

Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy #: 169

Latest Review Date: February 2023

Category: Surgery

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;*
- 2. Not experimental or investigational*;*
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - Furnished in a setting appropriate to the patient's medical needs and condition;*
 - Ordered and furnished by qualified personnel;*
 - One that meets, but does not exceed, the patient's medical need; and*
 - At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **semi-implantable middle ear hearing aid** for moderate to severe sensorineural hearing loss as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **fully implantable middle ear hearing aid (e.g. Esteem[®] implantable hearing system)** as a **non-covered benefit** and as **investigational**.

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

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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

Treatment

Sound amplification through the use of an air-conduction (AC) hearing aid can provide benefit to patients with sensorineural, conductive, or mixed hearing loss. Contralateral routing of signal 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 may not be able to 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 Food and Drug Administration (FDA) approval, the Vibrant Soundbridge (MED-EL Corporation, Durham, NC) and the Maxum System (Ototronix, Houston, TX).

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).

KEY POINTS:

This evidence review is updated regularly with searches of the MEDLINE database. The most recent literature review covers the period through December 14, 2022.

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.

Practice Guidelines and Position Statements

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:

“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. Preventative Services Task Force Recommendations

Not applicable.

KEY WORDS:

Sensorineural hearing loss, semi-implantable middle ear hearing aid, acoustic hearing aid, Vibrant[®] Soundbridge[™], SOUNDTEC[®] Direct System, Esteem[®], Esteem[®] implantable hearing system, Carina[®] Fully Implantable Hearing Device , Maxum System(Ototronix)

APPROVED BY GOVERNING BODIES:

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.”

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.”

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.

BENEFIT APPLICATION:

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

CURRENT CODING:

CPT codes:

69799	Unlisted procedure, middle ear
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HCPCS codes:

S2230	Implantation of magnetic component of semi-implantable
V5095	Semi-implantable middle ear hearing prosthesis

REFERENCES:

1. American Academy of Otolaryngology - Head and Neck Surgery. Implantable Hearing Devices. 2013; www.entnet.org/?q=node/932.
2. 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.
3. Barbara M, Volpini L, Monini S. Delayed facial nerve palsy after surgery for the Esteem ((R)) fully implantable middle ear hearing device. *Acta Otolaryngol*. Apr 2014; 134(4):429-432.
4. Barbara M, Biagini M, Monini S. The totally implantable middle ear device 'Esteem' for rehabilitation of severe sensorineural hearing loss. *Acta Otolaryngol* 2011; 131(4):399-404.
5. Bernardeschi D, Hoffman C, Benchaa T et al. Functional results of Vibrant Soundbridge middle ear implants in conductive and mixed hearing losses. *Audiol Neurotol* 2011; 16(6):381-7.

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*. Oct 31 2016.
7. 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.
8. Colletti L, Carner M, Mandala M et al. The floating mass transducer for external auditory canal and middle ear malformations. *Otol Neurotol* 2011; 32(1):108-15.
9. Colletti L, Mandala M, Colletti V. Long-term outcome of round window Vibrant SoundBridge implantation in extensive ossicular chain defects. *Otolaryngol Head Neck Surg* 2013; 149(1):134-41.
10. 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.
11. 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.
12. Ernst A, Todt I, Wagner J. Safety and effectiveness of the Vibrant Soundbridge in treating conductive and mixed hearing loss: a systematic review. *Laryngoscope*. Oct 15 2015.
13. 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.
14. Esteem Implantable Hearing System. FDA Summary of Safety and Effectiveness. Available online at: www.accessdata.fda.gov/cdrh_docs/pdf9/P090018b.pdf.
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.
16. Gerard JM, Thill MP, Chantrain G et al. Esteem 2 middle ear implant: our experience. *Audiol Neurotol* 2012; 17(4):267-74.
17. 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* 2012; 132(12):1306-10.
18. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
19. 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.
20. 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* 2012; 37(3):240-4.
21. 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* 2012; 33(6):916-21.

22. Kraus EM, Shohet JA, Catalano PJ. Envoy Esteem Totally Implantable Hearing System: phase 2 trial, 1-year hearing results. *Otolaryngol Head Neck Surg* 2011; 145(1):100-9.
23. 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* 2011; 32(8):1250-5.
24. 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* 2013; 52(4):209-18.
25. 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* 2012.
26. Pulcherio JO, Bittencourt AG, Burke PR, et al. Carina(R) and Esteem(R): a systematic review of fully implantable hearing devices. *PLoS One*. 2014; 9(10):e110636.
27. 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*. May 25 2020.
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* 2012; 76(12):1775-8.
29. 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.
30. 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.
31. Shohet J, Gende D, Tanita C. Totally Implantable Active Middle Ear Implant: Hearing and Safety Results in a Large Series. *Laryngoscope*, 2018.
32. Shohet J, Gende D, Bibee J, Patzkowski G, Tanita C. Speech Perception Gap Is Predictive of an Active Middle Ear Implant Advantage. *Otol Neurotol*, 2020. Vol. 41.
33. 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.
34. 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.
35. Sziklai I, Szilvassy J. Functional gain and speech understanding obtained by Vibrant Soundbridge or by open-fit hearing aid. *Acta Otolaryngol* 2011; 131(4):428-33.
36. Tsang WS, Yu JK, Wong TK et al. Vibrant Soundbridge system: application of the stapes coupling technique. *J Laryngol Otol* 2013; 127(1):58-62.
37. Tysome JR, Moorthy R, Lee A et al. Systematic review of middle ear implants: do they improve hearing as much as conventional hearing AIDS? *Otol Neurotol* 2010; 31(9):1369-75.

38. 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 Neurotol*. 2016; 21(2):105-112.
39. Vyskocil E, Riss D, Honeder C et al. Vibroplasty in mixed and conductive hearing loss: Comparison of different coupling methods. *Laryngoscope* 2013.
40. 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* 2013; 133(6):569-73.
41. 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* 2013; 34(5):855-61.
42. Zwartenkot JW, Mulder JJ, Snik AF et al. Vibrant Soundbridge surgery in patients with severe external otitis: complications of a transcanal approach. *Otol Neurotol* 2011; 32(3):398-402.
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):513-519.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005

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Medical Policy Group, June 2006

Medical Policy Group, June 2008

Medical Policy Group, June 2010

Medical Policy Group, December 2010

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

Medical Policy Group, April 2011

Medical Policy Group, April 2012

Medical Policy Group, March 2014

Medical Policy Group, March 2015

Medical Policy Group, February 2016

Available for comment February 26 through April 10, 2016

Medical Policy Group, February 2017

Medical Policy Group, February 2018

Medical Policy Group, February 2019

Medical Policy Group, February 2020

Medical Policy Group, March 2021

Medical Policy Group, July 2021

Medical Policy Group, February 2022

Medical Policy Group, February 2023

Medical Policy Group, November 2023: Archived effective 11/1/2023.

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

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