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OVERVIEW

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. This policy documents the coverage guidelines for cochlear implants.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Prior authorization is not required.

POLICY STATEMENT

Cochlear Implantation – Bilateral Hearing Loss

Medicare Advantage Plans

Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be considered medically necessary in patients with bilateral moderate to profound pre- or post-lingual (sensorineural) hearing loss and who have shown limited or no benefit from hearing aids.

Commercial Products

Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be considered medically necessary in patients age 9 months and older with bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss and who have shown limited or no benefit from hearing aids.

Medicare and Commercial

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 covered, as this is considered a convenience. Additionally, 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 covered, as this is considered a convenience.

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.

Hybrid Cochlear Implant/Hearing Aid

Medicare Advantage Plans

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 (eg, the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered medically necessary for patients who have bilateral moderate-to-profound high-frequency sensorineural hearing loss with residual low frequency hearing sensitivity and receive limited benefit from appropriately fit bilateral hearing aids.

Commercial Products
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 (eg, the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered medically necessary for patients ages 18 years and older who have 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.

Cochlear Implantation – Unilateral Hearing Loss
Medicare Advantage Plans
Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus may be covered as part of FDA-approved category B investigational device exemption clinical trials or as a routine cost in clinical trials. Please see the Coding and Related Policies sections for details.

Commercial Products
Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Surgery Services and Medical Equipment, Medical Supplies, and Prosthetic Devices/Diagnostic Imaging, Lab, Machine Tests/Speech Therapy, and Personal Appearance and/or Items coverage/benefits.

BACKGROUND
A cochlear implant, classified by Centers for Medicare and Medicaid Services (CMS) as a prosthetic device, is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

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 surgically implanted and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear.

Sounds that are picked up by the microphone are carried to the external sound processor, which transforms the sound into coded signals that are then transmitted through the skin 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.

Medicare Advantage Plans
Cochlear implantation may be utilized for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification (appropriate hearing, or vibrotactile, aids). Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition. Individuals should have the cognitive ability to use auditory clues and have 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; have no contraindications to surgery; and the device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

CMS, may provide coverage of cochlear implants for individuals not meeting coverage criteria when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR (Code of Federal Regulations), section 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

Commercial Products
Typically, 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.

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.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. A typical rehabilitation program consists of 6 to 10 sessions that last approximately 2½ hours each. A rehabilitation program would include development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

Bilateral cochlear implantation should be considered 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 (ie, in those individuals with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

Contraindications to cochlear implantation may include 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; and mastoid cavity or tympanic membrane perforation. Cochlear ossification may prevent electrode insertion, and the absence of cochlear development as demonstrated on computed tomography scans remains an absolute contraindication.

For individuals who have bilateral sensorineural hearing loss who receive the 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 an improvement in the net health outcome.

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."

In 2022, the Nucleus® Hybrid™ L24 Cochlear Implant System received expanded approval for single-sided deafness or unilateral hearing loss in adults and children age 5 or older. Other hybrid hearing devices have been developed. The Med-El EAS System received expanded PMA (pre-market approval) by the FDA in 2016 (PMA P000025/S084).

Clinical input obtained in 2016 supports the use of hybrid cochlear implants in patients with high-frequency hearing loss but preserved low frequency hearing.

For individuals who have unilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes small open-label RCTs, a feasibility study, 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 subjective measures of quality of life compared to baseline conditions. Inconsistent sound localization and binaural hearing outcomes have been reported in 2 small RCTs. Prospective studies assessing outcomes compared to best-aided hearing controls beyond 6 months are lacking. Ongoing post marketing studies in adults and children may further elucidate outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

In addition to the codes identified in this policy under the diagnostic imaging, lab, and machine tests benefit, there may be other therapeutic service codes related to cochlear implants (such as auditory rehabilitation) which would be applied to the member's speech therapy benefit.

Medicare Advantage Plans and Commercial Products

The following code is covered under the member's **surgery services** benefit:

69930 Cochlear device implantation, with or without mastoidectomy

The following codes are covered under the member's **speech therapy** benefit:

92626 Evaluation of auditory rehabilitation status; first hour

92627 Evaluation of auditory rehabilitation status; each additional 15 minutes
92630 Auditory rehabilitation; pre-lingual hearing loss
92633 Auditory rehabilitation; post-lingual hearing loss

The following codes are covered under the **diagnostic imaging, lab, and machine tests** benefit:
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

The following codes are covered under the **prosthetic devices** benefit:
L8614 Cochlear device, includes all internal and external components
L8615 Headset/headpiece for use with cochlear implant device, replacement
L8616 Microphone for use with cochlear implant device, replacement
L8617 Transmitting coil for use with cochlear implant device, replacement
L8618 Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8619 Cochlear implant, external speech processor and controller, integrated system, replacement
L8621 Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
L8622 Alkaline battery for use with cochlear implant device, any size, replacement, each
L8627 Cochlear implant, external speech processor, component, replacement
L8628 Cochlear implant, external controller component, replacement
L8629 Transmitting coil and cable, integrated, for use with cochlear implant device, replacement

The following codes are covered under the **durable medical equipment** benefit:
L8623 Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
L8624 Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each
L8625 External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each

Note: If you are treating a Medicare Advantage Plan member as part of an FDA-approved Category B investigational device exemption clinical trial or as a routine clinical trial, please follow the procedures for correct billing and coding of services found in the policy for Clinical Trials Mandate Medicare Advantage Plans.

Claims for services rendered as part of FDA-approved Category B investigational device exemption clinical trials or as a routine cost in clinical trials must be billed with an appropriate modifier:

The following modifier should be reported with the cochlear implantation device and all other related costs:
Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study

The following modifier must be reported for routine costs and not the device itself:
Q1 Routine clinical service provided in a clinical research study that is in an approved clinical research study

RELATED POLICIES

Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations
Clinical Trials Medicare Advantage Plans
Durable Medical Equipment

Speech Therapy

PUBLISHED

Provider Update, April 2024
Provider Update, June 2023
Provider Update, October 2022
Provider Update, June 2021
Provider Update, September 2020

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