) compared the audiologic outcome and feasibility of bone-anchored hearing aid (BAHA) and external auditory canal reconstruction (EACR) surgeries in pediatric patients presenting with a congenital aural atresia (CAA). Twenty patients underwent EACR, whereas another 20 patients were implanted with a BAHA device. Based on the results of the study, the authors concluded that EACR, although constituting an attractive option, does not give acceptable results alone. However, when combined to conventional air conduction hearing aids, it can provide excellent audiologic outcomes comparable to BAHA. BAHA implantation is a reliable, safe and efficient therapeutic option that allows a significantly better audiologic outcome when compared to unaided EACR for patients with CAA.

Bone-Anchored Hearing Aids (BAHAs) for Sensorineural Hearing Loss

The use of bone-anchored hearing aids for unilateral sensorineural hearing loss has been evaluated in 6 small studies published between 2005 and 1998 (studies published prior to 1998 were excluded). (Wazen et al, 2005; Stenfelt et al., 2000; Van der Pouw et al.,1998; Niparko et al, 2003; Wazen et al., 2003; Hol et al., 2004) Each of these studies included 7 to 20 patients. One of the studies indicated that unilateral sensorineural hearing loss did not improve with bone-anchored hearing aids. (Wazen et al, 2005) The remaining studies showed some benefits for sensorineural hearing loss with bone-anchored hearing aid implantation. Anderson et al. evaluated 59 patients with unilateral deafness after acoustic neuroma surgery. Significant improvement in speech discrimination and noise was found after BAHA implantation. However, after the evaluation only 25% of all patients wanted BAHA implants. (Anderson et al., 2006). Lin et al. (2006) conducted a prospective trial of subjects with unilateral deafness in adults Patients were fitted with contralateral routing of signal (CROS) devices for 1 month and tested before
Implantable/Non-Implantable Hearing Devices and Bone Anchored Hearing Aids: Clinical Policy (Effective 11/01/2013)

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(mastoid) implantation, fitting, and testing with BAHA. The investigators concluded that BAHA amplification on the side of a deaf ear yields greater benefit in subjects with monaural hearing than does CROS amplification.

In a prospective clinical trial, Gluth et al. (2010) longitudinally evaluated short- and long-term subject satisfaction/benefit perception, device usage rates, complication rates, and external device repair rates of bone-anchored hearing aid (BAHA) implantation on a cohort of adult subjects with profound unilateral sensorineural hearing loss (PUSHL). The study included 56 adults with PUSHL, 21 of which underwent BAHA implantation (followed for an average of 3.2 years after implantation. There were statistically significant improvements in nearly all measures of benefit perception documented as well as a high rate of long-term device usage (81%). Although satisfaction and benefit perception outcomes generally tended to regress over time when compared with initial short-term outcomes, long-term scores still tended to be significantly improved nevertheless as compared with preoperative levels. Approximately 38% of implants experienced severe local skin reactions (Grade 2 and above) around the implant site at some point throughout the follow-up period, whereas only one (4.8%) required implant removal. 66.7% of subjects required repair of their external sound processor. According to the investigators, BAHA implantation provides a high level of short- and long-term perceived benefit and satisfaction in subjects with PUSHL and high rate of long-term device usage. However, implant site adverse local skin reactions and repairs of the external sound processor were common.

Zeitler et al. (2012) evaluated objective hearing outcomes in patients undergoing bone-anchored implantation (BAI) for single-sided deafness (SSD) with residual hearing in the implanted ear. Patients were divided into 2 groups: (1) residual hearing in the affected ear (≤90 db hearing level pure-tone average) and (2) profound hearing loss in the affected ear (>90 dB hearing level pure-tone average). Patients in both groups showed significant improvement in all objective hearing measures following implantation, and there were no significant differences in objective hearing outcomes between groups. The authors concluded that individuals with SSD and residual cochlear reserve can be successfully implanted with BAI, achieving significant improvements in objective hearing measures.

In a prospective trial, Wazen et al. (2010) evaluated the effectiveness of the BAHA system (fitted with the Divino and Intenso processors) in 21 patients with single-sided deafness (SSD) and mild to moderate hearing loss in the better-hearing ear. The patients showed a statistically significant improvement in all measures with the use of the Divino or Intenso processors compared with the unaided situation. Change in hearing, as measured in noise testing word recognition scores, revealed a statistically significant difference between the two aided conditions favoring the Intenso. The Glasgow Benefit Inventory revealed that 91 percent of the patients reported improvement in their quality of life. The investigators concluded that the BAHA system is effective in the rehabilitation of patients with SSD and mild to moderate hearing loss in the only hearing ear.

Baguley et al. (2006) reviewed 4 controlled prospective studies for a meta-analysis. The four studies that were used all attempted to determine the benefit of contralateral BAHA insertion over contralateral routing of signal (CROS) hearing aids, versus no treatment. The authors note that while the U.S. Food and Drug Administration (FDA) has approved the BAHA device as safe for use in individuals with unilateral acquired sensorineural hearing loss, this review was conducted to measure the efficacy of using these devices within this population. The pooled mean data comparing the use of one device over no assistance produced the following: The studies showed that there was no significant improvement in auditory localization, however the BAHA device did significantly improve speech discrimination in noise abilities. Subjective data also showed improvement in auditory abilities with the BAHA device over CROS, as well as improvement over no assistance.

A systematic review focused on the non-acoustic benefits of BAHAs as compared with other devices and included seven observational non-controlled studies (three prospective and four retrospective). The studies are small in sample size and use mixed populations of individuals with previous experience in using bone- or air-conduction hearing aids. Due to small sample size,
pooling of data could not be done. The researchers did note that when a Visual Analog Scale, the Hearing Handicap Inventory for Adults (HHIA) or the Hearing Handicap Inventory for the Elderly (HHIE), was used to measure nonacoustic improvement, new users of the BAHA (single) implants did show statistically significant levels of improvement; however individuals who had previously used air-or bone-conducting aids did not experience this same level of improvement. The number of users who were fitted with a BAHA for binaural use was too small for effectiveness measures to be reported. (Johnson et al., 2006)

Unilateral implantation of a bone-anchored hearing aid is not indicated for complete sensorineural hearing loss in both ears. However, studies of the BAHA device have indicated that when the poorer ear has a speech reception threshold that is beyond that needed to obtain benefit with conventional amplification (typically a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%) and the better ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more, the BAHA device provides consistent benefit of an expanded sound field and improved hearing sensitivity. The reason for this, as described by Lin et al. (2006), relates to two phenomena:

1. the BAHA patient does not have to wear a mould in the better ear (as part of the CROS system of amplification) and
2. the transcranial transmission of sound from the BAHA system appears to attenuate sounds outside of the central speech frequencies, thus improving speech recognition in noise.

These observations are also supported in studies by Hol (2005); Newman (2008); and Linstrom (2009).

Bilateral Fitting of Bone-Anchored Hearing Aids (BAHAs)

Colquitt et al. (2011) performed a systematic review to assess the clinical effectiveness of BAHAs for people with bilateral hearing impairment. Nineteen electronic resources were searched from inception to November 2009. Twelve studies were included. Studies suggested audiological benefits of BAHAs when compared with bone-conduction hearing aids or no aiding. A mixed pattern of results was seen when BAHAs were compared to air-conduction hearing aids. Improvements in quality of life with BAHAs were found by a hearing-specific instrument but not generic quality of life measures. Issues such as improvement of discharging ears and length of time the aid can be worn were not adequately addressed by the studies. Studies demonstrated some benefits of bilateral BAHAs. The authors concluded that the available evidence is weak. As such, caution is indicated in the interpretation of presently available data. However, based on the available evidence, BAHAs appear to be a reasonable treatment option for people with bilateral conductive or mixed hearing loss. Further research

Dun et al. (2010) evaluated clinical data and quality of life questionnaire outcomes in 21 children and young adults with bilateral Bone-Anchored Hearing Aids (BAHAs). In 90%, both BAHAs were being used 7 days a week. Nine children reported that they switched off both BAHAs when the background became too noisy. Bilateral BAHAs provided better hearing quality according to 70%. The Glasgow Children's Benefit Inventory demonstrated subjective overall benefit of +38 (n = 20). The spatial domain of the Speech, Spatial and Qualities of Hearing scale showed a trend toward better spatial hearing with decreasing age at bilateral application. According to the investigators, bilateral BAHAs showed clear benefit in the vast majority of study participants.

Dutt reported patient satisfaction (Dutt et al., 2002c) and speech intelligibility (Dutt et al., 2002d) in 15 patients with bilateral BAHAs. A prospective study of 12 patients demonstrated a significant improvement of sound localization with the use of bilateral BAHAs. Speech reception threshold in quiet and in noise were also improved. The investigators concluded that the results with bilateral BAHAs were better than unilateral BAHAs. (Priwin et al., 2004) Bilaterally fitted BAHAs were evaluated in 25 patients, and directional hearing and speech recognition in noise improved significantly with a second BAHA. (Bosman et al., 2001)
Bilateral implantation of a bone-anchored hearing aid is not indicated for complete sensorineural hearing loss in both ears. However, studies of the BAHA device have indicated that when the poorer ear has a speech reception threshold that is beyond that needed to obtain benefit with conventional amplification (typically a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%) and the better ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more, the BAHA device provides consistent benefit of an expanded sound field and improved hearing sensitivity. The reason for this, as described by Lin et al. (2006), relates to two phenomena:

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2. The transcranial transmission of sound from the BAHA system appears to attenuate sounds outside of the central speech frequencies, thus improving speech recognition in noise.

These observations are also supported in studies by Hol (2005); Newman (2008); and Linstrom (2009).

Non-Implantable Bone-Anchored or Bone Conduction Hearing Aids

Bone-Anchored Hearing Aids Utilizing a Headband

Christensen et al. (2010) conducted a study to compare functional gain at 500, 1000, 2000, and 4000 Hz for infants and children with bilateral conductive hearing loss who were initially fitted with traditional bone-conduction devices then progressed to BAHA with Softband and finally to unilateral BAHA implants. Study participants included 10 children with bilateral conductive hearing loss due to congenital atresia and/or microtia. Single-factor, repeated analyses of variance were run to examine the amount of functional gain delivered by the various devices as well as the threshold measures with each device at each frequency. Participants in this study showed a statistically significant improvement when using the BAHA Softband over traditional bone-conduction hearing aids. An implanted BAHA has statistically as much gain as a bone-conduction transducer at all frequencies tested. The investigators concluded that the BAHA system is a valid treatment in conductive hearing loss via a Softband or implanted. They conclude that it outperforms the traditional bone-conduction hearing aids and should be used as a first choice in intervention rather than a last option for inoperable conductive hearing loss.

Ramakrishnan et al. (2011) retrospectively reviewed bone-anchored and Softband-held conductive hearing aids in 109 children and young adults. Criteria for the selection of the implanted device or the Softband were not described; however, the authors did note an uneven distribution by mean age, gender, and syndromic co-morbidity. The authors conclude that this population benefits from bone-anchored and Softband-held conductive hearing aids based on mean scores.

Priwin et al. (2007) investigated whether bilateral BAHAs in children with conductive bilateral hearing loss (BHL) gave additional hearing benefits and the effects of unilateral hearing aids in children with conductive unilateral hearing loss (UHL) in a prospective study involving 22 children with either conductive UHL (unaided or with unilateral hearing aid) or conductive BHL (with unilateral or bilateral BAHAs) and 15 controls. The investigators indicated that in order to assess the possible supplementary effects of hearing aids, a 3-month trial of BAHA on Softband, either unilaterally or bilaterally, may be of value in children with conductive UHL or BHL. However, the effectiveness of the BAHA Softband was not evaluated in this study.

Nicholson et al. (2011) determined the benefit of the BAHA Softband for infants and children with bilateral conductive hearing loss; and verified the audibility of the speech spectrum for octave frequencies 500 through 4000 Hz. Twenty-five children aged 6 months to 18 years with craniofacial disorders and bilateral conductive hearing loss participated in the study. Participants were consistent, full-time unilateral BAHA users with the BAHA Compact bone-conduction amplifier coupled to the head via the Softband. Results revealed an improvement in sound field thresholds with BAHA amplification for the four octave frequencies. Percentages of thresholds meeting target levels were significant at all frequencies, exceeding the 80% criterion. According
to the investigators, this study demonstrates the benefit of the BAHA in providing audibility of the speech spectrum for infants and children with bilateral congenital conductive hearing loss.

In a prospective trial of 10 adults (age 14 or older) with more than 6 months of BAHA experience, Verstraeten et al. (2009) quantified the audiometric differences between the preoperative tests with the Bone-Anchored Hearing Aid (BAHA) attached to the headband or the testband and the final postoperative result with the BAHA positioned at the implanted abutment. For frequencies 1 to 4 kHz, significant differences in the range of 5 to 20 dB were found between the BAHA coupled with the Snap abutment and the preoperative testing conditions with the BAHA positioned at the headband or the testband. These differences were also reflected in the speech audiometry with a difference in speech reception threshold of approximately 4 to 7 dB. The investigators concluded that significant differences in the audiometric thresholds and the speech understanding scores were found between the preoperative test conditions and the final postoperative result.

Clinical trials for bone-anchored hearing aids without osseointegration including the use of a headband are limited for the following reason: the headband is used in small, young children with congenital aural atresia who cannot be fitted for standard hearing aids placed in the ear canal and who, for technical reasons, cannot have a bone-anchored hearing aid implanted. Since this condition is rare, a statistically significant study population would be exceedingly difficult to achieve.

**Intraoral Bone Conduction Hearing Aid**

Murray et al. (2011a) determined the safety and benefit of the SoundBite Hearing System, an intraoral bone conduction device for single-sided deafness (SSD). The study was a multi-center, controlled, nonrandomized, prospective unblinded study of 22 SSD patients wearing the device over a 6-month period. There were no related adverse events or changes in the medical or audiologic findings at the end of the trial compared with the beginning. There were no significant changes in the mean aided thresholds or the mean dental measures at 3 or 6 months compared with prettrial measures. The mean Abbreviated Profile of Hearing Aid Benefit scores showed improvement for the Background Noise, Reverberation, and Ease of Communication subscales and the Global scale at 3 and 6 months. The results of the SSD questionnaire indicated that the vast majority (>90%) of the subjects reported satisfaction and improvement in a variety of areas after wearing the device. The authors concluded that the SoundBite system is safe and continues to provide substantial benefit for SSD patients with continual daily use over a 6-month period. The significance of this study is limited by non-randomization, small sample size, and short follow-up period.

Miller et al. (2011) evaluated 22 SSD patients wearing an intra-oral hearing device who were enrolled in a prospective study for six months. Differences between the device-anchoring teeth and the equivalent contralateral non-device teeth were evaluated with four dental parameters using a paired t-test. Compared to the non-device teeth, the hearing device teeth did not exhibit any increased recession, increased pocket depth, increased root resorption, or increased alveolar bone loss. There was no association between the amount of alveolar support and hearing thresholds. The authors concluded that the intra-oral component of the hearing device did not adversely affect the dental structures of the subjects in this trial. The significance of this study is limited by a small sample size and short follow-up period.

Murray et al. (2011b) determined the efficacy, benefit, and safety of a new in-the-mouth bone conduction device (SoundBite Hearing System) for single-sided deafness (SSD) in a multicenter, controlled, nonrandomized prospective unblinded study of 28 SSD patients wearing the device. The Hearing in Noise Test scores improved an average of -2.5 dB after 30 days, compared with wearing no device. The Abbreviated Profile of Hearing Aid Benefit scores improved for all subjects for the Global and Background Noise subscales and for all but 1 subject for the Reverberation and Ease of Communication subscales. There were no medical, audiologic, or dental complications. According to the authors, the SoundBite system is safe and effective and provides substantial benefit for SSD patients with continual daily use over a 30-day period. Limitations of the study include non-randomization and inadequate follow-up time.
Popelka et al. (2010) evaluated if the SoundBite intraoral bone-conduction device has advantages over existing bone-conduction devices for reducing the auditory deficits associated with single-sided deafness (SSD). According to the authors, auditory performance in a small sample of SSD subjects indicated a substantial advantage compared with not wearing the device. The authors stated that future studies need to involve performance measures on SSD patients wearing the device for longer periods.

There is insufficient evidence to conclude that intraoral bone conduction hearing aids are beneficial for patients with hearing loss. The quality of the studies was low due to small study populations, short follow-up, and lack of randomization and appropriate control groups. Clinical trials comparing the outcomes of this device with other conventional hearing aids are lacking. Additional studies with long-term

**Professional Societies**
The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) considers the implantation of a percutaneous bone conduction hearing device, a semi-implantable hearing device, or a totally implantable hearing device to be acceptable surgical procedures for the relief of hearing impairment when performed by a qualified otolaryngologist-head and neck surgeon. Use of any device must adhere to the restrictions and guidelines specified by the FDA (AAO-HNS, 2009).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

**Semi-Implantable Electromagnetic Hearing Aid**
Two semi-implantable, electromagnetic, direct drive, middle ear hearing devices have received FDA approval. Vibrant® received FDA approval on August 31, 2000. According to the FDA, Vibrant Soundbridge is utilized for providing a useful level of sound perception to individuals via mechanical stimulation of the ossicles.

According to the professional labeling information on the FDA Web site, the selection criteria for Vibrant Soundbridge includes the following:

- Adults aged 18 or older
- Audiologic results consistent with moderate to severe sensorineural hearing loss
- Pure tone air conduction threshold levels within the following ranges: 500 Hz: 30-65 dB; 1000 Hz: 40-75 dB; 1500 Hz: 45-80 dB; 2000 Hz: 45-80 dB; 3000 Hz: 50-85 dB; 4000 Hz: 50-85 dB
- Word recognition score of 50% or better using recorded material
- Normal middle ear anatomy
- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device.

See the following Web site for more information:
[http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm089772.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm089772.htm)  (Accessed June 2012)

The other semi-implantable electromagnetic device is the Maxum System (PMA number, 9010023), which was approved by the FDA on September 7, 2001. This device was manufactured initially under the name Soundtec Direct System (PMA number, 9010023) by Ototronix, and has been manufactured under the name Maxum System since October 8, 2009, by Ototronix LLC. See the following Web site for more information:

According to the FDA, regardless of the name or manufacturer changes, both systems have consistently been indicated for treating moderate to severe sensorineural hearing loss (SNHL) in
adults (age ≥ 18 years) who desire an alternative to acoustic hearing aids, particularly those who have had prior experience with appropriately fitted acoustic hearing aids.

**Bone-Anchored Hearing Aid with Osseointegration**

*BAHA® Devices and other Bone-Anchored Hearing Aid Devices:*

In 1995, the FDA granted approval to Nobelpharm USA to market the Branemark Bone-Anchored Hearing Aid (BAHA) System. Note: since 1995, the device was acquired by Entific Medical Systems and then in 2005, it was acquired by Cochlear Corp. The device was approved for adult patients with malformations of the external ear, chronically draining ear, a pure tone threshold hearing loss of ≥ 45 decibels (dB), and/or inability or unwillingness to use an air conduction hearing aid. In 1999, this approval was extended for use in children 5 years of age or older. See the following Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf/K984162.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/K984162.pdf). Accessed June 2012.

The indications for the BAHA System have broadened since the initial FDA approval. In 2001, the BAHA system was approved for bilateral implantation. For bilateral implantation of bone-anchored hearing aids, patients must have moderate to severe bilateral symmetrical conductive hearing loss (defined as less than 10 dB difference in average or less than 15 dB in bone-conduction thresholds at 500, 1000, 2000, and 4000 Hz) or mixed hearing loss with average bone conduction thresholds better than 45 dB hearing loss. See the following Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf/k011438.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/k011438.pdf). Accessed June 2012.

In 2002, the BAHA system was approved for single sided deafness (SSD) or unilateral sensorineural hearing loss. According to the FDA, the use of BAHA hearing aid for SSD is intended to improve speech recognition. The SSD indication for BAHA hearing aid is intended for patients who suffer from unilateral sensorineural deafness on one ear while the other ear has normal hearing. Normal hearing is defined as PTA AC threshold equal to or better than 20dB measured at 0.5, 1.2, and 3 kHz. BAHA for SSD is also indicated for patients who are indicated for an AC Contra-lateral Routing Of Signals (CROS) but who for some reason cannot or will not use an AC CROS. See the following Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf2/k021837.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf2/k021837.pdf). Accessed June 2012.

BAHA System models include the following:


In November 2008, the OBC Bone Anchored Hearing Aid System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices. See the following Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf8/k082108.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/k082108.pdf) Accessed June 2012.

In July 2009, the Pronto Pro Bone Anchored System (Oticon Medical) was cleared by the FDA for marketing through the 510(k) process. See the following Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090996.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090996.pdf) Accessed June 2012.

Other bone anchored hearing aid devices have also been approved by the FDA. See the following Web site for more information (Use product code LXB or MAH): [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). Accessed June 2012.
Non-Implantable Bone-Anchored Hearing Aids

In 2000, the FDA approved the BAHA headband. The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/K002913.pdf. Accessed June 2012.

In 2009, the FDA approved the Cochlear Baha BP100 sound processor that is intended for use with the Baha auditory osseointegrated implant (for children aged 5 and older, or adults), or with the Baha Headband or Baha Softband (no age limitations) for the following patients and indications:

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting of the BP100 is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. single-sided deafness or "SSD"). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to .20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.


In May 2010, the FDA approved the Otomag Alpha 1(S) Sound Processor for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 100dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear who for some reason will not or cannot use an AC CR05. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB H-IL (measured at 0.5, 1, 2 and 3 kHz).


Totally Implanted Hearing System

On March 17, 2010 the FDA announced approval of the Esteem® prosthetic hearing restoration device, the first completely implanted hearing system used to treat moderate-to-severe sensorineural hearing loss. See the following Web site for more information:
According to the FDA, The esteem is intended to alleviate hearing loss in patients by replicating the ossicular chain and providing additional gain. The esteem is indicated for patients with hearing loss that meet the following criteria:

- 18 years of age or older;
- stable bilateral sensorineural hearing loss;
- moderate to severe sensorineural hearing loss defined by pure tone average (PTA);
- unaided speech discrimination test score greater than or equal to 40%;
- normally functioning eustachian tube;
- normal middle ear anatomy;
- normal tympanic membrane;
- adequate space for esteem implant determined via a high resolution computed tomography (CT) scan; and
- minimum 30 days of experience with appropriately fit hearing aids.

See the following Web sites for more information:


**Partially Implantable Bone Conduction Hearing Aid with Magnetic Coupling**

The partially implanted Otomag Alpha 1 (M) Bone Conduction Hearing System received FDA approval in May 2011 as a bone conduction hearing aid. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102199.pdf Accessed June 2012.

**Additional Products**

Bone anchored hearing aid devices include but are not limited to the following: BAHA® HC200, HC220, HC300, Classic 300, Compact, Cordelle, Divino™ Hearing Aid (Ear Technology Corp.) Implantable electromagnetic hearing aids include Vibrant® Soundbridge® (VIBRANT MED-EL Hearing Technology GMBH, Innsbruck, Austria)

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### CPT™ Code | Description |
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69717 | Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy |
69718 | Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy |
69799 | Unlisted procedure, middle ear |

**HCPCS Code**

### HCPCS Code | Description |
--- | --- |
L8690 | Auditory osseointegrated device, includes all internal and external components |
L8691 | Auditory osseointegrated device, external sound processor, replacement |
L8692 | Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment |
L8693 | Auditory osseointegrated device abutment, any length, replacement only |
S2230 | Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear |
V5095 | Semi-implantable middle ear hearing prosthesis |

**REFERENCES**

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by the UnitedHealthcare Medical Technology Assessment Committee. [2010T0396K]


Hayes, Inc. Brief. Esteem Totally Implantable Hearing System (Envoy Medical Corp.) for Treatment of Moderate to Severe Sensorineural Hearing Loss in Adults. February 2012.


Verstraeten N, Zarowski AJ, Somers T, Riff D, Offeciers EF. Comparison of the audiological results obtained with the bone-anchored hearing aid attached to the headband, the testband, and to the "snap" abutment. Otol Neurotol. 2009 Jan;30(1):70-5.


**POLICY HISTORY/REVISION INFORMATION**

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<th>Date</th>
<th>Action/Description</th>
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<td>11/01/2013</td>
<td>• Removed list of applicable ICD-9 and ICD-10 diagnosis codes (previously included for informational purposes only); no change to coverage rationale&lt;br&gt;• Archived previous policy version ENT 007.12 T2</td>
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