

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

Medical Policy Cochlear Implant

Table of Contents

- Policy: Commercial
- Authorization Information
- Coding Information
- Description
- Policy History
- References
- Information Pertaining to All Policies
- Endnote

Policy Number: 478

BCBSA Reference Number: 7.01.05 (For Plan internal use only)

Related Policies

- Auditory Brainstem Implant, #481
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids, #479
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aid, #480
- Treatment of Tinnitus, #267

Policy¹

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

Cochlear implantation of a U.S. Food and Drug Administration (FDA) – approved cochlear implant device may be <u>MEDICALLY NECESSARY</u> in individual age 9 months and older when criteria 1-3 are met:

- 1. Individual has been diagnosed with **one** of the following:
 - a. Bilateral hearing loss defined as behavioral audiometric recorded word/sentence testing score (e.g. consonant-nucleus-consonant CNC) of ≤ 60% in the best aided binaural condition or Auditory Brainstem Response (ABR) hearing thresholds ≥ 70 dB (decibels) hearing level at frequencies 1000, 2000, and 4000 Hz (Hertz) who have shown limited or no benefit from hearing aids, **OR**
 - b. Unilateral Hearing Loss (UHL) includes Single Sided Deafness (SSD)
 - i. Absence of usable hearing in one ear (recorded word/sentence testing score ≤ 40% or ABR thresholds ≥ 70dB at frequencies 1000, 2000, and 4000 Hz); AND
 - ii. Normal to near-normal hearing in the contralateral ear (of note: hearing aid trial is not required if patient meets the above criteria), OR
 - c. Asymmetric Hearing Loss (AHL)
 - i. Absence of usable hearing in one ear (recorded word/sentence testing score ≤ 40% or ABR thresholds ≥ 70dB at frequencies 1000, 2000, and

- 4000 Hz). (Of note: hearing aid trial is not required if patient meets this criteria): **AND**
- ii. Sensorineural hearing loss in the other ear that is usable (recorded word/ sentence testing score > 60% or ABR thresholds < 70dB at frequencies 1000, 2000, and 4000 Hz).
- 2. Inner ear anatomy is expected to support cochlear implantation, AND
- 3. None of the following contraindications are present:
 - a. Absent cochlea or known absent cochlear nerve (e.g., post trauma or post-surgical)
 - b. Major cochlear ossification (defined as obliteration of both scala tympani and scala vestibuli in two or more turns of the cochlea)
 - c. Otologic conditions that contraindicate surgery, such as:
 - i. Active middle ear or mastoid infection
 - ii. Tympanic membrane perforation
 - d. Evidence of retrocochlear pathology (brainstem lesions involving cochlear nucleus, severe central auditory processing disorder)

Cochlear implantation as not otherwise meeting above criteria is INVESTIGATIONAL.

Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model, are **INVESTIGATIONAL**.

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 is considered **NOT MEDICALLY NECESSARY**.

Providers should determine the reasonable useful lifetime of the device to be five years—see <u>DME</u> Payment Policy.

Replacement of internal and/or external components is considered <u>MEDICALLY NECESSARY</u> only in a small subset of members 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. Copies of original medical records must be submitted either hard copy or electronically to support medical necessity.

Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant (e.g., the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered MEDICALLY NECESSARY for individuals ages 18 years and older who meet all of the following criteria:

- Bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; AND
- Receive limited benefit from appropriately fitted bilateral hearing aids; AND
- Have the following hearing thresholds:
 - \circ Low-frequency hearing thresholds \le 60 dB at frequencies 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 ≥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 ≥ 60 dB hearing level) in the contralateral ear; **AND**
 - Recorded word/sentence testing 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.

Prior Authorization Information

Inpatient

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

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

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

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

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes:

CPT codes:	Code Description
69930	Cochlear device implantation, with or without mastoidectomy

HCPCS Codes

HCPCS	
codes:	Code Description
L8614	Cochlear device; 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 or auditory osseointegrated
	device, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system,
	replacement
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,
	replacement

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if <u>medical necessity criteria</u> are met:

ICD-10 Diagnosis Codes

ICD-10-CM	
Diagnosis	
codes:	Code Description

H90.3	Sensorineural hearing loss, bilateral
	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the
H90.41	contralateral side
	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the
H90.42	contralateral side
H90.5	Unspecified sensorineural hearing loss

Description

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.

Summary

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.

Summary of Evidence

For individuals who have bilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes randomized controlled trials (RCTs) and multiple systematic reviews and technology assessments. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available studies have reported improvements in speech reception and quality of life measures. Although the available RCTs and other studies measured heterogeneous outcomes and included varying patient populations, the findings are consistent across multiple studies and settings. In addition to consistent improvement in speech reception (especially in noise), studies showed improvements in sound localization with bilateral devices. Studies have also suggested that earlier implantation may be preferred. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes small open-label RCTs, a feasibility study, prospective and retrospective studies reporting within-subjects comparisons, and systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Given the natural history of hearing loss, pre- and postimplantation comparisons may be appropriate for objectively measured outcomes. However, the available evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, is limited by small sample sizes and heterogeneity in evaluation protocols and outcome measurements. A small feasibility study in adults with single-sided deafness or asymmetric hearing loss demonstrated improvements in sound perception, sound localization, and subjective measures of quality of life compared to baseline conditions. Inconsistent sound localization and binaural hearing outcomes have been reported in 2 small RCTs. Prospective studies assessing outcomes compared to best-aided hearing controls beyond 6 months are lacking. Ongoing postmarketing in adults and children may further elucidate outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a high-frequency sensorineural hearing loss with preserved low-frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound

processor of the cochlear implant, the evidence includes prospective and retrospective studies using single-arm, within-subject comparisons pre- and postintervention and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available evidence has suggested that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. The available evidence has also suggested that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation after hybrid cochlear implantation if there is a loss of residual hearing. Studies reporting on long-term outcomes and results of re implantation are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Policy HIS	
Date	Action
4/2024	Annual policy review. References updated. Policy statements unchanged.
4/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2022	Clarified coding information
5/2021	Policy statement on replacement of internal and/or external components solely for the purpose of upgrading to a next-generation device clarified; providers should determine the reasonable useful lifetime of the device to be five years.
4/2021	Policy statements updated to reflect expanded indications in children aged 9 months and older with profound unilateral sensorineural hearing loss. Effective 4/1/2021.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
9/2020	Annual policy review. Policy statements updated to reflect expanded indications in children aged 9 months and older with profound bilateral sensorineural hearing loss. Effective 9/1/2020.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2018	Annual policy review. New references added.
1/2018	Clarified coding information.
7/2017	Annual policy review. New medically necessary and not medically necessary indications described. Clarified coding information. Effective 7/1/2017.
12/2016	Annual policy review. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria. References added. Effective 12/1/2016.
7/2015	Annual policy review. New references added.
12/2014	Correction made to last line of the Summary.
10/2014	Annual policy review. New references added.
10/2014	Annual policy review. New investigational indications described. Coding information clarified. Effective 10/1/2014.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
1/2014	Coding information clarified. Updated to add new CPT codes 92521-92524.
12/2013	Annual policy review. New investigational indications described. Effective 12/1/2013. Coding information clarified.
5/2013	Annual policy review. New references added.

11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No
4/2012	changes to policy statements.
12/2011	Annual policy review. Changes to policy statements.
3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
7/2007	Annual policy review. No changes to policy statements.
5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2007	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

References

- 1. Cochlear Implants in Adults and Children. NIH Consens Statement Online. 1995;13(2):1-30.
- 2. Bond M, Mealing S, Anderson R, et al. The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model. Health Technol Assess. Sep 2009; 13(44): 1-330. PMID 19799825
- 3. Gaylor JM, Raman G, Chung M, et al. Cochlear implantation in adults: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. Mar 2013; 139(3): 265-72. PMID 23429927
- 4. 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. Apr 2018; 128(4): 982-990. PMID 28731538
- 5. McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of Cochlear Implantation Outcomes Evaluated With General Health-related Patient-reported Outcome Measures. Otol Neurotol. Jan 2018; 39(1): 29-36. PMID 29227446
- 6. Crathorne L, Bond M, Cooper C, et al. A systematic review of the effectiveness and cost-effectiveness of bilateral multichannel cochlear implants in adults with severe-to-profound hearing loss. Clin Otolaryngol. Oct 2012; 37(5): 342-54. PMID 22928754
- Choi JS, Betz J, Li L, et al. Association of Using Hearing Aids or Cochlear Implants With Changes in Depressive Symptoms in Older Adults. JAMA Otolaryngol Head Neck Surg. Jul 01 2016; 142(7): 652-7. PMID 27258813
- van Zon A, Smulders YE, Ramakers GG, et al. Effect of unilateral and simultaneous bilateral cochlear implantation on tinnitus: A Prospective Study. Laryngoscope. Apr 2016; 126(4): 956-61. PMID 26255618
- Bond M, Elston J, Mealing S, et al. Effectiveness of multi-channel unilateral cochlear implants for profoundly deaf children: a systematic review. Clin Otolaryngol. Jun 2009; 34(3): 199-211. PMID 19531168

- 10. Baron S, Blanchard M, Parodi M, et al. Sequential bilateral cochlear implants in children and adolescents: Outcomes and prognostic factors. Eur Ann Otorhinolaryngol Head Neck Dis. Apr 2019; 136(2): 69-73. PMID 30314876
- 11. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Nucleus 24 Cochlear Implant System (P970051/S172). 2020; https://www.accessdata.fda.gov/cdrh_docs/pdf/P970051S172B.pdf. Accessed January 1, 2024.
- 12. Lyu J, Kong Y, Xu TQ, et al. Long-term follow-up of auditory performance and speech perception and effects of age on cochlear implantation in children with pre-lingual deafness. Chin Med J (Engl). Aug 20 2019; 132(16): 1925-1934. PMID 31365431
- 13. Karltorp E, Eklöf M, Östlund E, et al. Cochlear implants before 9 months of age led to more natural spoken language development without increased surgical risks. Acta Paediatr. Feb 2020; 109(2): 332-341. PMID 31350923
- 14. Sharma A, Dorman MF. Central auditory development in children with cochlear implants: clinical implications. Adv Otorhinolaryngol. 2006; 64: 66-88. PMID 16891837
- 15. Forli F, Arslan E, Bellelli S, et al. Systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in paediatric patients. Acta Otorhinolaryngol Ital. Oct 2011; 31(5): 281-98. PMID 22287820
- 16. Sterkers F, Merklen F, Piron JP, et al. Outcomes after cochlear reimplantation in children. Int J Pediatr Otorhinolaryngol. Jun 2015; 79(6): 840-843. PMID 25843784
- 17. Black J, Hickson L, Black B, et al. Prognostic indicators in paediatric cochlear implant surgery: a systematic literature review. Cochlear Implants Int. May 2011; 12(2): 67-93. PMID 21756501
- 18. Pakdaman MN, Herrmann BS, Curtin HD, et al. Cochlear implantation in children with anomalous cochleovestibular anatomy: a systematic review. Otolaryngol Head Neck Surg. Feb 2012; 146(2): 180-90. PMID 22140206
- 19. Fernandes NF, Morettin M, Yamaguti EH, et al. Performance of hearing skills in children with auditory neuropathy spectrum disorder using cochlear implant: a systematic review. Braz J Otorhinolaryngol. 2015; 81(1): 85-96. PMID 25458263
- 20. Bo D, Huang Y, Wang B, et al. Auditory and Speech Outcomes of Cochlear Implantation in Children With Auditory Neuropathy Spectrum Disorder: A Systematic Review and Meta-Analysis. Ann Otol Rhinol Laryngol. Apr 2023; 132(4): 371-380. PMID 35499129
- 21. Vlastarakos PV, Proikas K, Papacharalampous G, et al. Cochlear implantation under the first year of age--the outcomes. A critical systematic review and meta-analysis. Int J Pediatr Otorhinolaryngol. Feb 2010; 74(2): 119-26. PMID 19896223
- 22. Ching TY, Dillon H, Day J, et al. Early language outcomes of children with cochlear implants: interim findings of the NAL study on longitudinal outcomes of children with hearing impairment. Cochlear Implants Int. 2009; 10 Suppl 1(Suppl 1): 28-32. PMID 19067433
- 23. Colletti L, Mandalà M, Zoccante L, et al. Infants versus older children fitted with cochlear implants: performance over 10 years. Int J Pediatr Otorhinolaryngol. Apr 2011; 75(4): 504-9. PMID 21277638
- 24. Guerzoni L, Murri A, Fabrizi E, et al. Social conversational skills development in early implanted children. Laryngoscope. Sep 2016; 126(9): 2098-105. PMID 26649815
- 25. Lammers MJ, van der Heijden GJ, Pourier VE, et al. Bilateral cochlear implantation in children: a systematic review and best-evidence synthesis. Laryngoscope. Jul 2014; 124(7): 1694-9. PMID 24390811
- Broomfield SJ, Murphy J, Emmett S, et al. Results of a prospective surgical audit of bilateral paediatric cochlear implantation in the UK. Cochlear Implants Int. Nov 2013; 14 Suppl 4: S19-21. PMID 24533758
- 27. Sarant J, Harris D, Bennet L, et al. Bilateral versus unilateral cochlear implants in children: a study of spoken language outcomes. Ear Hear. 2014; 35(4): 396-409. PMID 24557003
- 28. Escorihuela García V, Pitarch Ribas MI, Llópez Carratalá I, et al. Comparative study between unilateral and bilateral cochlear implantation in children of 1 and 2 years of age. Acta Otorrinolaringol Esp. 2016; 67(3): 148-55. PMID 26632253
- 29. Friedmann DR, Green J, Fang Y, et al. Sequential bilateral cochlear implantation in the adolescent population. Laryngoscope. Aug 2015; 125(8): 1952-8. PMID 25946482

- 30. Illg A, Giourgas A, Kral A, et al. Speech comprehension in children and adolescents after sequential bilateral cochlear implantation with long interimplant interval. Otol Neurotol. Jun 2013; 34(4): 682-9. PMID 23640090
- 31. Oh SJ, Mavrommatis MA, Fan CJ, et al. Cochlear Implantation in Adults With Single-Sided Deafness: A Systematic Review and Meta-analysis. Otolaryngol Head Neck Surg. Feb 2023; 168(2): 131-142. PMID 35230924
- 32. Benchetrit L, Ronner EA, Anne S, et al. Cochlear Implantation in Children With Single-Sided Deafness: A Systematic Review and Meta-analysis. JAMA Otolaryngol Head Neck Surg. Jan 01 2021; 147(1): 58-69. PMID 33151295
- 33. Marx M, Mosnier I, Venail F, et al. Cochlear Implantation and Other Treatments in Single-Sided Deafness and Asymmetric Hearing Loss: Results of a National Multicenter Study Including a Randomized Controlled Trial. Audiol Neurootol. 2021; 26(6): 414-424. PMID 33789270
- 34. Peters JPM, van Heteren JAA, Wendrich AW, et al. Short-term outcomes of cochlear implantation for single-sided deafness compared to bone conduction devices and contralateral routing of sound hearing aids-Results of a Randomised controlled trial (CINGLE-trial). PLoS One. 2021; 16(10): e0257447. PMID 34644322
- 35. 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. PMID 29732951
- 36. Dillon MT, Buss E, O'Connell BP, et al. Low-Frequency Hearing Preservation With Long Electrode Arrays: Inclusion of Unaided Hearing Threshold Assessment in the Postoperative Test Battery. Am J Audiol. Mar 05 2020; 29(1): 1-5. PMID 31835906
- 37. Galvin JJ, Fu QJ, Wilkinson EP, et al. Benefits of Cochlear Implantation for Single-Sided Deafness: Data From the House Clinic-University of Southern California-University of California, Los Angeles Clinical Trial. Ear Hear. 2019; 40(4): 766-781. PMID 30358655
- 38. Peter N, Kleinjung T, Probst R, et al. Cochlear implants in single-sided deafness clinical results of a Swiss multicentre study. Swiss Med Wkly. Dec 16 2019; 149: w20171. PMID 31880806
- Poncet-Wallet C, Mamelle E, Godey B, et al. Prospective Multicentric Follow-up Study of Cochlear Implantation in Adults With Single-Sided Deafness: Tinnitus and Audiological Outcomes. Otol Neurotol. Dec 20 2019. PMID 31868784
- 40. Dillon MT, Buss E, Rooth MA, et al. Cochlear Implantation in Cases of Asymmetric Hearing Loss: Subjective Benefit, Word Recognition, and Spatial Hearing. Trends Hear. 2020; 24: 2331216520945524. PMID 32808881
- 41. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): MED-EL Cochlear Implant System (P000025/S104). 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf/P000025S104B.pdf. Accessed December 29, 2023.
- 42. Food and Drug Administration. Post-Approval Studies (PAS): MED-EL New Enrollment SSD/AHL Study. 2020; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=647845&c_id=5585. Accessed on January 4, 2024.
- 43. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Nucleus 24 Cochlear Implant System (P970051/S205). January 10, 2022; https://www.accessdata.fda.gov/cdrh_docs/pdf/P970051S205B.pdf. Accessed December 30, 2023.
- 44. Vlastarakos PV, Nazos K, Tavoulari EF, et al. Cochlear implantation for single-sided deafness: the outcomes. An evidence-based approach. Eur Arch Otorhinolaryngol. Aug 2014; 271(8): 2119-26. PMID 24096818
- 45. Ramos Macías A, Falcón González JC, Manrique M, et al. Cochlear implants as a treatment option for unilateral hearing loss, severe tinnitus and hyperacusis. Audiol Neurootol. 2015; 20 Suppl 1: 60-6. PMID 25997672
- 46. Távora-Vieira D, Marino R, Krishnaswamy J, et al. Cochlear implantation for unilateral deafness with and without tinnitus: a case series. Laryngoscope. May 2013; 123(5): 1251-5. PMID 23553411
- 47. Brown KD, Dillon MT, Park LR. Benefits of Cochlear Implantation in Childhood Unilateral Hearing Loss (CUHL Trial). Laryngoscope. Mar 2022; 132 Suppl 6(Suppl 6): S1-S18. PMID 34542181
- 48. Pillsbury HC, Dillon MT, Buchman CA, et al. Multicenter US Clinical Trial With an Electric-Acoustic Stimulation (EAS) System in Adults: Final Outcomes. Otol Neurotol. Mar 2018; 39(3): 299-305. PMID 29342054

- 49. Food and Drug Administration. Approval Letter: Nucleus Hybrid L24 Cochlear Implant System (P130016). 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130016a.pdf. Accessed January 1. 2024.
- 50. Roland JT, Gantz BJ, Waltzman SB, et al. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. Laryngoscope. Jan 2016; 126(1): 175-81. PMID 26152811
- 51. Roland JT, Gantz BJ, Waltzman SB, et al. Long-term outcomes of cochlear implantation in patients with high-frequency hearing loss. Laryngoscope. Aug 2018; 128(8): 1939-1945. PMID 29330858
- 52. Lenarz T, James C, Cuda D, et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. Int J Audiol. Dec 2013; 52(12): 838-48. PMID 23992489
- 53. Santa Maria PL, Gluth MB, Yuan Y, et al. Hearing preservation surgery for cochlear implantation: a meta-analysis. Otol Neurotol. Dec 2014; 35(10): e256-69. PMID 25233333
- 54. Causon A, Verschuur C, Newman TA. A Retrospective Analysis of the Contribution of Reported Factors in Cochlear Implantation on Hearing Preservation Outcomes. Otol Neurotol. Aug 2015; 36(7): 1137-45. PMID 25853614
- 55. Gantz BJ, Dunn C, Oleson J, et al. Multicenter clinical trial of the Nucleus Hybrid S8 cochlear implant: Final outcomes. Laryngoscope. Apr 2016; 126(4): 962-73. PMID 26756395
- 56. American Academy of Otolaryngology -- Head and Neck Surgery. Position Statement: Cochlear Implants. November 10, 2020; https://www.entnet.org/resource/position-statement-cochlear-implants/. Accessed January 2, 2024.
- 57. Raman G, Lee J, Chung MG, et al. Technology Assessment Report: Effectiveness of Cochlear Implants in Adults with Sensorineural Hearing Loss Rockville, MD: Agency for Healthcare Research and Quality; 2011.
- 58. National Institute for Health and Care Excellence (NICE). Cochlear Implants for Children and Adults With Severe to Profound Deafness [TA566]. 2019; https://www.nice.org.uk/guidance/ta566/. Accessed January 2, 2024.
- 59. Centers for Medicare & Medicaid. Cochlear Implantation. 2005; https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=134. Accessed January 2, 2024.

Additional References¹

- 1. Marx, M., Costa, N., Lepage, B, et al. (2019). Cochlear implantation as a treatment for single-sided deafness and asymmetric hearing loss: a randomized controlled evaluation of cost-utility. *BMC ear, nose, and throat disorders*, 19, 1. https://doi.org/10.1186/s12901-019-0066-7
- 2. Deep NL, Gordon SA, Shapiro WH, et al. Cochlear Implantation in Children with Single-Sided Deafness. Laryngoscope. 2020 Feb 17.
- 3. Legris E, Galvin J, Roux S, et al. Cortical reorganization after cochlear implantation for adults with single-sided deafness. PLoS One. 2018 Sep 24;13(9)
- 4. Huttunen K, Erixon E, Löfkvist U, et al. The impact of permanent early-onset unilateral hearing impairment in children A systematic review. Int J Pediatr Otorhinolaryngol. 2019 May;120:173-183.
- 5. Zeitler DM, Sladen DP, DeJong MD, et al. Cochlear implantation for single-sided deafness in children and adolescents. Int J Pediatr Otorhinolaryngol. 2019 Mar;118:128-133.
- 6. Huttunen K, Erixon E, Löfkvist U, et al. The impact of permanent early-onset unilateral hearing impairment in children A systematic review. Int J Pediatr Otorhinolaryngol. 2019 May;120:173-183.
- 7. Zeitler DM, Sladen DP, DeJong MD, et al. Cochlear implantation for single-sided deafness in children and adolescents. Int J Pediatr Otorhinolaryngol. 2019 Mar;118:128-133. 2019 Jan 2.
- 8. Liu YW, Cheng X, Chen B, et al. Effect of Tinnitus and Duration of Deafness on Sound Localization and Speech Recognition in Noise in Patients With Single-Sided Deafness. Trends Hear. 2018 Jan-Dec;22:2331216518813802
- 9. Legris E, Galvin J, Roux S, et al. Cortical reorganization after cochlear implantation for adults with single-sided deafness. PLoS One. 2018 Sep 24;13(9):e0204402.
- 10. Buss E, Dillon MT, Rooth MA, et al. Effects of Cochlear Implantation on Binaural Hearing in Adults With Unilateral Hearing Loss. Trends Hear. 2018 Jan-Dec;22:2331216518771173.
- 11. Bernstein JGW, Stakhovskaya OA, Schuchman GI, et al. Interaural Time-Difference Discrimination as a Measure of Place of Stimulation for Cochlear-Implant Users With Single-Sided Deafness. Trends Hear. 2018 Jan-Dec;22:2331216518765514.

- 12. Távora-Vieira D, Wedekind A, Marino R, et al. Using aided cortical assessment as an objective tool to evaluate cochlear implant fitting in users with single-sided deafness. PLoS One. 2018 Feb 22:13(2):e0193081.
- 13. Dillon MT, Buss E, Rooth MA, et al. Effect of Cochlear Implantation on Quality of Life in Adults with Unilateral Hearing Loss. Audiol Neurootol. 2017;22(4-5):259-271.
- 14. Polonenko MJ, Gordon KA, Cushing SL, et al. Cortical organization restored by cochlear implantation in young children with single sided deafness. Sci Rep. 2017 Dec 4;7(1):16900.
- 15. Döge J, Baumann U, Weissgerber T, et al. Single-Sided Deafness: Impact of Cochlear Implantation on Speech Perception in Complex Noise and on Auditory Localization Accuracy. Otol Neurotol. 2017 Dec;38(10).
- 16. Finke M, Bönitz H, Lyxell B, et al. Cochlear implant effectiveness in postlingual single-sided deaf individuals: what's the point? Int J Audiol. 2017 Jun:56(6):417-423
- 17. Bernstein JGW, Schuchman GI, Rivera AL. Head Shadow and Binaural Squelch for Unilaterally Deaf Cochlear Implantees. Otol Neurotol. 2017 Aug;38(7):e195-e202.
- 18. Polonenko MJ, Papsin BC, Gordon KA. Children With Single-Sided Deafness Use Their Cochlear Implant. Ear Hear. 2017 Nov/Dec;38(6):681-689.
- 19. Van de Heyning P, Távora-Vieira D et al. Framework for Single-Sided Deafness Studies: A Consensus Paper. Audiol Neurootol. 2016;21(6):391-398.
- 20. Thomas JP, Neumann K, Dazert S, et al. Cochlear Implantation in Children With Congenital Single-Sided Deafness. Otol Neurotol. 2017 Apr;38(4):496-503.
- 21. Finke M, Straus-Schier A, Kludt E,. Speech intelligibility and subjective benefit in single-sided deaf adults after cochlear implantation. Hear Res. 2017 May;348:112-119.
- 22. Louza J, Hempel JM, Krause E, et al. Patient benefit from Cochlear implantation in single-sided deafness: a 1-year follow-up. Eur Arch Otorhinolaryngol. 2017 Jun;274(6):2405-2409.
- 23. Arndt S, Laszig R, Aschendorff A, et al. Cochlear implant treatment of patients with single-sided deafness or asymmetric hearing loss. HNO. 2017 Aug;65(Suppl 2):98-108.
- 24. Holder JT, O'Connell B, Hedley-Williams A, et al. Cochlear implantation for single-sided deafness and tinnitus suppression. Am J Otolaryngol. 2017 Mar Apr;38(2):226-229.
- 25. Sangen A, Royackers L, Desloovere C, et al. Single-sided deafness affects language and auditory development a case-control study. Clin Otolaryngol. 2017 Oct;42(5):979-987.
- 26. Sladen DP, Carlson ML, Dowling BP, et al. Early outcomes after cochlear implantation for adults and children with unilateral hearing loss. Laryngoscope. 2017 Jul;127(7):1683-1688.
- 27. Rahne T, Plontke SK. Functional Result After Cochlear Implantation in Children and Adults With Single-sided Deafness. Otol Neurotol. 2016 Oct;37(9):e332-40.
- 28. Zhou X, Li H, Galvin JJ 3rd, et al. Effects of insertion depth on spatial speech perception in noise for simulations of cochlear implants and single-sided deafness. Int J Audiol. 2017;56(sup2):S41-S48.
- 29. Grossmann W, Brill S, Moeltner A, Mlynski R, Hagen R, Radeloff A. Cochlear Implantation Improves Spatial Release From Masking and Restores Localization Abilities in Single-sided Deaf Patients. Otol Neurotol. 2016 Jul;37(6):658-64.
- 30. Sladen DP, Frisch CD, Carlson ML, et al. Cochlear implantation for single-sided deafness: A multicenter study. Laryngoscope. 2017 Jan;127(1):223-228.
- 31. Hoth S, Rösli-Khabas M, Herisanu I,et al. Cochlear implantation in recipients with single-sided deafness: Audiological performance. Cochlear Implants Int. 2016 Jul;17(4):190-199.
- 32. Távora-Vieira D, Marino R, Acharya A, et al. Cochlear implantation in adults with unilateral deafness: A review of the assessment/evaluation protocols. Cochlear Implants Int. 2016 Jul;17(4):184-189.
- 33. Arts RA, George EL, Janssen M, et al. Tinnitus Suppression by Intracochlear Electrical Stimulation in Single Sided Deafness A Prospective Clinical Trial: Follow-Up. PLoS One. 2016 Apr 25:11(4):e0153131.
- 34. Friedmann DR, Ahmed OH, McMenomey SO, et al. Single-sided Deafness Cochlear Implantation: Candidacy, Evaluation, and Outcomes in Children and Adults. Otol Neurotol. 2016 Feb;37(2):e154-60.
- 35. Mertens G, Desmet J, De Bodt M, et al. Prospective case-controlled sound localisation study after cochlear implantation in adults with single-sided deafness and ipsilateral tinnitus. Clin Otolaryngol. 2016 Oct;41(5):511-8.

- 36. Härkönen K, Kivekäs I, Rautiainen M, et al. Single-Sided Deafness: The Effect of Cochlear Implantation on Quality of Life, Quality of Hearing, and Working Performance. ORL J Otorhinolaryngol Relat Spec.2015;77(6):339-45.
- 37. Arts RA, George EL, Griessner A, et al. Tinnitus Suppression by Intracochlear Electrical Stimulation in Single-Sided Deafness: A Prospective Clinical Trial Part I. Audiol Neurootol. 2015;20(5):294-313.
- 38. Kitterick PT, Lucas L, Smith SN. Improving health-related quality of life in single-sided deafness: a systematic review and meta-analysis. Audiol Neurootol. 2015;20 Suppl 1:79-86.
- 39. Mertens G, Hofkens A, Punte AK, et al. Hearing performance in single-sided deaf cochlear implant users after upgrade to a single-unit speech processor. Otol Neurotol. 2015 Jan;36(1):51-60.
- 40. Gartrell BC, Jones HG, Kan A, Buhr-Lawler M, et al. Investigating long-term effects of cochlear implantation in single-sided deafness: a best practice model for longitudinal assessment of spatial hearing abilities and tinnitus handicap. Otol Neurotol. 2014 Oct;35(9):1525-32.
- 41. Tokita J, Dunn C, Hansen MR. Cochlear implantation and single-sided deafness. Curr Opin Otolaryngol Head Neck Surg. 2014 Oct;22(5):353-8.
- 42. Hansen MR, Gantz BJ, Dunn C. Outcomes after cochlear implantation for patients with single-sided deafness, including those with recalcitrant Ménière's disease. Otol Neurotol. 2013 Dec;34(9):1681-7.
- 43. Punte AK, De Ridder D, Van de Heyning P. On the necessity of full length electrical cochlear stimulation to suppress severe tinnitus in single-sided deafness. Hear Res. 2013 Jan;295:24-9.
- 44. Arts RA, George EL, Stokroos RJ, Vermeire K. Review: cochlear implants as a treatment of tinnitus in single-sided deafness. Curr Opin Otolaryngol Head Neck Surg. 2012 Oct;20(5):398-403.
- 45. Punte AK, Vermeire K, Hofkens A, De Bodt M, De Ridder D, Van de Heyning P. Cochlear implantation as a durable tinnitus treatment in single-sided deafness. Cochlear Implants Int. 2011 May;12 Suppl 1:S26-9.
- 46. Vermeire K, Van de Heyning P. Binaural hearing after cochlear implantation in subjects with unilateral sensorineural deafness and tinnitus. Audiol Neurootol. 2009;14(3):163-71.
- 47. Van de Heyning P, Vermeire K, Diebl M, et al. Incapacitating unilateral tinnitus in single-sided deafness treated by cochlear implantation. Ann Otol Rhinol Laryngol. 2008 Sep;117(9):645-52.
- 48. Benchetrit L, Ronner EA, Anne S, et al. Cochlear Implantation in Children With Single-Sided Deafness: A Systematic Review and Meta-analysis. JAMA Otolaryngol Head Neck Surg. Published online November 05, 2020.

Endnotes

¹ Based on expert opinion