BlueCross BlueShield of Louisiana

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Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425
Original Effective Date: 09/17/2014
Current Effective Date: 09/17/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers semi-implantable and fully implantable middle ear hearing aids to be **investigational.***

Background/Overview

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 decibels (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 (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥80 dB).

Sound amplification through the use of an air-conduction 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.

For reference, the package insert of the Vibrant Soundbridge device describes the following patient selection criteria:

- Pure-tone air-conduction threshold levels shall fall at or within:

Limits	**Frequency, kHz**					
	0.5	**1**	**1.5**	**2**	**3**	**4**

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Lower limit	30	40	45	45	50	50
Upper limit	65	75	80	80	85	85

- 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

The Maxum System is indicated 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. Before receiving the device, it is recommended that patients have experience with appropriately fitted hearing aids.

The Esteem device is indicated for patients with hearing loss meeting the following criteria:

- 18 years of age or older
- Stable bilateral sensorineural hearing loss
- Moderate (hearing loss between 40 and 70 dB) to severe (hearing loss between 71 and 90 dB) sensorineural hearing loss defined by 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 high resolution CT [computed tomography] scan
- Minimum 30 days of experience with appropriately fit hearing aids.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Two semi-implantable devices received approval by the U.S. FDA, the Vibrant®‡ Soundbridge™‡, approved in August 2000, and the Soundtec®‡ Direct System™‡, approved in September 2001. The Soundtec was discontinued by the manufacturer Ototronix, LLC in 2004 due to performance issues; it was rereleased in 2009 under the name Maxum™‡ System. The FDA labeling approved 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 (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®‡ 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.

Centers for Medicare and Medicaid Services (CMS)
No national coverage determination has been published. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage. However, devices which produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery. The benefit manual does not specifically refer to semi- or fully implantable hearing aids as prosthetic devices.

Rationale/Source

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 focuses on various audiologic measures achieved with an externally worn hearing aid compared with 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 with 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 with 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 FDA-Approval of Semi-Implantable Middle Ear Hearing Aids

The 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 dB) 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 with 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 with 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 postimplant, 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 because 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 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.

Additional Studies for Semi-Implantable Middle Ear Hearing Aids

A systematic review by Tysome et al, in 2010, examined 17 studies (of 644 articles identified) comparing hearing improvements in middle-ear hearing implants with 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 with 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 2 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 6000 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 et al 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 (range, 5-25 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 2 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 with other therapies.

Vyskocil et al retrospectively compared hearing outcomes for 9 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) with 9 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 (eg, 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 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. 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 5 cases. After repair of the wire extrusions, 3 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 Virbant 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 4 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 15 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

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 10 months' postimplantation when compared with preimplant aided speech reception thresholds. Overall, word recognition scores were equal

to or better than preimplant aided scores in 93% of patients. The other 7% experienced lower word recognition scores than preimplant 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 et al reported on 1-year follow-up of the Esteem study in 2011. Results were similar to those reported to the FDA at 10 months' follow-up. Speech reception thresholds improved 11.8±1.8 dB from a mean preimplant aided score of 41.2 dB to 29.4 dB ($p \leq 0.001$). Word recognition scores improved by a mean of 19.8%±4.3% from preimplant 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 et al 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 6 patients implanted with the Esteem device, Barbara et al found the device improved hearing when assessed during postoperative fittings. Chen et al reported on the phase 1 results of the Envoy Totally Implantable Hearing System in 7 patients followed up at 2 and 4 months after activation of the device. 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 with best-fit hearing aid usage.

A systematic review of literature on the Esteem device included 7 articles that met inclusion criteria. 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 with 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.

Overall, studies related to fully implantable middle ear hearing aid devices report on short-term results from a small number of patients and demonstrate insufficient evidence to support the medical necessity of their use.

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Ongoing Clinical Trials
A search was conducted at online site ClinicalTrials.gov on February 18, 2014 to identify studies evaluating partially- or totally-implantable middle ear implants for hearing loss. One active study was identified:

- Esteem Totally Implantable Hearing System (NCT0192910) – This is a study sponsored by the Envoy Medical Corporation to follow up the Esteem Totally Implantable Hearing System in the 57 patients from the premarket approval clinical trial reported to FDA to further evaluate the long-term (5 years) hearing outcomes of speech reception threshold and word recognition score along with adverse events. This trial is expected to be completed in 2015.

Summary
The limited data suggest semi-implantable middle ear hearing aids may provide marginal improvement in hearing compared with 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 with 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 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.

Medicare National Coverage
No national coverage determination has been published. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage. However, devices which produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery. The benefit manual does not specifically refer to semi- or fully implantable hearing aids as prosthetic devices.

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	69799
HCPCS	S2230, V5095
ICD-9 Diagnosis	389.10, 389.11, 389.12, 389.14, 389.18
ICD-9 Procedure	20.99

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09/17/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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