CLINICAL MEDICAL POLICY	
Policy Name:	Cochlear Implants
Policy Number:	MP-084-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2023; 11/01/2022; 10/15/2021; 09/21/2020; 04/20/2020; 05/06/2019; 06/01/2018
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 12

Policy History

Date	Activity
12/01/2023	Provider Effective date
09/20/2023	QI/UM Committee review
09/20/2023	Annual Review: Reformatted 'Procedures' section and clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections. Added the following ICD-10 codes: H90.41, & H90.42.
12/01/2022	Provider Effective date
09/21/2022	QI/UM Committee review
09/21/2022	Annual Review: No changes to clinical criteria. Reformatted 'Procedure' section numbering. Updated 'Summary of Literature' and 'Reference Sources' sections.
11/15/2021	Provider Effective Date
09/15/2021	QIUM Committee Review
09/15/2021	Annual Review: Updated age for non-hybrid cochlear implants from 12 to 9 months of age. Added ICD-10 code Z45.321. Updated Summary of Literature and Reference Sections.
10/19/2020	Provider effective date
08/03/2020	Revision: Updated Operational Guidelines to remove the prior auth requirement. Removed hyperlinks.
08/03/2020	PARP Notification
05/18/2020	Provider effective date
02/18/2020	PARP approval
01/15/2020	Annual Review: No criteria changes other than addition of single or multi-channel under the Procedure section 1.A.

01/15/2020	QI/UM Committee Review
05/06/2019	Provider Effective Date
02/25/2019	PARP Approval
01/17/2019	QI/UM Committee review
01/17/2019	Annual Review: Added new attachment (E) defining degree of hearing loss; under Procedure section B added criteria requiring the ability to participate in an aural rehabilitation program; updated summary of literature and references; removed hyperlinks from all existing references; added HCPCS codes L8625 & V5273 as eligible and added diagnosis codes H90.8, H90.A21 & H90.A22 as eligible.
06/01/2018	Provider effective date
12/28/2017	Initial policy developed

Disclaimer

Highmark Wholecare℠ 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 Wholecare℠ 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.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

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 Implant - 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

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. Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA) approved cochlear implant device may be considered medically necessary when ALL of the following criteria have been met:
    A. Individuals greater than or equal to 9 (nine) months of age with bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss defined as a hearing threshold of pure-tone average of 70 decibels (dB) hearing loss or greater at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz, and have shown limited to no benefit from hearing aids. The age of the recipient at the time of implantation should be consistent with the FDA guidelines for the specific implant used; AND
    B. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation; AND
    C. Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, deafness due to lesions of the eighth (8^{th}) cranial nerve or brainstem, and absence of cochlear development).

Note: Bilateral cochlear implantation may be considered medically necessary when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in binaural benefit; (i.e., in individuals with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

2. A traditional cochlear implant FDA-approved for the treatment of single side profound sensorineural hearing loss or asymmetrical hearing loss may be considered medically necessary when the individual meets ALL of the following criteria:
    A. Age greater than or equal to five (5) years; AND
    B. Obtains limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted; AND
    C. At least one (1) month experience wearing a contralateral routing of signal (CROS) hearing aid or other relevant non-implantable device; AND
    D. ANY ONE of the following:
        1) Profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear (i.e., single sided deafness [SSD]); OR

2) 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 pure tone averages (PTAs) between ears (i.e., asymmetric hearing loss [AHL]).

3. 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 for individuals greater than or equal to 18 years of age who meet ALL of the following criteria:
    A. Bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; AND
    B. Receive limited benefit from appropriately fit bilateral hearing aids; AND
    C. Have the following hearing thresholds:
        1) 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
        2) Severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 75 dB hearing level) in the ear to be implanted; AND
        3) Moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 60 dB hearing level) in the contralateral ear; AND
        4) 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 greater than the ear to be implanted but not greater than 80% correct.

4. 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.

5. Contraindications
   A cochlear implant is contraindicated for the following conditions:
    - 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 that prevents electrode insertion
    - Absence of cochlear development as demonstrated on CT scans

6. When cochlear implants are not considered medically necessary
    - Cochlear implants are considered not medically necessary 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 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.

- Requests for replacements 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 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.

7. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

8. Place of Service
   The proper 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

The Centers for Medicare and Medicaid Services (CMS) have issued the following guidance:

- National Coverage Determination (NCD) Cochlear Implantation (50.3)

Summary of Literature

Approximately 6,500 U.S.-born infants were identified with a permanent hearing loss. Genes are responsible for 50% to 60% of the children with hearing loss. Infections during pregnancy in the mother, other environmental causes, and complications after birth are responsible for hearing loss among almost 30% of babies with hearing loss (CDC, 2020). According to the National Institute on Deafness and Other Communication Disorder (NIDCD), one in eight people in the Unites States (13% or 30 million) aged 12 years of age or older have hearing loss in both ears, based on standard hearing examinations (NIDCD, 2021).

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. There were approximately 324.000 cochlear implants worldwide as of December 2012. In the United States, roughly 58,000 devices have been implanted in adults and 38,000 in children (NIDCD, 2016).

A cochlear implant is a small, complex electronic device that can help to provide a sense of sound to a person who is profoundly deaf or severely hard-of-hearing. The implant consists of an external portion that sits behind the ear and a second portion that is surgically placed under the skin (see figure). An implant has the following parts:

- A microphone, which picks up sound from the environment
- A speech processor, which selects and arranges sounds picked up by the microphone
- A transmitter and receiver/stimulator, which receive signals from the speech processor and convert them into electric impulses
- An electrode array, which is a group of electrodes that collects the impulses from the stimulator and sends them to different regions of the auditory nerve

An implant does not restore hearing. Instead, it may provide a deaf person a useful representation of sounds in the environment and help them to understand speech (NIDCD, 2021).

The American Academy of Pediatrics (2010) recommends that children with profound deafness who are candidates for cochlear implants should receive all age-appropriate doses of pneumococcal conjugate and Haemophilus influenzae type b conjugate vaccines and appropriate annual immunization against influenza. In addition, starting at 24 months of age, a single dose of 23-valent pneumococcal polysaccharide vaccine should be administered. Before implant surgery, primary care providers and cochlear implant teams should ensure that immunizations are up-to-date, preferably with completion of indicated vaccines at least 2 weeks before implant surgery. Imaging of the temporal bone/inner ear should be performed before cochlear implantation in all children with congenital deafness and all patients with profound hearing impairment and a history of bacterial meningitis to identify those with inner-ear malformations/cerebrospinal fluid fistulas or ossification of the cochlea. During the initial months after cochlear implantation, the risk of complications of acute otitis media may be higher than during subsequent time periods. Therefore, it is recommended that acute otitis media diagnosed during the first 2 months after implantation be initially treated with a parenteral antibiotic (eg, ceftriaxone or cefotaxime).

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.

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

The American Academy of Otolaryngology-Head and Neck Surgery issued an original position statement in 1982 with the most recent revision on coverage of unilateral and bilateral cochlear implantation occurring in 2020. The American Academy of Otolaryngology-Head and Neck Surgery 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.

NICE recommendations for cochlear implants for children and adults with severe to profound deafness:

- 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.

- If different cochlear implant systems are considered to be equally appropriate, the least costly should be used. Assessment of cost should take into account acquisition costs, long-term reliability and the support package offered.

- 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, as defined in 1.5:
    - children
    - adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

- Acquisition of cochlear implant systems for bilateral implantation should be at the lowest cost and include currently available discounts on list prices equivalent to 40% or more for the second implant.

- 1.3 Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.

- 1.4 People who had a unilateral implant before publication of this guidance, and who fall into one of the categories described in 1.2, should have the option of an additional contralateral implant only if this is considered to provide sufficient benefit by the responsible clinician after an informed discussion with the individual person and their caregivers.

- 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 (pure-tone audiometric threshold equal to or greater than 80 dB HL) at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as:
  - for adults, a phoneme score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA
  - 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 When considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team should be mindful of the need to ensure equality of access. Tests should take into account a person's disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, and may need to be adapted. If it is not possible to administer tests in a language in which a person is sufficiently fluent for the tests to be appropriate, other methods of assessment should be considered.

The American Academy of Audiology advises that once a cochlear implant is inserted, the device programming is one of the most critical elements of a recipient's success and is heavily influenced by the programming audiologist's knowledge and experience with cochlear implants. The Academy provides recommendations outlining the possible procedures that can be followed or performed when programming a recipient's cochlear implant after surgery:

1. Review operative/intra-operative report
   - Prior to the initial stimulation, it can be helpful for the audiologist to obtain a copy of the imaging, operative and/or intra-operative monitoring report
2. Discuss progress or changes that have occurred with the recipient since his/her last appointment
3. Check skin flap
   - Check skin flap (i.e., skin between the headpiece and the internal magnet) integrity to ensure no irritation or tissue breakdown
4. Measure electrode impedances

- Electrode impedances should be measured as frequently as possible, at least during appointments where a change to programming is made, and compared across multiple visits to evaluate any sudden or slow changes in electrode function over time.

5. Select strategy/parameters
   - Because threshold (T) and upper stimulation levels can be affected by the processing/coding strategy used, it is important to set the processing/coding strategy prior to obtaining information used to establish the electrical dynamic range.
6. Establish the electrical dynamic range (EDR) on selected electrodes
   - Setting the EDR can be done through measurement of all or a subset of electrodes using a combination of psychophysical and objective measures. Common clinical practice varies regarding measurement of all or a subset of electrodes for creation of an adequate program.
7. Optimize program
   - Loudness balancing
     - Programming with equal loudness percepts across channels results in improved sound quality and speech recognition when compared to programs with unbalanced stimulation levels.
   - Pitch scaling
     - Electrodes that are enabled should provide increasing pitch perception as the electrode location progresses from apical to basal cochlear place. Electrodes that are reported by the recipient as deviating from this organization and/or those that are not perceived as differing in pitch may be considered for deactivation in programming.
8. Go live to ensure comfort and audibility
   - Informal speech testing, e.g., Ling sounds should be performed to ensure that the recipient has access to various frequencies across the speech domain.
9. Load program(s) into sound processor
   - When placing programs in the sound processor memory, the most effective program is the one that requires minimal manipulation.
10. Counsel
    - Counseling may include, but is not limited to:
      - Discussion of external device care, including proper use and maintenance of all components of the external equipment (i.e., processor, cable, coil, battery, remote, etc.).
      - Discussion of changes made to programs compared to the previous visit.
      - Discussion of different programs provided (if applicable) and when they should be used.
      - Discussion of importance of aural rehabilitation.
      - Discussion of consistent device use and realistic expectations.

Hayes, Inc.
Cochlear Implantation for Adults with Single-Sided Deafness and Tinnitus

- **C Rating** - For use of cochlear implantation for the treatment of hearing loss in adults with single-sided deafness (SSD). An overall low-quality body of evidence suggests that cochlear implantation may result in statistically significant improvement in objective hearing and sound localization relative to baseline and to no treatment for patients with SSD. Cochlear implantation may also yield both statistically and clinically significant improvement in subjective hearing, tinnitus control, and quality of life.

Coding Requirements

Procedure Codes

CPT Code	Description
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
HCPCS Code	**Description**
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)
L8625	External recharging system for batter for use with cochlear implant or auditory osseointegrated device, replacement only, 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
V5273	Assisted listening device, for use with cochlear implant

Note: All items are considered a purchase and not rentals.

Diagnosis Codes

ICD-10 Code	Description
H90.3	Sensorineural hearing loss, bilateral
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.5	Unspecified sensorineural hearing loss
H90.6	Mixed conductive and sensorineural hearing loss, bilateral

H90.8	Mixed conductive and sensorineural hearing loss, unspecified
H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side
Z45.321	Encounter for adjustment and management of cochlear device
Z96.21	Cochlear implant status

Informational

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

Degree of Hearing Loss

Degree of Hearing Loss	Hearing loss range (dB HL)
Normal	-10 to 15
Slight	16 to 25
Mild	26 to 40
Moderate	41 to 55
Moderately Severe	56 to 70
Severe	71 to 90
Profound	91 +

(ASHA, Type, Degree and Configuration of Hearing Loss; Clark, 1981)

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

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