

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Implantable Bone-Conduction and Bone-Anchored Hearing Aids is addressed separately in medical policy 00004.

Note: Cochlear Implant is addressed separately in medical policy 00017.

Note: Auditory Brainstem Implant is addressed separately in medical policy 00475.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers semi-implantable and fully implantable middle ear hearing aids to be **investigational**.*

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 greater than or equal to 50%, using recorded material.
- Normal middle ear anatomy.
- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device.

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

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^{TM†} System is indicated for use in adults (greater than or equal to 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 decibels [dB]) to severe (71-90 dB) sensorineural hearing loss defined by pure-tone average
- Unaided speech discrimination test score greater than or equal to 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.

Background/Overview

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,

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

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).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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^{TM†} (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...

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

in adults 18 years of age or older with stable bilateral sensorineural hearing loss.” FDA product code: OAF.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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.

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

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

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

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.

Consensus Statement

An expert consensus statement on bone conduction devices and active middle ear implants in conductive and mixed hearing loss was published in 2022. The statement provides information about patient education and technical aspects of device placement, but does not provide clear recommendations regarding the patients who are most likely to benefit from implantable middle ear hearing aids over other devices.

The American Academy of Otolaryngology Head and Neck Surgery

The American Academy of Otolaryngology Head and Neck Surgery (2021) 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. 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. 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.

Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in January 2026 did not identify any ongoing or unpublished trials that would likely influence this review.

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

References

1. 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.
2. 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
3. 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
4. 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
5. 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
6. 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
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. PMID 23790515
8. 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
9. 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
10. Lenarz T, Keintzel T, Sprinzl G, et al. Lifetime Real-World Evidence on Safety and Performance of the Only Active Middle Ear Implant (AMEI) Covering Conductive to Sensorineural Hearing Loss: Results From a Long-Term Retrospective Analysis. *Otol Neurotol*. Jan 01 2026; 47(1): 119-131. PMID 41373133
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

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

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 Neurotol.* 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

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

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 Neurotol.* 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

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

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. 2021; <https://www.entnet.org/resource/position-statement-active-middle-ear-implants/#:~:text=The%20American%20Academy%20of%20Otolaryngology,otolaryngologist%2Dhead%20and%20neck%20surgeon.>
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>.

Policy History

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. New policy.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2020	Medical Policy Committee review

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

09/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2025	Coding Update
09/04/2025	Medical Policy Committee review
09/10/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2026	Medical Policy Committee review
09/09/2026	Medical Policy Implementation Committee review
09/17/2026	Medical Quality Management Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0951T, 0952T, 0953T, 0954T, 0955T, 69799
HCPCS	S2230, V5095
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy # 00425

Original Effective Date: 09/17/2014

Current Effective Date: 10/01/2026

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.