

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>COCHLEAR IMPLANT</b>
<b>POLICY NUMBER</b>	<b>MP 1.023</b>

<b>Effective Date:</b>	<b>9/1/2023</b>
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**I. POLICY**

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

- age 9 months and older with bilateral severe-to-profound pre-or post-lingual (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 individuals 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:

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- Low-frequency hearing thresholds no poorer than 60 dB hearing level up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation; **AND**
- Severe to profound mid-to-high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz  $\geq 75$  dB hearing level) in the ear to be implanted; **AND**
- Moderately severe to profound mid-to-high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz  $\geq 60$  dB hearing level) in the contralateral ear; **AND**
- Aided consonant-nucleus-consonant word recognition score from 10% to 60% in the ear to be implanted in the preoperative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct.

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 general 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 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 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 brain stem; active or chronic infections of the external or middle ear and mastoid cavity or tympanic membrane perforation. Cochlear

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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**

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

**FEP PPO** - Refer to FEP Medical Policy Manual. 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**

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

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

**Table 1. Cochlear Implant Systems<sup>a</sup> Approved by the Food and Drug Administration**

<b>Variables</b>	<b>Manufacturer and Currently Marketed Cochlear Implants</b>		
	<b>Advanced Bionics® HiResolution® Bionic Ear System (HiRes 90K)</b>	<b>Cochlear® Nucleus 22 and 24</b>	<b>Med El® Maestro Combi 40+</b>

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<b>Variables</b>	<b>Manufacturer and Currently Marketed Cochlear Implants</b>		
PMA	P960058	P840024, P970051	P000025
Predicate devices	Clarion Multi-Strategy or HiFocus CII Bionic Ear (P940022)	Freedom with Contour	
<b>Indications</b>			
<b>Adults ≥18 y</b>	<ul style="list-style-type: none"> <li>• Postlingual onset of severe-to-profound bilateral SNHL (≥70 dB)</li> <li>• Limited benefit from appropriately fitted hearing aids, defined as scoring ≤50% on a test of open-set HINT sentence recognition</li> </ul>	<ul style="list-style-type: none"> <li>• Pre-, peri-, or postlingual onset of bilateral SNHL, usually characterized by:                             <ul style="list-style-type: none"> <li>○ Moderate-to-profound HL in low frequencies; and</li> <li>○ Profound (≥90 dB) HL in mid-to-high speech frequencies</li> </ul> </li> <li>• Limited benefit from binaural hearing aids (≤50% sentence recognition in ear to be implanted)</li> </ul>	<ul style="list-style-type: none"> <li>• Severe-to-profound bilateral SNHL (≥70 dB)</li> <li>• ≤40% correct HINT sentences with best-sided listening condition</li> <li>• SSD (≥90 dB) or AHL (Δ15 dB PTA)                             <ul style="list-style-type: none"> <li>○ Limited benefit from unilateral amplification, defined by test scores of 5% or less on monosyllabic CNC words in quiet when tested in the ear to be implanted alone</li> <li>○ Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit.</li> </ul> </li> </ul>

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<b>Variables</b>	<b>Manufacturer and Currently Marketed Cochlear Implants</b>		
<b>Children</b>	<p><b>12 mo to 17 y of age</b></p> <ul style="list-style-type: none"> <li>• Profound bilateral SNHL (&gt;90 dB)</li> <li>• 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</li> <li>• Lack of benefit in children &lt;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 &lt;20% correct on a simple open-set word recognition test (MLNT) administered using monitored live voice (70 dB SPL)</li> <li>• Lack of hearing aid benefit in children &gt;4 y defined as scoring &lt;12% on a difficult open-set word recognition test (PBK test) or &lt;30% on an open-set sentence test (HINT for Children) administered using recorded materials in the sound field (70 dB SPL)</li> </ul>	<p><b>25 mo to 17 y 11 mo</b></p> <ul style="list-style-type: none"> <li>• Severe-to-profound bilateral SNHL</li> <li>• MLNT scores ≤30% in best-aided condition in children</li> <li>• LNT scores ≤30% in best-aided condition in children</li> </ul> <p><b>9 to 24 mo</b></p> <ul style="list-style-type: none"> <li>• Profound SNHL bilaterally</li> <li>• Limited benefit from appropriate binaural hearing aids</li> </ul>	<p><b>12 mo to 18 y</b></p> <ul style="list-style-type: none"> <li>• Profound sensorineural HL (≥90 dB) <ul style="list-style-type: none"> <li>○ 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</li> <li>○ In older children, lack of aided benefit is defined as &lt;20% correct on the MLNT or LNT, depending on child’s cognitive ability and linguistic skills</li> <li>○ A 3- to 6-mo trial with hearing aids is required if not previously experienced</li> </ul> </li> </ul> <p><b>5 y to 18 y</b></p> <ul style="list-style-type: none"> <li>• SSD (≥90 dB) or AHL (Δ15 dB PTA) <ul style="list-style-type: none"> <li>○ 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</li> </ul> </li> </ul>

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<b>Variables</b>	<b>Manufacturer and Currently Marketed Cochlear Implants</b>		
			<ul style="list-style-type: none"> <li>lists when tested in the ear to be implanted</li> <li>o Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit</li> </ul>

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; PTA: pure tone average; SNHL: sensorineural hearing loss; SPL: sound pressure level; SSD: single-sided deafness.

In 2014, the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Americas) was approved by FDA through the premarket approval 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 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. The Med-EI EAS System received expanded premarket approval by the FDA in 2016 (PMA P000025/S084). FDA product code: PGQ

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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**

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**Summary of Evidence**

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.

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 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

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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 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-subjects 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 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 the effects of the technology on health outcomes.

**V. DEFINITIONS**

**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**

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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 Blue Cross. Members and



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providers should consult the member’s health benefit plan for information or contact Capital Blue Cross for benefit information.

**VII. DISCLAIMER**

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*Capital Blue Cross’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 Blue Cross’ Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

**VIII. CODING INFORMATION**

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**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.

**Covered when medically necessary:**

<b>Procedure Codes</b>							
69930	92507	92601	92602	92603	92604	92605	92606
92607	92608	92609	92618	L8614	L8615	L8616	L8617
L8618	L8619	L8621	L8622	L8623	L8624	L8625	L8627
L8628	L8629						

<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
H90.3	Sensorineural hearing loss, bilateral
H90.4	Sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side
H90.5	Unspecified sensorineural hearing loss
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
H90.7	Mixed conductive and sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side
H90.8	Mixed conductive and sensorineural hearing loss, unspecified

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<b>POLICY NUMBER</b>	<b>MP 1.023</b>

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**X. POLICY HISTORY**

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<b>MP 1.023</b>	<b>11/15/2018 Consensus.</b> No change to policy statements. References updated.
	<b>08/22/2019 Consensus.</b> No change to policy statements. References updated.
	<b>08/13/2020 Minor Review:</b> Policy Statement changed to include the age of 9 months. Product variation statement updated. References reviewed, updated. Coding checked, codes added.
	<b>08/31/2021 Consensus review.</b> No change to policy statement. Background, Rationale, and References updated. FEP language restructured.
	<b>03/22/2022 Consensus review.</b> No change to policy statement. References reviewed and updated. Coding table's format updated.
	<b>3/17/2023 Consensus review.</b> No change to policy statement. References updated. Coding reviewed.

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