Protocol

Cochlear Implant

(70105)

Medical Benefit		**Effective Date**: 01/01/17	**Next Review Date**: 07/17
Preauthorization	Yes	**Review Dates**: 04/07, 05/08, 05/09, 03/10, 03/11, 03/12, 03/13, 07/13, 03/14, 07/14, 07/15, 07/16, 09/16	

Preauthorization is required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With bilateral sensorineural hearing loss	Interventions of interest are: • Cochlear implant(s)	Comparators of interest are: • Best-aided hearing	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related mortality • Treatment-related morbidity
Individuals: • With unilateral sensorineural hearing loss	Interventions of interest are: • Cochlear implant(s)	Comparators of interest are: • Best-aided hearing	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related mortality • Treatment-related morbidity
Individuals: • With high-frequency sensorineural hearing loss with preserved low-frequency hearing	Interventions of interest are: • Hybrid cochlear implant that includes a hearing aid integrated into the external sound processor of the cochlear implant	Comparators of interest are: • Best-aided hearing	Relevant outcomes include: • Symptoms • Functional outcomes • Treatment-related mortality • Treatment-related morbidity

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.

Summary of Evidence

For individuals who have bilateral sensorineural hearing loss who receive 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. And, although the available RCTs and other studies measured heterogeneous outcomes and included varying patient popula-

tions, 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes prospective and retrospective studies reporting within-subjects comparisons and systematic reviews of these studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Given the natural history of hearing loss, pre- and postimplantation 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, 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.

For individuals who have high-frequency sensorineural hearing loss with preserved low-frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound processor, the evidence includes prospective and retrospective studies using single-arm, within-subjects comparison pre- and postintervention and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available evidence has suggested that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. The available evidence has also suggested that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation after a hybrid cochlear implantation if there is loss of residual hearing. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant 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, 1000 and 2000 Hz(hertz), who 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 (e.g., the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered **medically necessary** for patients ages 18 years and older who meet all of the following criteria:

- 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; AND
- 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.

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.

Background

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 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 United States and are manufactured by Cochlear Americas, Advanced Bionics, and the MED-EL Corp. 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 FDA for currently marketed implant devices are summarized in Table 1. FDA Product Code: MCM.

Table 1. Cochlear Implant Systems[a] Approved by the Food and Drug Administration

Variables	Manufacturer and Currently Marketed Cochlear Implants		
	Advanced Bionics® HiResolution Bionic Ear System (HiRes 90K)	**Cochlear® Nucleus 5**	**Med El® Maestro (Sonata or Pulsar)**
Predicate devices	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 HL (≥ 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-, peri-, or postlingual onset of bilateral sensorineural HL, usually characterized by: o Moderate-to-profound hearing loss in low frequencies; and o Profound (≥ 90 dB HL) HL in mid-to-high speech frequencies	• ≥ 18 y • Severe to profound bilateral sensorineural HL (≥ 70 dB) • ≤ 40% correct HINT sentences with best-sided listening condition

Variables	Manufacturer and Currently Marketed Cochlear Implants		
		• Limited benefit from binaural hearing aids (≤ 50% sentence recognition in ear to be implanted)	
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 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 defined as scoring < 12% on a difficult open-set word recognition test (PBK test) or < 30% on an open-set sentence test (HINT for Children) administered using recorded materials in the soundfield (70 dB SPL)	**25 mo to 17 y 11 mo** • Severe to profound bilateral sensorineural HL • 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 **12-24 mo** • Profound sensorineural HL bilaterally • Limited benefit from appropriate binaural hearing aids	• 12 mo to 18 y with profound sensori-neural HL (≥ 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 is required if not previously experienced

HINT: Hearing in Noise Test; HL: hearing loss; 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 reentry to market the device in September 2011.

In March 2014, the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Americas, Centennial, CO) was approved by FDA 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 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.

- 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.

Although cochlear implants have typically been used unilaterally, interest in bilateral cochlear implantation has arisen in recent years. The proposed benefits of bilateral cochlear implants are to improve understanding of speech occurring in noisy environments and localization of sounds. Improvements in speech intelligibility with bilateral cochlear implants may occur through binaural summation (i.e., signal processing of sound input from two sides may provide a better representation of sound and allow the individual to separate 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 receive it at a different frequency and with different intensity, allowing the individual 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 a single processor may be used. However, no single processor for bilateral cochlear implantation has been approved by FDA for use in the United States. 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

Treatment of Tinnitus

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.**

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

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