



National Coverage Determination: Cochlear Implantation

Related CR Release Date: **March 27, 2023**

MLN Matters Number: MM13073

Effective Date: September 26, 2022

Related Change Request (CR) Number: [CR 13073](#)

Implementation Date: March 24, 2023

Related CR Transmittal Numbers: [R11929CP](#)
and [R11929NCD](#)

Related CR Title: National Coverage Determination (NCD) 50.3 - Cochlear Implantation Manual Update

What's Changed: A revision to CR 13073 was released to correct the Claims Processing Manual Chapter 32, Section 105, diagnostic code reference. We made no substantive changes to the Article.

Affected Providers

- Audiologists
- Physicians
- Other providers billing Medicare Administrative Contractors (MACs) for cochlear implantation services they provide to Medicare patients

Action Needed

Make sure your staff knows about expanded coverage for cochlear implantation services:

- Performed as part of FDA-approved category B investigational device exemption clinical trials for patients not meeting the coverage criteria
- As a routine cost in certain clinical trials for patients not meeting the coverage criteria

Background

At least 1.2 million adults in the U.S. live with severe or profound hearing loss — a level of impairment that isn't sufficiently corrected with hearing aids. There are a number of other devices that can aid in the improvement of hearing in the appropriate patient. Among these devices are cochlear implants.

Cochlear implants bypass nonfunctional or missing cochlear hair cells and directly stimulate the surviving cells of the distal cochlear nerve. There are various cochlear implants available commercially.

Effective September 16, 2022, the expanded coverage applies to treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in people who demonstrate limited benefit from amplification as defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition.

CMS may provide coverage of cochlear implants for patients not meeting this coverage criteria when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at [42 CFR 405.201](#) or as a routine cost in clinical trials under Section 310.1 of the [NCD Manual](#) titled, "Routine Costs in Clinical Trials."

Billing and Coding Requirements

The billing requirements for expanded coverage of cochlear implantation effective for dates of service on or after September 26, 2022, are in the revised Chapter 32, Section 100 of the [Medicare Claims Processing Manual](#), attached to CR 13073.

More Information

We issued CR 13073 to your MAC as the official instruction for this change in 2 transmittals. Transmittal R11875NCD updates Section 50.3 of the NCD Manual. Transmittal R11875CP updates Chapter 32 of the Medicare Claims Processing Manual.

For more information, [find your MACs' website](#).

Document History

Date of Change	Description
March 27, 2023	A revision to CR 13073 was released to correct the Claims Processing Manual Chapter 32, Section 105, diagnostic code reference. We made no substantive changes to the Article.
March 1, 2023	Initial article released.

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