Cochlear Implantation, Replacement, and Upgrades

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured’s benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Cochlear implants are not hearing aids. While hearing aids function by amplifying sound, cochlear implants replace the functions of an absent or nonfunctioning cochlea. “A cochlear implant device is an electronic instrument, 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.” (National Coverage Determination 50.3)

Hybrid cochlear implant/hearing aid systems are devices that include a hearing aid integrated into the external sound processor of the cochlear implant.
MEDICARE ADVANTAGE POLICY CRITERIA

Notes:

- This policy does not apply to surgically anchored bone conduction hearing aids or externally worn air conduction hearing aids. See Cross References for more applicable Medicare Advantage medical policy.
- Repeat hearing tests or trials of hearing aids are not necessary for patients who have previously met initial criteria for placement of a cochlear implant, as it is unlikely that natural hearing or the benefit from hearing aids will improve significantly over time.

<table>
<thead>
<tr>
<th>Procedure(s):</th>
<th>CMS Coverage Manuals and National Coverage Determinations (NCDs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial placement</strong> <em>(unilateral or bilateral)</em></td>
<td>NCD for Cochlear Implantation <em>(50.3)</em></td>
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<tr>
<td>For individuals who satisfy the general coverage criteria, but with hearing test scores greater than 40% and less than or equal to 60%, coverage may only be allowed when provided within the context of a Medicare-approved trial for cochlear implants. See the Medicare Coverage with Evidence Development (CED) webpage for Medicare-approved Cochlear Implantation trials and registries.</td>
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<tr>
<td><strong>Replacement or Upgrade</strong></td>
<td>Prosthetic devices “replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.”(1) The Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §100 - Hearing Aids and Auditory Implants states cochlear implants are considered &quot;prosthetic&quot; devices. Therefore, rules for the replacement of prosthetics would apply to cochlear implants.</td>
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Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

See Section 120 in the following link:

§120 - Prosthetic Devices, Subsections A. General and D. Supplies, Repairs, Adjustments, and Replacement

See Section 110.2 in the following link:

§110.2 - Repairs, Maintenance, Replacement, and Delivery, C. Replacement
Procedure(s): CMS Coverage Manuals and National Coverage Determinations (NCDs)

While initial placement criteria would not need to be met for a replacement request because it is not expected the unaided hearing would spontaneously improve during the member's lifetime, the reason for replacement does need to be sufficiently documented (i.e., change in member's condition that warrants a different device or a replacement, the device or a component is no longer functional, the device or a component is irreparably damaged, etc.), as well as documentation the device is no longer serviced by a manufacturer warranty. Requests for the replacement of a cochlear implant will take into consideration the “reasonable useful lifetime” of the equipment or device. Under the aforementioned Medicare manual, this in no case can be less than five (5) years. Finally, requests for the replacement of properly functioning equipment to allow the member an upgrade to newer technology may be denied as not medically necessary if there is not a medical need sufficiently documented to support the provision of a different item.
REQUIRED DOCUMENTATION

The information below must be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Description of treatment (i.e., is the service the initial implant, a replacement, or an upgrade);
- Name and manufacturer of the cochlear implant device being used;
- Clinical documentation must include the following:
  - Diagnosis bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss;
  - Hearing test score results;
  - Medical records documenting the absence of any middle ear infection, that there is an accessible cochlear lumen structurally suited to implantation, and the absence of lesions in the auditory nerve and acoustic areas of the central nervous system;
  - No contraindications to surgery;
- If hearing test scores are greater than 40% but less than or equal to 60%, records must provide documentation the member is enrolled in either an FDA-approved category B investigational device exemption (IDE) clinical trial or another Medicare-approved trial.
- If the request is for a replacement or an upgrade, include the following information:
  - Does the device still function properly?
    - If not, provide information regarding whether or not the device is still under manufacturer warranty;
    - If so, provide medical reasons for the replacement (i.e., documentation of changes in patient condition, etc.).

REGULATORY STATUS

Several cochlear implants are commercially available in the United States. The U.S. Food and Drug Administration (FDA)-labeled indications for currently marketed items are summarized in the table below. Note, since children 17 years and younger are not generally part of the Medicare population, indications specific to children have not been included in the table. Over the years, subsequent generations of the various components of the devices have been FDA approved, focusing on improved electrode design and speech-processing capabilities.

<table>
<thead>
<tr>
<th>Manufacturer and FDA approved Cochlear Implants</th>
<th>Indications for Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYBRID COCHLEAR IMPLANTS</td>
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</tbody>
</table>
### Cochlear®
- **Nucleus® Hybrid™ L24 Cochlear Implant**
  - ≥ 18 years old
  - Residual low-frequency hearing sensitivity
  - Severe to profound high-frequency sensorineural hearing loss
  - Limited benefit from appropriately fit bilateral hearing aids

### Med El®
- **Med EL EAS™**
  - ≥ 18 years old
  - Residual low-frequency hearing sensitivity
  - Severe to profound high-frequency sensorineural hearing loss
  - Candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids

### CONVENTIONAL COCHLEAR IMPLANTS
#### Advanced Bionics®
- **HiResolution Bionic Ear System (HiRes 90K*)**
- Predecessors:
  - Clarion Multi-Strategy
  - HiFocus CII Bionic Ear
  - ≥ 18 years of age
  - Post-lingual onset of severe to profound bilateral sensorineural hearing loss [≥70 decibels (dBs)]
  - Limited benefit from appropriately fitted hearing aids, defined as scoring ≤ 50% on a test of open-set Hearing in Noise Test (HINT) sentence recognition

#### Cochlear®
- **Nucleus® 6**
- **Nucleus® 5**
- **Nucleus Freedom**
- Predecessors:
  - Nucleus 22, 24
  - ≥ 18 years old
  - Pre- or post-lingual onset of moderate to profound bilateral sensorineural hearing loss
  - ≤50% sentence recognition in the ear to be implanted
  - ≤60% sentence recognition in the opposite ear or binaurally

#### Med El®
- **Maestro (Sonata or Pulsar)**
- Predecessor:
  - Combi 40+
  - ≥ 18 years old
  - Severe to profound bilateral sensorineural hearing loss (≥70dB)
  - ≤40% correct Hearing in Noise test (HINT) sentences with best-sided listening condition

### CROSS REFERENCES
- **Clinical Trials and Investigational Device Exemption (IDE) Studies**, Medicine, Policy No. M-150
- **Coverage with Evidence Development (CED) Studies and Registries**, Medicine, Policy No. M-156
- **Implantable Bone Conduction and Bone-Anchored Hearing Aids**, Surgery, Policy No. M-121

### REFERENCES
1. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §10.1.2 - Prosthetic Devices - Coverage Definition
2. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §100 – Billing Requirements for Expanded Coverage of Cochlear Implantation
3. Noridian Healthcare Solutions Repairs and Replacement Workshop Q&A
4. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty

### CODING

**NOTE:** “The diagnostic analysis of a cochlear implant shall be billed using CPT codes 92601 through 92604.” *(Medicare Claims Processing Manual, Chapter 12 - Physicians/Nonphysician Practitioners, §30.3 - Audiology Services, C - Implant Processing)*

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>69930</td>
<td>Cochlear device implantation, with or without mastoidectomy</td>
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<td></td>
<td>92601</td>
<td>Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming</td>
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<tr>
<td></td>
<td>92602</td>
<td>; subsequent reprogramming</td>
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<tr>
<td></td>
<td>92603</td>
<td>Diagnostic analysis of cochlear implant, age 7 years or older; with programming</td>
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<tr>
<td></td>
<td>92604</td>
<td>; subsequent reprogramming</td>
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<tr>
<td>HCPCS</td>
<td>L8614</td>
<td>Cochlear device, includes all internal and external components</td>
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<td></td>
<td>L8615</td>
<td>Headset/headpiece for use with cochlear implant device, replacement</td>
</tr>
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<td></td>
<td>L8616</td>
<td>Microphone for use with cochlear implant device, replacement</td>
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<td></td>
<td>L8617</td>
<td>Transmitting coil for use with cochlear implant device, replacement</td>
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<td></td>
<td>L8618</td>
<td>Transmitter cable for use with cochlear implant device, replacement</td>
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<tr>
<td></td>
<td>L8619</td>
<td>Cochlear implant external speech processor and controller, integrated system, replacement</td>
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<tr>
<td></td>
<td>L8621</td>
<td>Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each</td>
</tr>
<tr>
<td></td>
<td>L8622</td>
<td>Alkaline battery for use with cochlear implant device, any size, replacement, each</td>
</tr>
<tr>
<td></td>
<td>L8623</td>
<td>Lithium ion battery for use with cochlear implant device speech processor</td>
</tr>
<tr>
<td></td>
<td>L8624</td>
<td>Lithium ion battery for use with cochlear implant device speech processor, ear</td>
</tr>
<tr>
<td></td>
<td>L8627</td>
<td>Cochlear implant, external speech processor, component, replacement</td>
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<tr>
<td></td>
<td>L8628</td>
<td>Cochlear implant, external controller component, replacement</td>
</tr>
<tr>
<td></td>
<td>L8629</td>
<td>Transmitting coil and cable, integrated, for use with cochlear implant device, replacement</td>
</tr>
</tbody>
</table>
*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.