MASSACHUSETTS

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Medical Policy

Semi-Implantable and Fully Implantable Middle Ear Hearing Aid

Table of Contents

Policy Number: 480

BCBSA Reference Number: 7.01.84 (For Plans internal use only)
NCD/LCD: NA

Related Policies

- Auditory Brainstem Implant, #481
- Cochlear Implant, #478
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids, #479

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Semi-implantable and fully implantable middle ear hearing aids are **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis

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 (eg, 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 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 the 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).

Summary

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.

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.

Policy History

Date	Action
5/2024	Clarified coding table.
4/2024	Annual policy review. References updated. Policy statements unchanged.
4/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2017	Annual policy review. New references added.
3/2016	Annual policy review. New references added.
5/2015	Annual policy review. New references added.
5/2014	Annual policy review. New references added.
5/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
12/2011	Annual policy review. No changes to policy statements.
5/2010	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.

3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
5/2008	Annual policy review. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2007	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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 13, 2023.
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, Schönweiler 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, Schörg 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. Bruchhage KL, Lupatsii M, Möllenkolk F, et al. Hearing rehabilitation and microbial shift after middle ear surgery with Vibrant Soundbridge in patients with chronic otitis media. Eur Arch Otorhinolaryngol. Jul 2023; 280(7): 3107-3118. PMID 36662266
17. 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
18. Gantner S, Epp A, Pollotzek M, et al. Long-term results and quality of life after vibrant soundbridge implantation (VSBs) in children and adults with aural atresia. Eur Arch Otorhinolaryngol. Jan 2024; 281(1): 129-139. PMID 37603051
19. 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
20. 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
21. 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
22. 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
23. 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
24. 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
25. 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
26. 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
27. 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
28. 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
29. 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
30. Sziklai I, Szilvássy 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
31. 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

32. 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
33. Cadre B, Simon F, Célérier C, et al. Long-term outcomes of retrospective case series of middle ear implantation with Vibrant Soundbridge in children with congenital aural atresia. Eur Arch Otorhinolaryngol. Apr 2023; 280(4): 1629-1637. PMID 36098862
34. 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
35. 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
36. 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
37. 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
38. 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
39. 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
40. Gerard JM, Thill MP, Chantrain G, et al. Esteem 2 middle ear implant: our experience. Audiol Neurootol. 2012; 17(4): 267-74. PMID 22627489
41. 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
42. 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
43. 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
44. Savaş VA, Gündüz 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
45. 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
46. 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
47. Consensus Statement on Bone Conduction Devices and Active Middle Ear Implants in Conductive and Mixed Hearing Loss. Otol Neurotol. Jun 01 2022; 43(5): 513-529. PMID 35383700
48. 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 13, 2023.
49. 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 13, 2023.