Subject: Cochlear Implants

Overview: Bilateral or unilateral cochlear implants are used in patients with hearing impairment caused by severe loss of cochlear hair cells. The goal of cochlear implantation is to restore hearing by converting received sounds into electrical impulses that stimulate the auditory nerve, thereby performing the function normally performed by cochlear hair cells.

Policy and Coverage Criteria:

NOTE: Prior Authorization is not required

HPHC covers unilateral and bilateral Cochlear Implants that the PCP or attending provider determines are medically necessary for members with prelingual or postlingual hearing loss.

Exclusions: N/A

Supporting Information:

1. Technology Assessment: Hearing depends on a series of mechanical and neural processes. Sound waves captured by the outer ear produce vibrations, which the middle ear amplifies and transmits to the cochlea of the inner ear, causing sensitive cochlear hair cells to vibrate. Cochlear hair cell vibration stimulates the auditory nerve, thereby converting sound vibrations into nerve impulses, which travel along the auditory nerve pathway to the auditory cortex of the brain, where they are interpreted as sound. While hearing loss may be related to abnormalities in the sound conduction system of the outer and middle ear, most hearing deficits in newborns and the elderly result from sensorineural abnormalities, particularly cochlear hair cell loss, which limits cochlear ability to convert sound vibrations into nerve impulses. Cochlear hair cell loss may be caused by a variety of disorders and mechanisms, and cannot be remedied by any known means. This type of hearing loss has typically been treated with rehabilitation strategies involving hearing aids, vibrotactile aids, lip reading, and/or sign language, as well as speech and language therapy. Of these techniques, all assist communication ability, but only hearing aids can improve hearing. This is achieved by amplifying incoming sounds, which amplifies vibrations received by remaining cochlear hair cells. However, amplification does not replace the function of lost cochlear hair cells and often cannot provide adequate hearing in the case of severe cochlear hair cell loss. If neural elements that transmit information from the cochlea to the auditory cortex remain intact and functional, it is possible to stimulate auditory nerve impulses with a prosthetic cochlear implantation (CI) device. With CI, externally worn components, including a microphone, a speech processor, and a transmitter, capture sounds from the environment, transform sounds into electronic impulses, and send electronic impulses to an implanted receiver/stimulator, which conveys electronic impulses to the auditory nerve via electrodes implanted in the cochlea. By electrically stimulating the auditory nerve, CI performs the function normally performed by cochlear hair cells, thereby restoring some degree of hearing.

2. Literature Review:

Unilateral Cochlear Implantation in Adults (18 years and older) and Children (1 to 18 years): There are a number of well designed case series and retrospective reviews reporting up to ten-years of data that demonstrate improved outcomes in adults and children with sensorineural hearing loss following unilateral

**Bilateral Cochlear Implantation in Adults or Children:**
Bilateral implantation has been proposed for use by patients eligible for unilateral implantation to enhance hearing capability in areas not achieved by unilateral cochlear implants. Some studies suggest the use of bilateral implants can improve speech perception in quiet and noisy environments, as well as the listener's ability to discriminate from which side the sound is coming, identify source position, and differentiate different talkers. Studies also suggest patients may also benefit from the summation effect that arises from hearing input from both ears (Broomfield, et al. 2014; Vincenti, et al. 2014; Gaylor, et al. 2013; Strom-Roum, et al. 2012; Sparreboom, et al. 2012; Brito, et al. 2012; Sparreboom, et al. 2010; Lovett, et al. 2010; Bond et al., 2009; Brown and Blakany, 2007; Murphy and O'Donoghue, 2007; Neuman, et al., 2007; Scherf, et al., 2007; Connell and Blakany, 2006; Litovsky, et al., 2006; Das and Buchman, 2005; Tyler et al., 2003).

**Cochlear Implants in Children < 12 months:**
Currently, there are no cochlear implant systems FDA approved for children less than 12 months of age. There are a number of studies with small patient populations and short-term follow-up that suggest preliminary results are encouraging for cochlear implantation in this age group (Lesinski-Schiiedat, et al., 2004; Colletti, et al., 2005; Dettman, et al., 2007; Valencia, et al., 2008; Migirov, et al., 2008).

NOTE: Children with cochlear implants are at increased risk for meningitis, particularly pneumococcal meningitis.

3. Professional/Governmental Agencies:

**NICE:** Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids. Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids:

- children
- adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.


**CMS:** Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for 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 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 sensorineural 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.

Effective for services performed on or after April 4, 2005, 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.


**Codes:**

**HCPCS codes:**

- L8614 - Cochlear device/system, 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
- L8628 - Cochlear implant, external controller component, replacement
- L8629 - Transmitting coil and cable, integrated for use with cochlear implant device replacement

**CPT Code:**

- 69930 – Cochlear device implantation, with or without mastoidectomy
- 92601 – Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
- 92602 – Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
- 92603 – Diagnostic analysis of cochlear implant, age 7 years or older; with programming
- 92604 – Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

**References:**


Summary of Changes

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/17</td>
<td>Removed Benchmarks</td>
</tr>
</tbody>
</table>