**EFFECTIVE DATE:** 06|07|2011
**POLICY LAST UPDATED:** 11|03|2015

## OVERVIEW
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. This policy documents the coverage guidelines for cochlear implants.

## MEDICAL CRITERIA
Not applicable

## PRIOR AUTHORIZATION
Prior authorization is not required.

## POLICY STATEMENT
**BlueCHiP for Medicare and 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 12 months and older with bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss 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 **not medically necessary**.

Hybrid cochlear implant devices that include a hearing aid integrated into the external sound processor of the cochlear implant, including but not limited to the Nucleus® Hybrid™ L24 Cochlear Implant System, are considered not medically necessary because the available evidence does not demonstrate that hybrid devices improve outcomes compared with standard cochlear implants.

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.

**Note**: Next-generation devices have typically offered a marginal improvement over previous devices. Replacement of the internally implanted components is not routinely performed and **may** be considered medically necessary **only** in the small subset of patients who have an inadequate response to existing components.

**Repair and Replacement:**
For requests for repair or replacement, please see the policy on Durable Medical Equipment (DME).

There are no participating providers who provide batteries for the hearing aid.

## 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 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 surgically implanted and include an internal receiver 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 aural (hearing) 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.

**BlueCHiP for Medicare**

Cochlear implantation may be covered for individuals meeting the selection guidelines (listed in the Background section of the policy) who also have 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 clinical trial, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards. Available clinical trials can be found at the Centers for Disease Control and Prevention (CDC) website: http://clinicaltrials.gov/

Typically, Medicare coverage is provided only for those patients who 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;
- 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;
- 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 FDA-approved labeling.

**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.

The available evidence, summarized in multiple systematic reviews and technology assessments, is sufficient to conclude that cochlear implants improve hearing outcomes for both adults and children. Studies show consistent improvement in speech reception (especially in noise) and in sound localization with bilateral devices. Studies also suggest that earlier implantation may be preferred. Based on these studies, and several systematic reviews that have provided additional evidence in support of unilateral and bilateral cochlear implantation, cochlear implants have been shown to provide benefits sufficient to improve net health outcomes in patients with bilateral hearing loss. Therefore, unilateral and bilateral cochlear implants are considered medically necessary for individuals with bilateral hearing loss in individuals aged 12 months and older.

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. Future controlled studies with appropriate patient selection comparing cochlear implants with alternative treatment options are needed. Therefore, cochlear implantation as a treatment for patients with unilateral hearing loss is considered to be not medically necessary.

Hybrid cochlear implant devices that include a hearing aid integrated into the external sound processor of the cochlear implant are considered not medically necessary because the available evidence does not demonstrate that hybrid devices improve outcomes compared with standard cochlear implants.

## 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.

The following code is covered for BlueCHiP for Medicare and Commercial products under the member's **surgery services** benefit:
**69930**

The following codes are covered for BlueCHiP for Medicare and Commercial products under the member's **speech therapy** benefit:
**92626**
**92627**
**92630**
**92633**

The following codes are covered for BlueCHiP for Medicare and Commercial products under the **diagnostic imaging, lab, and machine tests** benefi:
**92601**
**92602**
**92603**
**92604**

The following codes are covered for Commercial products under **prosthetic devices** benefit:

**L8614**
**L8615**
**L8616**
**L8617**
**L8618**
**L8619**
**L8621**
**L8622**
**L8627**
**L8628**
**L8629**

The following codes are covered for Commercial products under the **durable medical equipment** benefit:
**L8623**
**L8624**

## RELATED POLICIES

Autism Mandate
Durable Medical Equipment
Evaluation for Hearing Impairment/Loss
Hearing Aid Mandate
Speech Therapy

## PUBLISHED

Provider Update, January 2016
Provider Update, December 2013
Provider Update, August 2012
Provider Update, August 2011
Provider Update, September 2010
Provider Update, August 2009
Policy Update, June 2008

## REFERENCES


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