

Policy: MP053

Section: Medical Benefit Policy

Subject: Cochlear Implant

I. Policy: Cochlear Implant

II. Purpose/Objective:

To provide a policy of coverage regarding Cochlear Implant

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

Compressed array: electrodes placed along a shorter linear implant of approx. 12-13 mm for use in cases of cochlear ossification or malformation which makes complete insertion of a standard array impossible.

Limited benefit from amplification is defined as: Test scores of $\leq 30\%$ correct in the best-aided listening condition, in tests of open set sentence recognition.

Profound hearing loss – hearing threshold of 90 decibels or greater

Severe hearing loss – bilateral hearing threshold of 70-90 decibels (db)

Split array: electrodes are placed along two separate linear implants ranging from approx. 4-9 mm for use in cases of profound cochlear ossification.

Standard array: electrodes are placed along a linear implant of approx. 26 mm. Unless otherwise noted, cochlear implants use a standard array.

DESCRIPTION:

The cochlear implant is a single or multiple channel device intended to restore a level of auditory sensation to individuals with severe to profound sensorineural hearing loss by means of electrical stimulation of the auditory nerve. The components common to most models include: a microphone, an external signal processor, an internal receiver, and an electrode array implanted in the cochlea. Sounds picked up by the microphone are carried to the external signal processor that transforms sound into electrical signals. These signals are transmitted to the internal receiver implanted in the temporal bone, which activates the wire implanted in the cochlea.

INDICATIONS:

Single or multiple channel unilateral or bilateral cochlear implants will be considered medically necessary when **ALL** of the following criteria are met:

- The member must be at least 12 months of age with bilateral, moderate-to-profound sensorineural deafness (70 decibels or greater).
- The member must be unable to benefit from a hearing aid (open sentence recognition score of 40% or less under optimal aided circumstance)
- The device must be an FDA approved cochlear implant.

In addition, certain members in the Medicare Business Segment may be eligible for cochlear implants as listed below:

- Members with hearing test scores of greater than 40% to less than or equal to 60% when the device and services are provided as part of a prospective, controlled comparative trial approved by CMS

Hybrid cochlear implant will be considered medically necessary when **ALL** of the following criteria are met:

- The member is 18 years of age and has a diagnosis of bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; and
- The member obtains limited benefit from appropriately fit bilateral hearing aids; and
- The following hearing thresholds are met in the ear selected for implantation:
 - Low-frequency (125 -500hz) hearing thresholds no poorer than 60 dB hearing level
 - Severe to profound mid- to high-frequency (2000 - 4000 Hz) hearing loss ≥ 75 dB hearing level
 - Aided consonant-nucleus-consonant word recognition score from 10% to 60% in the preoperative aided condition
- The following hearing thresholds are met in the contralateral ear:
 - Moderately severe to profound mid-to-high frequency (2000 – 4000Hz) hearing loss greater than or equal to 60 dB hearing level; and
 - Aided consonant-nucleus-consonant word recognition score equal to or better than that of the ear selected for implantation but not more than 80 percent correct
- There are no contraindications including but not limited to **ANY** of the following:
 - Chronic or active infection of the external or middle ear or mastoid cavity in the ear selected for implantation; or
 - Tympanic membrane perforation; or
 - Evidence of agenesis of the cochlea in the ear selected for implantation; or
 - Etiology of deafness is due to lesions of the brainstem, or
 - Etiology of deafness is due to lesions of the eighth cranial nerve or central auditory pathway

***NOTE: Age-appropriate vaccination against pneumococcal disease, H influenza type B, and meningococcal disease is required prior to implantation.**

The Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommends vaccination against pneumococcal disease for persons at increased risk for pneumococcal meningitis. Because data suggest a higher risk for pneumococcal meningitis in cochlear implant recipients, the CDC recommends that these individuals should receive the age-appropriate vaccination using the 13 7-valent pneumococcal conjugate (Prevnar®) or 23-valent pneumococcal polysaccharide (Pneumovax® and Pne-Immune®) vaccine according to ACIP schedules for persons at high risk.

The FDA offered an additional recommendation to decrease the risk of meningitis in cochlear implant recipients. The document is available for review at: <http://www.fda.gov/cdrh/safety/101007-cochlear.html>

EXCLUSIONS:

Use of cochlear implant is contraindicated in the following:

- Deafness due to lesions of the acoustic nerve or central auditory pathway
- Otitis media or other unresolved ear problems
- Radiographic evidence of absent cochlear development

The Plan does not cover the replacement of external components with upgraded components when done solely to improve appearance or to treat psychological symptomatology or complaints because it is considered **not medically necessary**.

LIMITATIONS:

Repair and/or replacement of processor will be covered under the applicable benefit document if implant met FDA guidelines, and to the extent not covered by the warranty.

Replacement batteries and cables are not covered for most contracts.

Replacement batteries and cables are covered with prior authorization only for GHP Family line of business.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Cochlear Implant

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

- 69930 Cochlear device implantation, with or without mastoidectomy
- 92601 Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
- 92602 subsequent programming
- 92603 Diagnostic analysis of cochlear implant, patient age 7 years or older; with programming
- 92604 subsequent programming
- L8614 Cochlear device includes all internal and external components
- L8615 Headset/headpiece for Use with cochlear implant device, replacement
- L8616 Microphone for Use with cochlear implant device, replacement
- L8617 Transmitting coil for Use with cochlear implant device, replacement
- L8618 Transmitter cable for Use with cochlear implant device, replacement
- L8619 Cochlear implant external speech processor, replacement
- L8621 Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
- L8622 Alkaline battery for Use with cochlear implant device, any size, replacement, each
- L8623 Lithium ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
- L8624 Lithium ion battery for use with cochlear implant device speech processor, ear level, replacement, each
- L8625 External recharging system for battery for use with cochlear implant or auditory osseointegrated device,

replacement only, each
L8627 Cochlear implant, external speech processor component, replacement
L8628 Cochlear implant, external controller component, replacement
L8629 Transmitting coil and cable integrated, for use with cochlear implant device
L8694 Auditory osseointegrated device, transducer/actuator, replacement only, each

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LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/95

Revised: 11/95, 3/97, 8/98, 1/02, 1/03 Coding; 8/03 add vaccine requirement and limitation; 9/04 definitions, criteria clarification; 7/05 (CMS expanded criteria);8/06;8/07 (age Requirement); 8/08 (FDA recommendation); 12/10 (coding, removal of attachment), 12/11(added unilateral/bilateral to indications), 4/13 (clarification for battery coverage); 7/16, 8/18 (Revised Indications)

Reviewed: 11/09 (format), 12/12, 12/13, 12/14, 8/15, 7/17