Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP053

Section: Medical Benefit Policy

Subject: Cochlear Implant and Auditory Brainstem Implant

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Cochlear Implant and Auditory Brainstem Implant

II. Purpose/Objective:

To provide a policy of coverage regarding Cochlear Implant and Auditory Brainstem 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

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.
- 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 ≤ 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 9 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

Unilateral or Asymmetric Sensorineural Hearing Loss
Cochlear implants for unilateral sensorineural hearing loss are considered medically necessary when all of the following medical criteria are met:
- The member is 5 years of age or older; and
- The member has realized no or only marginal speech perception benefit from a one-month trial of hearing aid (CROS or other relevant nonimplantable device) in ear to be implanted; and
    - Single-sided deafness (SSD) with profound sensorineural hearing loss in in one ear and normal or mild to moderate sensorineural hearing loss in the other ear with a difference of at least 15 dB in pure tone averages (PTA) between ears.

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

Auditory Brainstem Implant

Unilateral auditory brainstem implant will be considered medically necessary when **ALL** of the following criteria are met:

- The member is 12 years of age or older; **and either**
    - A diagnosis of neurofibromatosis type 2 has been established; **or**
    - Deafness is the result of bilateral surgical resection of tumors (acoustic neuroma or vestibular schwannoma) of the auditory nerve

***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.**

Frequency modulated (FM) systems are used as an extension or accessory of cochlear implants and are not integral to the function of the cochlear implant itself. These devices are considered **not medically necessary**.

Bilateral use of an auditory brainstem implant is considered to be **Unproven** and therefore **NOT COVERED.** There is currently insufficient evidence in the per-reviewed published literature to support the use of bilateral auditory brainstem implants at this time.

The use of an auditory brainstem implant for all other conditions not specifically listed in this policy is considered to be **experimental, investigational or unproven** and therefore **NOT COVERED**.

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.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

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 and Auditory Brainstem 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

61889 Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)
61891 Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)
61892 Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed
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
92640 Diagnostic analysis with programming of auditory brainstem implant, per hour
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
S2235 Implantation of auditory brain stem implant

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 supercede 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); 8/19 (add FM system exclusion); 8/20 (lower age limitation to 9 mo); 8/21(added unilateral hearing loss indication); 8/23 (revise title, add Auditory Brainstem Implant criteria)

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