Protocol

Cochlear Implant

(70105)

Medical Benefit		**Effective Date**: 10/01/14	**Next Review Date**: 07/15
Preauthorization	Yes	**Review Dates**: 04/07, 05/08, 05/09, 03/10, 03/11, 03/12, 03/13, 07/13, 03/14, 07/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

A cochlear implant is a device for people with severe-to-profound hearing loss 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.

Background

The basic components of a cochlear implant include 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 that are 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 to electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve.

Regulatory Status

Several cochlear implants are commercially available in the U.S. and are manufactured by Cochlear Corporation, Advanced Bionics, and the Med El Corporation. Over the years, 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. The labeled indications from the FDA for currently marketed implant devices are summarized next. FDA Product Code: MCM.

FDA-Approved Cochlear Implant Systems[a]

Manufacturer and Currently Marketed Cochlear Implants	**Advanced Bionics® HiResolution Bionic Ear System (HiRes 90K)**	**Cochlear® Nucleus 5**	**Med El® Maestro (Sonata or Pulsar)**
Predecessor Cochlear Implants	Clarion Multi-Strategy or HiFocus CII Bionic Ear (P940022)	Nucleus 22, 24, Freedom with Contour (P840024)	Combi 40+ (P000025)

Indications			
Adults	• ≥ 18 y • Postlingual onset of severe-to-profound bilateral sensorineural hearing loss (≥ 70 dB) • Limited benefit from appropriately fitted hearing aids, defined as scoring ≤ 50% on a test of open-set HINT sentence recognition	• ≥ 18 y • Pre- or postlingual onset of moderate-to-profound bilateral sensorineural hearing loss • ≤ 50% sentence recognition in ear to be implanted • ≤ 60% sentence recognition in opposite ear or binaurally	• ≥ 18 y • Severe-to-profound bilateral sensorineural hearing loss (≥ 70 dB) • ≤ 40% correct HINT sentences with best-sided listening condition
Children	• 12 mo to 17 y of age • Profound bilateral sensorineural deafness (> 90 dB) • Use of appropriately fitted hearing aids for at least 6 mo in children 2-17 y or at least 3 mo in children 12-23 mo • Lack of benefit in children < 4 y is defined as a failure to reach developmentally appropriate auditory milestones (e.g., spontaneous response to name in quiet or to environmental sounds) measured using IT-MAIS or MAIS or < 20% correct on a simple open-set word recognition test (MLNT) administered using monitored live voice (70 dB SPL) • Lack of hearing aid benefit in children > 4 y is defined as scoring < 12% on a difficult open-set word recognition test (PKB test) or < 30% on an open-set sentence test (HINT for Children) administered using recorded materials in the soundfield (70 dB SPL)	<u>25 mo to 17 y 11 mo</u> • Severe-to-profound bilateral sensorineural hearing loss • MLNT scores ≤ 30% in best-aided condition in children 25 mo to 4 y 11 mo • LNT scores ≤ 30% in best-aided condition in children 5 y to 17 y and 11 mo • Lack of progress in development of auditory skills <u>12-24 mo</u> • Profound sensorineural hearing loss bilaterally • Limited benefit from appropriate binaural hearing aids • Lack of progress in development of auditory skills	• 12 mo to 18 y with profound sensorineural hearing loss (≥ 90 dB) • In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills with hearing aids over a 3- to 6-mo period • In older children, lack of aided benefit is defined as < 20% correct on the MLNT or LNT, depending on child's cognitive ability and linguistic skills • A 3- to 6-mo trial with hearing aids required if not previously experienced

HINT: Hearing in Noise Test; IT-MAIS: Infant-Toddler Meaningful Auditory Integration Scale; LNT: Lexical Neighborhood Test; MAIS: Meaningful Auditory Integration Scale; MLNT: Multisyllabic Lexical Neighborhood Test; PBK: Phonetically Balanced-Kindergarten; SPL: sound pressure level.

[a]Cochlear Ltd. voluntarily recalled the Nucleus CI500 range in September 2011 for device malfunction in the CI512 implant. The external Nucleus 5 sound processor is not a part of the recall. Advanced Bionics HiRes90K was voluntarily recalled in November 2010 and given FDA-approval for re-entry to market the device in September 2011.

In March 2014, FDA approved the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Corporation, Centennial, CO) through the premarket approval process. (1) 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 aged 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 appropriately fit bilateral hearing aid. The electrode array inserted into the cochlea is shorter than conventional cochlear implants. According to the 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.
- Consonant-Nucleus-Consonant (CNC) word recognition score between 10% to 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.

While cochlear implants have typically been used unilaterally, in recent years, interest in bilateral cochlear implantation has arisen. The proposed benefits of bilateral cochlear implants are to improve understanding of speech in noise and localization of sounds. Improvements in speech intelligibility may occur with bilateral cochlear implants through binaural summation; i.e., signal processing of sound input from two sides may provide a better representation of sound and allow one to separate out noise from speech. Speech intelligibility and localization of sound or spatial hearing may also be improved with head shadow and squelch effects, i.e., the ear that is closest to the noise will be received at a different frequency and with different intensity, allowing one to sort out noise and identify the direction of sound. Bilateral cochlear implantation may be performed independently with separate implants and speech processors in each ear or with a single processor. However, no single processor for bilateral cochlear implantation has been approved by the FDA for use in the U.S. In addition, single processors do not provide binaural benefit and may impair sound localization and increase the signal-to-noise ratio received by the cochlear implant.

Related Protocols

Implantable Bone-Conduction and Bone-Anchored Hearing Aids

Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

Policy (Formerly Corporate Medical Guideline)

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 12 months and older with bilateral severe-to-profound pre-or post-lingual (sensorineural) hearing loss defined as a hearing threshold of pure-tone average of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz, and have shown limited or no benefit from hearing aids.

Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered **investigational**.

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 medically necessary**.

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, including but not limited to the Nucleus® Hybrid™ L24 Cochlear Implant System, is considered **investigational**. (See Policy Guidelines section)

Policy Guidelines

Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit; i.e., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification.

In certain situations, implantation may be considered before 12 months of age. One scenario is post-meningitis when cochlear ossification may preclude implantation. Another is in cases with a strong family history, because establishing a precise diagnosis is less uncertain.

Hearing loss is rated on a scale based on the threshold of hearing. Severe hearing loss is defined as a bilateral hearing threshold of 70–90 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.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program consists of six 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.

Contraindications to cochlear implantation may include 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 may prevent electrode insertion, and the absence of cochlear development as demonstrated on computed tomography scans remains an absolute contraindication.

Medicare Advantage

Cochlear implantation may be considered **medically necessary** for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Patients need to meet all of the following selection guidelines:

- 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.

Individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% may be eligible under a clinical trial.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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