Protocol

Cochlear Implant

(70105)

Medical Benefit		**Effective Date**: 01/01/18	**Next Review Date**: 07/21
Preauthorization	No	**Review Dates**: 04/07, 05/08, 05/09, 03/10, 03/11, 03/12, 03/13, 07/13, 03/14, 07/14, 07/15, 07/16, 09/16, 07/17, 07/18, 03/20, 07/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

RELATED PROTOCOLS

Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Treatment of Tinnitus

Populations	Interventions	Comparators	Outcomes
Individuals: • With bilateral sensorineural hearing loss	Interventions of interest are: • Cochlear implant(s)	Comparators of interest are: • Best-aided hearing	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related mortality • Treatment-related morbidity
Individuals: • With unilateral sensorineural hearing loss	Interventions of interest are: • Cochlear implant(s)	Comparators of interest are: • Best-aided hearing	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related mortality • Treatment-related morbidity
Individuals: • With high-frequency sensorineural hearing loss with preserved low-frequency hearing	Interventions of interest are: • Hybrid cochlear implant that includes a hearing aid integrated into the external sound processor of the cochlear implant	Comparators of interest are: • Best-aided hearing	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related mortality • Treatment-related morbidity

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 a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes 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. However, studies assessing outcomes compared to best-aided hearing controls across multiple time points are lacking. An ongoing post-marketing study in adults and children may further elucidate outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 comparison 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 the effects of the technology on health outcomes.

POLICY

Bilateral or unilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant may be considered **medically necessary** in patients ages 12 months and older with bilateral severe-to-profound pre- or post-lingual (sensorineural) hearing loss, defined as a hearing threshold pure-tone average of 70 decibels (dB) hearing loss or greater at 500, 1000 and 2000 hertz (Hz), who have shown limited or no benefit from hearing aids.

Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered **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 (BTE) model, are considered **not medically necessary**.

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**.

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. 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 patients 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 fit bilateral hearing aids; AND
- 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 ≥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
    - 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.

POLICY GUIDELINES

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 (i.e., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

In certain situations, implantation may be considered before 12 months of age. One scenario is post-meningitis when cochlear ossification may preclude implantation. Another is in cases with a strong family history, because establishing a precise diagnosis is less uncertain.

Hearing loss is rated based on the threshold of hearing. Severe hearing loss is defined as a bilateral hearing threshold of 70–90 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 of 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.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program consists of six to ten sessions that last approximately 2.5 hours each. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

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.

MEDICARE ADVANTAGE

Cochlear implantation may be considered **medically necessary** 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 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Patients need to meet all of the following selection guidelines:

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and 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;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

Individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% may be eligible under a clinical trial.

BACKGROUND

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.

REGULATORY STATUS

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. The labeled indications from the FDA for currently marketed implant devices are summarized in Table 1. FDA product code: MCM.

Table 1. Cochlear Implant Systemsa Approved by the Food and Drug Administration

Variables	Manufacturer and Currently Marketed Cochlear Implants		
	Advanced Bionics® HiResolution® Bionic Ear System (HiRes 90K)	Cochlear® Nucleus 22 and 24	Med El® Maestro Combi 40+
PMA	P960058	P840024, P970051	P000025
Predicate devices	Clarion Multi-Strategy or HiFocus CII Bionic Ear (P940022)	Freedom with Contour	
Indications			
Adults ≥18 y	Postlingual onset of severe-to-profound bilateral SNHL (≥70 dB) Limited benefit from appropriately fitted hearing aids, defined as scoring ≤50% on a test of open-set HINT sentence recognition	Pre-, peri-, or postlingual onset of bilateral SNHL, usually characterized by: • Moderate-to-profound HL in low frequencies; and • Profound (≥90 dB) HL in mid-to-high speech frequencies Limited benefit from binaural hearing aids (≤50% sentence recognition in ear to be implanted)	Severe-to-profound bilateral SNHL (≥70 dB) ≤40% correct HINT sentences with best-sided listening condition
Children	**12 mo to 17 y of age** Profound bilateral SNHL (>90 dB) Use of appropriately fitted hearing aids for at least 6 mo in children 2-17 y or at least 3 mo in children 12-23 mo Lack of benefit in children <4 y defined as a failure to reach developmentally appropriate auditory milestones (e.g., spontaneous response to name in quiet or to environmental sounds) measured using IT-MAIS or MAIS or <20% correct on a simple open-set word recognition test (MLNT) administered using monitored live voice (70 dB SPL) Lack of hearing aid benefit in children >4 y defined as scoring <12% on a difficult open-set word recognition test (PBK test) or <30% on an open-set sentence test (HINT for Children) administered using recorded materials in the sound field (70 dB SPL)	**25 mo to 17 y 11 mo** Severe-to-profound bilateral SNHL MLNT scores ≤30% in best-aided condition in children 25 mo to 4 y 11 mo LNT scores ≤30% in best-aided condition in children 5 y to 17 y and 11 mo 12-24 mo Profound SNHL bilaterally Limited benefit from appropriate binaural hearing aids	**12 mo to 18 y** Profound sensorineural HL (≥90 dB) In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills with hearing aids over 3 to 6 mo In older children, lack of aided benefit is defined as <20% correct on the MLNT or LNT, depending on child's cognitive ability and linguistic skills A 3- to 6-mo trial with hearing aids is required if not previously experienced

HINT: Hearing in Noise Test; HL: hearing loss; IT-MAIS: Infant-Toddler Meaningful Auditory Integration Scale; LNT: Lexical Neighborhood Test; MAIS: Meaningful Auditory Integration Scale; MLNT: Multisyllabic Lexical Neighborhood Test; PBK: Phonetically Balanced-Kindergarten; SNHL: sensorineural hearing loss; SPL: sound pressure level.

[a] The external Nucleus 5 sound processor is not a part of the recall. Advanced Bionics HiRes90K was voluntarily recalled in 2010 and given approval by the Food and Drug Administration for reentry to market the device in 2011. Cochlear voluntarily recalled the Nucleus CI500 range in 2011 for device malfunction in the CI512 implant.

In 2014, the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Americas) was approved by the FDA through the premarket approval process.[1] 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 the 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."

Other hybrid hearing devices have been developed. The Med-El EAS System received expanded premarket approval by the FDA in 2016 (PMA P000025/S084). FDA product code: PGQ.

Although cochlear implants have typically been used unilaterally, interest in bilateral cochlear implantation has arisen in recent years. The proposed benefits of bilateral cochlear implants are to improve understanding of speech occurring in noisy environments and localization of sounds. Improvements in speech intelligibility with bilateral cochlear implants may occur through binaural summation (i.e., signal processing of sound input from two sides may provide a better representation of sound and allow the individual to separate noise from speech). Speech intelligibility and localization of sound or spatial hearing may also be improved with head shadow and squelch effects (i.e., the ear that is closest to the noise will receive it at a different frequency and with different intensity, allowing the individual to sort out the noise and identify the direction of sound). Bilateral cochlear implantation may be performed independently with separate implants and speech processors in each ear, or a single processor may be used. However, no single processor for bilateral cochlear implantation has been approved by the FDA for use in the United States. Also, single processors do not provide binaural benefit and may impair sound localization and increase the signal-to-noise ratio received by the cochlear implant.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. 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 14, 2020.
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):265-272. 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. 2018 Apr;128(4). 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. 2018 Jan;39(1). 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):342-354. 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):652-657. 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):956-961. 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. 2019 Apr;136(2). PMID 30314876
12. Sharma A, Dorman MF. Central auditory development in children with cochlear implants: clinical implications. Adv Otorhinolaryngol. Aug 2006;64:66-88. PMID 16891837
13. 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):281-298. PMID 22287820
14. 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
15. 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
16. 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):180-190. PMID 22140206
17. 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
18. 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): 119-126. PMID 19896223

19. 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. Dec 2009;10 Suppl 1:28-32. PMID 19067433
20. 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):504-509. PMID 21277638
21. Guerzoni L, Murri A, Fabrizi E, et al. Social conversational skills development in early implanted children. Laryngoscope. Sep 2016;126(9):2098-2105. PMID 26649815
22. 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):1694-1699. PMID 24390811
23. 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
24. 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
25. 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):148-155. PMID 26632253
26. Friedmann DR, Green J, Fang Y, et al. Sequential bilateral cochlear implantation in the adolescent population. Laryngoscope. Aug 2015;125(8):1952-1958. PMID 25946482
27. 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):682-689. PMID 23640090
28. 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):209-219. PMID 25502451
29. 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;22:2331216518771173. PMID 29732951
30. 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. 2019 Dec 13:1-5. PMID: 31835906.
31. Galvin JJ III, 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 Jul/Aug;40(4):766-781. PMID: 30358655.
32. Peter N, Kleinjung T, Probst R, et al. Cochlear implants in single-sided deafness - clinical results of a Swiss multicentre study. Swiss Med Wkly. 2019 Dec;149:w20171. PMID 31880806
33. 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. 2019 Dec. PMID 31868784
34. Food and Drug Administration. Approval Letter: MED-EL Cochlear Implant System (P000025/S104). 2019; https://www.accessdata.fda.gov/cdrh_docs/pdf/P000025S104A.pdf. Accessed January 14, 2020.
35. 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 20, 2020.
36. 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 14, 2020.
37. 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. Oct 15 2015;331:1-6. PMID 26433053

38. Rahne T, Plontke SK. Functional result after Cochlear implantation in children and adults with single-sided deafness. Otol Neurotol. Oct 2016;37(9):e332-340. PMID 27631656
39. 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):2119-2126. PMID 24096818
40. 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 1:60-66. PMID 25997672
41. 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):1251-1255. PMID 23553411
42. 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. 2018 Mar;39(3). PMID 29342054
43. Roland JT, Jr., Gantz BJ, Waltzman SB, et al. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. Laryngoscope. Jan 2016;126(1):175-181. PMID 26152811
44. Roland JT, Gantz BJ, Waltzman SB, et al. Long-term outcomes of cochlear implantation in patients with high-frequency hearing loss. Laryngoscope. 2018 Aug;128(8). PMID 29330858
45. 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):838-848. PMID 23992489
46. Santa Maria PL, Gluth MB, Yuan Y, et al. Hearing preservation surgery for cochlear implantation: a meta-analysis. Otol Neurotol. Dec 2014;35(10):e256-269. PMID 25233333
47. 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):1137-1145. PMID 25853614
48. Gantz BJ, Dunn C, Oleson J, et al. Multicenter clinical trial of the Nucleus Hybrid S8 cochlear implant: Final outcomes. Laryngoscope. 2016 Apr;126(4). PMID 26756395
49. American Academy of Otolarygology -- Head and Neck Surgery. Position Statement: Cochlear Implants. 2014; http://www.entnet.org/Practice/policyCochlearImplants.cfm. Accessed January 20, 2020.
50. 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.
51. 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 20, 2020.
52. Centers for Medicare & Medicaid. Cochlear Implantation. 2013; https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Cochlear-Implantation-.html. Accessed January 20, 2020.