FEP Medical Policy Manual

FEP 7.01.05 Cochlear Implant

Effective Policy Date: July 1, 2020

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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

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 ages 12 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 ≥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 (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 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 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).

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 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 (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)	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 (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 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 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. 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 post-intervention 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Otolaryngology - Head and Neck Surgery Foundation

In 2014, the American Academy of Otolaryngology - Head and Neck Surgery Foundation has a position statement on cochlear implants that was revised.[49] The Foundation "...considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can perform significantly better with two cochlear implants [rather] than one, bilateral cochlear implantation is accepted medical practice."

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.[50] The assessment conclusions are noted within the body of this evidence review.

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) released a technology appraisal guidance on cochlear implants for children and adults with severe-to-profound deafness. [51]

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 [2]:

"Cochlear implantation has a profound impact on hearing and speech perception in post-lingually deafened adults."

"Pre-lingually 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 post-implant 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 post-meningitis 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 states:[52,]

"...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..."

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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	Replace 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.