

01.03.02 Cochlear Implant Replacement *

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DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Note: Some group health plans may not have a cochlear implant benefit. Please refer to the member's benefit booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

For group health plans that offer benefits for a cochlear implant as a covered benefit, the [policy criteria](#) will be utilized to establish investigational and medical necessity and determine whether the procedure(s)/treatments is/are eligible for reimbursement under the member's medical health insurance benefits.

Summary

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. At times, cochlear implant procedures require revisional surgery or replacement of parts for a variety of reasons.

Additional Information

None

OBJECTIVE

The objective of this medical policy is to provide criteria for determining whether the replacement of a cochlear implant or parts are medically necessary and describe the required supporting documentation.

PRIOR APPROVAL

Prior approval is required.

POLICY

Medically Necessary

The replacement of a cochlear implant (external components) is considered **medically necessary** when documentation is provided to support **all** of the following criteria:

- Date the device was received; **and**
- Manufacturer warranty information including the currently used device is **not** under warranty; **and**
- Determination of the device to be non-repairable including objective documentation from the audiologist on how the device is non-repairable/malfunctioning; **and**
- The device currently used is no longer functional as evidenced by interfering with the individuals' activities of daily living (ADLs); **and**
- There is no evidence to suggest that the device has been lost, abused, or neglected; **and**
- The individual has been compliant with the use of the device and will continue to benefit from the device; **and**
- The device was being used daily until malfunction.

The replacement of a cochlear implant (external components) is considered **medically necessary** if there is a change in the individual's medical condition making the present unit non-functional and improvement is expected with a replacement unit.

Not Medically Necessary

The replacement of cochlear implants (external components) is considered **not medically necessary** including but not limited to the following the following situations:

- The replacement is solely for better technology or improved aesthetics.
- When the above criteria are not met.

POLICY GUIDELINES

Coding

See the [Codes](#) table for details.

BACKGROUND

Cochlear Implants (CI)

While hearing loss may relate to abnormalities in the sound conduction system of the outer and middle ear, most severe hearing deficits in newborns and the elderly result from sensorineural abnormalities, particularly cochlear hair cell loss which limits the ability of the cochlea to convert sound vibrations into nerve impulses. This type of hearing loss is usually irreversible and has been treated with rehabilitation strategies involving hearing aids, sign language, and speech and language therapy. Amplification does not replace the function of lost cochlear hair cells and often cannot provide adequate hearing in the case of severe cochlear hair loss. Because the cochlear implant does **not** magnify sound, none of its components are considered a hearing aid. If appropriate neural elements in the ear are intact and functional, it is possible to stimulate auditory nerve impulses with a cochlear implantation device to improve sound recognition.

The cochlear implant (CI) is composed of three parts which include external components and two internal surgically implanted components.

External

External components include a microphone, speech processor, and transmitter coil with cables are worn.

- The speech processor converts sound into electrical stimuli.

Internal

Internal components include an antenna and electrodes.

- The antenna electromagnetically captures the stimuli transmitted by the external speech processor and directs this information to internal electrodes.
- The electrodes provide direct electrical stimulation to the auditory nerve, bypassing the transducer cells which are absent or nonfunctional.

CI revision surgery is uncommon, a small percentage, 3% - 8%, of all CI procedures require revisional surgery and cochlear reimplantation may be necessary for a variety of reasons to include but not limited to:

- Electrode extrusions
- Hardware failure
- Improper initial placement
- Receiver-stimulator repositioning due to device migration
- Software failure
- Wound complications
 - In cases of infection the receiver-stimulator is removed there is a delayed reimplantation of a new device.

Regulatory Status

Several cochlear implants are commercially available in the United States and are manufactured by Cochlear Americas, Advanced Bionics, and the MED - EL Corporation. 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 Ultra)	Cochlear® Nucleus Nexa System	Med El® Maestro/SYNCHRONY2	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 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 • 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	• 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) ○ 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	• 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 listening condition

Variables	Manufacturer and Currently Marketed Cochlear Implants			
			ossification may preclude a hearing aid trial	
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 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	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 • 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,	MED-EL strongly recommends a hearing aid trial of 1-3 months; lack of aidable hearing may preclude a hearing aid trial 7 to <12 mo • Profound SNHL (≥90 dB) at 500, 1000, and 2000 Hz 1 to <6 y • Moderately-severe to profound SNHL (≥55 dB) at 500, 1000, and 2000 Hz 56 y to 18 y of age • Moderate to profound SNHL with a low-frequency PTA >40 dB HL at 250, 500, and 1000 Hz and unaided thresholds ≥65 dB HL at 3-8kHz	Not applicable

Variables	Manufacturer and Currently Marketed Cochlear Implants			
	- 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)	1000 Hz, 2000 Hz, and 4000 Hz of ≤ 30 dB HL - Limited benefit from an appropriately fitted unilateral hearing device		

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 2025, the Nucleus® Nexa™ System was approved as the first smart cochlear implant system that allows recipients to receive firmware updates without replacing the implant.

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

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

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 (i.e., 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 (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.

Warranty coverage is subject to the manufacturer's warranty for the individual's specific device.

SUPPLEMENTAL INFORMATION

Not applicable.

REFERENCES

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	69949	Unlisted procedure, inner ear [when specified as implantation of hybrid cochlear device]
HCPCS		
	L8619	Cochlear implant external speech processor and controller, integrated system, replacement
	L8627	Cochlear implant, external speech processor, component, replacement
	L8628	Cochlear implant, external controller component, replacement
	L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement
	L8699	Prosthetic implant, not otherwise specified [when specified as hybrid cochlear device, including all internal and external components]
Type of Service	Surgery	

Codes	Number	Description
Place of Service	Inpatient	

POLICY HISTORY

Date	Reason	Action
April 2026	Annual Review	Policy Renewed
July 2025	Interim Review	Policy Revised
February 2025	Annual Review	Policy Renewed
April 2024	Annual Review	Policy Revised
May 2023	Interim Review	Policy Revised
April 2023	Annual Review	Policy Revised
September 2022	Annual Review	Policy Renewed
September 2021	Annual Review	Policy Revised
September 2020	Annual Review	Policy Revised
September 2019	Annual Review	Policy Renewed
September 2018	Annual Review	Policy Renewed
September 2017	Annual Review	Policy Renewed
September 2016	Annual Review	Policy Renewed
October 2015		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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