

MEDICAL POLICY – 7.01.84

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

BCBSA Ref. Policy: 7.01.84

Effective Date: May 1, 2024

Last Revised: April 8, 2024

Replaces: N/A

RELATED MEDICAL POLICIES:

1.01.528 Hearing Aids (Excludes Implantable Devices)


7.01.83 Auditory Brainstem Implant

7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids

7.01.586 Cochlear Implant

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[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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Introduction

To hear, sound waves travel through the outer ear to the eardrum, to the tiny bones of the middle ear, and into inner ear. The structures in the inner ear convert the vibrations into nerve signals that then travel along the auditory nerve to the brain. Typical hearing aids amplify or increase sounds as they are passed through the outer ear and middle ear. Other types of hearing aids can be implanted in the middle ear. These require a sound processor and an internal implant, which is located on one of the bones of the middle ear or the membrane of the inner ear. The processor picks up the sound and transmits the vibrations to the implant. The implant vibrates, which then sends signals to the inner ear. Middle ear implantable and semi-implantable hearing aids are investigational (unproven). Studies to date have been small, and there's not enough information to determine the safety and effectiveness of these types of middle ear hearing aids. More and larger studies are needed.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Investigational
Middle ear hearing aids <ul style="list-style-type: none"> • Semi-implantable • Fully implantable 	Semi-implantable and fully implantable middle ear hearing aids are considered investigational (e.g., Vibrant Sound Bridge, Maxum System, and Esteem device)

Coding

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

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Related Information

Vibrant Soundbridge

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

- Pure-tone air-conduction threshold levels that fall at or within the limits outlined in [Table 1](#).
- Word recognition score of $\geq 50\%$, using recorded material
- Normal middle ear anatomy



- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device.

Table 1. 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 $\geq 40\%$
- 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.



Consideration of Age

The application of this policy to those 18 years of age or older is based on the US Food and Drug Administration (FDA) labeling. The FDA approval for the devices 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.

Benefit Application

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

Evidence Review

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.

Background

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 individuals 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.

Individuals 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 individuals, 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 US Food and Drug Administration (FDA) approval: the Vibrant Soundbridge and the Maxum System. The devices consist of three components: a magnetic component that is implanted onto the ossicles of the middle ear, a receiver, and a sound processor. The Soundbridge device is implanted subcutaneously behind the ear while the processor is worn externally on the scalp over the receiver unit and held in place by a magnet. The Maxum System device is placed in the user's ear canal while the processor rests over the external ear. In general, the sound processor receives and amplifies the sound vibrations and transforms the sound pressure into electrical signals that are received by the receiver unit. The receiver unit then transduces these electrical signals into electromagnetic energy and creates an alternating electromagnetic field with the magnetic component (floating mass transducer) implanted on the ossicles of the middle ear. This electromagnetic field results in attractive and repulsive forces on the magnetic implant, causing vibration of the bones of the middle ear similar to normal hearing.

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 that are delivered to the stapes by another piezoelectric transducer (the driver).

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 US Food and Drug Administration, systematic reviews, and a number of observational series. The 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 individuals 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 individuals have been included in the clinical trials, and with a median duration of follow-up less than five years. Studies of individuals with conductive or mixed hearing loss and aural atresia, when external acoustic hearing aids are not an option, have also demonstrated hearing benefit with semi-implantable middle ear hearing aids. However, these studies are few and limited to small numbers of individuals. 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 individuals 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 outcomes.

Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in December 2023 did not identify any ongoing or unpublished trials that would likely influence this policy.



Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion in the remaining sections 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 stated⁴⁸:

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 FDA-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency...

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.⁴⁹ 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.



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 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

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 March 25, 2024.
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, Benchaâ 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, 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): 1306-10. 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 March 25, 2024.
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 March 25, 2024.

History

Date	Comments
04/15/03	Add to Surgery Section - New Policy
06/08/04	Replace Policy - Policy reviewed; no change in policy statement.
06/14/05	Replace Policy - Policy reviewed with literature search; no change in policy statement.
07/11/06	Replace Policy - Policy updated with literature search; reference added; no change in policy statement.
05/13/08	Replace Policy - Policy updated with literature search; no change to the policy statement. Reference added.
01/12/10	Replace Policy - Policy updated with literature search; no change to the policy statement. Reference added.
06/13/11	Replace Policy - Policy updated with literature review, reference numbers 10-14 added, "fully implantable" hearing aid added to policy, title changed to reflect addition, fully implantable device, previously not addressed, is now considered investigational. ICD-10 codes added to policy.
06/26/12	Replace policy. Policy updated with literature review, rationale section reorganized, reference numbers 10-12, 14, 16 and 20 added, policy title changed with the removal of "for moderate to severe sensorineural hearing loss." Policy statement unchanged. HCPCS code L8613 removed, as it does not apply to this policy.
09/28/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014
10/18/12	Update Related Policy – 7.01.03 renumbered to 7.01.547.



Date	Comments
05/28/13	Replace policy. Rationale section updated based on a literature review through February 2013; references 10, 12, 15, 23-27 added; others renumbered or removed. Policy statement unchanged.
03/21/14	Update Related Policies. Add 1.01.528.
06/13/14	Annual Review. Policy updated with literature review through February 11, 2014; references 1, 18-20, and 23 added; policy statement unchanged.
05/27/15	Annual Review. Policy updated with literature review through February 2, 2015. References 7, 22-25, 31, and 40-41 added. Policy statement unchanged.
05/01/16	Annual Review, changes approved April 12, 2016. Policy updated with literature review through December 17, 2015; references 6 and 10-11 added; outdated references removed. Policy statement unchanged.
11/08/16	Minor update. Language was added to support that this policy applies to those ages 18 or older to align with FDA-labelling of the devices addressed. No change in policy statements.
05/01/17	Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 1, 6-7, 41, and 43 added. Policy statement unchanged.
10/24/17	Policy moved to new format; no change to policy statements.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through December 2017; no references added; reference 43 updated. Policy statement unchanged.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through January 2019; no references added. Policy statement unchanged. Removed CPT code 69799.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through December 11, 2019; no references added. Policy statement unchanged.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through January 7, 2021; references added. Policy statements unchanged.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through November 15, 2021; no references added. Policy statements unchanged.
02/01/23	Updated Related Policies. 7.01.03 is replaced by 7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids



Date	Comments
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through December 14, 2022; references added. Minor edits to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/15/23	Updated Related Policies. 7.01.05 is replaced with 7.01.586 Cochlear Implant.
05/01/24	Annual Review, approved April 8, 2024. Policy updated with literature review through December 13, 2023; references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.





Discrimination is Against the Law

LifeWise Health Plan of Washington (LifeWise) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). LifeWise provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-6396, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@LifeWiseHealth.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx>.

Language Assistance

- ATENCIÓN:** si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-817-3056 (TTY: 711).
- 注意:** 如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-817-3056 (TTY: 711)。
- CHÚ Ý:** Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-817-3056 (TTY: 711).
- 주의:** 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-817-3056 (TTY: 711) 번으로 전화해 주십시오.
- ВНИМАНИЕ:** Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-817-3056 (телетайп: 711).
- PAUNAWA:** Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-817-3056 (TTY: 711).
- УВАГА!** Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-817-3056 (телетайп: 711).
- ប្រយ័ត្ន:** បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតលុយ គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 800-817-3056 (TTY: 711)។
- 注意事項:** 日本語を話される場合、無料の言語支援をご利用いただけます。800-817-3056 (TTY:711) まで、お電話にてご連絡ください。
- ማስታወሻ:** የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያገለግሉት ተዘጋጅተዋል። ወደ ሚከተለው ቁጥር ይደውሉ 800-817-3056 (መስማት ለተሳናቸው፡ 711)።
- XIYYEEFFANNA:** Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-817-3056 (TTY: 711).
- ملحوظة:** إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-817-3056 (رقم هاتف الصم والبكم: 711).
- ਧਿਆਨ ਦਿਓ:** ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-817-3056 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।
- ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-817-3056 (TTY: 711).
- ໂປດອຸບ:** ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ຄ່າສ່ຽງຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 800-817-3056 (TTY: 711).
- ATANSYON:** Si w pale Kreyòl Ayisyen, gen sévis èd pou lang ki disponib gratis pou ou. Rele 800-817-3056 (TTY: 711).
- ATTENTION:** Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-817-3056 (ATS : 711).
- UWAGA:** Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-817-3056 (TTY: 711).
- ATENÇÃO:** Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).
- ATTENZIONE:** In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-817-3056 (TTY: 711) تماس بگیرید.