Medical Coverage Policy | Cochlear Implants

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OVERVIEW
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. This policy documents the coverage guidelines for cochlear implants.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Prior authorization is not required.

POLICY STATEMENT
Cochlear Implantation - Bilateral

Medicare Advantage Plans
Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be considered medically necessary in patients with bilateral moderate to profound pre- or post-lingual (sensorineural) hearing loss and who have shown limited or no benefit from hearing aids.

Commercial Products
Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be considered medically necessary in patients age 9 months and older with bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss and who have shown limited or no benefit from hearing aids.

Medicare and Commercial
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 (BTE) model, are considered not covered, as this is considered a convenience. Additionally, 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 covered, as this is considered a convenience.

Replacement of internal and/or external components is considered medically necessary 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.

Hybrid Cochlear Implant/Hearing Aid
Medicare Advantage Plans
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 (eg, the Nucleus® Hybrid™ L24

Cochlear Implant System) may be considered medically necessary for patients ~~ages 18 years and older~~ who have bilateral moderate-to-profound high-frequency sensorineural hearing loss with residual low frequency hearing sensitivity and receive limited benefit from appropriately fit bilateral hearing aids.

Commercial Products
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 (eg, the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered medically necessary for patients ages 18 years and older who have bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low frequency hearing sensitivity and receive limited benefit from appropriately fit bilateral hearing aids.

Cochlear Implantation - Unilateral
Medicare Advantage Plans
Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus may be covered as part of FDA-approved category B investigational device exemption clinical trials or as a routine cost in clinical trials. Please see the Coding and Related Policies sections for details.

Commercial Products
Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Surgery Services and Medical Equipment, Medical Supplies, and Prosthetic Devices/Diagnostic Imaging, Lab, Machine Tests/Speech Therapy, and Personal Appearance and/or Items coverage/benefits.

BACKGROUND
A cochlear implant, classified by Centers for Medicare and Medicaid Services (CMS) as a prosthetic device, is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

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

Medicare Advantage Plans
Cochlear implantation may be utilized for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition. Individuals should have the cognitive ability to use auditory clues and have a willingness to undergo an extended program of rehabilitation; freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; have no contraindications to surgery; and the device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

CMS, may provide coverage of cochlear implants for individuals not meeting coverage criteria when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR (Code of Federal Regulations), section 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

Commercial Products
Typically, severe hearing loss is defined as a bilateral hearing threshold of 70 to 90 dB, and profound hearing loss is defined as a bilateral hearing threshold of 90 dB and above. In adults, limited benefit from hearing aids is defined as scores 50% correct or less in the ear to be implanted on tape-recorded sets of open-set sentence recognition. In children, limited benefit is defined as failure to develop basic auditory skills, and in older children, 30% or less correct on open-set tests.

Several cochlear implants are commercially available in the United States and are manufactured by Cochlear Americas, Advanced Bionics, and the MED-EL Corp. Over time, subsequent generations of the various components of the devices have been approved by the U.S. Food and Drug Administration (FDA), focusing on improved electrode design and speech-processing capabilities. Furthermore, smaller devices and the accumulating experience in children have resulted in broadening of the selection criteria to include children as young as 12 months.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. A typical rehabilitation program consists of 6 to 10 sessions that last approximately 2½ hours each. A rehabilitation program would include development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implantation plus hearing aid in the contralateral ear will not result in a binaural benefit (ie, in those individuals with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

Contraindications to cochlear implantation may include 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; and mastoid cavity or tympanic membrane perforation. Cochlear ossification may prevent electrode insertion, and the absence of cochlear development as demonstrated on computed tomography scans remains an absolute contraindication.

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.

In 2014, the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Americas) was approved by FDA through the premarket approval process. This system is a hybrid cochlear implant and hearing aid, with the hearing aid integrated into the external sound processor of the cochlear implant. It is indicated for unilateral use in patients ages 18 years and older who have residual low-frequency hearing sensitivity and severe-to-profound high-frequency sensorineural hearing loss, and who obtain limited benefit from an appropriately fit bilateral hearing aid. The electrode array inserted into the cochlea is shorter than conventional cochlear implants. According to FDA's premarket approval notification, labeled indications for the device include:

- Preoperative hearing in the range from "normal to moderate hearing loss [HL] in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz)"
- Preoperative hearing with "severe to profound mid to high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥75 dB HL) in the ear to be implanted"
- Preoperative hearing with "moderately severe to profound mid to high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥60 dB HL) in the contralateral ear"
- "The CNC [Consonant-Nucleus-Consonant] word recognition score will be between 10% and 60%, inclusively, in the ear to be implanted in the preoperative aided condition and in the contralateral ear equal to or better than that of the ear to be implanted but not more than 80% correct."

In 2022, the Nucleus® Hybrid™ L24 Cochlear Implant System received expanded approval for single-sided deafness or unilateral hearing loss in adults and children age 5 or older. Other hybrid hearing devices have been developed. The Med-El EAS System received expanded PMA (pre-market approval) by the FDA in 2016 (PMA P000025/S084).

Clinical input obtained in 2016 supports the use of hybrid cochlear implants in patients with high-frequency hearing loss but preserved low frequency hearing.

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 post- implantation 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 post marketing studies 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.

CODING

In addition to the codes identified in this policy under the diagnostic imaging, lab, and machine tests benefit, there may be other therapeutic service codes related to cochlear implants (such as auditory rehabilitation) which would be applied to the member's speech therapy benefit.

Medicare Advantage Plans and Commercial Products

The following code is covered under the member's **surgery services** benefit:

69930 Cochlear device implantation, with or without mastoidectomy

The following codes are covered under the member's **speech therapy** benefit:

92626 Evaluation of auditory rehabilitation status; first hour
92627 Evaluation of auditory rehabilitation status; each additional 15 minutes
92630 Auditory rehabilitation; pre-lingual hearing loss
92633 Auditory rehabilitation; post-lingual hearing loss

The following codes are covered under the **diagnostic imaging, lab, and machine tests** benefit:

92601 Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602 Diagnostic analysis of cochlear implant, patient younger than 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

The following codes are covered under the **prosthetic devices** benefit:

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
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
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 codes are covered under the **durable medical equipment** benefit:

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 or auditory osseointegrated 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

Note: If you are treating a Medicare Advantage Plan member as part of an FDA-approved Category B investigational device exemption clinical trial or as a routine clinical trial, please follow the procedures for correct billing and coding of services found in the policy for Clinical Trials Mandate Medicare Advantage Plans.

Claims for services rendered as part of FDA-approved Category B investigational device exemption clinical trials or as a routine cost in clinical trials must be billed with an appropriate modifier:

The following modifier should be reported with the cochlear implantation device and all other related costs:

Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study

The following modifier must be reported for routine costs and not the device itself:

Q1 Routine clinical service provided in a clinical research study that is in an approved clinical research study

RELATED POLICIES

Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations
Clinical Trials Medicare Advantage Plans
Durable Medical Equipment
Speech Therapy

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Provider Update, June 2023
Provider Update, October 2022
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Provider Update, September 2020
Provider Update, May 2020

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 50.3, https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=245&ncdver=3&bc=0.
2. Cochlear Implants in Adults and Children. NIH Consens Statement Online. 1995;13(2):1-30.
3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
11. 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
12. 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 2, 2022.
13. 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
14. Karltorp E, Eklof M, Ostlund 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
15. Sharma A, Dorman MF. Central auditory development in children with cochlear implants: clinical implications. Adv Otorhinolaryngol. 2006; 64: 66-88. PMID 16891837

16. 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
17. 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
18. 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
19. 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
20. 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. Jan-Feb 2015; 81(1): 85-96. PMID 25458263
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: 28-32. PMID 19067433
23. Colletti L, Mandala 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
26. 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. Jul-Aug 2014; 35(4): 396-409. PMID 24557003
28. Escorihuela Garcia V, Pitarch Ribas MI, Llopez Carratala I, et al. Comparative study between unilateral and bilateral cochlear implantation in children of 1 and 2 years of age. Acta Otorrinolaringol Esp. May-Jun 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. van Zon A, Peters JP, Stegeman I, et al. Cochlear implantation for patients with single-sided deafness or asymmetrical hearing loss: a systematic review of the evidence. Otol Neurotol. Feb 2015; 36(2): 209-19. PMID 25502451
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 andAsymmetric Hearing Loss: Results of a National Multicenter Study Including a Randomized Controlled Trial. AudiolNeurootol. 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-sideddeafness compared to bone conduction devices and contralateral routing of sound hearing aids-Results of aRandomised 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. Jan-Dec 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. Jul/Aug 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
39. 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. Jan-Dec 2020; 24: 2331216520945524. PMID 32808881
41. 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, 2022.
42. 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 January 16, 2021.
43. Mertens G, De Bodt M, Van de Heyning P. Cochlear implantation as a long-term treatment for ipsilateral incapacitating tinnitus in subjects with unilateral hearing loss up to 10 years. Hear Res. Jan 2016; 331: 1-6. PMID 26433053
44. Rahne T, Plontke SK. Functional Result After Cochlear Implantation in Children and Adults With Single-sided Deafness. Otol Neurotol. Oct 2016; 37(9): e332-40. PMID 27631656
45. 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
46. Ramos Macias A, Falcon Gonzalez 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
47. Tavora-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
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 5, 2022.
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; http://www.entnet.org/Practice/policyCochlearImplants.cfm. Accessed January 7, 2022.
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 7, 2022.