



<b>CLINICAL MEDICAL POLICY</b>	
<b>Policy Name:</b>	Cochlear Implants
<b>Policy Number:</b>	MP-084-MD-DE
<b>Responsible Department(s):</b>	Medical Management
<b>Provider Notice Date:</b>	04/01/2019; 07/15/2018
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<b>Products:</b>	Highmark Health Options Medicaid
<b>Application:</b>	All participating hospitals and providers
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**DISCLAIMER**

**Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.**

**POLICY STATEMENT**

Highmark Health Options may provide coverage under the medical-surgical and DME benefits of the Company's Medicaid products for medically necessary cochlear implants.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

## **DEFINITIONS**

### **Cochlear Implant**

An electronic prosthetic hearing device that is used in the treatment of severe to profound hearing loss in adult and pediatric patients. It provides electrical stimulation to the auditory spiral ganglion to provide sound to the hearing impaired.

### **Hybrid Cochlear Implants**

Cochlear implant devices that include a hearing aid integrated into the external sound processor of the cochlear implant.

### **Hearing Loss**

Classified into five broad categories based on a person's auditory thresholds, or the softest sounds (decibels [dB]) that are heard. In normal to slight hearing loss, the degree of loss is 0 to 25 dB, making it difficult to hear faint (quiet) speech.

- Mild – the degree of hearing loss is 26 to 40dB, making it difficult to understand speech with trouble hearing faint or distant speaking.
- Moderate – the degree of loss is 41 to 55 dB, making it difficult hearing moderate speech when background noise is present, thereby missing 50% to 77% of speech in a conversation
- Moderately severe – the degree of loss is 56 to 70 dB, making it difficult to hearing loud speech, thereby missing up to 100% of speech in a conversation
- Severe – the degree of loss is 71 to 90 dB, making it difficult hearing loud speech, but it can be heard if the person speaking is one foot away from the person's ear.
- Profound – the degree of loss is 91 dB or more, making it difficult hearing and understanding, even with amplification. At this level, people are considered to be deaf.

Source: American Speech-Language-Hearing Association: <http://www.asha.org/public/hearing/Degree-of-Hearing-Loss/>

### **Sensorineural Hearing Loss (SNHL)**

A type of hearing loss, or deafness, in which the cause lies in the inner ear or sensory organ (cochlea and associated structures) or the vestibulocochlear nerve (cranial nerve VIII) or neural part.

## **PROCEDURES**

1. Coverage for cochlear implantation
  - A. Coverage for non-hybrid cochlear implantation (monaural or bilateral) may be provided when the following criteria are met:
    - 1) The prescribed device must be FDA approved and used in accordance with FDA labeling indications; AND
    - 2) The patient has been assessed by an audiologist and otolaryngologist experienced with cochlear implants; AND
    - 3) The patient must be 12 months of age and older; AND
    - 4) The patient must be current on age-appropriate pneumococcal vaccinations in accordance with the Centers for Disease Control Advisory Committee on Immunization Practices; AND
    - 5) The patient must have been diagnosed with bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss; AND
    - 6) The patient must have had limited benefit from hearing aids; AND

- 7) The patient must not have middle-ear infection, must have an accessible cochlear lumen to accept the implant, and must not have lesions in the auditory nerve and acoustic areas of the central nervous system; AND
- 8) The patient must have the cognitive ability to use auditory clues; AND
- 9) The patient is enrolled in an education program dedicated to listening and speaking with aided hearing; AND
- 10) The patient has the ability to participate in, and must enroll in, a post-cochlear implant rehabilitation program

**Note:** A post-cochlear implant rehabilitation program is necessary to learn the skills 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.

B. Coverage for hybrid cochlear implant devices may be provided when the following criteria are met:

- 1) The patient is 18 years of age and older; AND
- 2) The patient has bilateral severe to profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; AND
- 3) The patient has received limited benefit from bilateral hearing aids; AND
- 4) The patient has the ability to follow and/or participate in an aural rehabilitation program; AND
- 5) The patient has the following hearing thresholds:
  - a. 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
  - b. 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 selected for implantation; AND
  - c. 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
  - d. Consonant-Nucleus-Consonant (CNC) word recognition score between 10% to 60% (inclusively) in the ear selected for implantation in the preoperative aided condition and in the contralateral ear equal to or better than that of the ear selected for implantation but not more than 80%.

**\*Note:** Requests for cochlear implants that do not meet the criteria listed above (e.g., moderately severe hearing loss), must be referred to a Medical Director for consideration on a case-by-case basis.

Replacement of internal/external components is considered medically necessary in those patients who have had inadequate response to existing component(s) to the point of interfering with the patient's activities of daily living, OR the component(s) is/are no longer functional and beyond repair.

## 2. Contraindications

A cochlear implant is contraindicated for the following conditions:

- 1) Deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brain stem
- 2) Active or chronic infections of the external or middle ear and mastoid cavity, or tympanic membrane perforation
- 3) Cochlear ossification that prevents electrode insertion
- 4) Absence of cochlear development as demonstrated on CT scans.

3. When the cochlear implant services are not covered

Cochlear implants are not covered for conditions other than those listed above because the scientific evidence has not yet been established. Conditions may include but are not limited to unilateral hearing loss with or without tinnitus.

Requests for replacement of internal and/or external components for the sole purpose of upgrading to a system with advanced technology or to a next-generation device will be denied and considered not medically necessary.

No coverage will be provided for classroom hearing assistive technologies also known as remote-microphone hearing assistance technology (RM-HAT) (e.g., Frequency Modulation (FM) Systems and Digital Modulation (DM)). These portable devices are typically utilized in academic and social settings. These devices do not prevent, diagnose, or treat a sickness or injury and are not integral to the function of the cochlear implant. Requests for this type of technology will be denied as not medically necessary.

4. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

5. Place of Service

The place of service for cochlear implantation is outpatient.

### **GOVERNING BODIES APPROVAL**

There are several cochlear implants that have received FDA approval. Examples of FDA-approved devices include:

- Conventional Cochlear Implants
  - The Clarion® HiFocus
  - Nucleus® 24
  - Nucleus® 24 Contour
  - HiResolution Bionic Ear System
  - Nucleus® 6
  - Nucleus® 5
  - Nucleus Freedom
  - Med EL Combi 40: Approved for children 18 months to 18 years old with profound hearing loss; for adults with bilateral severe to profound hearing loss.
  
- Hybrid Cochlear Implants
  - Nucleus® Hybrid™ L24

- Med EL EAS

## CMS

Effective in April 2005, Medicare provides coverage for cochlear implants, per NCD 50.3, when the following eligibility criteria are met:

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle-ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device-exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

Additional information is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm>.

## **CODING REQUIREMENTS**

### Procedure Codes

<b>CPT Codes</b>	<b>Description</b>
69930	Cochlear device implantation, with or without mastoidectomy
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
92626	Evaluation of auditory rehabilitation status, first hour
92627	Evaluation of auditory rehabilitation status, each additional 15 minutes
92630	Auditory rehabilitation; pre-lingual hearing
92633	Auditory rehabilitation; post-lingual hearing loss
<b>HCPCS Codes</b>	<b>Description</b>
L8614	Cochlear device, includes all internal and external components (includes hybrid devices)

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, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, 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 device speech processor, ear level, replacement, each ((purchase)
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

All items are considered a purchase and not rentals.

#### Diagnosis Codes

ICD-10 Codes	Description
H90.3	Sensorineural hearing loss, bilateral
H90.5	Unspecified sensorineural hearing loss
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
Z96.21	Cochlear implant status

#### Supply Replacement Table

HCPCS Code	Item	Life Expectancy	Frequency of Replacements
L8621, L8622	Batteries (disposable)	60 hours (1-3 days)	33 batteries a month
L8623, L8624	Batteries (rechargeable)	1 year or more	1 battery every 2 years
L8627, L8328	Cochlear implant, external speech processor, component replacement	3 years or longer	1 every 3 years
L8615, L8616	Headpieces/microphones for use with cochlear implant device, replacement	1 – 2 years	1 replacement per year
L8617	Transmitting coil for use with cochlear implant device, replacement		4 replacements per 6 months
L8618	Transmitting cable for use with cochlear implant device, replacement		4 replacements per 6 months
L8619	Cochlear implant external speech processor and controller, integrated system, replacement	3 years or longer	1 every 3 years
L8629	Transmitting cable and coil		4 replacement per 6 months

Adapted North Dakota Department of Human Services. Accessed December 2017.

<https://www.nd.gov/dhs/services/medicalserv/medicaid/docs/dme/policy-cochlear-baha.pdf>

## **REIMBURSEMENT**

Participating facilities will be reimbursed per their Highmark Health Options contract.

## **SUMMARY OF LITERATURE**

Hearing deficits in newborns and the elderly are the result of sensorineural abnormalities, specifically cochlear hair cell loss. The hair cell loss limits the ability of the cochlea to convert sound vibrations into nerve impulses. This type of hearing loss is not reversible and has been treated with different modalities, which include rehabilitation with hearing aids, sign language, and speech and language therapy. However, it is not possible to replace the loss of cochlear hair cells with amplification. With the cochlear implant, it is now possible to stimulate the auditory nerve impulses in order to improve sound recognition.

The cochlear implant (CI) is comprised of three components: the external components and two internal surgically implanted components. The external components include a microphone, speech processor, and transmitter coil with cables that rest behind the ear. The internal components are surgically placed under the skin and include the antenna and electrodes. The battery operated sound processor captures sound and turns it into digital code, and transmits the digital coded sound through the coil. The implant converts the code into electrical impulses and sends them along the electrode array placed in the cochlea. The electrodes stimulate the auditory nerve, which then sends the impulses to the brain where they are interpreted as sound. Because the cochlear implant does not amplify sound, it is not classified as a hearing aid.

On average, patients have unilateral cochlear implantation. Bilateral implantation is being performed with two devices implanted at the same time or sequentially. The advantages of bilateral implantation are improved localization of sound and improved speech recognition.

The American Academy of Otolaryngology-Head and Neck Surgery issued an original position statement in 1982 with subsequent reviews on coverage of unilateral and bilateral cochlear implantation (2014). The statement indicates that the implantation is appropriate treatment for adults and children with severe to profound hearing loss. In addition, clinically selected adults and children can perform significantly better with two implants than with one, making bilateral cochlear implantation an accepted medical practice.

The American Academy of Pediatrics (2007) supported the coverage of cochlear implants and that careful consideration should be given for any child who seemed to have received limited benefit from a trial with appropriately fitted hearing aids. In 2010, the Academy issued a new policy statement on cochlear implants regarding surgical site infection and prevention and treatment of acute otitis media and meningitis. It states that children with profound deafness who are candidates for the implants should receive all age-appropriate doses of pneumococcal conjugate and *Haemophilus influenzae* type b conjugate vaccines and appropriate annual immunization against influenza in order to avoid complications.

In 2014, Sarant et al. compared the spoken language outcomes of children with unilateral and bilateral cochlear implants. The authors evaluated 91 children at ages 5 or 8 years and found that cochlear implants offered binaural redundancy through the involvement of two ears. The brain has two opportunities to process sound: binaural summation and the head-shadow effect. As a result children with bilateral cochlear implants achieved significantly better vocabulary outcomes than compared to children with unilateral.

The National Institute for Health and Care Excellence (NICE, 2011) published guidance for cochlear implants for children and adults with severe to profound deafness. The guidance states that for unilateral cochlear implantation, this should be an option for those with severe to profound deafness who did not receive adequate benefit from acoustic hearing aids. The use of simultaneous bilateral cochlear implants is recommended for children and adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness. NICE did not recommend sequential bilateral cochlear implantation as an option for people with severe to profound deafness.

A technology assessment was performed by the Agency for Healthcare Research and Quality (AHRQ) (2011), on the effects of cochlear implants in adults with sensorineural hearing loss. It was noted that the initial use of cochlear implants was restricted to adults who were postlinguistically deaf with profound hearing loss. However, criteria has expanded, along with improved cochlear implant technology, to include adults with residual hearing who are either prelinguistically or postlinguistically deaf with moderate-to-profound hearing loss. The assessment cited published studies of bilateral cochlear implantation that showed greater benefit in speech perception and localization among adults compared with unilateral cochlear implantation, with or without hearing aids. It was reported that bilateral cochlear implantation provides added improvements for adults in speech perception outcomes in noisy environment over unilateral cochlear implantation.

#### Cochlear Hybrid Implants

The cochlear hybrid implants are used in patients who are not candidates for conventional implants since their low-frequency hearing exceeds current guidelines. Shortened implant electrodes are placed in the cochlea to preserve low-frequency hearing.

The hybrid devices combine electric stimulation for mid-to-high frequency hearing and acoustic amplification for low-frequency hearing. The cochlear implant electrode array is shorter and inserted 10 mm - 20 mm (compared with 20 mm - 30 mm used with conventional implants).

In a prospective, single-arm clinical trial, Roland et al. (2015) reported on the safety and efficacy of cochlear nucleus hybrid implant systems. The study involved 50 patients that were 18 years of age and older with low frequency hearing and severe high-frequency loss, who had the cochlear hybrid implanted at 10 investigational sites. The authors reported that there were significant mean improvements in speech intelligibility in quiet and noise for patients with severe high-frequency loss and some low-frequency hearing. The cochlear hybrid implant expands the indications to hearing-impaired individuals who perform poorly with amplification due to bilateral high-frequency hearing loss and who previously were not implant candidates. FDA approval was based on the results of this trial.

The Hayes analysis (2017) stated that overall, there is low quality but consistent evidence suggesting that the majority of patients who received the Nucleus Hybrid 24 experienced residual hearing preservation and increased mid- to high-frequency hearing. The report listed limitation of the individual studies that included small sample size, short follow-up, and inadequate statistical analyses. Additional studies were recommended that would include a control or parallel comparison group and studies conducted independently of the manufacturer. Hayes rated the device as a level C due to the small studies, the risk of loss of residual hearing, and paucity of data on long-term and quality-of-life outcomes.

The available evidence indicates that use of the hybrid implant provides evidence of improved speech recognition compared to that of a hearing aid alone.





## **POLICY SOURCE(S)**

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American Academy of Otolaryngology. Position statement: cochlear implants. Revised 3/2/2014. Accessed on December 29, 2017.

Agency for Healthcare Research and Quality. Effectiveness of cochlear implants in adults with sensorineural hearing loss. Original April 11, 2011; correction June 17, 2011. Accessed on January 11, 2017.

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Hayes, Inc. New Brief: Nucleus Hybrid L24 Cochlear Implant System (Cochlear Limited) for hearing loss. July 2015. Reviewed April 2017. Accessed on December 28, 2017.

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Centers for Disease Control and Prevention. Hearing loss in Children: Basics. February 18, 2015. Accessed on January 8, 2019.

National Institute on Deafness and Other Communication Disorders (NIDCD). Quick statistics about hearing. Last update December 15, 2016. Accessed on January 8, 2019.

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**Policy History**

<b>Date</b>	<b>Activity</b>
12/28/2017	Initial policy developed
04/17/2018	Operational Guidelines were updated; procedure and diagnosis codes must match to be considered medically necessary, all other services to deny as not medically necessary; Quantity Limits in Table D are to be applied and once limit is met, services to deny as not medically necessary.
06/19/2018	QI/UM Committee Approval
08/15/2018	Provider effective date