Cochlear and Auditory Brainstem Implants
Policy Number: PG0281
Last Review: 10/22/2021

GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE
- Professional
- Facility

DESCRIPTION
The basic structure of a cochlear implant includes both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are implanted surgically and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear.

- The Cochlear implant’s external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and
- The implantable components are considered under the medical-surgical benefit.

Traditional Cochlear Implant
Children and adults with a moderate to profound hearing loss who cannot be helped with hearing aids may be helped with cochlear implants. This type of hearing loss is sensorineural, which means there is damage to the tiny hair cells in the part of the inner ear called the cochlea. Sound cannot reach the auditory nerve because of this damage. With a cochlear implant, the damaged hair cells are bypassed, and the auditory nerve is stimulated directly. A cochlear implant device is an electronic instrument part that 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 patient awareness and identification of sounds, and to facilitate communication for persons who are hearing impaired and perceive limited benefit from appropriately fitted hearing aids.

Hybrid Cochlear Implant
A hybrid cochlear device uses two different technologies at the same time to provide low-frequency and high-frequency hearing. The low-frequency technology (acoustic) is proposed to preserve any natural residual hearing while the traditional cochlear implant provides high frequency hearing (electrical). Hybrid devices combine electrical hearing from direct stimulation of the basal cochlea with acoustical hearing from surviving apical hair cells. To allow the combined stimulation, a shorter and softer electrode array is inserted into the basal turn of the cochlea. The basal cochlea is then stimulated electrically via the implant. The apical cochlea functions via native physiology amplified as needed by an externally worn hearing aid. The external hearing aid and the implanted device are both attached to the external processor. An example of a hybrid cochlear implant includes, but may not be limited to, the Nucleus® Hybrid™ L24 Cochlear Implant System.
**Auditory Brainstem Implant**
An auditory brainstem implant (ABI) is a device designed to restore some hearing in individuals with neurofibromatosis type 2 rendered deaf by bilateral surgical removal of neurofibromas involving the auditory nerve. The ABI is a modification of the cochlear implant, in which the electrode array is placed directly into the brain. The device consists of an externally worn speech processor that provides auditory information to an electrical signal that is transferred to a receiver/stimulator implanted in the temporal bone. The receiver stimulator is, in turn, attached to an electrode array implanted on the surface of the cochlear nerve in the brainstem, thus bypassing the inner ear and auditory nerve. The electrode stimulates multiple sites on the cochlear nucleus, which is then processed normally by the brain.

**POLICY**

**HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage**

Traditional & Hybrid cochlear implants (69930, L8614-L8624, L8627-L8629) and auditory brainstem implants (S2235) require prior authorization for all product lines.

An external recharging system for battery (L8625) requires prior authorization for HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan.

An external recharging system for battery (L8625) is non-covered for Advantage.

An assistive listening device for use with cochlear implant (V5273) is non-covered for all product lines.

Non-participating providers are required to obtain prior authorization for all services BEFORE any services are rendered.

**COVERAGE CRITERIA**

**HMO, PPO, Individual Marketplace, Advantage**

The following cochlear implantation coverage criteria are proven and medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions. The current criteria used for assessing candidacy may vary slightly. The variation in criteria is related to each manufacturer's original submission to the FDA for device approval.

**Traditional Cochlear Implant**

Paramount may cover, with prior authorization, cochlear implantation, when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, approved hybrid cochlear implant device, (e.g., Nucleus® Hybrid™ L24 Cochlear Implant System), in members who meet ALL of these criteria:

### Adults
- Individuals 18 years of age or older
- Moderate to profound sensorineural hearing loss in both ears
- Limited or no benefit from amplification defined by preoperative test scores of ≤ 50% sentence recognition in the ear to be implanted and ≤60% in the opposite ear or binaurally

### Children (2-17 Years)
- Severe to profound sensorineural hearing loss in both ears
- Limited benefit from binaural amplification
- Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT) scores ≤ 30%

### Children (9-24 Months)
- Profound sensorineural hearing loss in both ears
- Limited benefit from binaural amplification
No contraindications to surgery (e.g., deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brainstem; active or chronic infections of the external or middle ear; mastoid cavity or tympanic membrane perforation, cochlear ossification, the absence of cochlear development as demonstrated on computed tomography scan)

Hearing loss is rated on a scale based on the threshold of hearing.

<table>
<thead>
<tr>
<th>Degree of Hearing Loss</th>
<th>Range (dbHL = Decibels Hearing Level)</th>
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</thead>
<tbody>
<tr>
<td>Normal Hearing</td>
<td>-10 to 15 dBHL</td>
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<tr>
<td>Slight Loss</td>
<td>16 to 25 dBHL</td>
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<tr>
<td>Mild Loss</td>
<td>26 to 40 dBHL</td>
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<tr>
<td>Moderate Loss</td>
<td>41 to 55 dBHL</td>
</tr>
<tr>
<td>Moderately Severe Loss</td>
<td>56 to 70 dBHL</td>
</tr>
<tr>
<td>Severe Loss</td>
<td>71 to 90 dBHL</td>
</tr>
<tr>
<td>Profound Loss</td>
<td>91 dBHL or more</td>
</tr>
</tbody>
</table>

**Hybrid Cochlear Implant**

Paramount may cover, with prior authorization, cochlear implantation, when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions, approved hybrid cochlear implant device, (e.g., Nucleus® Hybrid™ L24 Cochlear Implant System), in members who meet ALL of these criteria:

The Nucleus Hybrid System is indicated for unilateral use in patients aged 18 years and older who have residual low frequency hearing sensitivity and severe to profound high-frequency sensorineural hearing loss, and who obtain limited benefit from appropriately fitted bilateral hearing aids.

- Typical preoperative hearing of candidates ranges from normal to moderate hearing loss in the low frequencies (thresholds better than 60 dB HL up to and including 500 Hz) and
- Severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL) in the ear to be implanted.
- For individuals with post-surgical low frequency hearing, the sound processor combines acoustic amplification for the low frequencies with electric stimulation for the high frequencies.
- The CNC word recognition score criteria are between 10% and 60%, inclusively, in the ear to be implanted in the preoperative aided condition.
- The contralateral ear’s CNC score criteria are equal to or better than that of the ear to be implanted, but not better than 80% correct.
- Moderately severe to profound mid- to high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 60 dB HL) in the contralateral ear.

**Cochlear implantation Eligibility Criteria for Single Sided Deafness (SSD) and Asymmetric Hearing Loss (AHL):**

- Indication of severe-to-profound sensorineural hearing loss in the affected ear with hearing thresholds that fall within the shaded area in the chart below
- Indication of normal hearing or mild-to-moderate hearing loss in the contralateral ear with hearing thresholds that fall within the shaded area in the chart below
- Functional auditory nerve
- Prior use of optimally fitted hearing aid, if appropriate
- Little or no benefit from acoustic amplification
- Adequate motivation and expectations

Before implantation, individuals with SSD or AHL must have at least one (1) month experience with a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant non-implantable device and not obtain any benefit.

At the present time, FDA-approved cochlear implant devices are manufactured by Cochlear™ (previously Cochlear Corp.), Advanced Bionics Corp., and MED-EL Corp. Since the first cochlear implant device was approved in the 1980s, these devices have undergone progressive technological refinement, and approved indications for their use gradually have expanded and have become more specific. Specific criteria vary with the device.
Elite/ProMedica Medicare Plan – NCD 50.3
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.

HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage
Traditional & Hybrid Cochlear Implants
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 may be considered medically necessary in children less than 12 months of age who are deafened by bacterial meningitis and demonstrate onset of cochlear ossification based on an imaging study.

Unilateral cochlear implantation may be considered medically necessary in children less than one year of age who are diagnosed with profound deafness and meet the following criteria:

- Diagnosis is confirmed by objective audiology measures such as an auditory brainstem response (ABR) or an auditory steady-state response (ASSR), AND
- Documentation that the child demonstrates lack of significant threshold improvement in the frequencies important for hearing spoken language when using appropriately fitted hearing aids, in conjunction with aural habilitation, for a minimum of three months. NOTE 1: The hearing aids the child uses during the hearing aid trial must be appropriate for optimal amplification of the child’s degree of profound hearing loss.

In adults, limited benefit from hearing aids is defined as scores of 50% correct or less in the ear to be implanted on tape-recorded sets of open-set sentence recognition. In children, limited benefit is defined as failure to develop basic auditory skills, and in older children, 30% or less correct on open-set tests.

The member must be able to participate in a post-implant rehabilitation program in order to achieve benefit from the implant. 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.

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.
Replacement of cochlear implant components not otherwise covered under a manufacturer's warranty:

There are very few mechanical problems associated with cochlear implants, and replacement of existing components due to device failure occurs infrequently. However, there have been many revisions and upgrades to the various components leading to improvements in design and speech perception. Replacement of an existing, functioning cochlear implant component is covered only when a physician certifies that:

1. The existing component is ineffective to the point of interfering with the activities of daily living, or
2. When there is a change in the patient's medical condition necessitating a different type of component and improvement is expected with a replacement unit, or
3. The existing component has reached its reasonable useful life. The reasonable useful life of a sound processor is not less than 5 years.

Replacement or upgrades of existing, functioning cochlear implants or cochlear implant components for any reason before the component has reached its reasonable useful life are not covered. For example, upgrading to next generation, smaller profile external components, or switching from a body worn sound processor to a behind-the-ear model is considered a convenience.

Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear model (BTE), are considered not medically necessary.

Separate assessment will be performed for the medical necessity of recommended accessories and upgrades for a cochlear implant. The patient's current condition, capability with his/her current cochlear implant, and the capability of the upgrade or accessory will be considered in determining whether the upgrade or accessory offers clinically significant benefits to the patient.

Supplies or accessories that are not necessary for the functionality of the cochlear implant device are not covered. The following are examples of items classified as convenience, not all-inclusive:

- Attachment/Connection/Safety Clips
- Audio interface device
- Car adapters
- Cable adapters
- Carrying cases
- Cell phone adaptors
- Ear hook pins
- DaCapo extension kits
- Device protectors
- Drying supplies - Manual/Electrical
- Fine Tuner/Fine tuner batteries
- Fixation bar
- Headset/headpiece (V5273)
- Keychain wallets
- Mini battery packs
- Microphone tester device kit
- Remote battery packs
- Repair kits
- Telephone adapter
- T Mic Microphone
- Upgrades to accommodate personal convenience or deluxe items

Following is an example of items that are considered a major part of the device and should be billed under the specific L code listed in CPT/HCPC.S

- Batteries
- Cables
- Coils
The following items are considered a major part of the device and would be replaced every three years for reasonable use:
- Battery Chargers
- Battery Packs
- Ear Hook
- Microphone cover

NonCoverage/Contraindications to cochlear implantation, because the effectiveness have not been established, may include, not all-inclusive:
- Dysynchrony
- Deafness due to lesions of the eighth cranial (acoustic) nerve
- Auditory neuropathy spectrum disorder
- Single sided deafness or unilateral Sensorineural Hearing Loss Central auditory pathway
- Active or chronic infections of the external or middle ear
- Mastoid cavity tympanic membrane perforation
- Cochlear ossification may prevent electrode insertion
- Absence of cochlear development as demonstrated on computed tomography scans remains an absolute contraindication

HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage

Auditory Brainstem Implant
Paramount may cover with prior authorization an auditory brainstem implant when ALL of the following criteria are met:
- Loss of both auditory nerves due to disease (e.g., diagnosis of neurofibromatosis type 2 or von Recklinghausen's)
- Age 12 years or older
- Individual is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the individual will become completely deaf as a result of the surgery

Auditory brainstem implant for the treatment of cochlear nerve deficiency, congenital deafness and tinnitus is considered experimental and investigational because its effectiveness for these indications has not been established.

Upgrade to or replacement of an existing external sound processor, remote assistant or both components is considered medically necessary for an individual whose response to existing components is inadequate/malfunctions to the point of interfering with the activities of daily living or when components are no longer functional.

CODING/BILLING INFORMATION
The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only.
Codes that are covered may have selection criteria that must be met.
Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODES</th>
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<tr>
<td>69930  Cochlear device implantation, with or without mastoidectomy</td>
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<tr>
<td>92601  Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming</td>
</tr>
</tbody>
</table>
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
92640 Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS CODES

- L8614 Cochlear device/system
- 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 or auditory osseointegrated 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 or auditory osseointegrated device speech processor, ear level, replacement, each
- L8625 External recharging system for battery 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, replacement
- L8699 Prosthetic implant, not otherwise specified
- S2235 Implantation of auditory brain stem implant
- V5273 Assistive listening device, for use with cochlear implant

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/services/providers/medical-policies/.

REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 09/01/2009

<table>
<thead>
<tr>
<th>Date</th>
<th>Explanation &amp; Changes</th>
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<tbody>
<tr>
<td>04/01/11</td>
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</tbody>
</table>
| 08/22/14   | • Changed title from Cochlear Implant Prostheses and Services to Cochlear and Auditory Brainstem Implants  
|            | • ABI may now be covered with prior authorization for all members                     |
|            | • Removed codes 61875 & L7368                                                         |
|            | • Added code 92640                                                                   |
|            | • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG). |
| 08/20/15   | • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG). |
| 08/26/16   | • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG). |
| 09/22/17   | • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG). |
| 07/26/18   | • Hybrid cochlear implants are now covered with prior authorization for all product lines |

PG0281 – 10/22/2021
<table>
<thead>
<tr>
<th>Date</th>
<th>Actions</th>
</tr>
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<tbody>
<tr>
<td>12/18/2020</td>
<td>- Medical policy placed on the new Paramount Medical Policy Format</td>
</tr>
<tr>
<td>10/22/2021</td>
<td>- Policy reviewed and updated to reflect most current clinical evidence</td>
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<tr>
<td></td>
<td>- Subspecialist review completed</td>
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<tr>
<td></td>
<td>- Updated Cochlear Implant coverage criteria, indicating Paramount allowed</td>
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<tr>
<td></td>
<td>coverage to follow the U.S. Food and Drug Administration (FDA) labeled</td>
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<tr>
<td></td>
<td>indications, contraindications, warnings and precautions, for each</td>
</tr>
<tr>
<td></td>
<td>individual cochlear implant.</td>
</tr>
</tbody>
</table>

**REFERENCES/RESOURCES**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid


Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets


Industry Standard Review

Hayes, Inc.

Industry Standard Review