MEDICAL POLICY

POLICY TITLE	COCHLEAR IMPLANT
POLICY NUMBER	MP-1.023

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**8/22/2019**
Effective Date:	**10/1/2019**

I. POLICY

Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be considered **medically necessary** in patients who meet the following criteria:

- age 12 months and older with bilateral severe-to-profound pre-or postlingual (sensorineural) hearing loss defined as a hearing threshold of pure-tone average of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz, and 2,000 Hz, and
- 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** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components, or a switch from a body-worn, external sound processor to a behind-the-ear (BTE) model are considered **not medically necessary**.

Replacement of internal and/or external components solely for the purpose of upgrading to a system with advanced technology or to a next-generation device is considered **not medically necessary.**

Replacement of internal and/or external components is considered **medically necessary** only in a small subset of members who have inadequate response to existing component(s) to the point of interfering with the individual's activities of daily living, or the component(s) is/are no longer functional and cannot be repaired. Copies of original medical records must be submitted either hard copy or electronically to support medical necessity

Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant, including but

not limited to 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.

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, including but not limited to the Nucleus® Hybrid™ L24 Cochlear Implant System, that does not meet the above criteria is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

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

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

Hearing loss is rated on a scale based on the threshold of hearing. Severe hearing loss is defined as a bilateral hearing threshold of 70–90 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 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% correct on open–set tests.

POLICY TITLE	COCHLEAR IMPLANT
POLICY NUMBER	MP-1.023

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 brain stem, 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.

Cross-reference:

MP 1.019 Implantable Bone-Conduction and Bone-Anchored Hearing Prosthetic Devices
MP 1.130 Semi-Implantable and Fully Implantable Middle Ear Hearing Aid
MP 2.038 Treatment of Tinnitus

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual MP- 7.01.05, Cochlear Implants. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

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 that are 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 to electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve.

Regulatory Status

POLICY TITLE	COCHLEAR IMPLANT
POLICY NUMBER	MP-1.023

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 FDA for currently marketed implant devices are summarized in Table 1. FDA product code: MCM.

Table 1. Cochlear Implant Systems[a] 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 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 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 but do not have FDA approval, including the Med El® EAS Hearing Implant System.

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 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.

IV. RATIONALE

TOP

Summary of Evidence

POLICY TITLE	COCHLEAR IMPLANT
POLICY NUMBER	MP-1.023

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. 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 cochlear implant(s), the evidence includes prospective and retrospective studies reporting within-subjects comparisons and systematic reviews of these 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, short follow-up times, and heterogeneity in evaluation protocols and outcome measurements. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have 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, the evidence includes prospective and retrospective studies using single-arm, within-subjects 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 a hybrid cochlear implantation if there is loss of residual hearing. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

TOP

AUDITORY pertains to the sense of hearing and the hearing organs.

BASIC ACTIVITIES OF DAILY LIVING- include and are limited to walking in the home, eating, bathing, dressing, and homemaking.

DECIBEL refers to a unit of measure of the intensity of sound.

NEUROFIBROMA is a tumor of the connective tissue of the nerve.

NEUROFIBROMATOSIS is a group of genetic disorders that affects the cell growth of neural tissues.

NEUROFIBROMATOSIS TYPE II (NF-2) is an autosomal dominant disease affecting 1 in 50,000 persons and which causes intracranial and spinal tumors.

PROFOUND HEARING LOSS is defined as a bilateral hearing threshold of 90 dB and above.

SEVERE HEARING LOSS is defined as a bilateral hearing threshold of 70–90 dB.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

POLICY TITLE	COCHLEAR IMPLANT
POLICY NUMBER	MP-1.023

Covered when medically necessary:

CPT Codes ®							
69930	92601	92602	92603	92604			

HCPCS Code	Description
L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device replacement
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for use with cochlear implant device, replacement, each
L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
L8623	Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each
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

ICD-10-CM Diagnosis Codes	Description
H90.3	Sensorineural hearing loss, bilateral

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 1.023	**CAC 1/28/03**
	CAC 7/29/03
	CAC 10/26/04
	CAC 9/27/05
	CAC 9/26/06
	CAC 4/24/07
	CAC 3/25/08
	CAC 1/27/09 Consensus

POLICY TITLE	COCHLEAR IMPLANT
POLICY NUMBER	MP-1.023

	CAC 3/30/10 Expanded coverage for bilateral cochlear implants, clarified coverage criteria for unilateral and bilateral cochlear implants, clarified investigational status of bilateral auditory brain stem implants.
	CAC 4/26/11 Consensus
	CAC 8/28/12 Adopting BCBSA. Information on Auditory Brain Stem Implants extracted and new policy MP 1.085 created. For this review deleted medically necessary criteria for upgrades of existing components with next-generation devices. Updated codes 7/25/12.
	CAC 11/26/13 Minor revision. Policy statement added that cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered investigational. Rationale added. References updated.
	CAC 5/20/ 14 Consensus. No change to policy statements. References updated. Coding reviewed.
	CAC 6/2/15 Minor revision. Policy statement added that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered investigational. Background, references, and rationale updated**.** Codes reviewed. **Admin update 1/1/17:** Product variation section updated.
	CAC 9/27/16 Minor revision. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria. Description/Background, Regulatory Status, Rationale and Reference sections updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	12/28/17 Minor revision. The following two policy statements were added regarding the replacement of internal and/or external components: 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. Background, rationale, and references updated. Coding updated.
	11/15/18 Consensus. No change to policy statements. References updated.
	8/22/19 Consensus. No change to policy statements. References updated.

Top