Cochlear Implants
Clinical Coverage Criteria

Description

A cochlear implant is an electronic device, 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:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Fallon Health requires prior authorization for cochlear implants. Requests for prior authorization for cochlear implantation must be submitted by the clinician performing the procedure and accompanied by clinical documentation that supports the medical necessity of the procedure.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for cochlear implantation. Medicare has an NCD for Cochlear Implantation (50.3) Version Number 3, Effective Date of this Version 09/26/2022. National Government Services, Inc., the Part A and B Medicare Administrative Contractor with jurisdiction in the Plan's service area does not have an LCD for cochlear implantation (Medicare Database Search 08/26/2024).

Coverage criteria for cochlear implantation are fully established by Medicare, therefore Fallon Health Clinical Coverage Criteria are not applicable.

Link: **NCD Cochlear Implantation 50.3**

> **Indications and Limitations of Coverage**
> **B. Nationally Covered Indications**
> Effective for dates of services on or after September 26, 2022, 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 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition. Patients must meet all of the following criteria:

- 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.

C. Nationally Non-Covered Indications
Medicare members not meeting all of the coverage criteria listed above are deemed not eligible for coverage for cochlear implantation except as described below.

D. Other
CMS may provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed in Section B 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 National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

Effective September 26, 2022, Medicare beneficiaries not meeting the coverage criteria listed above may have coverage for cochlear implants when performed in context of an FDA-approved Category B investigational device exemption (IDE) clinical trials as defined at 42 CFR § 405.201 or as a routine cost in clinical trials under National Coverage Determination (NCD) 310.1 Routine Costs in Clinical Trials.

FDA-approved Category B IDE clinical trials as defined at 42 CFR § 405.201 are listed on the CMS website at: https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved. For Medicare Advantage plan members enrolled in CMS-approved Category B IDE trials, Fallon Health provides coverage for routine care items and services and CMS-approved Category B devices (42 CFR § 422.109(f)). Claims for services related to CMS-approved Category B IDE trials should be submitted to Fallon Health. For information on Billing and Coding for CMS-approved Category B IDE trials, refer to Fallon Health's **Clinical Trials Payment Policy**.

Original Medicare is responsible for coverage for Medicare Advantage plan members participating CMS-approved clinical trials under NCD 310.1 – Routine Costs in Clinical Trials. The Medicare Administrative Contractors will reimburse providers on a fee-for-service basis for the routine costs of qualifying clinical trials, as well as costs for the diagnosis and treatment of complications arising from participation in qualifying clinical trials. Fallon Health will reimburse the difference between Original Medicare cost-sharing for qualified clinical trial items and services and the member's in-network cost-sharing for the same category of items and services (42 CFR § 422.109(e)).

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth has Guidelines for Medical Necessity Determination for Cochlear Implantation (MassHealth website search 08/26/2024), therefore Fallon Health Clinical Coverage Criteria are not applicable.

Link: **Guidelines for Medical Necessity Determination for Cochlear Implantation**

MassHealth does not consider cochlear implantation to be medically necessary under certain circumstances. Examples of circumstances when cochlear implants may not be medically necessary include, but are not limited to, the following:

a) The member is younger than nine months of age.
   Rare cases requiring coverage before nine months will be considered on a case-by-case basis (example: the member developed meningitis and there is concern for cochlea ossification before the nine-month mark).
b) Cochlear implantation is proposed as a form of treatment for tinnitus.
c) The member has active middle-ear infections, infection of the mastoid cavity, or tympanic membrane perforation at time of PA request and/or on day of procedure.
d) The member's deafness is due to lesions of the eighth cranial nerve or absence of the eighth cranial nerve.

For replacement and repair of cochlear implant external components, refer to **MassHealth Audiologist regulations at 130 CMR 426.416(K)**:

(1) Replacement of a cochlear implant processor is covered, only when:
   (a) the existing processor is obsolete; that is, the manufacturer no longer supports repairs on the existing processor; or
   (b) the existing processor is lost. A lost cochlear implant processor will be replaced by the same make/model as the lost processor, unless the processor is obsolete, in which case it would be substituted by the replacement model; and
   (c) the existing processor is beyond repair.

(2) Replacement of cochlear implant external components, other than the cochlear implant external processor, are covered only when:
   (a) the existing component is lost. A lost cochlear implant component will be replaced by the same make/mode as the lost component.
   (b) the existing processor is beyond repair.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
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

Fallon Health Clinical Coverage Criteria apply to Community Care members only.

Effective for dates of service on or after September 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for cochlear implants.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Cochlear Implantation
- InterQual® CP:Procedures, Unilateral Hybrid Cochlear Implantation
- InterQual® CP:Procedures, Cochlear Implantation External Component Replacement
- InterQual® CP:Procedures, Cochlear Implantation Internal Component Replacement
- InterQual® CP:Procedures, Cochlear Implantation (Pediatric)
- InterQual® CP:Procedures, Cochlear Implantation External Component Replacement (Pediatric)
- InterQual® CP:Procedures, Cochlear Implantation Internal Component Replacement (Pediatric)

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

Medical necessity determination requires review of medical records. Specific elements of a member's medical records commonly required to establish medical necessity include recent clinical evaluation which includes a detailed history and physical examination; laboratory and imaging studies, procedure reports, and reports from other providers participating in the treatment of the relevant condition.

Exclusions

- The member is younger than nine months of age.
  - Rare cases requiring coverage before nine months will be considered on a case-by-case basis (example: the member developed meningitis and there is concern for cochlea ossification before the nine-month mark).
- Cochlear implantation is proposed as a treatment for tinnitus.
- The member has active middle-ear infections, infection of the mastoid cavity, or tympanic membrane perforation at time of PA request and/or on day of procedure.
- The member's deafness is due to lesions of the eighth cranial nerve or absence of the eighth cranial nerve.
- Supplies or accessories that are not necessary for the functioning of the cochlear implant, such as cell phone adapters, telecoils, carrying cases, keychain wallets, or car charger adapters, and accessories and upgrades to accommodate personal convenience or deluxe items are not covered.

Coding

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

Implantation of a cochlear device is a surgical procedure (CPT 69930). Cochlear devices, including all internal and external components are prosthetic devices.

When a repair is being done on a prosthetic device, the labor component is billed with HCPCS code L7520. Each billable unit represents 15 minutes of labor time.

When replacing headset/headpiece, microphone, transmitting coil or transmitter cable for use with cochlear implant, the correct HCPCS code should be used instead of L7510. Replacement of minor parts and pieces can be billed under code L7510.

Code	Description
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 programming
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 programming

L7510	Repair of prosthetic device, repair or replace minor parts (use for repairs that are not covered under any manufacturer or supplier warranty)
L7520	Repair prosthetic device, labor component, per 15 minutes
L8614	Cochlear device, 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 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
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

References

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6. McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of quality-of-life improvement after cochlear implantation and associations with speech recognition abilities. *Laryngoscope*. 2018 Apr;128(4):982-990.
7. van Zon A, Smulders YE, Stegeman I, et al. Stable benefits of bilateral over unilateral cochlear implantation after two years: A randomized controlled trial. *Laryngoscope*. 2017 May;127(5):1161-1168.
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10. U.S. Food & Drug Administration. Premarket Approval (PMA) Nucleus® Hybrid™ L24 Cochlear Implant (Cochlear Americas) (P130016). Original Approval Date 04/10/2014. Available at:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130016. Accessed 05/22/2023.

Policy history

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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), 05/23/2023 (annual review, updated coverage criteria for Community Care members effective for dates of service on or after March 1, 2024), 08/27/2024 (annual review, adopted InterQual® Criteria)

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.