# Cochlear Implants
# Clinical Coverage Criteria

## Overview

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.

## Policy

This Policy applies to the following Fallon Health products:
☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Cochlear Implantation (50.3). National Government Services, Inc., the Medicare Administrative Contractor (MAC) with jurisdiction in our service area does not have an LCD or LCA for cochlear implantation (MCD search 06/15/2021).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

See Part II. below for coverage for cochlear implants for Medicare Advantage and NaviCare plan members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria are used to determine medical necessity for MassHealth members. Fallon Health Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Prior authorization is required.

## Part I. Fallon Health Clinical Coverage Criteria

Cochlear implantation may be covered for the 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. Coverage is provided only for those plan members who meet all of the following criteria:

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment (hearing threshold of pure-tone average of 70 dB (decibels) hearing loss or greater at 500, 1000, and 2000 Hz) 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.

## Part II. Medicare Advantage and NaviCare plan members

In accordance with Medicare **National Coverage Determination (NCD) for Cochlear Implantation (50.3)**, cochlear implantation may be covered for the 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. Coverage is provided only for those Medicare beneficiaries who meet all of the following criteria:

1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
2. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
3. 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;
4. No contraindications to surgery; and
5. The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

Cochlear implantation may also be covered for Medicare beneficiaries meeting the criteria listed above (1-5) and with hearing test scores of greater than 40% and less than or equal to 60%, only when the provider is participating in, and the beneficiary is enrolled in either:

- An FDA-approved category B investigational device exemption (IDE) clinical trial as defined at 42 CFR 405.201 (CMS-approved IDE studies are listed on the CMS website at: https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies), or
- A clinical trial under 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. CMS-approved Coverage with Evidence Development (CED) clinical trials are listed on the CMS website at: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Cochlear-Implantation-.

Claims for services related to IDE or CED clinical trials should be submitted to Fallon Health with the NCT Identifier, ICD-10-CM diagnosis code Z00.6 in either the primary/secondary position and modifier Q0/Q1 as appropriate.

Claims for services related to clinical trials covered under the CMS Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual should be submitted to Original Medicare.

## Exclusions

- Non-covered indications: Unilateral hearing loss with or without tinnitus.
- 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.
- Upgrades of an existing, functional system for technological improvements that do not statistically significantly improve the clinical outcome of doing basic ADLs.
- Replacement of a device that is out of warranty but still functioning to address the member's typical needs.

## Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

| Code | Description |
|---|---|
| 69930 | Cochlear device implantation, with or without mastoidectomy |
| L8614 | Cochlear device, includes all internal and external components |
| L8619 | Cochlear implant external speech processor, replacement |

## References


1. Medicare National Coverage Determination for Cochlear Implantation (50.3).Version Number 2. Effective 04/04/2005. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Accessed 06/15/2021.


## Policy history

Origination date: 01/01/2014

Approval(s): Technology Assessment Committee 10/23/2013 (Adopted Interqual Criteria) 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review), 05/27/2020 (adopted Fallon Health criteria), 6/22/2021 (annual review, no changes; 6/15/2021: Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).

*Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates 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.*