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MEDICAL POLICY – 7.01.586

Cochlear Implant

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RELATED MEDICAL POLICIES:

1.01.528	Hearing Aids (Excludes Implantable Devices)
7.01.83	Auditory Brainstem Implant
7.01.84	Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
7.01.547	Implantable Bone Conduction and Bone-Anchored Hearing Aids

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

The cochlea is part of the inner ear. Its job is to help convert vibrations from sound into nerve signals. The signals then travel along the auditory nerve to the brain, and we interpret the signals as sound. A cochlear implant is a hearing device that may be used for certain types of severe or profound hearing loss. Cochlear implants work differently than typical hearing aids. Hearing aids amplify or increase sounds. A cochlear implant, however, bypasses certain hearing parts of the ear and instead directly stimulates the auditory nerve. A cochlear implant has internal and external parts. The external parts include a microphone, sound processor, and a transmitter. The internal components include a receiver and an electrode-type device that stimulates the auditory nerve. The external microphone picks up sound and carries it to the external sound processer, which then transmits it to the internal receiver. The internal receiver converts the signals into electrical impulses. The impulses then travel to the electrode-type device to stimulate the auditory nerve. This policy describes when a cochlear implant may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Subject	Medical Necessity
Bilateral Hearing Loss	**Unilateral or bilateral cochlear implantation of a US Food and Drug Administration (FDA)-approved cochlear implant device may be considered medically necessary in individuals with bilateral severe-to-profound pre- or post-lingual (sensorineural) hearing loss when ALL of the following criteria are met:** • The individual is aged 9 months or older **AND** • Has a hearing threshold pure-tone average (PTA) of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1,000 Hz, and 2,000 Hz **AND** • Has tried standard hearing aids but had limited or no benefit from their use

Single-sided deafness (SSD) and asymmetrical sensorineural hearing loss (AHL)	**Unilateral cochlear implantation of an FDA-approved, non-hybrid cochlear implant device may be considered medically necessary when ALL of the following criteria are met:**
	• The individual is aged 5 years or older
	AND
	• Has limited or no benefit after a minimum one-month trial wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device
	AND
	• One of the following:
	  ○ Single-sided deafness (defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear) **OR**
	  ○ Asymmetrical sensorineural hearing loss (defined as profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in PTAs between ears)

Subject	Medical Necessity
	Note: Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz
Hybrid cochlear implant/hearing aid	**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 when ALL of the following criteria are met:** • The individual is aged 18 years or older **AND** • Has bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity **AND** • Receives limited benefit from appropriately fitted bilateral hearing aids **AND** • Has 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**

Subject	Medical Necessity
	○ 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
Replacements	**Replacement of internal and/or external components (speech controller or speech processor) may be considered medically necessary only in a subset of individuals when:** • The processor is not working or broken (no longer functional) and cannot be repaired or replaced under a manufacturer's warranty. **OR** • Replacement is needed because the individual's condition has changed to the extent that the current components (e.g., processor) are inadequate and interfere with the individual's activities of daily living, and improvement is expected with a replacement device. **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.**
Upgrades	**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.**

Subject	Investigational
Tinnitus	**Cochlear implantation as a treatment for individuals with tinnitus is considered investigational.**

Limited Benefit from Hearing Aids

Hearing loss is rated on a scale 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, scores of 30% or less correct on open-set tests.

Bilateral Cochlear Implantation

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

Post- Cochlear Implantation Rehabilitation

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

Contraindications to cochlear implantation may include:

- Absence of cochlear development as demonstrated on a computed tomography (CT) scan is an absolute contraindication
- Cochlear ossification, may prevent electrode insertion
- Deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brainstem

- Infections, active or chronic, of the external or middle ear; or mastoid cavity
- Tympanic membrane perforation.

Children Less Than 12 Months of Age

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.

Reasonable Useful Life Expectancy for External Cochlear Implant Parts

Parts	Life Expectancy	Comments
Batteries - Disposable	60 hours (1-3 days)	Replaced as needed
Batteries - Rechargeable	1 year or more	Many will last longer than 1 year
External speech processor	3 years or longer	The manufacturer's warranty is usually 3 years. The component may last longer depending on care & maintenance.
Headpieces/microphones	1-2 years	May last longer depending on care & maintenance.

Adapted from Gift of Hearing Foundation (GOHF).

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history and physical

AND

- Manufacturer and Model Name of Cochlear Implant being requested

AND

- Audiology test results

Coding

Code	Description
CPT	
69930	Cochlear device implantation, with or without mastoidectomy
HCPCS	
L8614	Cochlear device, includes all internal and external components
L8619	Cochlear implant external speech processor and controller, integrated system, replacement

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

The ages in this policy for which cochlear implants are considered medically necessary are based on the FDA approved age and are varied for each device. The labeled indications from the FDA for currently marketed implant devices are summarized in **Table 2**.

Benefit Application

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

A cochlear implant is a surgically implanted hearing device. The implanted receiver and electrode system device and implantation surgery should be reimbursed under the medical benefit.

Evidence Review

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 the deaf cochlea.

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.

Summary of Evidence

For individuals who have bilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes randomized controlled trials (RCTs) and multiple systematic reviews and technology assessments. The 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 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. The 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 individuals 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 six months are lacking. Ongoing post-marketing studies in adults and children may further elucidate outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. The 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 a hybrid cochlear implantation if there is 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 on health outcome.

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

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05250414	Cochlear Implantation in the Single-Sided Deafness in the Medicare Population	15	July 2025 (recruiting)
NCT04793412	Cochlear Implantation in Children With Asymmetric Hearing Loss or Single-Sided Deafness Clinical Trial	80	Dec 2025 (recruiting)
NCT04506853[a]	Single-Sided Deafness and Asymmetric Hearing Loss Post-Approval Study	65	Sep 2026 (recruiting)
NCT04738968	Cochlear Implant for Young Children and One Deaf Ear	70	Dec 2026 (recruiting)
NCT05318417[a]	A Post-approval, Prospective, Nonrandomized, Single-arm Multicenter Investigation to Evaluate the Safety and Effectiveness of Cochlear Implantation in Children and Adults With Unilateral Hearing Loss/Single-sided Deafness	60	Jun 2027 (recruiting)
NCT05154188[a]	Post Approval Study to Assure the ContInued saFety and effectIveness of Neuro Cochlear Implant System in Adult Users (PACIFIC)	60	Feb 2028 (not yet recruiting)
NCT05775367	Cochlear Implantation in Infants and Toddlers With Single-Sided Deafness	60	May 2030 (recruiting)
Unpublished			
NCT03900897[a]	Expanded Indications in the MED-EL Pediatric Cochlear Implant Population	60	Nov 2023 (completed)
NCT03236909[a]	Expanded Indications in the Adult Cochlear Implant Population	44	Mar 2023 (completed)
NCT02203305[a]	Cochlear Implantation in Cases of Single-Sided Deafness	43	Sep 2021 (completed)
NCT05052944	Single-sided Deafness and Cochlear Implantation	78	Nov 2023 (completed)
NCT02379819[a]	Nucleus Hybrid L24 Implant System: New Enrollment Study	52	Apr 2022 (completed)
NCT03052920	Cochlear Implantation in Adults With Asymmetric Hearing Loss Clinical Trial	40	Mar 2021 (completed)

NCT02105441	Cochlear Implantation Among Adults and Older Children With Unilateral or Asymmetric Hearing Loss	40	Mar 2018 (completed)

NCT: national clinical trial.

[a] Industry-sponsored or co-sponsored.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2016 Input

In response to requests, input was received from two specialty societies, one of which provided four responses and one of which provided three responses, and three academic medical centers while this policy was under review in 2016. Input focused on the use of hybrid cochlear implants. Input was consistent that the use of a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant improves outcomes for individuals with high-frequency hearing loss but preserved low-frequency hearing.

2010 Input

In response to requests, input was received from two physician specialty societies and four academic medical centers while this policy was under review in 2010. Also, unsolicited input was received from a specialty society. Most providing input supported the use of cochlear implants in infants younger than 12 months of age; many supporting this use noted that there are major issues when determining hearing level in infants of this age group, and others commented that use could be considered in these young infants only in certain situations. Those providing input were divided on the medical necessity of upgrading functioning external systems; some agreed, and others did not.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered 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 (AAO-HNSF) released an updated position statement on cochlear implants.[60] 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."

In 2024, the AAO-HNSF published clinical practice guidance for age-related hearing loss.[61] The authors give a strong recommendation that "Clinicians should refer patients for an evaluation of cochlear implantation candidacy when patients have appropriately fit amplification and persistent hearing difficulty with poor speech understanding" based on evidence from multiple systematic reviews and meta-analyses of prospective clinical trials which observed a more significant benefit than harm.

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.[62] The assessment conclusions are noted within the body of this policy.

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.[63]

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 reception in post-lingually 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 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 cochlear implantation at a later date."

Medicare National Coverage

Existing national coverage effective for services performed on or after April 4, 2005, states[64]:

"…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 ≤ 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 (IDE) clinical trial…or a prospective, controlled comparative trial approved by CMS…".

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 US 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 2**.

FDA Product Code: MCM.

Table 2. Cochlear Implant Systems Approved by the US Food and Drug Administration

Variables	Manufacturer and Currently Marketed Cochlear Implants			
Device	Advanced Bionics HiResolution Bionic Ear System (HiRes90K)	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	Postlingual onset of severe to profound bilateral SNHL (≥70 dB) Limited benefit from appropriately fitted hearing aids, defined as scoring ≤50% on a	Pre-, peri-, or postlingual onset of bilateral SNHL, usually characterized by: ○ Moderate-to-profound HL in low frequencies; and	Moderate to profound bilateral SNHL defined as PTA at 250 Hz, 500 Hz, and 1000 Hz of > 40 dB HL and ≤ 65 HL at 3000-8000 Hz SSD (≥90 dB) or AHL (Δ15 dB PTA)	Severe-to-profound bilateral SNHL (≥70 dB at 500, 1000, and 2000 Hz) Limited benefit from appropriately fit

Variables	Manufacturer and Currently Marketed Cochlear Implants			
	test of open-set HINT sentence recognition	○ Profound (≥90 dB) HL in mid-to-high speech frequencies Severe to profound unilateral SNHL (SSD or AHL ○ PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of > 80 dB HL ○ Normal or near normal hearing in the contralateral ear defined as PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of ≤ 30 dB HL ○ Limited benefit from an appropriately fitted unilateral hearing device	○ Limited benefit from unilateral amplification, defined by test scores of 50% or less on monosyllabic CNC words in quiet when tested in the ear to be implanted alone and 60% or less in the non-implant ear ○ Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit, but radiological evidence of cochlear ossification may preclude a hearing aid trial	hearing aids, defined as scoring ≤50% correct HINT sentences in quiet or noise 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 2-17y or at least 3 mo in children 12-23 mo Lack of benefit in children <4 y defined as a failure to reach	25 mo to 17 y, 11 mo of age Severe to profound bilateral SNHL MLNT scores ≤30% in best-aided condition in children LNT scores ≤30% in best-aided condition in children 9 to 24 mo of age	12 mo to 18 y of age Profound SNHL (≥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	Not applicable

Variables	Manufacturer and Currently Marketed Cochlear Implants			
	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)	Profound SNHL bilaterally Limited benefit from appropriate binaural hearing aids 5 y to 18 y of age Severe to profound unilateral SNHL (SSD or AHL) ○ PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of > 80 dB HL ○ Normal or near normal hearing in the contralateral ear defined as PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of ≤ 30 dB HL Limited benefit from an appropriately fitted unilateral hearing device	○ 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 5 y to 18 y of age SSD (≥90 dB) or AHL (Δ15 dB PTA) ○ 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.

Hybrid Cochlear Implant System

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 individuals 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 ≥75 dB HL) in the ear to be implanted."
- Preoperative hearing with "moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥60 dB HL) in the contralateral ear."
- "The CNC (Consonant-Nucleus-Consonant) word recognition score will be between 10% and 60% (inclusively) in the ear to be implanted in the preoperative aided condition and in the contralateral ear equal to or better than that of the ear to be implanted but not more than 80% correct."

In 2022, the Nucleus Hybrid L24 Cochlear Implant System received expanded approval for single-sided deafness or unilateral hearing loss in adults and children aged 5 or older (P970051/S205).

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.

Bilateral Cochlear Implants

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.

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History

Date	Comments
01/97	Add to Surgery Section - New Policy

Date	Comments
11/03/98	Replace Policy - Revised Description and Policy Guidelines
01/04/99	Replace Policy - Policy reviewed; new devices added.
10/09/01	Replace Policy - Policy reviewed; new devices and FDA approval status added.
10/08/02	Replace Policy - Policy reviewed; new FDA-approved device added (Med E1 Combi 40+).
03/11/03	Replace Policy - Policy Benefit Application section added. No change to Policy Statement.
05/13/03	Replace Policy - Update CPT code only.
05/11/04	Replace Policy - Policy reviewed without literature review; no change to policy statement.
07/13/04	Replace Policy - Policy reviewed; discussion of bilateral cochlear implants and its investigational status added.
08/09/05	Replace Policy - Policy reviewed with literature search; policy statement unchanged.
02/06/06	Codes updated - No other changes.
06/09/06	Disclaimer and Scope update - No other changes.
08/08/06	Replace Policy - Policy updated with literature review; no change in policy statement.
04/10/07	Replace Policy - Policy updated with literature review. Policy statement changed to indicate bilateral cochlear implants are medically necessary. Reference numbers added.
05/13/08	Replace Policy - Policy updated with literature search; no change to the policy statement. References and codes added.
04/13/10	Replace Policy - Policy updated with literature search. Policy statements modified for clarity, intent unchanged. References and codes added.
08/09/11	Replace Policy – Policy updated with literature review; Rationale section and references reorganized. No changes in policy statements. Reference numbers 3-4, 6, 12, 16-17 added; numerous references to early, small studies removed. ICD-10 codes added to policy.
08/24/11	Benefit Application updated.
02/09/12	The CPT codes 92605 and 92606 were removed from the policy.
06/26/12	Related Policies update; title for 7.01.84 has been changed.
08/20/12	Replace policy. Clarification statement added to the policy guidelines second paragraph: In addition, unique clinical circumstance may justify individual consideration for implantation before 12 months of age, based on review of applicable medical records to verify the other pediatric criteria noted in this policy are met. Rationale section revised based on literature review through April 2012. Reference

Date	Comments
	numbers 7-9, 13 and 22-24 added. Other references renumbered. CPT codes 92605 and 92606 added. Policy statements unchanged.
09/25/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
10/18/12	Update Related Policies – 7.01.03 renumbered to 7.01.547.
08/12/13	Replace policy. Policy statement added: cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered investigational. Rationale updated based on literature review through May 2013. References 7, 10, 11, 28-32 added; others renumbered/removed. Policy statement changed as noted.
03/11/14	Coding Update. Remove codes 20.96, 20.97, and 20.98 per ICD-10 mapping project; these codes are not utilized for adjudication of policy.
03/21/14	Update Related Policies. Add 1.01.528
05/15/14	Coding update. CPT codes 92607 and 92608 removed from the policy; these codes address the evaluation portion; this policy is specific to the device and evaluation is not addressed herein.
07/14/14	Annual Review. Policy statement added that cochlear implantation with a hybrid cochlear implant/ hearing aid system is considered investigational. Rationale section reorganized and policy updated with literature review through April 4, 2014. References reorganized, numbers 1, 20, 21, 27, 29, 30-32, 36-40 added, others renumbered/removed. Policy statement changed as noted. Coding update: Remove CPT codes 92507-92606 & 92626-92633 from policy. Remove ICD-9 and ICD-10 diagnosis codes and ICD-10-PCS codes.
07/14/15	Annual Review. Policy updated with literature review through April 19, 2015; references 17, 23-24, 36-37, and 45 added. Policy statements unchanged. CPT codes 92626, 92627, 92630 and 92633 removed; these are codes that fall under the rehabilitation benefit. HCPCS codes L8616, L8617, L8618, L8621, L8622, L8623 and L8624 removed; these are for replacement and do not fall within the scope of the policy.
12/12/15	Policy statement formatted to differentiate between different types of hearing loss/implants.
10/01/16	Annual Review, changes approved September 13, 2016. Policy updated with results of clinical input. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria. CPT codes 92601-92606, 92609 removed; these are not supportive of policy intent.
10/07/16	Update coding section. Changed code L8328 to L8628. Removed paragraph regarding codes 92601-92606, and 92609 as they were removed from policy.
01/01/17	Interim review, changes approved December 13, 2016. Removed age limit for policy statement about cochlear implants for bilateral hearing loss; added statement about replacement of cochlear implant components. Policy guidelines about individual

Date	Comments
	review consideration for implantation in children under 12 months of age added. RUL table for cochlear implant components added to Policy Guidelines.
05/01/17	Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 16 and 43-45 added. Coding updated; removed HCPCS codes L8627, L8628, and L8629. Policy statements unchanged.
10/24/17	Policy moved to new format, no changes to policy statement.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through December 2017; references 35 and 38 updated. Policy statements unchanged; only minor edits made.
09/01/18	Minor update. Re-added the Consideration of Age information which was inadvertently deleted in a previous update.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through January 2019. Policy statements unchanged. Removed HCPCS code L8615.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
05/01/20	Annual Review, approved April 7, 2020. Policy updated with literature review through November 2019; references added. Policy statements unchanged.
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through April 2020; references added. Policy statements updated to reflect expanded indications in children aged 9-12 months with profound bilateral sensorineural hearing loss.
01/12/21	Coding update. Added HCPC L8625.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through November 17, 2020; references added. Policy statements unchanged.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through January 7, 2022; references added. Policy statements unchanged.
02/01/23	Updated Related Policies. 7.01.03 is replaced by 7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids
05/01/23	Policy renumbered, approved April 11, 2023, from 7.01.05 to 7.01.586 Cochlear Implant. Policy updated with literature review through January 9, 2023; references added. Policy statements unchanged except for minor editorial refinements ; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
05/01/24	Annual Review, approved April 8, 2024. Policy updated with literature review through January 2, 2024; references added. Policy statements unchanged.

Date	Comments
01/01/25	Interim Review, approved December 10, 2024. Changed policy statement for cochlear implant for individuals with unilateral hearing loss from investigational to medically necessary when criteria are met.
05/01/25	Annual Review, approved April 21, 2025. Policy updated with literature review through January 2, 2025; references added. Policy statements unchanged. Removed HCPCS code L8625.

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