



FEP Medical Policy Manual

FEP 7.01.05 Cochlear Implant

Effective Policy Date: July 1, 2022

Original Policy Date: March 2012

Related Policies:

- 7.01.03 - Implantable Bone-Conduction and Bone-Anchored Hearing Aids
- 7.01.84 - Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Cochlear Implant

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether use of a cochlear implant improves the net health outcome for patients with unilateral or bilateral hearing loss.

POLICY STATEMENT

Bilateral or unilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant may be considered **medically necessary** in patients age 9 months and older with bilateral severe-to-profound pre- or postlingual (sensorineural) hearing loss, defined as a hearing threshold pure-tone average of 70 dB hearing loss or greater at 500, 1000, and 2000 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 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 (eg, 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 \geq 75 dB hearing level) in the ear to be implanted; AND
 - Moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz \geq 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 (ie, 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 after 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 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 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 6 to 10 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

The issue of upgrading components of a cochlear implant or bilateral cochlear implantation may be best addressed contractually.

Some facilities may negotiate a global fee for the implantation of the device and the associated aural rehabilitation. However, charges for rehabilitation may be subject to individual contractual limitations.

FDA 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 Systems Approved by the U.S. Food and Drug Administration

Variables	Manufacturer and Currently Marketed Cochlear Implants			
Device	Advanced Bionics HiResolution Bionic Ear System (HiRes 90K)	Cochlear Nucleus 22 and 24	Med El Maestro Combi 40+	Neuro Cochlear Implant System (Oticon Medical)
PMA	P960058	P840024, P970051	P000025	P200021
Indications				
Adults ≥18 y	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Pre-, peri-, or postlingual onset of bilateral SNHL, usually characterized by: <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Severe-to-profound bilateral SNHL (≥70 dB) ≤40% correct HINT sentences with best-sided listening condition SSD (≥90 dB) or AHL (Δ15 dB PTA) <ul style="list-style-type: none"> Limited benefit from unilateral amplification, defined by test scores of 5% or less on monosyllabic CNC words in quiet when tested in 	<ul style="list-style-type: none"> Severe-to-profound bilateral SNHL (≥70 dB at 500, 1000, and 2000 Hz) Limited benefit from appropriately fit hearing aids, defined as scoring ≤50% correct HINT sentences in quiet or noise with best-sided

			<p>the ear to be implanted alone</p> <ul style="list-style-type: none"> o Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit 	listening condition
Children	<p>12 mo to 17 y of age</p> <ul style="list-style-type: none"> • Profound bilateral SNHL (>90 dB) Use of appropriately fitted hearing aids for at least 6 mo in children 2 to 17 y or at least 3 mo in children 12 to 23 mo • Lack of benefit in children <4 y defined as a failure to reach developmentally appropriate auditory milestones (eg, 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) 	<p>25 mo to 17 y, 11 mo of age</p> <ul style="list-style-type: none"> • Severe-to-profound bilateral SNHL • MLNT scores ≤30% in best-aided condition in children • LNT scores ≤30% in best-aided condition in children <p>9 to 24 mo of age</p> <ul style="list-style-type: none"> • Profound SNHL bilaterally • Limited benefit from appropriate binaural hearing aids 	<p>12 mo to 18 y of age</p> <ul style="list-style-type: none"> • Profound sensorineural HL (≥90 dB) <ul style="list-style-type: none"> o 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 o 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 o A 3- to 6-mo trial with hearing 	Not applicable

			<p>aids is required if not previously experienced</p> <p>5 y to 18 y of age</p> <ul style="list-style-type: none"> • SSD (≥ 90 dB) or AHL ($\Delta 15$ dB PTA) • <ul style="list-style-type: none"> ◦ Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted ◦ Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit 	
--	--	--	--	--

AHL: asymmetric hearing loss; CNC: consonant-nucleus-consonant; CROS: contralateral routing of signal; 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; PMA: premarket approval; PTA: pure tone average; SNHL: sensorineural hearing loss; SPL: sound pressure level; SSD: single-sided deafness.

In 2014, the Nucleus Hybrid™ L24 Cochlear Implant System (Cochlear Americas) was approved by the FDA through the premarket approval (PMA) 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 aged 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 PMA 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 \geq 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 \geq 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 PMA 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 (ie, signal processing of sound input from 2 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 (ie, 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.

RATIONALE

Summary of Evidence

For individuals who have bilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes randomized controlled trial's (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. An ongoing post marketing study 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 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology - Head and Neck Surgery Foundation

In 2020, the American Academy of Otolaryngology - Head and Neck Surgery Foundation released an updated position statement on cochlear implants.⁵⁵ The Foundation "...considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children over 9 months of age with moderate to profound hearing loss who have failed a trial with appropriately fit hearing aids."

Agency for Health Care Research and Quality

In 2011, a technology assessment for the Agency for Health Care Research and Quality assessed the effectiveness of cochlear implants in adults.⁵⁶ The assessment conclusions are noted within the body of this evidence review.

National Institute for Health and Care Excellence

In 2019, the NICE released a technology appraisal guidance on cochlear implants for children and adults with severe-to-profound deafness.⁵⁷

The guidance included the following updated recommendations:

- 1.1 "Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, as defined in 1.5.
- 1.2 Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.
 - a. Children
 - b. Adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.
- 1.3 Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.
- 1.5 For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL [hearing level] at 2 or more frequencies bilaterally (500 Hz, 1 kHz, 2 kHz, 3 kHz, 4 kHz) without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as:
 - a. for adults, a phoneme score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA
 - b. for children, speech, language and listening skills appropriate to age, developmental stage, and cognitive ability.
- 1.6 Cochlear implantation should be considered for children and adults only after an assessment by a multidisciplinary team. As part of the assessment, children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate)."
- 1.7 Cochlear implantation should be considered for ... adults only after an assessment by a multidisciplinary team. As part of the assessment ... [implant candidates] should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate)."

National Institutes of Health

Cochlear implants are recognized as an effective treatment of sensorineural deafness, as noted in a 1995 National Institutes of Health Consensus Development conference, which offered the following conclusions ¹:

- "Cochlear implantation has a profound impact on hearing and speech perception in postlingual deafened adults."
- "Prelingually deafened adults generally show little improvement in speech perception scores after cochlear implantation, but many of these individuals derive satisfaction from hearing environmental sounds and continue to use their implants." However, improvements in other basic benefits, such as sound awareness, may meet safety needs.
- "...training and educational intervention are fundamental for optimal postimplant benefit."

The conference offered the following conclusions regarding cochlear implantation in children:

- "Cochlear implantation outcomes are more variable in children. Nonetheless, gradual, steady improvement in speech perception, speech production, and language does occur."

Cochlear implants in children under 2 years old are complicated by the inability to perform a detailed assessment of hearing and functional communication. However, "[a] younger age of implantation may limit the negative consequences of auditory deprivation and may allow more efficient acquisition of speech and language." Some children with a postmeningitis hearing loss under the age of 2 years have received an implant due to "the risk of new bone formation associated with meningitis, which might preclude implantation at a later date."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Existing national coverage established in 2005 states:⁵⁸.

"...cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification.... [which 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."

Coverage for cochlear implants may also be provided when the patient has

"...hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA approved category B investigational device exemption clinical trial ..., or a prospective, controlled comparative trial approved by CMS..."

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
7. 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
8. 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
9. 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 2, 2022.
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, 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
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.* Jan-Feb 2015; 81(1): 85-96. PMID 25458263
20. 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
21. 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
22. 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
23. 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
24. 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
25. 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
26. 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
27. 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
28. 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
29. Ilig 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
30. 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
31. 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
32. 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
33. 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
34. 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
35. 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
36. 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
37. 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
38. Poncet-Wallet C, Mabelle 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
39. 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

40. 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 3, 2022.
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. 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
43. 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
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 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
46. 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
47. 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
48. 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.
49. 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
50. 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
51. 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
52. 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
53. 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
54. 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
55. 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 7, 2022.
56. 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.
57. 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.
58. Centers for Medicare & Medicaid. Cochlear Implantation. 2013; <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Cochlear-Implantation-.html>. Accessed January 7, 2022.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2012	New policy	
September 2013	Replace policy	Policy updated with literature; references added and removed. Review of unilateral hearing loss added to rationale section; policy statement added that cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered not medically necessary.
December 2014	Replace policy	Policy updated with literature review through April 4, 2014. References 1, 21, 22, 28, 32-35, 41-45 added. Rationale and references reorganized. Policy statement added that cochlear implantation with a hybrid cochlear implant/ hearing aid system is considered medically necessary.
September 2016	Replace policy	Policy updated with literature review references 14-15, 29, 38, 40-40-41, 44-45, 47 and 52-53 added. Policy statement on hybrid device revised to include criteria for use.
June 2018	Archive policy	Policy updated with literature review through December 11, 2017 and archived; references 35 and 38 updated. Policy statements unchanged.
June 2019	Reactivate policy	Policy reinstated and updated with literature review through January 11, 2019, references 5-6, 11, and 29 added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through November 26, 2019; references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through November 17, 2020; references added. Policy statements updated to reflect expanded indications in children aged 9-12 months with profound bilateral sensorineural hearing loss. The unilateral indication added to Table 1 in the Regulatory Status section for the Med-EI Cochlear Implant System.
June 2022	Replace policy	Policy updated with literature review through January 7, 2022; references added. Policy statements unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.