



**BlueCross BlueShield  
of Alabama**

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**Name of Policy:**

**Semi-Implantable/Implantable Middle Ear Hearing Aids**

Policy #: 169

Latest Review Date: March 2014

Category: Surgery

Policy Grade: B

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**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

## **Description of Procedure or Service:**

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.

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 (ASHA) 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 than 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.

The most common type of hearing aid for moderate to severe sensorineural hearing loss is an external acoustic hearing aid, which is placed in the external ear canal and functions to amplify sound. However, this type of hearing aid may not be acceptable to some patients, due 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.

Two semi-implantable middle ear implants received FDA approval: The Vibrant<sup>®</sup> Soundbridge<sup>™</sup> (VBS), approved August 2000, and the SOUNDTEC<sup>®</sup> Direct System, approved September 2001. The Soundtec was discontinued by the manufacturer Ottronix, LLC in 2004 due to performance issues; it was re-released in 2009 under the name Maxum™ System. The FDA label 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 three components: a magnetic component that is implanted onto the ossicles of the middle ear, a receiver, and a sound processor. The Soundbridge device is implanted subcutaneously behind the ear while the processor is worn externally on the scalp over the receiver unit and held in place by a magnet. The Soundtec (Maxum System) device is placed in the user's ear canal while the processor rests over the external ear. In general, the sound processor receives and amplifies the sound vibrations and transforms the sound pressure into electrical signals that are received by the receiver unit. The receiver unit then transduces these electrical signals into electromagnetic energy and creates an alternating electromagnetic field with the magnetic component (floating mass transducer) implanted on the ossicles of the middle ear. This electromagnetic field results in attractive and repulsive forces on the magnetic implant, causing vibration of the bones of the middle ear similar to normal hearing.

The Esteem<sup>®</sup> 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 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.

### **Policy:**

**Semi-implantable middle ear hearing aid** for moderate to severe sensorineural hearing loss **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is not a covered benefit.

### **Effective for dates of service on or after January 25, 2011:**

**Implantable middle ear hearing aid (e.g. Esteem® implantable hearing system)** for stable bilateral sensorineural hearing loss **meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when **all** of the following criteria are met:

- 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 and tympanic membrane
- Adequate space for implantation
- Minimum 30 days of experience with appropriately fit hearing aids

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

### **Key Points:**

Externally worn acoustic hearing aids are widely accepted devices for patients hearing loss. Therefore, the assessment of semi-implantable and fully implantable hearing aids will focus on various audiology 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 related to external hearing aids. In contrast, a semi-implantable hearing aid does require 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 a semi-implantable hearing aid must be balanced against the potential risks inherent in a surgical procedure.

### **Semi-Implantable Hearing Aids**

#### *Clinical trials for US 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. The results of the Soundbridge and Soundtec trials have also been reported in the peer-reviewed published literature. 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 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 seven 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 seven 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.

### 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 seven 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.

### *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. 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, but this publication lags behind the data included in the FDA summary of safety and effectiveness. An additional case series of 64 SoundTec implants was published in 2005. 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. Additional small studies report early results of coupling the Vibrant Soundbridge system to the cochlea round window for patients with mixed hearing loss and for conductive and mixed hearing loss, sloping high-frequency sensorineural hearing loss, and aural atresia. Marino et al. reported results of round window-coupled Vibrant Soundbridge implantation in 18 subjects with conductive or mixed hearing loss who could not derive benefit from conventional hearing aids due to chronic otitis externa, blind sac closure, pain with hearing aid mold use, and severe to profound mixed hearing loss. Speech recognition

in quiet settings with the Soundbridge device was similar to conventional hearing aids, while speech recognition in noisy settings was improved with the Soundbridge device. However, these studies are small (ranging from 5 to 25 patients) and report only short-term follow up and should be considered preliminary.

Colletti et al reported longer term outcomes for a case series of 50 patients aged two months to 74 years with severe conductive or mixed hearing loss due to ossicular chain defects who underwent coupling of the Vibrant Soundbridge system to the round window. Although subjects demonstrated improvements in speech perception and pure-tone audiometry (in adults) and auditory brainstem response thresholds (in infants), the study's implications for practice are limited due to a large number of subjects with missing data (17/50) and a lack of comparison to other therapies.

Vyskocil et al retrospectively compared hearing outcomes for nine patients who received the Vibrant Soundbridge device with a modified coupling method (attachment of the floating mass transducer to the stapes/oval window, round window, or a drilled promontory bone) to nine patients who received standard vibroplasty with the Vibrant Soundbridge device among patients with mixed and conductive hearing loss. The authors reported similar hearing improvements in both groups. Overall, several studies have evaluated alternative coupling methods for the Vibrant Soundbridge for patients with conductive or mixed hearing loss, but these studies are small, generally have not included a control group (e.g., bone-anchored hearing aids or surgical reconstruction of the external ear, as appropriate for the underlying condition), and include a heterogeneous set of underlying hearing problems, so provide relatively limited evidence for its use in this setting. 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 four patients. 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. 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 five cases. After repair of the wire extrusions, three cases experienced repeated extrusion. Therefore, the transcanal approach is not recommended for Soundbridge system implantation in patients with external otitis.

Subsequently, Zwartenkot et al reported longer term (mean 7.5 years) follow up outcomes for 33 patients with moderate-to-severe sensorineural hearing loss with severe chronic otitis externa who were implanted with the Vibrant Soundbridge system or the Otologics MET system, a middle ear implant system not available in the United States. Compared with baseline, at long-term follow up subjects had statistically significant improvements in total scores on the Abbreviated Profile of Hearing Aid Benefit, but the magnitude of the difference was small (63.3 at baseline vs. 55.6 at follow up,  $P<0.05$ ). Eighty-five percent of subjects reported wearing the device more than four hours a day. This study provides some evidence that middle ear implantable hearing aids have some benefit over the longer term for patients with chronic otitis

externa; however, this study is limited by self-reported outcome measures, the fact that approximately 20% of respondents received a device that is not available in the U.S., and that fifteen subjects who were considered potentially eligible were either excluded due to insufficient follow up duration or complications from the device or failed to respond to the questionnaire.

### **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. 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 ten 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 six of the 57 patients implanted and included three revisions due to fibrous adhesions which limited implant benefit, one incision breakdown which required explantation, and one wound infection and one severe pain and facial weakness case, both of which resolved when treated with medication. Overall, 70% of all adverse events resolved at ten-month follow-up. However, the serious adverse event of facial paralysis/palsy had not resolved in two patients.

Kraus and colleagues reported on one-year follow-up of the Esteem study in 2011. Results were similar to those reported to the FDA at ten months' follow-up. Speech reception thresholds improved 11.8 dB + 1.8 dB from a mean pre-implant aided score of 41.2 dB to 29.4 dB (p<0.001). Word recognition scores improved by a mean of 19.8 % + 4.3 from pre-implant aided scores. The authors reported 133 adverse events including three 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. The authors reported mean hearing threshold levels improved overall from 70 to 48 dB. In another article reporting on six patients implanted with the Esteem device, Barbara et al. found the device improved hearing when assessed during postoperative fittings. Chen and colleagues reported on the Phase I results of the Envoy Totally Implantable Hearing System in seven patients followed up at two and four months after activation of the device. Improvements in word recognition and communication in background noise over best-fit hearing aid usage was perceived in five patients. Patient outcomes in functional gain and speech reception thresholds were comparable to best-fit hearing aid usage.

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.

### **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-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 one 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 available evidence for use of fully implantable middle ear hearing aids is limited and preliminary. This limited evidence suggests these devices may offer a relatively safe and effective treatment option. Therefore, limited coverage for implantable middle ear hearing aids with strict criteria noted below will be provided for stable bilateral sensorineural hearing loss:

- 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 and tympanic membrane
- Adequate space for implantation
- Minimum 30 days of experience with appropriately fit hearing aids

### **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 at Guidelines.gov.

## **Key Words:**

Sensorineural hearing loss, semi-implantable middle ear hearing aid, acoustic hearing aid, Vibrant® Soundbridge™, SOUNDTEC® Direct System, Esteem, Esteem implantable hearing system

## **Approved by Governing Bodies:**

Vibrant® Soundbridge™ (VB) (Symphonix Devices, Inc.) approved by FDA, August 2000.  
SOUNDTEC® Direct System (Soundtec, Inc.), approved by FDA, September 2001.

Esteem Hearing Implant (Envoy Medical) FDA approved March 2010.

## **Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will review for medical necessity

## **Current Coding:**

CPT codes: **69799** Unlisted procedure, middle ear

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## **Policy History:**

Medical Policy Group, June 2004 (1)

Medical Policy Administration Committee, July 2004

Available for comment July 12-August 25, 2004

Medical Policy Group, June 2006 (1)

Medical Policy Group, June 2008 (1)

Medical Policy Group, June 2010 (1): Key points updated

Medical Policy Group, December 2010 (1) Description, Key Points and reference list updated, added coverage for the Implantable middle ear device

Medical Policy Administration Committee, December 2010

Available for comment December 10, 2010 through January 24, 2011

Medical Policy Group, April 2011 (3): Added FDA approval for Esteem under Approved by Governing Bodies; Updated Codes

Medical Policy Group, September 2012: Updated Description, Key Points and References

Medical Policy Panel, March 2014

Medical Policy Group, March 2014 (3): 2013 & 2014 Updates to Description, Key Points & References; no change in policy statement

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*