Service: Cochlear Implants and Auditory Brainstem Implants

Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

Service: Cochlear Implants and Auditory Brainstem Implants

Prior Authorization: Required.

Policy: SWHP follows Medicare rules in considering cochlear implants and auditory brainstem implants as prosthetics. Medicare considers as prosthetics “cochlear implants and auditory brainstem implants, i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.”

SWHP may consider a unilateral cochlear implant as medically necessary for a member with bilateral sensori-neural hearing loss when there is reasonable expectation that a significant benefit will be achieved from the device and when the following age-specific criteria are met:

- Cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensori-neural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. 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. Medicare coverage is provided only for those patients who meet all of the following selection guidelines.
  - Diagnosis of bilateral moderate-to-profound sensori-neural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
  - 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 Food and Drug Administration (FDA)-approved labeling.

- Cochlear implantation may be covered for individuals meeting the selection guidelines above and with 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 as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or

- A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

In addition, the following requirements must be met:

- The member must have had an assessment by an audiologist and from an otolaryngologist experienced in this procedure indicating the likelihood of success with this device; AND

- Cognitive ability to use auditory clues and a willingness to undergo an extended program of post-operative aural rehabilitation program; AND

- There are no medical contraindications to cochlear implantation (e.g., cochlear aplasia, active middle ear infection); AND

- Use meets Food and Drug Administration (FDA)-approved labeling requirements

SWHP may covers a second cochlear implant in the contralateral (opposite) ear as medically necessary in an individual with an existing unilateral cochlear implant when the hearing aid in the contralateral ear produces limited or no benefit.

SWHP may consider the replacement of an existing cochlear implant as medically necessary when EITHER of the following criteria is met:

- currently used component is no longer functional and cannot be repaired
- currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living

SWHP does not consider the upgrading of a cochlear implant system or component (e.g., upgrading processor from body-worn to behind-the-ear, upgrading from single- to multi-channel electrodes) of an existing, properly functioning cochlear implant as medically necessary.

SWHP considers a cochlear implant for the treatment of tinnitus in an individual who does not also have profound or severe sensori-neural deafness/hearing loss warranting the need for cochlear implantation as experimental, investigational or unproven.

OVERVIEW: The cochlear implant is an electronic prosthesis, 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 device stimulates cells of the auditory spiral ganglion to provide a sense of sound to persons with hearing impairment. The patient selection criteria for cochlear implants were adapted from the FDA approved indications for cochlear implants.

An Auditory Brainstem Implant (ABI) is a modified cochlear implant intended to be used to stimulate the cochlear nucleus in the brainstem of patients who have had their eighth nerves severed during surgery for removal of bilateral neurofibromata, as in patients with Neurofibromatosis 2 (NF2).
MANDATES: There are no mandated benefits or regulatory requirements for SWHP to provide coverage for these services.

CMS:

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

| CPT Codes: | 61875, 92640, 69930, 92506, 92507-92508, 92601-92602, 92603-92604, 92626-92627, 92630-92633, 69714-69715, 69717-69718, 90669, 90732 |
| ICD9 Codes: | 237.70 - 237.72 – Neurofibromatosis, 388.5 - Disorders of acoustic nerve 389.11 - Sensory hearing loss, bilateral 389.12 - Neural hearing loss, bilateral 389.18 - Sensorineural hearing loss, bilateral 389.22 - Mixed hearing loss, bilateral 389.25 - Mixed hearing loss, bilateral 381.00- 382.9 - Otitis media 744.05 Anomalies of inner ear [cochlear aplasia] |
| ICD10 Codes: | Q85.00, Q85.02 - Neurofibromatosis H93.3X3 - D/O bilateral acoustic nerves H90.5 - Sensory/Neural hearing loss H90.3 - Sensorineural hearing loss, bilateral H90.6 - Mixed hearing loss, bilateral H80.23 - Cochlear otosclerosis, bilateral Q16.5 - Congenital malformation of inner ear |
| HCPCS Codes: | S2235 - Implantation of auditory brain stem implant 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, 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 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, replacement |
| Other Codes | L8699 - Prosthetic implant, not otherwise specified [auditory brainstem implant] G0009 - Administration of pneumococcal vaccine S0195 - Pneumococcal conjugate vaccine, polyvalent, intramuscular, for children from five to nine years of age who have not previously received the vaccine V5273 - Assistive listening device, for use with cochlear implant |
INFORMATION:
Typical life of related cochlear implant parts:

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<th>Part</th>
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<tbody>
<tr>
<td>Battery charger kit</td>
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<tr>
<td>Cochlear auxiliary cable adapter</td>
<td>1 per 3 years</td>
</tr>
<tr>
<td>Cochlear belt clip</td>
<td>1 per 3 years</td>
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<tr>
<td>Cochlear harness extension adapter</td>
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<tr>
<td>Cochlear signal checker</td>
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<td>Disposable batteries for ear-level processors</td>
<td>72 per 6 months</td>
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<td>Headset (3-piece component)</td>
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<tr>
<td>Headset cochlear coil (individual component)</td>
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<tr>
<td>Headset cochlear magnet (individual component)</td>
<td>1 per year</td>
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<tr>
<td>Headset microphone (individual component)</td>
<td>1 per year</td>
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<tr>
<td>Headset cable or cord</td>
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</tr>
<tr>
<td>Microphone cover</td>
<td>1 per year</td>
</tr>
<tr>
<td>Pouch</td>
<td>1 per year</td>
</tr>
<tr>
<td>Rechargeable batteries (per set of 2)</td>
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<tr>
<td>Transmitter cable or cord</td>
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POLICY HISTORY:

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REFERENCES: The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.


Cochlear Implants and Auditory Brainstem Implants
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### MEDICAL COVERAGE POLICY

**SERVICE:** Cochlear Implants and Auditory Brainstem Implants

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MEDICAL COVERAGE POLICY

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Last Review: 03/05/2015
Next Review Date: 03/05/2016

2007;117:1412-1418.


