MEDICAL POLICY – 7.01.05
Cochlear Implant

BCBSA Ref. Policy: 7.01.05*

Effective Date: May 1, 2018
Last Revised: Sept. 1, 2018
Replaces: N/A

RELATED MEDICAL POLICIES:
1.01.528  Hearing Aids (Excludes Implantable Devices)
7.01.84  Semi-Implantable and Fully Implantable Middle Ear Hearing Aids
7.01.547  Implantable Bone Conduction and Bone-Anchored Hearing Aids

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞  Clicking this icon returns you to the hyperlinks menu above.

Introduction

The cochlea is part of the inner ear. Its job is to help convert vibrations from sound into nerve signals. The signals then travel along the auditory nerve to the brain and we interpret the signals as sound. A cochlear implant is a hearing device that may be used for certain types of severe or profound hearing loss. Cochlear implants work differently than typical hearing aids. Hearing aids amplify or increase sounds. A cochlear implant, however, bypasses certain hearing parts of the ear and instead directly stimulates the auditory nerve. A cochlear implant has internal and external parts. The external parts include a microphone, sound processor, and a transmitter. The internal components include a receiver and an electrode-type device that stimulates the auditory nerve. The external microphone picks up sound and carries it to the external sound processor, which then transmits it to the internal receiver. The internal receiver converts the signals into electrical impulses. The impulses then travel to the electrode-type device to stimulate the auditory nerve. This policy describes when a cochlear implant may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bilateral Hearing Loss</strong></td>
<td>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 severe-to-profound pre- or post-lingual (sensorineural) hearing loss when ALL of the following criteria are met:                                                                                                                                  • Patient is 12 months of age or older AND • The patient has a hearing threshold of pure-tone average (PTA) of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1,000 Hz, and 2,000 Hz AND • The patient has tried standard hearing aids but had limited or no benefit from their use</td>
</tr>
<tr>
<td><strong>Hybrid cochlear implant/hearing aid</strong></td>
<td>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 when ALL of the following criteria are met:                                                                                                           • Patient is 18 years of age or older AND • The patient has bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity AND • The patient receives limited benefit from appropriately fit bilateral hearing aids AND • The patient has the following hearing thresholds: o 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</td>
</tr>
<tr>
<td><strong>Subject</strong></td>
<td><strong>Medical Necessity</strong></td>
</tr>
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</tr>
</tbody>
</table>
| AND | o 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 | o 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 | o 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 |
| **Replacements** | **Replacement of an internal and/or external components (speech controller or speech processor) may be considered medically necessary only in a small subset of patients when:**  
• | The processor is not working or broken and cannot be repaired or replaced under a manufacturer’s warranty.  
OR | Replacement is needed because the patient’s condition has changed to the extent that the current processor is inadequate and no longer meets the functional needs for activities of daily living, and improvement is expected with a replacement device.  
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 medically necessary. |
<p>| <strong>Upgrades</strong> | <strong>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 model, are considered not medically necessary.</strong> |</p>
<table>
<thead>
<tr>
<th>Subject</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral Hearing Loss</td>
<td>Cochlear implantation as a treatment for patients with unilateral hearing loss, with or without tinnitus, is considered investigational.</td>
</tr>
</tbody>
</table>

**Limited Benefit from Hearing Aids**

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 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 of 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, scores of 30% or less correct on open-set tests.

**Bilateral Cochlear Implantation**

Bilateral cochlear implantation (CI) should be considered only when it has been determined that the alternative of unilateral cochlear implantation plus a hearing aid in the opposite ear will not improve hearing in both ears (ie, the hearing loss is considered severe to profound and a hearing aid will not deliver the required amplification of sound).

**Post- Cochlear Implantation Rehabilitation**

A post cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program consists of 6 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**

Contraindications to cochlear implantation may include:
- Absence of cochlear development as demonstrated on a computed tomography (CT) scan is an absolute contraindication
- Cochlear ossification, may prevent electrode insertion
- Deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway or brain stem
- Infections, active or chronic, of the external or middle ear; or mastoid cavity
- Tympanic membrane perforation.

**Children Less Than 12 Months of Age**

The cochlear device is FDA labeled only for use in children 12 months of age and older. In certain situations, off-label use for CI may be considered before 12 months of age for severe bilateral hearing loss as defined in the policy statement. Each request for CI for children less than 12 months of age should be reviewed on an individual basis. One example situation is post-meningitis when cochlear ossification may prevent implantation. Another example is in children with a strong family history of profound hearing impairment/loss, when establishing a precise diagnosis is less uncertain.

**Reasonable Useful Life Expectancy for External Cochlear Implant Parts**

<table>
<thead>
<tr>
<th>Parts</th>
<th>Life Expectancy</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batteries - Disposable</td>
<td>60 hours (1-3 days)</td>
<td>Replaced as needed</td>
</tr>
<tr>
<td>Batteries - Rechargeable</td>
<td>1 year or more</td>
<td>Many will last longer than 1 year</td>
</tr>
<tr>
<td>External speech processor</td>
<td>3 years or longer</td>
<td>Manufacturer’s warranty is usually 3 years. The component may last longer depending on care &amp; maintenance.</td>
</tr>
<tr>
<td>Headpieces/microphones</td>
<td>1-2 years</td>
<td>May last longer depending on care &amp; maintenance.</td>
</tr>
</tbody>
</table>

Adapted from Gift of Hearing Foundation (GOHF).

**Documentation Requirements**

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:
Documentation Requirements

- Office visit notes that contain the relevant history and physical

**AND**

- Manufacturer and Model Name of Cochlear Implant being requested

**AND**

- Audiology test results

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>69930</td>
<td>Cochlear device implantation, with or without mastoidectomy</td>
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</table>

<table>
<thead>
<tr>
<th><strong>HCPCS</strong></th>
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<tbody>
<tr>
<td>L8614</td>
</tr>
<tr>
<td>L8615</td>
</tr>
<tr>
<td>L8619</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Consideration of Age

The ages in this policy for which cochlear implants are considered medically necessary is based on the FDA approved age and is varied for each device. The labeled indications from the FDA for currently marketed implant devices are summarized in Table 2.
Benefit Application

Some facilities may negotiate a global fee for the implantation of the device and the associated auditory rehabilitation. However, charges for rehabilitation services may be subject to individual contractual limitations.

A cochlear implant is a surgically implanted hearing device. The implanted receiver and electrode system device and implantation surgery should be reimbursed under the medical benefit.

Hearing aids may be excluded by contract. See Scope.

Evidence Review

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 the deaf cochlea.

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 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.
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. 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 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-subject 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.
Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT00960102</td>
<td>Children’s Bilateral Cochlear Implantation in Finland: a Prospective, Controlled, Multicenter Study (FinBiCI)</td>
<td>40</td>
<td>Dec 2017</td>
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<tr>
<td>NCT02075229</td>
<td>A Proposal to Evaluate Revised Indications for Cochlear Implant Candidacy for the Adult CMS Population</td>
<td>90</td>
<td>Jun 2019 (ongoing)</td>
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<tr>
<td>NCT02203305</td>
<td>Cochlear Implantation in Cases of Single-Sided Deafness</td>
<td>50</td>
<td>Dec 2018</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01256229</td>
<td>Outcomes in Children With Developmental Delay and Deafness: A Prospective, Randomized Trial</td>
<td>303</td>
<td>Sep 2016 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
2016 Input

In response to requests, input was received from 2 specialty societies, one of which provided 4 responses and one of which provided 3 responses, and 3 academic medical centers while this policy was under review in 2016. Clinical input focused on the use of hybrid cochlear implants. Input was consistent that the use of a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant improves outcomes for patients with high-frequency hearing loss but preserved low-frequency hearing.

2010 Input

In response to requests, input was received from 2 physician specialty societies and 4 academic medical centers while this policy was under review in 2010. In addition, unsolicited input was received from a specialty society. Most providing input supported the use of cochlear implants in infants younger than 12 months of age; many supporting this use noted that there are major issues determining hearing level in infants of this age group, and others commented that use could be considered in these young infants only in certain situations. Those providing input were divided in their comments regarding the medical necessity of upgrading functioning external systems; some agreed and others did not.

Practice Guidelines and Position Statements

The American Academy of Otolaryngology-Head and Neck Surgery

The American Academy of Otolaryngology-Head and Neck Surgery has a position statement on cochlear implants that was revised in 2014. The Foundation “considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can significantly perform better with two cochlear implants rather than one, bilateral cochlear implantation is accepted medical practice.”
Agency for Health Care Research and Quality

In April 2011, a technology assessment for the Agency for Health Care Research and Quality (AHRQ) on the effectiveness of cochlear implants in adults. The assessment conclusions are noted within the body of this policy.

National Institute for Health and Care Excellence

In 2009, the National Institute for Health and Care Excellence (NICE) released a technology guidance, on cochlear implants for children and adults with severe to profound deafness. This guidance was originally based on Bond’s (2009) technology assessment, and no changes to guidance were made following an updated review of the evidence in 2001.

The guidance included the following recommendations:

1.1 "Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, as defined in 1.5

1.2 Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.
   
   a. Children
   
   b. Adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

1.3 Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.

1.5 For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL [hearing level] at frequencies of 2 and 4 kHz without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as:

   a. for adults, a score of 50% or greater on Bamford-Kowal-Bench (BKB) sentence testing at a sound intensity of 70 dB SPL
   
   b. for children speech, language and listening skills appropriate to age, developmental stage, and cognitive ability.
1.4 Cochlear implantation should be considered for children and adults only after an assessment by a multidisciplinary team. As part of the assessment, children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).”

1.7 Cochlear implantation should be considered for ... adults only after an assessment by a multidisciplinary team. As part of the assessment ... [implant candidates] should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).”

**National Institutes of Health**

Cochlear implants are recognized as an effective treatment of sensorineural deafness, as noted in a 1995 National Institutes of Health (NIH) Consensus Development conference, which offered the following conclusions²:

- “Cochlear implantation has a profound impact on hearing and speech reception in post-lingually deafened adults.”

- “Pre-lingually deafened adults generally show little improvement in speech perception scores after cochlear implantation, but many of these individuals derive satisfaction from hearing environmental sounds and continue to use their implants.”. However, improvements in other basic benefits, such as improved sound awareness, may meet safety needs.

- “…training and educational intervention are fundamental for optimal post-implant benefit.”

The conference offered the following conclusions regarding cochlear implantation in children:

- “Cochlear implantation outcomes are more variable in children. Nonetheless, gradual, steady improvement in speech perception, speech production, and language does occur.”

- Cochlear implants in children under 2-years-old are complicated by the inability to perform detailed assessment of hearing and functional communication. However, “a younger age of implantation may limit the negative consequences of auditory deprivation and may allow more efficient acquisition of speech and language.” Some children with a post meningitis hearing loss under the age of 2 years have received an implant due to “the risk of new bone formation associated with meningitis, which might preclude cochlear implantation at a later date.
Medicare National Coverage

Existing national coverage states 38:

“...cochlear implantation may be covered “for treatment of bilateral pre-or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification which is defined by test scores of ≤ 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition.”

Coverage for cochlear implants may also be provided when the patient has:

“...hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption (IDE) clinical trial..., or a prospective, controlled comparative trial approved by CMS...”.

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 time, subsequent generations of the various components of the devices have been approved by the 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 2. FDA Product Code: MCM.

Table 2. Cochlear Implant Systemsa Approved by the Food and Drug Administration

<table>
<thead>
<tr>
<th>Variables</th>
<th>Manufacturer and Currently Marketed Cochlear Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Advanced Bionics® HiResolution Bionic Ear System (HiRes 90K)</td>
</tr>
<tr>
<td>PMA</td>
<td>P960058</td>
</tr>
<tr>
<td>Predicate devices</td>
<td>Clarion Multi-Strategy or HiFocus CII Bionic Ear (P940022)</td>
</tr>
<tr>
<td>Variables</td>
<td>Manufacturer and Currently Marketed Cochlear Implants</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 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  
| | • Pre-, peri-, or postlingual onset of bilateral sensorineural HL, usually characterized by:  
• Moderate-to-profound hearing loss in low frequencies; and  
• Profound (≥90 dB HL) in mid-to-high speech frequencies  
• Limited benefit from binaural hearing aids (≤50% sentence recognition in ear to be implanted)  
| | • Severe to profound bilateral sensorineural HL (≥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 defined as a failure to reach developmentally appropriate auditory milestones (eg, 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 mo to 18 y with profound sensorineural 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.
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. Cochlear Ltd. voluntarily recalled the Nucleus CI500 range in 2011 for device malfunction in the CI512 implant.

*The FDA website is the resource for the most up to date approvals of accessories and technology related to the Nucleus cochlear implant system. (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S129).

Accessed April 2018.

Hybrid Cochlear Implant System

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 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.”

- “The Consonant-Nucleus-Consonant (CNC) 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.
**Bilateral Cochlear Implants**

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 2 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 the 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 the 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.

**References**


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/97</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>11/03/98</td>
<td>Replace Policy - Revised Description and Policy Guidelines</td>
</tr>
<tr>
<td>01/04/99</td>
<td>Replace Policy - Policy reviewed; new devices added.</td>
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<tr>
<td>10/09/01</td>
<td>Replace Policy - Policy reviewed; new devices and FDA approval status added.</td>
</tr>
<tr>
<td>10/08/02</td>
<td>Replace Policy - Policy reviewed; new FDA-approved device added (Med E1 Combi 40+).</td>
</tr>
<tr>
<td>03/11/03</td>
<td>Replace Policy - Policy Benefit Application section added. No change to Policy Statement.</td>
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<td>05/13/03</td>
<td>Replace Policy - Update CPT code only.</td>
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<td>05/11/04</td>
<td>Replace Policy - Policy reviewed without literature review; no change to policy statement.</td>
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<tr>
<td>07/13/04</td>
<td>Replace Policy - Policy reviewed; discussion of bilateral cochlear implants and its investigational status added.</td>
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<td>08/09/05</td>
<td>Replace Policy - Policy reviewed with literature search; policy statement unchanged.</td>
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<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
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<tr>
<td>06/09/06</td>
<td>Disclaimer and Scope update - No other changes.</td>
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<tr>
<td>08/08/06</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statement.</td>
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<tr>
<td>04/10/07</td>
<td>Replace Policy - Policy updated with literature review. Policy statement changed to indicate bilateral cochlear implants are medically necessary. References numbers added.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References and codes added.</td>
</tr>
<tr>
<td>04/13/10</td>
<td>Replace Policy - Policy updated with literature search. Policy statements modified for clarity, intent unchanged. References and codes added.</td>
</tr>
<tr>
<td>08/09/11</td>
<td>Replace Policy – Policy updated with literature review; Rationale section and references reorganized. No changes in policy statements. Reference numbers 3-4, 6, 12, 16-17 added; numerous references to early, small studies removed. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>08/24/11</td>
<td>Benefit Application updated.</td>
</tr>
<tr>
<td>02/09/12</td>
<td>The CPT codes 92605 and 92606 were removed from the policy.</td>
</tr>
<tr>
<td>06/26/12</td>
<td>Related Policies update; title for 7.01.84 has been changed.</td>
</tr>
<tr>
<td>08/20/12</td>
<td>Replace policy. Clarification statement added to the policy guidelines second paragraph: In addition, unique clinical circumstance may justify individual consideration for implantation before 12 months of age, based on review of applicable medical records to verify the other pediatric criteria noted in this policy are met. Rationale section revised based on literature review through April 2012. Reference numbers 7-9, 13 and 22-24 added. Other references renumbered. CPT codes 92605 and 92606 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>09/25/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>10/18/12</td>
<td>Update Related Policies – 7.01.03 renumbered to 7.01.547.</td>
</tr>
<tr>
<td>08/12/13</td>
<td>Replace policy. Policy statement added: cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered investigational. Rationale updated based on literature review through May 2013. References 7, 10, 11, 28-32 added; others renumbered/removed. Policy statement changed as noted.</td>
</tr>
<tr>
<td>03/11/14</td>
<td>Coding Update. Remove codes 20.96, 20.97, and 20.98 per ICD-10 mapping project; these codes are not utilized for adjudication of policy.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. Add 1.01.528</td>
</tr>
<tr>
<td>05/15/14</td>
<td>Coding update. CPT codes 92607 and 92608 removed from the policy; these codes address the evaluation portion; this policy is specific to the device and evaluation is not addressed herein.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>07/14/14</td>
<td>Annual Review. Policy statement added that cochlear implantation with a hybrid cochlear implant/ hearing aid system is considered investigational. Rationale section reorganized and policy updated with literature review through April 4, 2014. References reorganized, numbers 1, 20, 21, 27, 29, 30-32, 36-40 added, others renumbered/removed. Policy statement changed as noted. Coding update: Remove CPT codes 92507-92606 &amp; 92626-92633 from policy. Remove ICD-9 and ICD-10 diagnosis codes and ICD-10-PCS codes.</td>
</tr>
<tr>
<td>07/14/15</td>
<td>Annual Review. Policy updated with literature review through April 19, 2015; references 17, 23-24, 36-37, and 45 added. Policy statements unchanged. CPT codes 92626, 92627, 92630 and 92633 removed; these are codes fall under the rehabilitation benefit. HCPCS codes L8616, L8617, L8618, L8621, L8622, L8623 and L8624 removed; these are for replacement and do not fall within the scope of the policy.</td>
</tr>
<tr>
<td>12/12/15</td>
<td>Policy statement formatted to differentiate between different types of hearing loss/implants.</td>
</tr>
<tr>
<td>10/01/16</td>
<td>Annual Review, changes approved September 13, 2016. Policy updated with results of clinical input. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria. CPT codes 92601-92606, 92609 removed; these are not supportive of policy intent.</td>
</tr>
<tr>
<td>10/07/16</td>
<td>Update coding section. Changed code L8328 to L8628. Removed paragraph regarding codes 92601-92606, and 92609 as they were removed from policy.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Interim review, changes approved December 13, 2016. Removed age limit for policy statement about cochlear implants for bilateral hearing loss; added statement about replacement of cochlear implant components. Policy guidelines about individual review consideration for implantation in children under 12 months of age added. RUL table for cochlear implant components added to Policy Guidelines.</td>
</tr>
<tr>
<td>05/01/17</td>
<td>Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 16 and 43-45 added. Coding updated; removed HCPCS codes L8627, L8628, and L8629. Policy statements unchanged.</td>
</tr>
<tr>
<td>10/24/17</td>
<td>Policy moved to new format, no changes to policy statement.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through December 2017; references 35 and 38 updated. Policy statements unchanged; only minor edits made.</td>
</tr>
<tr>
<td>09/01/18</td>
<td>Minor update. Re-added the Consideration of Age information which was inadvertently deleted in a previous update.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review
and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-845-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at:
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-845-5357).

Arabic (Arabic):
يكون هذا الإشعار معلومة هامة. قد يكون هذا الإشعار معلومات مهمة بخصوص طلبك أو العملية التي تريد الحصول عليها من خلال خدمة Premera Blue Cross. تحتاج للحصول على هذه المعلومات والحصول عليها من خلال تلقي نسق الاتصال والمساعدة في ذلك كليلة. يحق لك الحصول على هذه المعلومات والمساعدة بذلك دون تكبد أي نقدة. قد تصل
800-722-1471 (TTY: 800-845-5357)

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-845-5357).

Oromoo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Illoko (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaa mabilin nga adda ket naglaon iti napateg nga impormasion maianggep iti aplikasyonuyo wennu coverage babaen iti Premera Blue Cross. Daytoy ket mabilin dagiti importante a penta iti daytoy a pakdaa. Mabilin nga adda rumbeng nga aramidenyo nga addang sakkay dagiti partikular a naituding nga adda tidaw tapo mapagtalainedyo ti coverage ti salun-atyo wennu tulong kadedgyo gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodyo a pagasasao nga awan ti bayadanoy. Tumawag ti numero nga 800-722-1471 (TTY: 800-845-5357).

Italiano (Italian):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que debo tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).


ไทย (Thai): ประกาศนี้มีข้อมูลสำคัญเกี่ยวกับการสมัครเข้ารับการประกันสุขภาพของคุณผ่าน Premera Blue Cross และความจำเป็นในการให้การช่วยเหลือที่มีสิทธิ์ คุณควรให้ความสำคัญกับสิทธิ์และข้อกำหนดที่ปรากฏในประกาศนี้ที่มีสิทธิ์ คุณมีสิทธิ์ที่จะได้รับข้อมูลและข้อมูลที่มีสิทธิ์ในภาษาของคุณใช้ได้ โทร 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian): Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам буде зобов'язано зробити вибір у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації і допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).