POLICY AND PROCEDURE MANUAL

Policy Title: Cochlear Implant  
Policy Number: A.04

Primary Department: Medical Management  
Affiliated Department(s): N/A

NCQA Standard: N/A  
URAC Standard: N/A

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Special Instructions Alert: N/A

State/Program  
Medicare: ☐SNP ☐MMAI ☐MA ☐PDP ☐SNP ☐MMAI ☐MA ☐PDP ☐SNP ☐MMAI ☐MA ☐PDP
Medicaid: ☐TANF ☐SPD ☐SCHIP ☐TANF ☐SPD ☐SCHIP ☐TANF ☐SPD ☐SCHIP
Commercial: ☐Exchange ☐Exchange ☐Exchange ☐Exchange ☐Exchange ☐Exchange

Definitions:

Cochlear implant  
The cochlear implant is composed of three parts, which include external components and two internal surgically implanted components. Externally, a microphone, speech processor, and transmitter coil with cables are worn. The speech processor converts sound into electrical stimuli. Internal components include an antenna and electrodes. The antenna electromagnetically captures the stimuli transmitted by the speech processor and directs this information to internal electrodes. The electrodes provide direct electrical stimulation to the auditory nerve, bypassing the transducer cells which are absent or nonfunctional. Because the cochlear implant does not magnify sound, none of its components are considered a hearing aid.

Degree of hearing loss  
The degree of hearing loss is defined as:

- Mild: 26 to 40 decibels (dB) hearing loss
- Moderate: 41 to 55 dB hearing loss
- Moderately Severe: 56 to 70 dB hearing loss
- Severe: 71 to 90 dB hearing loss
- Profound: 91 dB or more hearing loss (ASHA, Type, Degree and Configuration of Hearing Loss).

Policy: Cochlear implants (unilateral or bilateral) are a covered benefit for specific indications listed below when preauthorized. A cochlear implant is a device for individuals 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.

The Centers for Medicare and Medicaid Services (2005) has determined that the evidence is adequate to conclude that cochlear implantation is reasonable and necessary for the 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 40% correct or less in the best-aided listening condition on tape recorded tests of open-set sentence cognition.
Audiologic criteria for pediatric patients follow guidelines similar to those for adults. For adults and children able to respond reliably, standard pure-tone and speech audiometry tests are used to screen likely candidates. For children, the speech reception threshold (SRT) and/or pure-tone average (PTA) should equal or exceed 90 dB; for adults, the SRT/PTA should equal or exceed 70 dB. If the patient can detect speech with best-fit hearing aids in place, a speech-recognition test in a sound field of 55 dB hearing level (HL) sound pressure level (SPL) is performed. A number of speech recognition tests are in current use.

Children should be receptive to wearing a hearing aid before cochlear implantation because all current implants require an external processor. A period of hearing aid use to ascertain development of aided communication ability is the critical criterion for determining candidacy of young children.

For adults and children, 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. Unilateral cochlear implantation and associated mapping/calibration are covered and reimbursable under Medicaid and Children's Special Health Care Services (CSHCS) programs with prior authorization for eligible beneficiaries using Food and Drug Administration (FDA) approved implants.

There is evidence of the effectiveness of binaural cochlear implants in improving audition over uniaural (monaural) cochlear implants. A recent technology appraisal prepared by the National Institute for Health and Clinical Excellence (NICE, 2007) recommended simultaneous bilateral cochlear implantation as an option for 3 groups of persons with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids: prelingual children, persons who are blind, and persons at risk for cochlear ossification.

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. Bilateral cochlear implantation and associated mapping/calibration are covered and reimbursable under Medicaid and CSHCS programs with prior authorization only for beneficiaries ages 12 months through 20 years using FDA-approved implants. Hearing aids, hearing aid services, and accessories may be covered after the beneficiary has received a unilateral cochlear implant with prior authorization. Cochlear implants are internal prosthetics. Cochlear implants are not hearing aids. The Cochlear implant must be used in accordance with FDA-approved labeling.

Procedure: When used according to U.S. FDA labeled indications, bilateral or unilateral cochlear implantation is proven and medically necessary for patients who meet all of the following criteria:

General Criteria for Adults and Children:
Unilateral or bilateral cochlear implantation of an FDA approved cochlear implant device may be considered medically necessary in all beneficiaries, regardless of age, who meet these criteria:
  a. Submission of a letter from the treating otolaryngologist establishing medical necessity and recommending implantation.
  b. Diagnosis of bilateral severe to profound pre- or post-lingual sensorineural hearing loss defined as a hearing threshold of pure-tone average of 70dB (decibels) hearing loss or greater; and with limited benefit from appropriate hearing aids for beneficiaries ages 24 months and older. Beneficiaries 12 through 23 months old must experience a profound hearing loss, which is a hearing threshold of pure tone average of 90 dB hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz.
**In adults,** limited benefit from hearing aids is defined as scores 40% correct or less in the ear to be implanted on tape recorded sets of open-set sentence recognition. **In young children,** limited benefit is defined as failure to develop basic age appropriate auditory skills, and in older children, < 40% correct on open-set tests.

c. Limited or no benefit from appropriately-fitted hearing aids with consistent use over a three to six month period. The trial period may be waived or shortened with appropriately submitted documentation of medical necessity.

d. Evidence of a functioning auditory nerve

e. Freedom from middle ear infection or any other active disease

f. An accessible cochlear lumen structurally suited to implantation. No evidence of lesions in the auditory nerve and acoustic areas of the central nervous system. This may be demonstrated by CT scan or other appropriate radiological evaluation.

g. No contraindication to anesthesia/surgery (medically, surgically, and psychologically)

h. 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.

i. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation

j. Psychological development, motivation of the candidate, and/or commitment of the beneficiary and family/caregiver(s) to undergo a program of prosthetic fitting, training, and long-term rehabilitation

k. Realistic expectations of candidate and/or family/caregiver(s) for post-implant educational/vocational rehabilitation, as appropriate

l. Reasonable anticipation by treating providers that the cochlear implant(s) will confer awareness of speech at conversational levels

m. Documented intervention and/or school placement, as appropriate, supporting a concentrated Oral/Auditory or Total Communication approach to learning/communication. The educational plan should include professionals with specialization in education of the deaf and hard of hearing.

**Contraindications for cochlear implantation include:**

a. Deafness due to lesions of the acoustic nerve or central auditory pathways or brainstem

b. Radiographic evidence of absent cochlear development.

c. Active or chronic infections of the external or middle ear and mastoid cavity, or tympanic membrane perforation,

d. Cochlear ossification that prevents electrode insertion, or

e. Inability or lack of willingness to participate in post-implantation aural rehabilitation.

A multi-channel model should be used, if possible. An upgrade from single to multi-channel electrodes or the newer processor is considered not medically necessary. If an existing implant is functioning, an upgrade or replacement of electrodes to another processor should **not** be made.

**Special Instructions:** N/A

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Approved by: ____________________________ Date: 06/26/2015  
Corporate Chief Operating Officer

Reviewed and approved by Policy and Procedure Committee: Date: 04/10/2015

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References: