

POLICY TITLE	SEMI-IMPLANTABLE AND FULLY IMPLANTABLE MIDDLE EAR HEARING AIDS
POLICY NUMBER	MP- 1.130

Original Issue Date (Created):	October 25, 2011
Most Recent Review Date (Revised):	September 24, 2013
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I. POLICY

Semi-implantable and fully implantable middle ear hearing aids are considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-Reference

MP-1.019 Implantable Bone Conduction and Bone-Anchored Hearing Prosthetic Devices

MP-1.023 Cochlear Implants

MP-1.085 Auditory Brain Stem Implants

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] Indemnity

[N] PPO

[N] SpecialCare

[N] HMO

[N] POS

[N] SeniorBlue HMO

[Y] FEP PPO*

[N] SeniorBlue PPO

* Refer to FEP Medical Policy Manual MP-7.01.84 Semi-Implantable and Fully Implantable Middle Ear Hearing Aid. The FEP Medical Policy manual can be found at: <http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980>.

III. DESCRIPTION/BACKGROUND

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

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Hearing loss is described as conductive, sensorineural, or mixed, and can be unilateral or bilateral. Normal hearing is the detection of sound at or below 20 dB. The American Speech Language- Hearing Association (ASLHA) has defined the degree of hearing loss based on pure-tone average (PTA) detection thresholds as mild (20 to 40 dB), moderate (40 to 60 dB), severe (60 to 80 dB), and profound (greater or equal to 80 dB).

Sound amplification through the use of an air-conduction (AC) hearing aid can provide benefit to patients 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.

Patients with moderate to severe sensorineural hearing loss are typically fitted with external acoustic hearing aids. However, these hearing aids may not be acceptable to patients, either due to issues related to anatomic fit, sound quality, or personal preference. Conductive hearing loss may be treated with acoustic or bone conduction hearing aids when surgical or medical interventions are unable to correct hearing loss. Semi-implantable and fully implantable middle ear hearing aids have been developed as an alternative to external acoustic hearing aids

Regulatory Status

Two semi-implantable devices received approval by the U.S. Food and Drug Administration (FDA), the Vibrant® Soundbridge™, approved in August 2000, and the Soundtec® Direct System™, approved in September 2001. The Soundtec was subsequently discontinued by the manufacturer. The FDA-approved labeling for both devices states that they are "... intended for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid." The devices consist of 3 components: a magnetic component that is implanted onto the ossicles of the middle ear, a receiver, and a sound processor. The Soundbridge device is implanted subcutaneously behind the ear while the processor is worn externally on the scalp over the receiver unit and held in place by a magnet. The Soundtec device was placed in the user's ear canal while the processor would rest over the external ear. In general, the sound processor receives and amplifies the sound vibrations and transforms the sound pressure into electrical signals that are received by the receiver unit. The receiver unit then transduces these electrical signals into electromagnetic energy and creates an alternating electromagnetic field with the magnetic component implanted on the ossicles of the middle ear. This electromagnetic field results in attractive and repulsive forces on the magnetic implant, causing vibration of the bones of the middle ear similar to normal hearing.

The Esteem® Implantable Hearing System by Envoy Medical Corporation is a fully implantable middle ear hearing aid that received FDA approval in March 2010. The FDA-approved labeling for the Esteem hearing implant indicates it is "intended to alleviate hearing loss...in adults 18 years of age or older with stable bilateral sensorineural hearing loss." This device uses piezoelectric transduction as opposed to the electromagnetic transduction used in the semi-implantable devices. A piezoelectric transducer, the sensor, is placed at the head of the

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incus and converts mechanical vibrations detected from the tympanic membrane to electrical signals that are delivered to the stapes by another piezoelectric transducer, the driver.

IV. RATIONALE

The most recent literature search for this policy was performed through February 11, 2013.

Externally worn acoustic hearing aids are widely accepted devices for patients with hearing loss. Therefore this policy of semi-implantable and fully implantable hearing aids will focus on various audiologic measures achieved with an externally worn hearing aid compared to a semi- or fully implantable hearing aid in the same patient. Another outcome that has been studied is patient preference for an implantable device compared to an externally worn device. However, it must be determined to what extent patient preference is based on convenience, which is not an element of medical necessity, compared to preference based on improved hearing. Only minimal safety concerns are related to external hearing aids. In contrast, an implantable hearing aid requires a surgical procedure for implantation. Potential risks cited for semi-implantable middle ear hearing aids include decrease in residual hearing in the implanted ear, infection in the ear and adjacent structures, and general anesthesia. 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 improvement in audiologic outcomes associated with an implantable hearing aid must be balanced against the potential risks inherent in a surgical procedure.

Semi-Implantable Hearing Aids

Clinical trials for U.S Food and Drug Administration (FDA) Approval of Semi-Implantable Middle Ear Hearing Aids

FDA approval of the Soundbridge and Soundtec devices was based in part on clinical trials of 53 and 108 respective patients who had moderate to severe sensorineural hearing loss and who were dissatisfied with their existing external acoustic hearing aid. Results of these trials are available in the FDA Summaries of Safety and Effectiveness. (1, 2) The results of the Soundbridge and Soundtec trials have also been reported in the peer-reviewed published literature. (3) The principal outcome measures were the audiologic outcomes before (with the hearing aid in use) and after the implant. The following audiologic outcomes were reported:

Functional Gain

Functional gain is defined as the difference in sound field threshold (measured in decibels, dBs) and is an indicator of functional benefit from an amplification device. For the Soundbridge device, the improvement in functional gain was 14.1 dB, while for the Soundtec device, it was 7.9 dB; both are considered a modest improvement. The clinical significance of

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this improvement is difficult to determine. For example, this level of improvement may be more clinically significant in patients with moderate hearing loss, for whom a 14-dB improvement in threshold might move them into the normal range for the spoken voice.

Speech Recognition

Speech recognition is assessed using Speech Perception in Noise (SPIN) test and the Northwestern University-6 test (NU-6), which consists of a 50-item word list. For the Soundbridge device, no significant difference in word recognition was found in quiet or noisy conditions between the implant and acoustic hearing aid. For the Soundtec device, a statistically significant improvement was noted in results of the NU-6 and SPIN test at 52 weeks compared to an optimally fitted hearing aid. However, only 12 patients had completed the 52-week follow-up.

Patient Assessments

Patient self-evaluation was performed in a variety of ways. The Profile of Hearing Aid Performance (PHAP) consists of 7 subscales that measure several dimensions of hearing aid effectiveness, such as ease of communications, reverberation, distortion of sound, etc. The Hearing Device Satisfaction Scale (HDSS) was developed by Symphonix, the manufacturer. This scale evaluated hearing aid and Soundbridge use and the general satisfaction level. The number of subjects who reported improvement was significant across all 7 subscales of the PHAP. The largest improvements in the Soundbridge compared to the acoustic hearing aid were reported for reverberation, reduced cues, and background noise. Based on the HDSS, 94% reported improved overall sound quality for the Soundbridge. For the Soundtec device, patient satisfaction was based on the Hough Ear Institute Profile. This profile assesses patient preference, acoustic feedback, perception of speech quality, occlusion, and tinnitus. At 20 weeks post-implant, improvements in all of the parameters were clinically significant. For example, 89% of patients preferred the implantable hearing aid to the acoustic hearing aid, although this result is not surprising since only patients who were dissatisfied with their previous acoustic hearing participated in the trial. A total of 67% of patients reported feedback with their previous acoustic hearing aid, while only 9% reported feedback with the implanted device. The clinical significance of the improvement in functional gain and speech perception is uncertain, although there appears to be a clear patient preference for the implantable devices.(4)

Safety

Minimal safety issues appeared associated with either device. In the Soundbridge device, the most common complication was a fullness sensation in 18, which did not resolve in 13. Altered taste sensation was reported in 7 and transient pain in 13. Two patients reported a reduction in residual hearing. In the Soundtec device, the most common complication included device noise, ear pain, ear irritation, and processor failure. These complications resolved in almost all patients; no patient requested removal of the device. However, risks can only be adequately evaluated in broader populations over time.

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Additional Studies for Semi-Implantable Middle Ear Hearing Aids

A systematic review by Tysome and colleagues, in 2010, examined 17 studies (out of 644 articles identified) comparing hearing improvements in middle-ear hearing implants to conventional hearing aids. (5) The authors noted high-quality, long-term studies are not available. However, 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.

Results of a 2002 Phase II trial of the SoundTec system were published, (6) but this publication lags behind the data included in the FDA summary of safety and effectiveness. (2) An additional case series of 64 SoundTec implants was published in 2005. (7) The average functional gain varied with frequency, with the lowest functional gain in the lower speech frequencies (7.9 dB), with increasing functional gain at higher frequencies, ranging up to 27 dB at the highest frequency of 6,000 Hz. The functional gain of 7.9 dB at the speech frequencies is similar to that reported in the FDA summary of safety and effectiveness, while it is markedly higher in the higher frequencies. The cause of this marked discrepancy is not apparent. In this case series, the authors also reported that a high percentage of patients were hearing the magnet move inside the ear, resulting in a refinement of the surgical procedure to better stabilize the magnet.

Truy and colleagues reported on the Vibrant Soundbridge versus conventional hearing aids in 6 patients with sensorineural high-frequency hearing loss and found some improvements in hearing with the Soundbridge system. (8) Additional small studies report early results of coupling the Vibrant Soundbridge system to the cochlea round window for patients with mixed hearing loss (9, 10) and for conductive and mixed hearing loss, (11) sloping high-frequency sensorineural hearing loss, (12) and aural atresia. (13-15) However, these studies are small (ranging from 5 to 25 patients) and should be considered preliminary. Additionally, the Vibrant Soundbridge is not approved by the FDA for use in conductive and mixed hearing loss.

Studies from European centers reported early results of combining the Soundbridge system with stapes surgery for otosclerosis. For example, in 2007, Venail et al. report on results of using this combined approach in 4 patients. (16) These results should be considered preliminary. In addition, in the United States, this use would not be consistent with the FDA-approved labeling.

Zwartenkot et al. reported on a transcanal approach to implantation of the Vibrant Soundbridge in 13 adults with chronic external otitis and sensorineural hearing loss. (17) 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 cases. After repair of the wire extrusions, 3 cases experienced repeated extrusion. Therefore,

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the transcanal approach is not recommended for Soundbridge system implantation in patients with external otitis.

Fully Implantable Hearing Aid

Clinical trials for FDA Approval of a Fully-Implantable Middle Ear Hearing Aid

The U.S. Food and Drug Administration (FDA) approval of the Esteem device was based on a prospective, nonrandomized, multicenter clinical trial of 60 patients with moderate-to-severe sensorineural hearing loss designed to assess the safety and efficacy of the Esteem Hearing System. (18) Patients served as both control and test subject as hearing was tested before (with and without hearing assistive devices) and after Esteem implantation. Results of this trial are available in the FDA Summaries of Safety and Effectiveness. In this study, patients experienced an improvement of 11.4 dB in mean speech reception threshold at 10 months' post-implantation when compared to pre-implant aided speech reception thresholds. Overall, word recognition scores were equal to or better than pre-implant aided scores in 93% of patients. The other 7% experienced lower word recognition scores than pre-implant scores using hearing aids.

Ninety-six adverse device events occurred and were considered to be not serious. Taste disturbance was reported to be the most common side effect reported at 42% followed by tinnitus in 18% and facial paralysis/paresis in 7% of patients. Severe adverse device effects were experienced in 6 of the 57 patients implanted and included 3 revisions due to fibrous adhesions which limited implant benefit, 1 incision breakdown which required explantation, and 1 wound infection and 1 severe pain and facial weakness case, both of which resolved when treated with medication. Overall, 70% of all adverse events resolved at 10-month follow-up. However, the serious adverse event of facial paralysis/palsy had not resolved in 2 patients.

Kraus and colleagues reported on 1-year follow-up of the Esteem study in 2011. (19) Results were similar to those reported to the FDA at 10 months' follow-up. Speech reception thresholds improved $11.8 \text{ dB} \pm 1.8 \text{ dB}$ from a mean pre-implant aided score of 41.2 dB to 29.4 dB ($p \leq 0.001$). Word recognition scores improved by a mean of $19.8 \% \pm 4.3$ from pre-implant aided scores. The authors reported 133 adverse events including 3 cases of facial paresis resolved with medication.

- Additional Studies for a Fully-Implantable Middle Ear Hearing Aid

Reports in the literature on use of a totally implantable hearing device are few. Barbara and colleagues reported on use of the 2010 FDA-approved totally implantable Esteem device in 21 patients with severe bilateral sensorineural hearing loss. (20) The authors reported mean hearing threshold levels improved overall from 70 to 48 dB. In another article reporting on 6 patients implanted with the Esteem device, Barbara et al. found the device improved hearing

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when assessed during postoperative fittings. (21) Chen and colleagues reported on the Phase I results of the Envoy Totally Implantable Hearing System in 7 patients followed up at 2 and 4 months after activation of the device. (22) Improvements in word recognition and communication in background noise over best-fit hearing aid usage was perceived in 5 patients. Patient outcomes in functional gain and speech reception thresholds were comparable to best-fit hearing aid usage.

Several recent small case series (23-26) provide insufficient evidence to alter the conclusions of the current policy (see the Literature Review for this Policy update). A systematic review of literature on the Esteem device included 7 articles that met inclusion criteria. (27) Complication rates with the Esteem device most commonly included taste disturbance. Clinically significant improvements in functional gain, speech reception, and speech recognition over the unaided condition were reported. In studies comparing the Esteem implant to conventional hearing aids, findings were mixed. Improvements in functional gain were similar to those for hearing aids; however, speech recognition and quality of life were greater with the implants. This limited evidence suggests these devices may offer a relatively safe and effective treatment option, particularly for patients who are medically unable to wear conventional hearing aids. However, the included studies were primarily quasi-experimental, pre/post comparisons of aided and unaided conditions. Furthermore, because of heterogeneity across studies, meta-analysis was not performed, and comparisons were made by structured review.

The publications cited herein report on short-term results from a small number of patients and overall, demonstrate insufficient evidence to support the medical necessity of available fully implantable hearing aid device(s).

Ongoing Clinical Trials

Only one active study on middle ear hearing aids was identified at online site ClinicalTrials.gov. The Envoy Medical Corporation continues to study the Esteem Totally Implantable Hearing System in the 57 patients from the premarket approval (PMA) clinical trial reported to the FDA. The study will further evaluate the long-term (5 years) hearing outcomes of speech reception threshold and word recognition score along with adverse events (NCT01092910). This trial is expected to be completed in 2015. Per agreement with the FDA, Envoy will also conduct a new prospective, multi-center, non-randomized, audiologist-blinded, 1-arm observational study of 120 patients. This study, which has not yet begun, will address safety at 1 month by evaluating the incidence of facial pareses/paralyses and effectiveness at 5 years by evaluating speech reception threshold and word recognition score.

Summary

The limited data suggest semi-implantable middle ear hearing aids may provide marginal improvement in hearing compared to conventional external acoustic hearing aids in patients with sensorineural hearing loss. However, given the safety and effectiveness of external acoustic hearing aids and the increased risks inherent in a surgical procedure, the semi-

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implantable device must be associated with clinically significant improvement in various hearing parameters compared to external hearing aids. While safety concerns appear to be minimal, only a limited number of patients have been included in the clinical trials, and few have completed more than 1 year of follow-up. Given the small number of patients and the limited safety data, risks cannot be adequately evaluated and compared with the marginal improvement in hearing. Studies on patients with conductive or mixed hearing loss and aural atresia, when external acoustic hearing aids are not an option, have also demonstrated hearing benefit with semi-implantable middle ear hearing aids. However, these studies are few and limited to small numbers of patients. Therefore, conclusions on the safety and effectiveness of semi-implantable hearing aids in these patients cannot be made, and further study with longer term follow-up is needed. Comparisons of semi-implantable devices with alternative hearing devices such as implantable bone-conduction and bone-anchored hearing aids would also be useful to determine device appropriateness for patients who are unable to use external air-conduction hearing aids. Due to the lack of adequate safety data in broader patient populations over a longer period of time, semi-implantable middle ear hearing aids are investigational for all indications. The impact on net health outcome cannot be determined.

The available evidence for use of fully implantable middle ear hearing aids is insufficient to demonstrate long-term improvement in net health outcome. Concerns exist about adverse events with these devices. Therefore, fully implantable middle ear hearing aids are considered investigational.

Practice Guidelines and Position Statements

No national guidelines on the use of semi- or fully-implantable hearing aids were identified on the National Guidelines Clearinghouse online at Guidelines.gov.

V. DEFINITIONS

HEARING AID is any device that does not produce as its output an electrical signal that directly stimulates the auditory nerve. Examples of hearing aids are devices that produce air-conducted sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window. Devices such as cochlear implants, which produce as their output an electrical signal that directly stimulates the auditory nerve, are not considered to be hearing aids.

OSSICLE refers to any small bone, especially one of the three bones of the ear.

SENSORINEURAL HEARING LOSS refers to a form of hearing loss in which sound is conducted normally through the external and middle ear but a defect in the inner ear or auditory nerve results in hearing loss. The loss is measured in decibels and may be described as mild, moderate, severe, or profound.

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VI. BENEFIT VARIATIONS

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VII. DISCLAIMER

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IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Semi-implantable and fully implantable middle ear hearing aids are considered **investigational**; therefore the following code is investigational when billed for semi-implantable and fully implantable middle ear hearing aids and not covered:

CPT Codes®							
69799							

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Investigational; therefore not covered:

HCPSC Code	Description
S2230	IMPLANTATION OF MAGNETIC COMPONENT OF SEMI-IMPLANTABLE HEARING DEVICE ON OSSICLES IN MIDDLE EAR

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V5095	SEMI-IMPLANTABLE MIDDLE EAR HEARING PROSTHESIS
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X. POLICY HISTORY

MP-1.130	CAC 10/25/11 New policy. Semi-implantable middle ear hearing aid criteria previously were in MP-1.019 Implantable Bone Conduction and Bone-Anchored Hearing Prosthetic Devices. For this review, the policies were separated. Fully implantable hearing aids were added to the policy and the title changed to reflect addition, Both fully implantable and semi-implantable hearing aids are considered investigational.
	CAC 10/30/12 Consensus. No change to policy statements which match BCBSA. References updated. With this review title changed to Semi-Implantable and Fully Implantable Middle Ear Hearing Aids (formerly Semi-Implantable and Fully Implantable Middle Ear Hearing Aid for Moderately to Severe Sensorineural Hearing Loss) . codes reviewed 11/1/12 klr
	7/25/13 Admin coding review complete--rsb
	CAC 9/24/13 Consensus. No change to policy statements. Rationale section added. References updated.

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