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Subject: Cochlear Implants

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

A cochlear implant is a device for treatment of severe-to-profound hearing loss in individuals who only receive limited benefit from amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea.

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

POSITION STATEMENT:

Unilateral or bilateral** implantation of a U.S. Food and Drug Administration (FDA) approved **cochlear implant** in adults and children **meets the definition of medical necessity** when **ALL** of the following criteria are met:

- Bilateral severe-to-profound prelingual or postlingual (sensorineural) hearing loss, defined as a hearing threshold pure-tone average of 70 dB hearing loss or greater at 500, 1000, and 2000 Hz

- Limited or no benefit from appropriately fit conventional hearing aids (defined in adults as scores of 50% correct or less in the ear to be implanted on tape-recorded sets of open-set sentence recognition; defined in children as failure to develop basic auditory skills, and in older children, 30% or less correct on open-set tests)
- The individual is able to participate in a post-implant rehabilitation program in order to achieve benefit from the implant
- No contraindications to surgery (e.g., deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brainstem; active or chronic infections of the external or middle ear; mastoid cavity or tympanic membrane perforation, cochlear ossification which prevents electrode insertion, the absence of cochlear development as demonstrated on computed tomography scan)

Cochlear implantation of a U.S. Food and Drug Administration (FDA) approved hybrid cochlear implant/hearing aid device (e.g., the Nucleus® Hybrid™ L24 Cochlear Implant System) **meets the definition of medical necessity** when **ALL** of the following are met:

- Age 18 years or older
- Bilateral severe to profound high frequency sensorineural hearing loss with residual low-frequency hearing sensitivity
- Receive limited benefit from appropriately fit conventional bilateral hearing aids
- 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

Diagnostic analysis and programming of cochlear implants **meets the definition of medical necessity** when criteria for the implant device are met.

Replacement of internal and/or external components **meets the definition of medical necessity** only in those 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.

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 **does not meet the definition of medical necessity**.

Upgrades of an existing, functioning external system to achieve a cosmetic 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 cosmetic in nature and **do not meet the definition of medical necessity**.

Cochlear implantation as a treatment for unilateral hearing loss, with or without tinnitus, is considered **experimental or investigational**. There is insufficient clinical evidence in the peer-reviewed literature to permit conclusions on safety and efficacy.

** Bilateral cochlear implantation **meets the definition of medical necessity** only when it has been determined that the alternative of unilateral cochlear implantation plus hearing aid in the contralateral ear will not result in a binaural benefit (eg, in those with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

BILLING/CODING INFORMATION:

The following codes may be used to describe services related to cochlear implantation and diagnostic analysis of cochlear implant.

CPT Coding:

69930	Cochlear device implantation, with or without mastoidectomy
92601	Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient under 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

HCPCS Coding:

L7510	Repair prosthetic device, repair or replace minor parts (excludes repair of oral or laryngeal prosthesis or artificial larynx)
L8614	Cochlear device/system 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, 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
L8625	External recharging system for battery 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
V5273	Assistive listening device, for use with cochlear implant

REIMBURSEMENT INFORMATION:

Reimbursement for replacement of a cochlear implant **AND** its external components may be covered for any one of the following:

- When the existing device cannot be repaired; **OR**
- When replacement is required because a change in condition makes the present unit non-functional and improvement is expected with a replacement unit.

Reimbursement for batteries and replacement batteries for cochlear implant devices are covered when criteria for the cochlear implant device are met.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Cochlear Implantation (50.3) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Auditory nerve: either of the 8th pair of cranial nerves connecting the inner ear with the brain; transmits impulses relating to hearing and balance; composed of the cochlear nerve and the vestibular nerve.

Cochlea: a division of the labyrinth of the ear coiled into the form of a snail shell consisting of a spiral canal.

Conductive hearing loss: the result of disorders of the external or middle ear.

Consonant-Nucleus-Consonant Test (CNC): An open set word recognition test (administered in quiet) consisting of 10 recorded lists of 50 monosyllabic words used to determine speech intelligibility in listeners with hearing impairments.

Decibel (dB): Unit that measures the intensity or loudness of sound.

Hybrid cochlear implant: a unilateral implant with a shorter cochlear electrode in combination with a hearing aid-like amplification device; intended to provide electric stimulation to the mid-to-high frequency region of the cochlea and acoustic amplification to the low frequency regions.

Labyrinth: the internal ear or its bony or membranous part.

Neural hearing loss: results from disease or the auditory (eighth) nerve or central auditory channel connections.

Perlingual deafness: around or during the time speech begins.

Postlingual deafness: after speech has started.

Prelingual deafness: before speech begins.

Profound sensorineural hearing impairment: a bilateral hearing threshold of 90 decibels and above.

Sensorineural hearing loss: the result of damage to the inner ear (cochlea), or to the nerve pathways from the inner ear to the brain.

Severe sensorineural hearing impairment: a bilateral hearing threshold of 70-90 decibels (dB).

RELATED GUIDELINES:

Implantable Bone-Conduction and Bone-Anchored Hearing Aids, 02-69000-06
Prosthetics, 09-L0000-05
Treatment of Tinnitus, 01-92502-11

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Cochlear implant systems:

Advanced Bionics® HiResolution Bionic Ear System

Clarion Multi-Strategy or HiFocus CII Bionic Ear

Cochlear® Nucleus 22 and 24

Freedom with Contour

Med El® Maestro Combi 40+

Neuro Cochlear Implant System

Nucleus Profile Plus Cochlear Implant System

Synchrony 2 Cochlear Implant

Hybrid cochlear implant systems:

Nucleus® Hybrid™ L24 Cochlear Implant System

Med El® EAS Hearing Implant System

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

GUIDELINE UPDATE INFORMATION:

08/15/03	Annual review/new Medical Coverage Guideline. Implanted Devices for Hearing Loss and Aural Rehabilitation guideline 02-69000-02 archived.
09/15/04	Added investigational statement for bilateral cochlear implantation. Updated references.
01/15/05	HCPCS update; added codes: L8615, L8616, L8617, L8618, L8620, L8621, and L8622.
07/01/05	HCPCS update. Added codes K0731 and K0732.
08/15/05	Scheduled review; no change in coverage statement; added reimbursement information regarding batteries.
01/01/06	HCPCS update; Deleted codes L8620, K0731 and K0732. Added codes L8623 and L8624. Updated references.

08/15/06	Revised DESCRIPTION section. Revised WHEN SERVICES ARE COVERED section; add coverage statement for post-cochlear rehabilitation program (aural rehabilitation). Revised BILLING/ CODING INFORMATION section, delete 2003 CPT statement regarding codes: 92601, 92602, 92603, 92604, and 92606. Added program exception for Medicare Advantage products. Updated references.
11/15/06	Added coverage statement for bilateral cochlear implant. Added coverage statement for upgrades of an exiting functioning system. Revised definition for postlingual deafness and prelingual deafness. Updated references.
01/01/07	HCPCS update. Revise code L8614 descriptor.
08/15/07	Annual review, coverage statements maintained, Description section updated, guideline reformatted, references updated.
08/15/09	Scheduled review; no change in position statement. Update references.
01/01/10	Annual HCPCS coding update: add HCPCS codes L8627, L8628, and L8629; update descriptor for code L8619.
10/15/10	Revision; related ICD-10 codes added.
07/15/11	Scheduled review; position statements maintained and references updated.
03/15/13	Unscheduled review. Revised description, position statement, reimbursement section, Medicare Advantage program exception, definitions and related guidelines. Updated references.
05/11/14	Revision: Program Exceptions section updated.
11/15/14	Unscheduled review. Revised description, position statement and definitions. Updated references.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/15	Unscheduled review. Revised description section and index terms. Updated references.
01/01/16	Annual CPT/HCPCS coding update. Revised code L8621 descriptor.
09/15/16	Unscheduled review. Revised Position Statement section and Definitions section. Updated references.
01/01/18	Annual CPT/HCPCS coding update: added L8625.
02/15/20	Scheduled review. Revised description and position statement (revised definition of severe to profound hearing loss; added definition of “limited or no benefit from conventional hearing aids”), and index terms. Updated references.
10/15/21	Scheduled review. Added statements regarding replacement of components and bilateral implantation. Updated references.
11/15/22	Scheduled review. Updated references and maintained position statement.
08/21/23	Update to Program Exceptions section.
09/15/24	Scheduled review. Maintained position statement and updated references.