Policy Number	**SUR714.008**
Policy Effective Date	**10/15/2023**
Policy End Date	**12/31/2024**

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Table of Contents

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Arkansas, § 23-79-1502 relating to craniofacial anomaly corrective surgery, requires coverage and benefits for reconstructive surgery and related medical care for a person of any age who is diagnosed as having a craniofacial anomaly if the surgery and treatment are medically necessary to improve a functional impairment that results from the craniofacial anomaly. Coverage shall also be required, annually, for Sclera contact lenses, including coatings, office visits, an ocular impression of each eye, and any additional tests or procedures that are medically necessary for a craniofacial patient. Coverage shall also be required every two [2] years, two [2] hearing aids and two [2] hearing aid molds for each ear; this includes behind the ear, in the ear, wearable bone conductions, surgically implanted bone conduction services, and cochlear implants. Medical care coverage required includes coverage for reconstructive surgery, dental care, and vision care. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

Coverage

NOTE: Benefit/contractual restrictions or exclusions for hearing aids would apply to this technology.

Semi-Implantable
Semi-implantable middle ear hearing aids (e.g., Vibrant Soundbridge and Maxum™ System) **may be considered medically necessary** for patients with moderate to severe sensorineural bilateral hearing loss who are unable to use a standard hearing aid device because of at least one of the following anatomic criteria or medical conditions:

- Congenital or surgically-induced malformations (e.g., atresia) of the external ear canal or middle ear; OR
- Chronic external otitis or otitis media; OR
- Tumors of the external canal and/or tympanic cavity; OR
- Dermatitis of the external canal.

Semi-implantable middle ear hearing aids for all other indications **are considered experimental, investigational and/or unproven.**

Upgrades of existing components **may be considered medically necessary** only for patients in whom response to existing components is inadequate to the point of interfering with the activities of daily living, or when components are no longer functional.

Fully Implantable
Fully implantable middle ear hearing aids (e.g., Esteem®) **are considered experimental, investigational and/or unproven** for all indications.

Policy Guidelines

None.

Description

Hearing Loss
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 has defined the degree of hearing loss based on pure-tone average detection thresholds as mild (20-40 dB), moderate (40-60 dB), severe (60-80 dB), and profound (≥80 dB).

Treatment
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 the

signal 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. Conductive hearing loss may be treated with acoustic or bone-conduction hearing aids when surgical or medical interventions are unable to correct hearing loss. However, these hearing aids may not be acceptable to patients, either due to issues related to anatomic fit, sound quality, or personal preference. In some cases, external acoustic hearing aids cannot be used due to external ear pathologies (e.g., otitis externa).

Semi- and Fully Implantable Middle Ear Hearing Aids
Semi-implantable and fully implantable middle ear hearing aids are alternatives to external acoustic hearing aids. Two semi-implantable devices have the U.S. Food and Drug Administration (FDA) approval: the Vibrant Soundbridge and the Maxum System. The devices consist of three components: a magnet 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 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 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.

One fully implantable middle ear hearing aid has FDA approval: the Esteem Implantable Hearing System. Similar to the semi-implantable devices, the fully implantable device consists of a sensor, a sound processor, and a driver connected to the ossicles. The sensor detects vibrations of the tympanic membrane and transforms the vibrations into electrical signals that are processed by the sound processor. The processor transduces these signals via 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 into electrical signals delivered to the stapes by another piezoelectric transducer (the driver).

Regulatory Status
Two semi-implantable devices were approved by the FDA through the premarket approval process: the Vibrant® Soundbridge™ (MED-EL Corp.) in 2000 and the Direct System™ (Soundtec) in 2001. The Soundtec System was discontinued by the manufacturer Ototronix in 2004 due to performance issues; it was re-released in 2009 under the name Maxum™ System. Approved FDA labeling for both states that the devices 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." FDA product code: MPV.

In 2010, the Esteem® Implantable Hearing System (Envoy Medical, St. Paul, MN), a fully implantable middle ear hearing aid, was approved by the FDA through the premarket approval process. 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." FDA product code: OAF.

Another fully implantable middle ear hearing aid, the Carina® Fully Implantable Hearing Device, is in development (Otologics, now Cochlear), but does not have FDA approval. Phase 1 and 2 trials have been conducted in the United States under investigational device exemptions. (1)

Rationale

This medical policy review was originally created in October 2004 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through November 15, 2021.

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Semi-Implantable Middle Ear Hearing Aids

Clinical Context and Therapy Purpose

The purpose of semi-implantable middle ear hearing aids for the treatment of hearing loss is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does the use of semi-implantable middle ear hearing aids for the treatment of hearing loss improve net health outcomes?

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is patients with hearing loss who are unable to use external hearing aids or who are not candidates for cochlear implants.

Interventions
The therapy being considered is the use of semi-implantable middle ear hearing aids as treatment of hearing loss.

Comparators
The following therapies and practices are currently being used to make decisions about treatment with external hearing aids. Externally worn acoustic hearing aids are widely accepted devices for patients with hearing loss. Therefore, this review of semi-implantable and fully implantable hearing aids focuses on comparisons of various audiologic outcome measures between an externally worn hearing aid and a semi- or fully implantable hearing aid in the same patient. Studies of semi- and fully implantable middle ear hearing aids have frequently reported a 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 compared with improved hearing.

Outcomes
The general outcomes of interest include symptoms, functional outcomes, QOL, and treatment-related morbidity. Only minimal safety concerns are related to external hearing aids. In contrast, an implantable hearing aid requires a surgical procedure. Potential risks cited for semi-implantable middle ear hearing aids include a decrease in residual hearing in the implanted ear, infection in the ear and adjacent structures, and risks associated with 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. Patients with hearing loss who receive a semi-implantable middle ear hearing aid will require acute post-procedure follow-up for at least 6-12 months to ascertain the impact on hearing.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Trials Supporting Regulatory Approval of Semi-Implantable Hearing Aids for Sensorineural Hearing Loss

The U.S. Food and Drug Administration (FDA) approvals of the Soundbridge and Soundtec (now marketed as the Maxum System) devices were based in part on clinical trials of 53 and 108 patients, respectively, who had a moderate-to-severe sensorineural hearing loss and who were dissatisfied with their existing external acoustic hearing aids. Results of these trials are available in the FDA Summary of Safety and Effectiveness. (2, 3) The results of the Soundbridge and Soundtec trials have also been reported in the peer-reviewed published literature. (4) The principal outcome measures were audiologic before (with the hearing aid in use) and after the implant. The following audiologic outcomes were reported: functional gain, speech recognition, patient assessments, and safety. Each is discussed below.

Functional Gain

Functional gain is defined as the difference in sound-field thresholds (measured in decibels [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; for the Soundtec device, it was 7.9 dB. Both gains were considered modest improvements. The clinical significance of the improvements 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 the Speech Perception in Noise test and the Northwestern University 6 test, 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 the acoustic hearing aid. For the Soundtec device, a statistically significant improvement was noted in Northwestern University 6 and Speech Perception in Noise test results 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 measure consists of seven subscales that assess several dimensions of hearing aid effectiveness, such as ease of communications, reverberation, and distortion of sounds. The Hearing Device Satisfaction Scale was developed by Symphonix, the manufacturer. This scale evaluates hearing aid and Soundbridge use and general satisfaction level. The number of subjects who reported improvements was significant across all seven Profile of Hearing Aid Performance subscales. The largest improvements in the Soundbridge compared with the acoustic hearing aid were reported for the reverberation, reduced cues, and background noise

subscales. Based on Hearing Device Satisfaction Scale scores, 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, the perception of speech quality, occlusion, and tinnitus. At 20 weeks postimplant, improvements in all 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 improvements in functional gain and speech perception is uncertain, although there appeared to be a clear patient preference for the implantable devices. (5)

Safety

Minimal safety issues were associated with either device. For 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 Hearing Aids for Sensorineural Hearing Loss

Systematic Reviews

Systematic reviews of semi-implantable hearing aids for sensorineural hearing loss are described below and in Tables 1 through 3.

Bruchhage et al. (2017) reported on a systematic review of the Vibrant Soundbridge for the treatment of sensorineural hearing loss. (6) Reviewers included comparative and noncomparative studies with 5 or more patients published through 2012, which resulted in 24 studies reported in 22 articles, a conference proceeding, and an FDA report, with a total of 679 subjects (range, 5-125 subjects) in the articles and 1100 in the conference proceeding. In total, 14 studies had level 4, and 9 studies had level 3 evidence. Regarding adverse events, reviewers concluded: “Adverse events occurring with VSB [Vibrant Soundbridge] implantation were in general low, presenting mainly aural fullness (27%) or taste disturbances (9%).” Studies varied in the audiologic outcomes, but all reported functional gains and improvements in speech perception in noise and quiet.

Ernst et al. (2016) reported on a systematic review of the Vibrant Soundbridge for the treatment of mixed or conductive hearing loss. (7) Thirty-four studies (total n=294 patients) were selected: 19 studies (n=294 patients) reporting on Vibrant Soundbridge outcomes; 13 studies (n=666 patients) reporting on bone-conduction hearing implants; and 4 studies (n=43 patients) reporting on middle ear surgery plus hearing aid outcomes. No studies directly compared methods. The functional gains with the Vibrant Soundbridge at 3 months ranged

from 12.5 to 43.4 dB hearing loss, averaging 29.6 dB. Significant improvements in speech recognition occurred, although methods of measuring speech differed across studies.

A systematic review by Kahue et al. (2014) evaluated studies of 3 FDA-approved middle ear hearing aids, the Vibrant Soundbridge, the Maxum System, and the Envoy Esteem (discussed in the following section on conductive and mixed hearing loss). (8) Studies eligible for inclusion addressed purely sensorineural hearing loss, had at least five implanted ears, and reported comparative data between preoperative and postoperative audiometric performance. Seventeen studies (503 ears) were included, 3 of which evaluated the Soundtec System (now Maxum System, 190 ears), 5 of which evaluated the Envoy Esteem (102 ears), and 9 of which evaluated the Vibrant Soundbridge (211 ears). The 14 studies comparing preoperative *unaided* hearing with postoperative middle ear implant-assisted hearing demonstrated improvement in hearing thresholds (weight mean, 25.2 dB improvement; range, 15.6-48.2 dB). However, for the 12 studies that compared the *best-aided* preoperative condition with the postoperative assisted performance, the functional gain was smaller (weighted mean, 8.1 dB improvement; range, -9.4 to 13 dB), and only 1 reported statistically significant improvements over optimally fitting hearing aids. Similarly, studies that compared the preoperative *unaided* condition with the postoperative middle ear implant-assisted hearing demonstrated improvements in speech recognition (weighted average, 44.8% improvement; range, 8.8%-64.0%), while speech recognition was similar for the middle ear implant-assisted condition and best-aided preoperative condition. Ten studies reported on safety outcomes, including 5 studies that focused on partially implantable middle ear implants; in those studies, 15 (11.4%) of 132 implants malfunctioned and were explanted.

Butler et al. (2013) published the results of a systematic review of comparative studies evaluating partially and fully implantable middle ear hearing devices for sensorineural hearing loss. (9) Reviewers included 14 studies, none of which was an RCT, 13 of which evaluated a semi-implantable device (most often the Vibrant Soundbridge), with 1 study evaluating the Envoy fully implantable system. Outcomes reported across studies were heterogeneous. Among the nine studies reporting on the primary outcome (functional hearing gain), one found that middle ear implants were statistically significantly better than hearing aids, one found that hearing aids were statistically significantly better than implants, and six found that middle ear implants were better than hearing aids, but without a clinically significant difference. Reviewers concluded that middle ear implants were at least as effective as hearing aids in improving hearing outcomes.

Table 1. Comparison of Studies included in Systematic Reviews

Study	Bruchhage et al. (2017) (6)	Ernst et al. (2016) (7)	Kahue et al. (2014) (8)	Butler et al. (2013) (9)
Fisch et al. (2001)	●			
Fraysse et al. (2001)	●		●	●
Labassi and Beliaeff (2005)	●			

Mosnier et al. (2008)	●			
Luetje et al. (2010)	●		●	●
Schmuziger et al. (2006)	●			
Sterkers et al. (2003)	●			
Frenzel et al. (2009)		●		
Baumgartner et al. (2010)		●		
Boheim et al. (2012)		●		
Verhaert et al. (2013)		●		
Silverstein et al. (2005)			●	
Gerard et al. (2012)			●	
Kraus et al. (2011)			●	
Memari et al. (2011)			●	
Monini et al. (2012)			●	
Pok et al. (2010)			●	
Rameh et al. (2010)			●	
Sziklai et al. (2011)			●	
Truy et al. (2008)			●	
Todt et al. (2005)			●	●
Chen et al. (2004)			●	●
Uziel et al. (2008)			●	●
Todt et al. (2002)			●	●
Hough et al. (2001)			●	●
Snik & Cremers et al. (2000)			●	●
Roland et al. (2001)			●	●
Thill et al. (2002)				●
Verhaegen et al. (2008)				●
Jenkins et al. (2007)				●
Jenkins et al. (2004)				●
Matthews et al. (2002)				●

Table 2. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration

Bruchhage et al. (2017) (6)	2001-2010	7	Patients with Vibrant Soundbridge for the treatment of sensorineural hearing loss who failed all other conservative medical, surgical, pharmaceutical treatment and could not benefit from conventional hearing aids	679 (5-125) in articles and 1100 in the conference proceeding	Comparative and non-comparative studies	2-24 months
Ernst et al. (2016) (7)	2006-2014	34 (Vibrant Soundbridge, n=19; bone-conduction hearing implants, n=13; middle ear surgery plus hearing aid, n=4)	Patients with Vibrant Soundbridge for the treatment of mixed or conductive hearing loss	1003 (NR)	16 single cohort before-after studies, 2 concurrent cohort studies, and 1 non-randomized clinical trial	12-65 months
Kahue et al. (2014) (8)	2001-2012	19 (Maxum System, n=3; Envoy Esteem, n=5; Vibrant Soundbridge, n=9)	Patients with purely sensorineural hearing loss treated with MEI	503 (6-103)	7 prospective, 10 retrospective comparative studies	2-143 months
Butler et al. (2013) (9)	2001-2008	14	Patients with purely sensorineural hearing loss treated with MEI	617 (6-103)	Non-randomized, uncontrolled comparative studies	2-18 months

MEI: middle ear implant; NR: not reported.

Table 3. Systematic Review Results

Study	Speech recognition	Functional gain	Adverse events
Bruchhage et al. (2017) (6)			
Total N		370	3562
Effects		Range, 12.5-33 dB	Any adverse event: 39%
Range of N		NR	77-1172
Ernst et al. (2016) (7)			
Total N	Italian disyllabic score: 94 Freiburger monosyllable score: 90	NR	
Effects	Italian disyllabic score: pooled mean difference, 71.46 (95% CI, 56.63-86.28) Freiburger monosyllable score: pooled mean difference, 69.03 (95% CI, 58.83-79.22)	29.6 dB (range, 12.5-43.4)	
I^2 (p)	Italian disyllabic score: 0% (0.62) Freiburger monosyllable score: 90% (<0.001)		
Range of N	Italian disyllabic score: 7-16 Freiburger monosyllable score: 5-19	NR (6 studies)	
Kahue et al. (2014) (8)			
Effects	Unaided: weighted average, 44.8% improvement; range, 8.8%-64.0% Best-aided: weighted average, 9.2%	Unaided: weighted mean, 25.2 dB improvement; range, 15.6 and 48.2 dB Best-aided: weighted mean, 8.1 dB	15/132 MEIs required explantation due to malfunction

	improvement; range reported between 9.8% and +22.6%	improvement; range, -9.4 to 13 dB	
Range of N	Unaided: NR (4 studies) Best-aided: NR (5 studies)	Unaided: NR (9 studies) Best-aided: NR (6 studies)	
Butler et al. (2013) (9)			
Effects		MEI: range, 17-31.2 dB Hearing aid: range, 14.6-20 dB	
Range of N		NR (6 studies)	

CI: confidence interval; MEI: middle ear implant; NR: not reported.

Nonrandomized Studies

Rahne et al. (2020) performed a retrospective cohort analysis of 21 patients with sensorineural or mixed hearing loss implanted with the Vibrant Soundbridge (Tables 4 and 5). (10) The mean word recognition score improved from baseline by 57.8%. Results were not reported by each type of hearing loss. There were no significant differences between coupler types (round window membrane, long process, or incus body and short process of the incus).

Seebacher et al. (2020) performed a retrospective cohort study in 21 patients with sensorineural, conductive, or mixed hearing loss implanted with unilateral Vibrant Soundbridge implantation to analyze patient-reported quality of life outcomes after bilateral implantation (Tables 4 and 5). (11) Measures used included the Speech, Spatial, and Qualities of Hearing Scale (SSQ12-B, with 12 items scored from -5 to +5 to rate benefit in listening situations) and the Glasgow Benefit Inventory (GBI, with 18 items scored on a 5-point Likert scale normalized from -100 to +100 measuring generic quality of life in otolaryngological interventions). Improvements in SSQ12-B and GBI scores were statistically significant following bilateral implantation. Results were not by each type of hearing loss.

Table 4. Summary of Key Observational Study Characteristics

Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
Rahne et al. (2020) (10)	Retrospective cohort study	Germany, Poland, Spain, Italy	2014-2016	Patients with sensorineural or mixed hearing loss	Vibrant Soundbridge	12 months
Seebacher et al.	Retrospective cohort study	Austria	2018-2020	Patients with sensorineural,	Bilateral Vibrant	NR

(2020) (11)				conductive, or mixed hearing loss and unilateral Vibrant Soundbridge implantation	Soundbridge implantation	

NR: not reported.

Table 5. Summary of Key Observational Study Results

Study	Speech Recognition	Self-Reported Hearing Benefit
Rahne et al. (2020) (10)	N=21	
Preoperative	Mean WRS: 14.8% (SD, 21.9)	
Postoperative	Mean WRS: 72.6% (SD, 18.6)	
Seebacher et al. (2020) (11)		N=21
SSQ12-B		+2.73 (p<0.001)
GBI		+23.6 (p<0.001)

GBI: Glasgow Benefit Inventory; SD: standard deviation; SSQ12-B: Speech, Spatial, and Qualities of Hearing Scale; WRS: word recognition score.

Case Series

Select case series are described below and in Tables 6 and 7.

One series with long-term follow-up (mean, 7.5 years) focused on middle ear implants in patients who failed external hearing aids. Zwartenkot et al. (2013) described outcomes for 33 patients with moderate-to-severe sensorineural hearing loss who had severe chronic otitis externa and were implanted with the Vibrant Soundbridge system or the Otologics MET system, a middle ear implant system not available in the United States. (12) Compared with baseline, at long-term follow-up, subjects had statistically significant improvements in total scores on the Abbreviated Profile of Hearing Aid Benefit (63.3 at baseline vs 55.6 at follow-up, p<0.05). Eighty-five percent of subjects reported wearing the device for more than four hours a day.

Results of a 2002, phase 2 trial of the Soundtec System were published, (13) but this publication lagged behind the data included in the FDA Summary of Safety and Effectiveness. (3) An additional case series of 64 Soundtec implants was published in 2005. (14) The average functional gain varied with frequency, with the lowest functional gain in lower speech frequencies (7.9 dB) and 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 lower speech frequencies was similar to that reported in the FDA Summary of Safety and Effectiveness, while the 27 dB gain at higher frequencies was higher than reported in the FDA summary. The cause of this marked discrepancy is not apparent. In this case series, the authors also reported that a high

percentage of patients heard the magnet move inside the ear, resulting in a refinement of the surgical procedure to better stabilize the magnet.

Table 6. Summary of Key Case Series Characteristics

Study	Country	Participants	Follow-Up
Zwartenkot et al. (2013) (12)	Netherlands	N=33 patients with moderate-to-severe sensorineural hearing loss who had severe chronic otitis externa	Mean, 7.5 years
Silverstein et al. (2005) (14)	United States	N=64 patients with bilateral moderately severe sensorineural hearing loss	1 month

Table 7. Summary of Key Case Series Results

Study	Treatment	Speech Perception	Patient Satisfaction	Functional Gain
Zwartenkot et al. (2013) (12)	Vibrant Soundbridge system or the Otologics MET system		Significant improvements occurred between baseline and follow-up in APHAB Global score (63.3 at baseline vs 55.6 at follow-up, $p<0.05$) and NCIQ Total score (49.7 at baseline vs 61.1 at follow-up, $p<0.01$)	
Silverstein et al. (2005) (14)	Soundtec implant			The average functional gain (frequencies 250–6,000 Hz) was 26 dB, ranging from 7 dB at 250 Hz to 32 dB at 2,000 Hz.

Off-Label Use of Semi-Implantable Hearing Aids for Conductive or Mixed Hearing Loss

While the Vibrant Soundbridge received FDA approval for sensorineural hearing loss, several studies have evaluated it for off-label use in conductive or mixed hearing loss with the coupling of the device's floating mass transducer to the middle ear's round or oval window, instead of the incus, bypassing the middle ear structures.

Ernst et al. (2016) published the results of a systematic review of studies reporting on the Vibrant Soundbridge for conductive or mixed hearing loss. (7) Reviewers included studies that compared the Vibrant Soundbridge with no intervention, bone-conduction hearing implants (the Bonebridge implant, a fully implantable bone-conduction hearing implant that uses a bone-conduction floating mass transducer to transmit signals to the cochlea), and middle ear surgery plus hearing aids. Nineteen articles (total n=294 individuals) comparing the Vibrant Soundbridge with no intervention were identified, including 16 cohort before-after studies, 2 concurrent cohort studies, and a nonrandomized clinical trial. No improvements in bone-conduction thresholds were reported. Studies reported a variety of methods for determining air-conduction thresholds, precluding pooling of results, but hearing thresholds improved substantially in all studies. For speech recognition, a meta-analysis of results for change in score on the Italian disyllabic word lists and Freiburg Monosyllabic Word Test was conducted, with pooled mean improvements of 71.5% and 69%, respectively. No studies were identified that compared the Vibrant Soundbridge with the Bonebridge. Four studies (n=43 individuals) compared the Vibrant Soundbridge with middle ear surgery plus hearing aids. Improvements in air-conduction thresholds and functional gain were generally better with the Vibrant Soundbridge, but studies were mixed regarding whether the Vibrant Soundbridge was associated with greater improvements in speech recognition.

Since the publication of the Ernst systematic review, Frenzel et al. (2015), using a single-subject repeated-measures design, reported on outcomes from a prospective study of the Vibrant Soundbridge among 19 patients ages 5 to 17 with conductive or mixed hearing loss. (15) Younger children (age range, 5-9 years) improved monosyllable word recognition score from a mean of 28.9% preoperatively to 80% at the initial fitting (p=0.005) and to 95.5% at 6-month testing (p=0.001). Older children (age range, 10-17 years) improved on word recognition score from a mean of 18.5% preoperatively to 80.5% at the initial fitting (p=0.001) and to 89% at 6 months postoperative (p=0.001). Improvements in speech recognition threshold and signal-to-noise ratio were also reported.

Earlier series have reported within-subject comparisons of hearing outcomes before and after hearing aid amplification and patient-reported outcomes with implantable hearing devices. One study focused on implantable hearing aid outcomes in patients who failed external hearing aids. Marino et al. (2013), which was included in the Ernst systematic review, 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. (16) 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.

In the largest case series identified, Colletti et al. (2013) reported on longer-term outcomes for 50 patients (age range, 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. (17) 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).

Other series, with sample sizes ranging from 9 to 25 subjects, have reported on hearing outcomes with the Vibrant Soundbridge, using various coupling methods. (18-30) These studies generally reported improvements in hearing measures and good patient satisfaction relative to external hearing aids. Among the group, Skarzynski et al. (2014) reported up to 3 years of follow-up in adults who received the Vibrant Soundbridge. (20) Over the three years, bone-conduction hearing thresholds were stable. There were no cases of device extrusion or significant complications; 19% of patients had tinnitus, which resolved within 2 months postoperatively.

Section Summary: Semi-Implantable Middle Ear Hearing Aids

The evidence for the use of semi-implantable middle ear hearing aids includes the clinical trials that supported the FDA approval of the Vibrant Soundbridge and the Soundtec devices, along with a large number of observational series. Most available studies have addressed the Vibrant Soundbridge device. For the use of semi-implantable middle ear hearing aids in patients with sensorineural hearing loss, the body of evidence has suggested these devices may be associated with a modest improvement in functional gain compared with external hearing aids, with similar improvements in speech recognition scores.

Case series reporting on off-label alternative coupling methods for the Vibrant Soundbridge for patients with conductive or mixed hearing loss have also reported improved hearing thresholds and word recognition.

Although the devices appear to have a good safety profile in the short-term, given existing alternatives, studies in larger series reporting on longer-term durability, safety, and efficacy are needed to permit conclusions about the devices' risks and benefits relative to external hearing aids.

Fully Implantable Middle Ear Hearing Aid for Sensorineural Hearing Loss

Clinical Context and Therapy Purpose

The purpose of fully implantable middle ear hearing aids for the treatment of hearing loss is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does the use of fully implantable middle ear hearing aids for the treatment of hearing loss improve net health outcomes?

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is patients with hearing loss who are unable to use external hearing aids or who are not candidates for cochlear implants.

Interventions
The therapy being considered is the use of fully implantable middle ear hearing aids as treatment of hearing loss.

Comparators
The following therapies and practices are currently being used to make decisions about treatment with external hearing aids. Externally worn acoustic hearing aids are widely accepted devices for patients with hearing loss. Therefore, this review of semi-implantable and fully implantable hearing aids focuses on comparisons of various audiologic outcome measures between an externally worn hearing aid and a semi- or fully implantable hearing aid in the same patient. Studies of semi- and fully implantable middle ear hearing aids have frequently reported a 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 compared with improved hearing.

Outcomes
The general outcomes of interest include symptoms, functional outcomes, QOL, and treatment-related morbidity. Only minimal safety concerns are related to external hearing aids. In contrast, an implantable hearing aid requires a surgical procedure. Potential risks cited for semi-implantable middle ear hearing aids include a decrease in residual hearing in the implanted ear, infection in the ear and adjacent structures, and risks associated with 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. Patients with hearing loss who receive a fully implantable middle ear hearing aid will require acute post-procedure follow-up for at least 6-12 months to ascertain the impact on hearing.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Trials Supporting Regulatory Approval of a Fully Implantable Hearing Aid

The FDA approval of the Esteem Hearing System was based on a prospective, nonrandomized, multicenter trial of 60 patients with moderate-to-severe sensorineural hearing loss designed to assess safety and efficacy. (31) Patients served as both control and test subjects as hearing was tested before (with and without hearing assistive devices) and after Esteem implantation. Results of this trial are available in the FDA Summary of Safety and Effectiveness. In this trial, patients experienced an improvement of 11.4 dB in mean speech reception threshold at 10 months postimplantation 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 postimplant.

Ninety-six adverse device events occurred and were not considered serious. Taste disturbance was the most common, reported at 42%, followed by tinnitus at 18% and facial paralysis/paresis at 7% of patients. Severe adverse device events were experienced by 6 of the 57 patients implanted and included 3 revisions due to fibrous adhesions that limited implant benefit, 1 incision breakdown that required explantation, and 1 wound infection and 1 case of severe pain and facial weakness, both of which resolved 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 two patients by the time of reporting.

Kraus et al. (2011) reported on 1-year follow-up of the Esteem study. (32) Results were similar to those reported to the FDA at ten-month follow-up. Mean speech reception thresholds improved 11.8 dB from a preimplant-aided score of 41.2 to 29.4 dB ($p \leq 0.001$). Mean word recognition scores improved by 19.8% from preimplant-aided scores. The authors reported 133 adverse events, including 3 cases of facial paresis that resolved with medication.

Additional Studies of a Fully Implantable Hearing Aid for Sensorineural Hearing Loss

Systematic Reviews

Pulcherio et al. (2014) reported on results of a systematic review of studies of 2 fully implantable middle ear hearing devices: the FDA-approved Esteem device and the Carina device. (33) Reviewers included 22 studies with a total of 244 patients, 134 implanted with the Esteem device and 110 with the Carina device. No RCTs were identified, and most studies were small, with the largest series including 57 subjects and 12 series including fewer than 10 subjects. All studies showed improvements in sound-field threshold from unaided to aided conditions with the fully implantable device, but the magnitudes of the improvements varied.

A systematic review of the literature by Klein et al. (2012) assessing the Esteem device included seven articles that met inclusion criteria. (34) Complications 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 QOL were greater with the implants. This limited evidence suggested these

devices might offer a relatively safe and effective treatment option, particularly for patients 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, a meta-analysis was not performed.

Case Series
Several representative case series provide additional data. Barbara et al. (2011) reported on the use of the Esteem device in 21 patients with severe bilateral sensorineural hearing loss. (35) 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. (2009) found the device improved hearing when assessed during postoperative fittings. (36) Chen et al. (2004) reported on phase 1 results for the Envoy Totally Implantable Hearing System in 7 patients followed at 2 and 4 months after device activation. (37) Improvements in word recognition and communication in background noise over best-fit hearing aid usage were reported by five patients. Patient outcomes in functional gain and speech reception thresholds were comparable with best-fit hearing aid usage.

Other small case series have also reported on hearing outcomes associated with the Esteem device, which were generally on the order of that seen with best-aided hearing. (38-41) More recently, Savas et al. (2016) reported on comparisons between air and bone-conduction hearing thresholds with best-aided hearing and hearing with the Carina fully implantable middle ear implant in a study with 9 adults with bilateral mixed hearing loss. (42)

In addition, a 2014 case series, published since the Pulcherio et al. (2014) and the Klein et al. (2012) systematic reviews, has reported high rates of facial nerve palsies (10/34 [29.4%] subjects) after implantation of the Esteem device, which persisted to the 3-month follow-up in 6 (17.6%) of 34 subjects. (43)

Section Summary: Fully Implantable Middle Ear Hearing Aids for Sensorineural Hearing Loss
The evidence on the use of fully implantable middle ear hearing aids includes the clinical trial supporting the FDA approval of the Esteem device, along with systematic reviews and observational series reporting short-term results. These studies have generally found improved hearing over unaided hearing, with modest improvements over hearing with best-fit aids.

Adverse Events for Semi- and Fully Implantable Aids
Zwartenkot et al. (2016) reported on a single-center retrospective cohort study summarizing the long-term complications of active middle ear implants in 94 patients. (44) Subjects were implanted with a total of 128 devices, including 92 Vibrant Soundbridge devices, 32 Otologics middle ear transducer devices, and 4 Otologics fully implantable ossicular devices (the Carina device). During an average follow-up of 4.4 years (range, 1-15 years), 28 patients were considered lost to follow-up, including 7 deaths, 12 explantations, and 6 missed follow-up appointments. During follow-up, 36 devices were replaced or explanted, most commonly soon after implantation, with 36% replaced within 18 months of implantation. Twenty (21%) patients had a complication during follow-up, of which 17 were considered serious.

Summary of Evidence

For individuals who have hearing loss who receive semi-implantable or fully implantable middle ear hearing aids, the evidence includes the single-arm interventional studies submitted to the U.S. Food and Drug Administration (FDA), systematic reviews and a number of observational series. Relevant outcomes include symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. The data have suggested implantable middle ear hearing aids may provide some 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- and fully 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 with a median duration of follow-up less than five years. Studies of patients with conductive or mixed hearing loss and aural atresia, when external acoustic hearing aids are not an option, have also demonstrated a hearing benefit with semi-implantable middle ear hearing aids. However, these studies are few and limited to small numbers of patients.

Practice Guidelines and Position Statements

The American Academy of Otolaryngology - Head and Neck Surgery (2016) issued a position statement on implantable hearing devices which stated (45):

"The American Academy of Otolaryngology - Head and Neck Surgery considers active middle ear implants as appropriate treatment for adults with moderate to severe hearing loss when performed by a qualified otolaryngologist-head and neck surgeon. Based on available literature demonstrating that clinically selected adults receive substantial benefit, implanting active middle ear implants is accepted medical practice in those who benefit from amplification but are unable to benefit from the amplification provided by conventional hearing aids. Use of active middle ear implants, which have been Food and Drug Administration (FDA)-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency…."

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in January 2022 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	69799
HCPCS Codes	S2230, V5095

*Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.

References

1. Uhler K, Anderson MC, Jenkins HA. Long-term outcome data in patients following one year's use of a fully implantable active middle ear implant. Audiol Neurootol. 2016; 21(2):105-112. PMID 27031589
2. Food and Drug Administration. Vibrant Soundbridge. Summary of safety and effectiveness. (2000). Available at: <http://www.accessdata.fda.gov> (accessed November 1, 2022).
3. Food and Drug Administration. Soundtec Direct System. Summary of safety and effectiveness (2001). Available at: <http://www.accessdata.fda.gov> (accessed November 1, 2022).
4. Luetje CM, Brackman D, Balkany TJ, et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: A prospective controlled multicenter study. Otolaryngol Head Neck Surg. Feb 2002; 126(2):97-107. PMID 11870337
5. Sterkers O, Boucarra D, Labassi S, et al. A middle ear implant, the Symphonix Vibrant Soundbridge: Retrospective study of the first 125 patients implanted in France. Otol Neurotol. May 2003; 24(3):427-436. PMID 12806295
6. Bruchhage KL, Leichtle A, Schonweiler R, et al. Systematic review to evaluate the safety, efficacy and economical outcomes of the Vibrant Soundbridge for the treatment of sensorineural hearing loss. Eur Arch Otorhinolaryngol. Apr 2017; 274(4):1797-1806. PMID 27796557
7. Ernst A, Todt I, Wagner J. Safety and effectiveness of the Vibrant Soundbridge in treating conductive and mixed hearing loss: A systematic review. Laryngoscope. Jun 2016; 126(6):1451-1457. PMID 26468033
8. Kahue CN, Carlson ML, Daugherty JA, et al. Middle ear implants for rehabilitation of sensorineural hearing loss: a systematic review of FDA approved devices. Otol Neurotol. Aug 2014; 35(7):1228-1237. PMID 24643033
9. Butler CL, Thavaneswaran P, Lee IH. Efficacy of the active middle-ear implant in patients with sensorineural hearing loss. J Laryngol Otol. Jul 2013; 127 Suppl 2:S8-S16. PMID 23790515
10. Rahne T, Skarzynski PH, Hagen R, et al. A retrospective European multicenter analysis of the functional outcomes after active middle ear implant surgery using the third generation vibroplasty couplers. Eur Arch Otorhinolaryngol. Jan 2021; 278(1):67-75. PMID 32451668
11. Seebacher J, Weichbold V, Schorg P, et al. Subjective hearing impression and quality of life in patients with bilateral active middle ear implants. Otol Neurotol. Jul 2020; 41(6):e641-e647. PMID 32569243

12. Zwartenkot JW, Hashemi J, Cremers CW, et al. Active middle ear implantation for patients with sensorineural hearing loss and external otitis: Long-term outcome in patient satisfaction. Otol Neurotol. Jul 2013; 34(5):855-861. PMID 23739560
13. Hough JV, Matthews P, Wood MW, et al. Middle ear electromagnetic semi-implantable hearing device: Results of the phase II SOUNDTEC Direct System clinical trial. Otol Neurotol. Nov 2002; 23(6):895-903. PMID 12438853
14. Silverstein H, Atkins J, Thompson JH, Jr., et al. Experience with the SOUNDTEC implantable hearing aid. Otol Neurotol. Mar 2005; 26(2):211-217. PMID 15793407
15. Frenzel H, Sprinzl G, Streitberger C, et al. The Vibrant Soundbridge in children and adolescents: Preliminary European multicenter results. Otol Neurotol. Aug 2015; 36(7):1216-1222. PMID 26107139
16. Marino R, Linton N, Eikelboom RH, et al. A comparative study of hearing aids and round window application of the vibrant sound bridge (VSB) for patients with mixed or conductive hearing loss. Int J Audiol. Apr 2013; 52(4):209-218. PMID 23527900
17. Colletti L, Mandala M, Colletti V. Long-term outcome of round window Vibrant SoundBridge implantation in extensive ossicular chain defects. Otolaryngol Head Neck Surg. Jul 2013; 149(1):134-141. PMID 23585147
18. Vyskocil E, Riss D, Honeder C, et al. Vibroplasty in mixed and conductive hearing loss: comparison of different coupling methods. Laryngoscope. Jun 2014; 124(6):1436-1443. PMID 24338550
19. Atas A, Tutar H, Gunduz B, et al. Vibrant SoundBridge application to middle ear windows versus conventional hearing aids: A comparative study based on international outcome inventory for hearing aids. Eur Arch Otorhinolaryngol. Jan 2014; 271(1):35-40. PMID 23400404
20. Skarzynski H, Olszewski L, Skarzynski PH, et al. Direct round window stimulation with the Med-El Vibrant Soundbridge: 5 years of experience using a technique without interposed fascia. Eur Arch Otorhinolaryngol. Mar 2014; 271(3):477-482. PMID 23512431
21. De Abajo J, Sanhueza I, Giron L, et al. Experience with the active middle ear implant in patients with moderate-to-severe mixed hearing loss: indications and results. Otol Neurotol. Oct 2013; 34(8):1373-1379. PMID 24005166
22. Dillon MT, Tubbs RS, Adunka MC, et al. Round window stimulation for conductive and mixed hearing loss. Otol Neurotol. Oct 2014; 35(9):1601-1608. PMID 25111522
23. Beltrame AM, Martini A, Prosser S, et al. Coupling the Vibrant Soundbridge to cochlea round window: Auditory results in patients with mixed hearing loss. Otol Neurotol. Feb 2009; 30(2):194-201. PMID 19180678
24. Bernardeschi D, Hoffman C, Benchaa T, et al. Functional results of Vibrant Soundbridge middle ear implants in conductive and mixed hearing losses. Audiol Neurootol. 2011; 16(6):381-387. PMID 21228566
25. Colletti L, Carner M, Mandala M, et al. The floating mass transducer for external auditory canal and middle ear malformations. Otol Neurotol. Jan 2011; 32(1):108-115. PMID 21131892
26. Gunduz B, Atas A, Bayazit YA, et al. Functional outcomes of Vibrant Soundbridge applied on the middle ear windows in comparison with conventional hearing aids. Acta Otolaryngol. Dec 2012; 132(12):1306-1310. PMID 23039370

27. Mandala M, Colletti L, Colletti V. Treatment of the atretic ear with round window vibrant soundbridge implantation in infants and children: Electrocochleography and audiologic outcomes. Otol Neurotol. Oct 2011; 32(8):1250-1255. PMID 21897320
28. Roman S, Denoyelle F, Farinetti A, et al. Middle ear implant in conductive and mixed congenital hearing loss in children. Int J Pediatr Otorhinolaryngol. Dec 2012; 76(12):1775-1778. PMID 22985678
29. Sziklai I, Szilvassy J. Functional gain and speech understanding obtained by Vibrant Soundbridge or by open-fit hearing aid. Acta Otolaryngol. Apr 2011; 131(4):428-433. PMID 21401449
30. Zernotti ME, Arauz SL, Di Gregorio MF, et al. Vibrant Soundbridge in congenital osseous atresia: multicenter study of 12 patients with osseous atresia. Acta Otolaryngol. Jun 2013; 133(6):569-573. PMID 23448351
31. Food and Drug Administration. Esteem Implantable Hearing System. Summary of Safety and Effectiveness (2010). Available at: <http://www.accessdata.fda.gov> (accessed January 29, 2022).
32. Kraus EM, Shohet JA, Catalano PJ. Envoy Esteem totally implantable hearing system: Phase 2 trial, 1-year hearing results. Otolaryngol Head Neck Surg. Jul 2011; 145(1):100-109. PMID 21493292
33. Pulcherio JO, Bittencourt AG, Burke PR, et al. Carina® and Esteem®: A systematic review of fully implantable hearing devices. PLoS One. 2014; 9(10):e110636. PMID 25329463
34. Klein K, Nardelli A, Stafinski T. A systematic review of the safety and effectiveness of fully implantable middle ear hearing devices: The Carina and Esteem systems. Otol Neurotol. Aug 2012; 33(6):916-921. PMID 22772013
35. Barbara M, Biagini M, Monini S. The totally implantable middle ear device 'Esteem' for rehabilitation of severe sensorineural hearing loss. Acta Otolaryngol. Apr 2011; 131(4):399-404. PMID 21198340
36. Barbara M, Manni V, Monini S. Totally implantable middle ear device for rehabilitation of sensorineural hearing loss: Preliminary experience with the Esteem, Envoy. Acta Otolaryngol. Apr 2009; 129(4):429-432. PMID 19117172
37. Chen DA, Backous DD, Arriaga MA, et al. Phase 1 clinical trial results of the Envoy System: A totally implantable middle ear device for sensorineural hearing loss. Otolaryngol Head Neck Surg. Dec 2004; 131(6):904-916. PMID 15577788
38. Gerard JM, Thill MP, Chantrain G, et al. Esteem 2 middle ear implant: Our experience. Audiol Neurootol. 2012; 17(4):267-274. PMID 22627489
39. Kam AC, Sung JK, Yu JK, et al. Clinical evaluation of a fully implantable hearing device in six patients with mixed and sensorineural hearing loss: Our experience. Clin Otolaryngol. Jun 2012; 37(3):240-244. PMID 22708943
40. Monini S, Biagini M, Atturo F, et al. Esteem(R) middle ear device versus conventional hearing aids for rehabilitation of bilateral sensorineural hearing loss. Eur Arch Otorhinolaryngol. Jul 2013; 270(7):2027-2033. PMID 23143506
41. Tsang WS, Yu JK, Wong TK, et al. Vibrant Soundbridge system: Application of the stapes coupling technique. J Laryngol Otol. Jan 2013; 127(1):58-62. PMID 23218176

42. Savas VA, Gunduz B, Karamert R, et al. Comparison of Carina active middle-ear implant with conventional hearing aids for mixed hearing loss. J Laryngol Otol. Apr 2016; 130(4):340-343. PMID 26991874
43. Barbara M, Volpini L, Monini S. Delayed facial nerve palsy after surgery for the Esteem® fully implantable middle ear hearing device. Acta Otolaryngol. Apr 2014; 134(4):429-432. PMID 24433055
44. Zwartenkot JW, Mulder JJ, Snik AF, et al. Active middle ear implantation: Long-term medical and technical follow-up, implant survival, and complications. Otol Neurotol. Jun 2016; 37(5):513-519. PMID 27023016
45. American Academy of Otolaryngology and Head and Neck Surgery. Position Statement on Active Middle Ear Implants (2016). Available at: <http://www.entnet.org> (accessed January 31, 2022).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2023	Reviewed. Coverage unchanged.
01/01/2023	Document updated with literature review. Coverage unchanged. Added references 10 and 11.
05/15/2021	Reviewed. Coverage unchanged.
03/15/2020	Document updated with literature review. Coverage unchanged. Added reference 43.
06/15/2018	Reviewed. Coverage unchanged.
07/15/2017	Document updated with literature review. Coverage unchanged.
07/01/2016	Reviewed. Coverage unchanged.
04/15/2015	Document updated with literature review. Coverage unchanged. Title changed from: Semi-Implantable and Fully Implantable Middle Ear Hearing Aids for Moderate to Severe Sensorineural Hearing Loss.
08/15/2012	Document updated with literature review. The following was added to coverage: Fully implantable middle ear hearing aids are considered experimental, investigational and unproven for all indications. Title was changed from: Semi-Implantable Middle Ear Hearing Aid for Moderate to

	Severe Sensorineural Hearing Loss to: Semi-Implantable and Fully Implantable Middle Ear Hearing Aid for Moderate to Severe Sensorineural Hearing Loss. CPT/HCPCS code(s) updated
03/01/2010	Revised/updated entire document, conditional coverage position unchanged.
10/01/2007	Revised/Updated Entire Document
07/01/2004	New Medical Document