BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.84 Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Effective Policy Date: July 1, 2023

Original Policy Date: June 2012

Related Policies:

7.01.05 - Cochlear Implant
7.01.83 - Auditory Brainstem Implant

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Description

Description

Moderate-to-severe sensorineural hearing loss is often treated with external acoustic hearing aids, while conductive hearing loss can be treated with acoustic or bone-conduction hearing aids when surgical or medical interventions do not correct hearing loss. Semi-implantable and fully implantable middle ear hearing aids detect sound and transduce signals directly to the ossicles in the middle ear and have been used as an alternative to external acoustic hearing aids.

OBJECTIVE

The objective of this evidence review is to evaluate the evidence for hearing improvements with semi- and fully implantable middle ear hearing aids for patients with moderate-to-severe hearing loss.

POLICY STATEMENT

Semi-implantable and fully implantable middle ear hearing aids are considered **not medically necessary.**

POLICY GUIDELINES

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

- Pure-tone air-conduction threshold levels that fall at or within the limits outlined in Table PG1.
- Word recognition score of ≥50%, using recorded material.
- Normal middle ear anatomy.
- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device.

Table PG1. Pure-Tone Air-Conduction Threshold Levels

Limits	Frequency, kHz					
	0.5	**1**	**1.5**	**2**	**3**	**4**
Lower limit	30	40	45	45	50	50
Upper limit	65	75	80	80	85	85

The Maxum System is indicated for use in adults (≥18 years of age) who have moderate-to-severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid. Before receiving the device, it is recommended that individuals have experience with appropriately fitted hearing aids.

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

- 18 years of age or older
- Stable bilateral sensorineural hearing loss
- Moderate (40-70 dB) to severe (71-90 dB) sensorineural hearing loss defined by pure-tone average
- Unaided speech discrimination test score ≥40%
- Normally functioning eustachian tube
- Normal middle ear anatomy
- Normal tympanic membrane
- Adequate space for Esteem implant determined via high-resolution computed tomography scan
- Minimum 30 days of experience with appropriately fit hearing aids.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Benefit/contractual restrictions or exclusions for acoustic hearing aids for moderate-to-severe sensorineural hearing loss may apply.

The issue of upgrading components of middle ear implants may be best addressed contractually.

Some facilities may negotiate a global fee for the implantation of the device and the associated aural rehabilitation. However, charges for rehabilitation may be subject to individual contractual limitations.

FDA 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 the FDA approval. Phase 1 and 2 trials have been conducted in the United States under investigational device exemptions.[1,]

RATIONALE

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, systematic reviews, and a number of observational series. Relevant outcomes include symptoms, functional outcomes, quality of life, 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 5 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. Therefore, conclusions on the safety and effectiveness of semi-implantable hearing aids are limited. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

The American Academy of Otolaryngology Head and Neck Surgery

The American Academy of Otolaryngology Head and Neck Surgery (2016) issued a position statement on implantable hearing devices, recently updated, which stated [44,]:

"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 U.S. Food and Drug Administration approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency...."

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.[45,] However, devices producing 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.

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): 105-12. PMID 27031589
2. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Esteem Implantable Hearing System. 2010; https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090018b.pdf. Accessed December 16, 2022.
3. 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
4. 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): 427-36. PMID 12806295
5. Bruchhage KL, Leichtle A, Schnweiler 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
6. 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): 1451-7. PMID 26468033
7. 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): 1228-37. PMID 24643033
8. 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: S8-16. PMID 23790515
9. 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
10. Seebacher J, Weichbold V, Schrg 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
11. 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): 855-61. PMID 23739560
12. 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
13. Silverstein H, Atkins J, Thompson JH, et al. Experience with the SOUNDTEC implantable hearing aid. Otol Neurotol. Mar 2005; 26(2): 211-7. PMID 15793407
14. 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): 1216-22. PMID 26107139
15. 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): 209-18. PMID 23527900
16. Colletti L, Mandalà 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): 134-41. PMID 23585147
17. 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): 1436-43. PMID 24338550
18. 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
19. 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): 477-82. PMID 23512431
20. 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): 1373-9. PMID 24005166
21. Dillon MT, Tubbs RS, Adunka MC, et al. Round window stimulation for conductive and mixed hearing loss. Otol Neurotol. Oct 2014; 35(9): 1601-8. PMID 25111522
22. 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

23. 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): 381-7. PMID 21228566
24. Colletti L, Carner M, Mandalà M, et al. The floating mass transducer for external auditory canal and middle ear malformations. Otol Neurotol. Jan 2011; 32(1): 108-15. PMID 21131892
25. Gunduz B, Atas A, Bayazıt 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): 1306-10. PMID 23039370
26. Mandalà 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): 1250-5. PMID 21897320
27. 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): 1775-8. PMID 22985678
28. Sziklai I, Szilvssy J. Functional gain and speech understanding obtained by Vibrant Soundbridge or by open-fit hearing aid. Acta Otolaryngol. Apr 2011; 131(4): 428-33. PMID 21401449
29. 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): 569-73. PMID 23448351
30. Song CI, Cho HH, Choi BY, et al. Results of Active Middle Ear Implantation in Patients With Mixed Hearing Loss After Middle Ear Surgery: A Prospective Multicenter Study (the ROMEO Study). Clin Exp Otorhinolaryngol. Feb 2022; 15(1): 69-76. PMID 33848418
31. 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): 100-9. PMID 21493292
32. 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
33. 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): 916-21. PMID 22772013
34. 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
35. 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): 429-32. PMID 19117172
36. 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): 904-16. PMID 15577788
37. Gerard JM, Thill MP, Chantrain G, et al. Esteem 2 middle ear implant: our experience. Audiol Neurootol. 2012; 17(4): 267-74. PMID 22627489
38. 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): 240-4. PMID 22708943
39. Monini S, Biagini M, Atturo F, et al. Esteem middle ear device versus conventional hearing aids for rehabilitation of bilateral sensorineural hearing loss. Eur Arch Otorhinolaryngol. Jul 2013; 270(7): 2027-33. PMID 23143506
40. 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
41. Savaş VA, Gndz 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): 340-3. PMID 26991874
42. 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): 429-32. PMID 24433055
43. 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): 513-9. PMID 27023016
44. American Academy of Otolaryngology - Head and Neck Surgery. Position Statement: Active Middle Ear Implants. 2016; https://www.entnet.org/resource/position-statement-active-middle-ear-implants/#:~:text=The%20American%20Academy%20of%20Otolaryngology,otolaryngologist%2Dhead%20and%20neck%20surgeon. Accessed December 16, 2022.
45. Centers for Medicare & Medicaid Services. Medicare Policy Benefit Manual. Chapter 16 - General Exclusions from Coverage. 2014; https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf. Accessed December 16, 2022.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	Semi-implantable and fully implantable middle ear hearing aids are considered not medically necessary.
June 2013	Replace policy	Policy updated with literature review. References 10, 12, 15, 23-28 added; policy statement unchanged.
June 2014	Replace policy	Policy updated with literature review, adding references 16-19 & 22.Policy statement was unchanged.
June 2015	Replace policy	Policy updated with literature review, adding references 1, 7, 22-25, 31,and 40- 41. Policy statements unchanged.
September 2016	Replace policy	Policy updated with literature review; references 6 and 10-11 added; outdated references removed. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through December 11, 2017;references 1, 6-7, 41, and 43 added. Policy statement unchanged
June 2019	Replace policy	Policy updated with literature review through January 26, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through December 11, 2019; no references added. Policy statement unchanged
June 2021	Replace policy	Policy updated with literature review through January 7, 2021; references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through November 15, 2021; no references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through December 14, 2022; references added. Minor edits to policy statements; intent unchanged.