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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

Medicare Advantage Plans and Commercial Products

Cochlear Implantation

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.

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

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.

Medicare Advantage Plans

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

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.

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.

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.

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.

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 \geq 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 \geq 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 but do not have FDA approval, including the Med El® EAS Hearing Implant System.

For individuals who have unilateral sensorineural hearing loss who receive the cochlear implant(s), the 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, short follow-up times, and heterogeneity in evaluation protocols and outcome measurements. The evidence is insufficient to determine the effects of the technology on health outcomes.

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:

Note: There are no participating providers for batteries for cochlear devices. Therefore, batteries are paid as an in-network 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

RELATED POLICIES

Clinical Trials Medicare Advantage Plans
 Clinical Trials Mandate Commercial
 Durable Medical Equipment
 Speech Therapy

PUBLISHED

Provider Update, June 2021
 Provider Update, September 2020
 Provider Update, May 2020
 Provider Update, September 2019
 Provider Update, November 2018

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