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Subject: Cochlear Implants

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

A cochlear implant is a device for treatment of severe-to-profound hearing loss in individuals who only receive limited benefit from amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea.

The basic structure of a cochlear implant includes both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are implanted surgically and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear.

Sounds picked up by the microphone are carried to the external sound processor, which transforms sound into coded signals that are then transmitted transcutaneously to the implanted internal receiver. The receiver converts the incoming signals into electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve.

POSITION STATEMENT:

Unilateral or bilateral implantation of a U.S. Food and Drug Administration (FDA) approved **cochlear implant** in adults and children **meets the definition of medical necessity** when **ALL** of the following criteria are met:

- Unilateral or bilateral severe-to-profound prelingual or postlingual (sensorineural) hearing loss (in the ear(s) to be implanted), defined as a hearing threshold pure-tone average of 70 dB hearing loss or greater at 500, 1000, and 2000 Hz

- Limited or no benefit from appropriately fit conventional hearing aids (defined in adults as scores of 50% correct or less in the ear to be implanted on tape-recorded sets of open-set sentence recognition; defined in children as failure to develop basic auditory skills, and in older children, 30% or less correct on open-set tests)
- The individual is able to participate in a post-implant rehabilitation program in order to achieve benefit from the implant
- No contraindications to surgery (e.g., deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brainstem; active or chronic infections of the external or middle ear; mastoid cavity or tympanic membrane perforation, cochlear ossification which prevents electrode insertion, the absence of cochlear development as demonstrated on computed tomography scan)

Implantation may be unilateral, bilateral-simultaneous (implantation performed in the same operative session), or bilateral-sequential (implantation performed in different operative sessions). If implantation is bilateral-sequential, it is not required that hearing tests be repeated between implantation procedures.

Cochlear implantation of a U.S. Food and Drug Administration (FDA) approved hybrid cochlear implant/hearing aid device (e.g., the Nucleus® Hybrid™ L24 Cochlear Implant System) **meets the definition of medical necessity** when **ALL** of the following are met:

- Age 18 years or older
- Bilateral severe to profound high frequency sensorineural hearing loss with residual low-frequency hearing sensitivity
- Receive limited benefit from appropriately fit conventional bilateral hearing aids
- Have the following hearing thresholds:
 - Low-frequency hearing thresholds no poorer than 60 dB hearing level up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation, **AND**
 - Severe to profound mid-to-high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz \geq 75 dB hearing level) in the ear to be implanted, **AND**
 - Moderately severe to profound mid-to-high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz \leq 60 dB hearing level) in the contralateral ear, **AND**
 - Aided consonant-nucleus-consonant word recognition score from 10% to 60% in the ear to be implanted in the preoperative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct

Diagnostic analysis and programming of cochlear implants **meets the definition of medical necessity** when criteria for the implant device are met.

Replacement of internal and/or external components **meets the definition of medical necessity** only in those who have inadequate response to existing component(s) to the point of interfering with the individual's activities of daily living, or the component(s) is/are no longer functional and cannot be repaired.

Replacement of internal and/or external components solely for the purpose of upgrading to a system with advanced technology or to a next-generation device **does not meet the definition of medical necessity**.

Upgrades of an existing, functioning external system to achieve a cosmetic improvement, such as smaller profile components, are considered cosmetic in nature and **do not meet the definition of medical necessity**.

BILLING/CODING INFORMATION:

The following codes may be used to describe services related to cochlear implantation and diagnostic analysis of cochlear implant.

CPT Coding:

69930	Cochlear device implantation, with or without mastoidectomy
92601	Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

HCPCS Coding:

L7510	Repair prosthetic device, repair or replace minor parts (excludes repair of oral or laryngeal prosthesis or artificial larynx)
L8614	Cochlear device/system includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device, replacement
L8619	Cochlear implant external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
L8623	Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
L8624	Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement each
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement

L8629	Transmitting coil and cable, integrated, for use with cochlear implant device
V5273	Assistive listening device, for use with cochlear implant

REIMBURSEMENT INFORMATION:

Reimbursement for replacement of a cochlear implant **AND** its external components may be covered for any one of the following:

- When the existing device cannot be repaired; **OR**
- When replacement is required because a change in condition makes the present unit non-functional and improvement is expected with a replacement unit.

Reimbursement for batteries and replacement batteries for cochlear implant devices are covered when criteria for the cochlear implant device are met.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Cochlear Implantation (50.3) located at [cms.gov](https://www.cms.gov).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

Auditory nerve: either of the 8th pair of cranial nerves connecting the inner ear with the brain; transmits impulses relating to hearing and balance; composed of the cochlear nerve and the vestibular nerve.

Cochlea: a division of the [labyrinth](#) of the ear coiled into the form of a snail shell consisting of a spiral canal.

Conductive hearing loss: the result of disorders of the external or middle ear.

Consonant-Nucleus-Consonant Test (CNC): An open set word recognition test (administered in quiet) consisting of 10 recorded lists of 50 monosyllabic words used to determine speech intelligibility in listeners with hearing impairments.

Decibel (dB): Unit that measures the intensity or loudness of sound.

Hybrid cochlear implant: a unilateral implant with a shorter cochlear electrode in combination with a hearing aid-like amplification device; intended to provide electric stimulation to the mid-to-high frequency region of the cochlea and acoustic amplification to the low frequency regions.

Labyrinth: the internal ear or its bony or membranous part.

Neural hearing loss: results from disease or the auditory (eighth) nerve or central auditory channel connections.

Perlingual deafness: around or during the time speech begins.

Postlingual deafness: after speech has started.

Prelingual deafness: before speech begins.

Profound sensorineural hearing impairment: a bilateral hearing threshold of 90 decibels and above.

Sensorineural hearing loss: the result of damage to the inner ear (cochlea), or to the nerve pathways from the inner ear to the brain.

Severe sensorineural hearing impairment: a bilateral hearing threshold of 70-90 decibels (dB).

RELATED GUIDELINES:

[Implantable Bone-Conduction and Bone-Anchored Hearing Aids, 02-69000-06](#)

[Prosthetics, 09-L0000-05](#)

[Treatment of Tinnitus, 01-92502-11](#)

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Cochlear implant systems:

Advanced Bionics® HiResolution Bionic Ear System

Clarion Multi-Strategy or HiFocus CII Bionic Ear

Cochlear® Nucleus 22 and 24

Freedom with Contour

Med El® Maestro Combi 40+

Neuro Cochlear Implant System

Nucleus Profile Plus Cochlear Implant System

Synchrony 2 Cochlear Implant

Hybrid cochlear implant systems:

Nucleus® Hybrid™ L24 Cochlear Implant System

Med El® EAS Hearing Implant System

REFERENCES:

1. Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program, Effectiveness of Cochlear Implants in Adults with Sensorineural Hearing Loss, 04/11/11.
2. Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse NGC:008637: Quality of life in children with sequential bilateral cochlear implants. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2011 Jun 9.
3. Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse NGC:007126: Cochlear implants for children and adults with severe to profound deafness. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jan.
4. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Position Statement: Cochlear Implants (11/10/20). Accessed at <http://www.entnet.org/Practice/Position-Statements.cfm>.
5. American Academy of Otolaryngology — Head and Neck Surgery: Response to Washington State Health Technology Assessment for Unilateral/Bilateral Cochlear Implants. June 2012. Accessed at <http://www.entnet.org>.
6. American Academy of Otolaryngology–Head and Neck Surgery or Foundation (AAO-HNS/F). Position Statement: Cochlear Implantation for Single Sided Deafness in Adults (April 2023). Accessed at <https://www.entnet.org/>.
7. American Speech-Language-Hearing Association (ASHA). Cochlear implants. Accessed at http://www.asha.org/public/hearing/treatment/cochlear_implant.htm.
8. Arras T, Rachman L, van Wieringen A, Başkent D. Perception of voice cues and speech-in-speech by children with prelingual single-sided deafness and a cochlear implant. *Hear Res*. 2024 Dec;454:109133. doi: 10.1016/j.heares.2024.109133. Epub 2024 Oct 17.
9. Bittencourt A G et al . Post-lingual deafness: benefits of cochlear implants vs. conventional hearing aids. *Braz. J. Otorhinolaryngol.*, São Paulo, v. 78, n. 2, Apr. 2012.
10. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.05 - Cochlear Implant, 03/25.
11. Brown C, Gifford RH. Expansion of Audiologic Criteria for Pediatric Cochlear Implantation. *Otolaryngol Clin North Am*. 2021 Dec;54(6):1181-1191. doi: 10.1016/j.otc.2021.08.002.
12. Büchner A, Schüssler M, Battmer RD, Stöver T, Lesinski-Schiedat A, Lenarz T. Impact of low-frequency hearing. *Audiol Neurotol*. 2009;14 Suppl 1:8-13.
13. Buss E, Dillon MT, Rooth MA, et al. Effects of Cochlear Implantation on Binaural Hearing in Adults With Unilateral Hearing Loss. *Trends Hear*. 2018;22:2331216518771173. doi:10.1177/2331216518771173.
14. Centers for Disease Control and Prevention (CDC). Vaccines and preventable diseases: cochlear implants & meningitis vaccination. June 1, 2012. Accessed at <http://www.cdc.gov/Vaccines/vpd-vac/mening/cochlear/dis-cochlear-faq-hcp.htm>.
15. Centers for Medicaid & Medicare Services (CMS), MEDCAC Meeting – Cochlear Implants for Sensorineural Hearing Loss (05/11/11).
16. Centers for Medicaid & Medicare Services (CMS), National Coverage Determination (NCD) for Cochlear Implantation (50.3) (09/26/22) (Revised 03/24/23).
17. Ching TY, Incerti P, Plant K. Electric-acoustic stimulation: for whom, in which ear, and how. *Cochlear Implants Int*. 2015 Jan;16 Suppl 1:S12-5.

18. ClinicalTrials.gov. NCT00960102: Children's Bilateral Cochlear Implantation in Finland (FinBiCI). Kuopio University Hospital. Last updated: August 8, 2012.
19. ClinicalTrials.gov. NCT01256229: Outcomes In Children With Developmental Delay And Deafness. Stanford University. Last updated: July 28, 2011.
20. CliniciTrials.gov. NCT01975571: Hybrid Cochlear Implants in Severe to Profound Adults, Children, and Adolescents. Sponsored by University of Iowa. Results posted June 8, 2022.
21. Daher GS, Kocharyan A, Dillon MT, Carlson ML. Cochlear Implantation Outcomes in Adults With Single-Sided Deafness: A Systematic Review and Meta-analysis. *Otol Neurotol*. 2023 Apr 1;44(4):297-309. doi: 10.1097/MAO.0000000000003833. Epub 2023 Feb 15. PMID: 36791341.
22. Dazert S, Thomas JP, Loth A, Zahnert T, Stöver T. Cochlear Implantation. *Dtsch Arztebl Int*. 2020 Oct 9;117(41):690-700. doi: 10.3238/arztebl.2020.0690.
23. Deeks JM, Carlyon RP. Simulations of cochlear implant hearing using filtered harmonic complexes: implications for concurrent sound segregation. *J Acoust Soc Am*. Apr; 115(4): 1736-46.
24. Diab K, Pashchinina O, Kondratchikov D, Panina O, Balakina L, Korobkin A. Spontaneous bone bed formation in pediatric cochlear implantation is associated with duration of implantation. *Int J Pediatr Otorhinolaryngol*. 2021 Nov;150:110897. doi: 10.1016/j.ijporl.2021.110897. Epub 2021 Aug 26.
25. Domenico C, Erica P, Andrea L, Daria S, Ghiselli S. Cochlear implant benefits over time in adult patients with Single Sided Deafness. *Eur Arch Otorhinolaryngol*. 2025 Mar 21. doi: 10.1007/s00405-025-09298-9. Epub ahead of print. PMID: 40119142.
26. ECRI Institute, Bilateral Cochlear Implantation, updated 04/28/06.
27. Erixon E, Rask-Andersen, H. Hearing and Patient Satisfaction Among 19 Patients Who Received Implants Intended for Hybrid Hearing: A Two-Year Follow-Up. *Ear Hear*. 2015 Sep; 36(5): e271–e278.
28. Hayes Medical Technology Directory-Cochlear Implantation, 09/12/05, update 09/30/06.
29. Health Quality Ontario . Bilateral Cochlear Implantation: A Health Technology Assessment. *Ont Health Technol Assess Ser*. 2018;18(6):1–139. Published 2018 Oct 24.
30. Jinka S, Wase S, Jeyakumar A. Complications of cochlear implants: a MAUDE database study. *J Laryngol Otol*. 2023 Nov;137(11):1267-1271. doi: 10.1017/S0022215123000828. Epub 2023 Jun 6. PMID: 37278214.
31. Jurawitz MC, Büchner A, Harpel T, Schüssler M, Majdani O, Lesinski-Schiedat A, Lenarz T. Hearing preservation outcomes with different cochlear implant electrodes: Nucleus® Hybrid™-L24 and Nucleus Freedom™ CI422. *Audiol Neurotol*. 2014;19(5):293-309.
32. Kay-Rivest E, Schlacter J, Waltzman SB. Cochlear implantation outcomes in the older adult: a scoping review. *Cochlear Implants Int*. 2022 Sep;23(5):280-290. doi: 10.1080/14670100.2022.2091723. Epub 2022 Jun 30. PMID: 35774034.
33. Kuhn-Inacker H, Shehata-Dieler W, Muller J et al. Bilateral Cochlear Implants: A Way to Optimize Auditory Perception Abilities in Deaf Children? *International Journal of Pediatric Otorhinolaryngology* 2004; 68(10): 1257-1266.
34. Lahlou G, Daoudi H, Ferrary E, Jia H, De Bergh M, Nguyen Y, Sterkers O, Mosnier I. Candidacy for Cochlear Implantation in Prelingual Profoundly Deaf Adult Patients. *J Clin Med*. 2022 Mar 28;11(7):1874. doi: 10.3390/jcm11071874.
35. Lammers MJ, Lenarz T, van Zanten GA, Grolman W, Buechner A. Sound localization abilities of unilateral hybrid cochlear implant users with bilateral low-frequency hearing. *Otol Neurotol*. 2014 Sep;35(8):1433-9.

36. Laszig R, Aschendorff A, Stecker M et al. Benefits of Bilateral Electrical Stimulation with the Nucleus Cochlear Implant in Adults: 6-Month Postoperative Results. *Otology & Neurotology* 2004; 25(6): 658-968.
37. Lenarz T, James C, Cuda D, et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. *Int J Audiol*. 2013 Dec;52(12):838-48.
38. Litovsky RY, Parkinson A, Arcaroli J et al. Bilateral Cochlear Implants in Adults and Children. *Archives of Otolaryngology-Head & Neck Surgery* 2004; 130: 648-655.
39. Loundon N, Blanchard M, Roger G, Denoyelle F, Garabedian EN. Medical and Surgical Complications in Pediatric Cochlear Implantation. *Arch Otolaryngol Head Neck Surg*. 2010;136(1):12-15.
40. Macielak RJ, Richard C, Malhotra PS, Adunka OF, Findlen UM. Cochlear Implantation for Single-Sided Deafness in Pediatric Patients: A Critical Assessment of Usage Rate. *Otol Neurotol*. 2024 Dec 1;45(10):1122-1127. doi: 10.1097/MAO.0000000000004331. Epub 2024 Sep 25. PMID: 39379007.
41. McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of quality-of-life improvement after cochlear implantation and associations with speech recognition abilities. *Laryngoscope*. 2018;128(4):982–990. doi:10.1002/lary.26738.
42. Moody-Antonio S, Takayanagi S, Masuda A et al. Improved Speech Perception in Adult Congenitally Deafened Cochlear Implant Recipients. *Otology & Neurotology* 2005; 26(4): 649-654.
43. National Institute on Deafness and Other Communication Disorders (NIDCD)-Cochlear Implants, 05/06.
44. National Institute on Deafness and Other Communication Disorders (NIDCD). Cochlear Implants (2013). Accessed at <http://www.nidcd.nih.gov/health/hearing/Pages/Default.aspx>.
45. National Institute for Health and Clinical Excellence (NICE). Technology Appraisal 166: Cochlear implants for children and adults with severe to profound deafness. January 2009.
46. Nelson HD, Bougatsos C, Nygren P. Universal Newborn Hearing Screening: Systematic Review to Update the 2001 U.S. Preventive Services Task Force Recommendation. Evidence Synthesis No. 62. AHRQ Publication No. 08-05117-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality, July 2008.
47. Offeciers E, Morera C, Muller J et al. International Consensus on Bilateral Cochlear Implants and Bimodal Stimulation. *Acta Oto-Laryngologica* 2005; 125(9): 918-919.
48. Osberger M et al. Cochlear Implant Candidacy and Performance Trends in Children. *Ann Otol Rhinol Laryngol Suppl* 2002; 189:62-65.
49. Rauch AK, Arndt S, et al. Long-term results of cochlear implantation in children with congenital single-sided deafness. *Eur Arch Otorhinolaryngol*. 2021 Sep;278(9):3245-3255. doi: 10.1007/s00405-020-06409-6. Epub 2020 Oct 20.
50. Reiss LAJ, et al. Pitch Adaptation Patterns in Bimodal Cochlear Implant Users: Over Time and After Experience. *Ear Hear*. 2015 Mar-Apr; 36(2): e23–e34.
51. Roland, J. Thomas, et al. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. *The Laryngoscope* (2015).
52. Roland Jr, J. T, et al. United States Multicenter Clinical Trial of the Cochlear Nucleus Hybrid Implant System. *The Laryngoscope* 126.1 (2016): 175.
53. Rubin LG, Papsin B. American Academy of Pediatrics Committee on Infectious Diseases and Section on Otolaryngology-Head and Neck Surgery. Cochlear implants in children: surgical site infections and prevention and treatment of acute otitis media and meningitis. *Pediatrics*. 2010; 126(2):381-391.
54. Sargent EW. Cochlear Implants, Indications. *eMedicine*. 2005.

55. Szyfter W, Wróbel M, et al. Observations on hearing preservation in patients with hybrid-L electrode implanted at Poznan University of Medical Sciences in Poland. *Eur Arch Otorhinolaryngol.* 2013; 270(10): 2637–2640.
56. Tan VYJ, Hollow R, Tari S, Rousset A, Wills R, Briggs RJS, Dowell RC. Cochlear implant usage in single sided deafness and factors affecting usage. *Cochlear Implants Int.* 2024 Sep;25(5):387-393. doi: 10.1080/14670100.2024.2403224. Epub 2024 Oct 9. PMID: 39381935.
57. Tanamati Liege F, Bevilacqua MC, Costa OA. Cochlear implant in postlingual children: functional results 10 years after the surgery. *Braz. J. Otorhinolaryngol.*, São Paulo, v. 78, n. 2, Apr. 2012.
58. Tyler RS, Dunn CC, Witt S et al. Update on Bilateral Cochlear Implantation. *Current Opinion Otolaryngology & Head and Neck Surgery* 2003; 11(5): 388-393.
59. UpToDate. Cochlear implant infections. 2025. Accessed at [uptodate.com](https://www.uptodate.com).
60. UpToDate. Hearing amplification in adults. 2025. Accessed at [uptodate.com](https://www.uptodate.com).
61. UpToDate. Hearing loss in children: Treatment. 2025. Accessed at [uptodate.com](https://www.uptodate.com).
62. U.S. Food and Drug Administration website for cochlear implants, (10/26/04).
63. U.S. Food and Drug Administration. FDA Public Health Notification: Continued Risk of Bacterial Meningitis in Children with Cochlear Implants with a Positioner Beyond Twenty-Four Months Post-Implantation. February 6, 2006. Accessed at <http://www.fda.gov> on 01/16/13.
64. Völter C, Götze L, Haubitz I, Dazert S, Thomas JP. Benefits of Cochlear Implantation in Middle-Aged and Older Adults. *Clin Interv Aging.* 2020 Sep 7;15:1555-1568. doi: 10.2147/CIA.S255363.
65. U.S. Food and Drug Administration (FDA). 510(k) Number K220922 (Cochlear Osia 2 System, Cochlear Osia OSI200 Implant, Cochlear Osia 2 Sound Processor, Cochlear Osia Fitting Software 2, Cochlear MRI Kit) (06/23/22). Accessed at https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220922.pdf.
66. U.S. Food and Drug Administration (FDA). 510(k) Number K231204 (Cochlear™ Osia® System; Cochlear™ Osia® OSI300 Implant; Cochlear™; Magnet Cassette; Cochlear™ Non-Magnetic Cassette; Cochlear™ Osia® 2(I); Sound Processor; Cochlear™ Osia® Fitting Software 2; Cochlear™ Osia® Smart App) (07/19/23). Accessed at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K231204>.
67. U.S. Food and Drug Administration (FDA). Premarket Approval Database. Approval Order P130016. Rockville, MD: FDA. Nucleus Hybrid L24 Cochlear Implant System. Accessed at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P130016> on 09/24/15.
68. U.S. Food and Drug Administration (FDA). Premarket Approval Database. Summary of Safety and Effectiveness. Rockville, MD: FDA. Nucleus Hybrid L24 Cochlear Implant System. Accessed at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P130016> on 09/30/14.
69. U.S. Food and Drug Administration (FDA). Approval Letter: Nucleus Hybrid L24 Cochlear Implant System -- P130016. 03/20/14. Accessed at http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130016a.pdf.
70. U.S. Food and Drug Administration (FDA). Approval Supplement P970051/S205: Nucleus 24 Cochlear Implant System. January 10, 2022. Accessed at file:///C:/Users/local_he27/INetCache/Content.Outlook/1SUFQOVW/Approval%20order%20for%20Nucleus%2024%20Cochlear%20Implant%20System.pdf.
71. U.S. Preventive Services Task Force (USPSTF), Universal Screening for Hearing Loss in Newborns: Clinical Summary of U.S. Preventive Services Task Force Recommendation. AHRQ Publication No. 08-05117-EF-3, July 2008, accessed at: [uspreventiveservicestaskforce.org](https://www.uspreventiveservicestaskforce.org) 05/23/11.
72. University of Miami School of Medicine-Active Research Studies Recruiting Subjects-Clinical Study of Bilateral Implantation in children, 2005.

73. Wedekind A, Távora-Vieira D, Nguyen AT, Marinovic W, Rajan GP. Cochlear implants in single-sided deaf recipients: Near normal higher-order processing. Clin Neurophysiol. 2021 Feb;132(2):449-456. doi: 10.1016/j.clinph.2020.11.038. Epub 2020 Dec 29.
74. Wendrich AW, Assouly KKS, van Heteren JAA, Peters JPM, Grolman W, Stokroos RJ, Versnel H, Smit AL. Tinnitus reduction in patients with single-sided deafness: the effect of cochlear implantation, bone conduction devices, and contralateral routing of sound hearing aids investigated in a randomized controlled trial. Front Neurol. 2024 Jul 23;15:1428106. doi: 10.3389/fneur.2024.1428106.
75. Wesarg T, Aschendorff A, Baumgaertel R, Böttcher J, De Coninck L, Dhooge I, Dierckx A, Klenzner T, Schörg P, Sprinzl G, Swinnen F, Verhaert N, Vermeiren A, Volpert S, Zarowsk A, Ernst A. Cochlear Implantation in Single-Sided Deafness and Asymmetric Hearing Loss: 12 Months Follow-up Results of a European Multicenter Evaluation. J Int Adv Otol. 2024 Jul 29;20(4):289-300. doi: 10.5152/iao.2024.231457.
76. Yawn R, Hunter JB, Sweeney AD, Bennett ML. Cochlear implantation: a biomechanical prosthesis for hearing loss. F1000 Prime Rep. 2015 Apr 2;7:45.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/24/25.

GUIDELINE UPDATE INFORMATION:

08/15/03	Annual review/new Medical Coverage Guideline. Implanted Devices for Hearing Loss and Aural Rehabilitation guideline 02-69000-02 archived.
09/15/04	Added investigational statement for bilateral cochlear implantation. Updated references.
01/15/05	HCPCS update; added codes: L8615, L8616, L8617, L8618, L8620, L8621, and L8622.
07/01/05	HCPCS update. Added codes K0731 and K0732.
08/15/05	Scheduled review; no change in coverage statement; added reimbursement information regarding batteries.
01/01/06	HCPCS update; Deleted codes L8620, K0731 and K0732. Added codes L8623 and L8624. Updated references.
08/15/06	Revised DESCRIPTION section. Revised WHEN SERVICES ARE COVERED section; add coverage statement for post-cochlear rehabilitation program (aural rehabilitation). Revised BILLING/ CODING INFORMATION section, delete 2003 CPT statement regarding codes: 92601, 92602, 92603, 92604, and 92606. Added program exception for Medicare Advantage products. Updated references.
11/15/06	Added coverage statement for bilateral cochlear implant. Added coverage statement for upgrades of an exiting functioning system. Revised definition for postlingual deafness and prelingual deafness. Updated references.
01/01/07	HCPCS update. Revise code L8614 descriptor.
08/15/07	Annual review, coverage statements maintained, Description section updated, guideline reformatted, references updated.
08/15/09	Scheduled review; no change in position statement. Update references.
01/01/10	Annual HCPCS coding update: add HCPCS codes L8627, L8628, and L8629; update descriptor for code L8619.
10/15/10	Revision; related ICD-10 codes added.

07/15/11	Scheduled review; position statements maintained and references updated.
03/15/13	Unscheduled review. Revised description, position statement, reimbursement section, Medicare Advantage program exception, definitions and related guidelines. Updated references.
05/11/14	Revision: Program Exceptions section updated.
11/15/14	Unscheduled review. Revised description, position statement and definitions. Updated references.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/15	Unscheduled review. Revised description section and index terms. Updated references.
01/01/16	Annual CPT/HCPCS coding update. Revised code L8621 descriptor.
09/15/16	Unscheduled review. Revised Position Statement section and Definitions section. Updated references.
01/01/18	Annual CPT/HCPCS coding update: added L8625.
02/15/20	Scheduled review. Revised description and position statement (revised definition of severe to profound hearing loss; added definition of “limited or no benefit from conventional hearing aids”), and index terms. Updated references.
10/15/21	Scheduled review. Added statements regarding replacement of components and bilateral implantation. Updated references.
11/15/22	Scheduled review. Updated references and maintained position statement.
08/21/23	Update to Program Exceptions section.
09/15/24	Scheduled review. Maintained position statement and updated references.
08/15/25	Scheduled review. Revised position statement to include coverage criteria for unilateral hearing loss. Updated references.