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:
☒ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
☒ MassHealth ACO
☒ NaviCare (NaviCare HMO SNP, NaviCare SCO)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care

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 has an **NCD for Cochlear Implantation (50.3)** Version Number 3, Effective Date of this Version 09/26/2022 (Medicare Database Search 05/22/2023). Per NCD 50.3, 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.

Medicare members not meeting all of the coverage criteria listed above are deemed not eligible for coverage for cochlear implantation except as described below.

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)).

Coverage criteria for cochlear implantation are fully established in applicable Medicare statutes, regulations, NCDs or LCDs, therefore Fallon Health Clinical Coverage Criteria are not applicable.

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 05/22/2023), therefore Fallon Health Clinical Coverage Criteria are not applicable.

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

The following Fallon Health Clinical Coverage Criteria apply to Community Care members effective for dates of service on or after March 1, 2024.

1. Unilateral or bilateral cochlear implantation - Unilateral or bilateral cochlear implantation of an FDA-approved cochlear implant device may be considered medically necessary when all of the following criteria have been met.
   a. The candidate must be older than or equal to nine months of age with bilateral, severe-to-profound pre- or post-lingual (sensorineural) hearing loss, defined as a hearing threshold of pure-tone average of 70 decibels (dB) hearing loss or greater at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz, and have shown limited or no benefit from hearing aids. The age of the recipient at the time of implantation should be consistent with the FDA guidelines for the specific implant used; and
   b. 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.
   c. Cases of profound unilateral hearing loss will be considered on a case-by-case basis. Submissions of such cases should include relevant diagnostic data. including audiograms and speech recognition testing.
   d. The candidate must have cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation; and

e. The candidate must be free from middle-ear infection, have an accessible cochlear lumen that is structurally suited to implantation, and be free from lesions in the auditory nerve and acoustic areas of the central nervous system; and
f. The candidate must NOT have medical contraindications to cochlear implantation (including, but not limited to, active middle-ear or mastoid infection, major cochlear ossification, tympanic membrane perforation, deafness due to absence or lesions of the eighth cranial nerve or brainstem, and absence of cochlear development); and
g. The member must be following current age-appropriate pneumococcal vaccination (ideally two or more weeks before surgery when possible) in accordance with the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP). The member and member's family should also be educated on the nature of middle-ear infections post-implantation, the appropriate use of antibiotics, and the risks and monitoring for infections such as meningitis; and
h. The proposed use of the device must be in accordance with FDA-approved labeling.

In addition, bilateral cochlear implantation may be considered medically necessary 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 individuals with hearing loss of a magnitude where a hearing aid will not produce the required amplification.)

2. Hybrid cochlear implant/hearing aid device - Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant (including, but not limited to, the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered medically necessary for individuals older than or equal to 18 years of age, who meet all of the following criteria:
   a. The candidate must have bilateral, severe-to-profound, high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; and
   b. The candidate must exhibit limited benefit from appropriately fit bilateral hearing aids per the thresholds defined in 2.d; and
   c. The candidate must fulfill the criteria in 1(d) through (g) above; and
   d. Have the following hearing thresholds:
      i. Low-frequency hearing thresholds no poorer than 60 dB hearing level up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation; and
      ii. Severe to profound mid-to-high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 75 dB hearing level) in the ear to be implanted; and
      iii. Moderately severe to profound mid-to-high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 60 dB hearing level) in the contralateral ear; and
   e. An aided consonant-nucleus-consonant word recognition score from 10% to 60% in the ear to be implanted in the preoperative aided condition; and
   f. An aided consonant-nucleus-consonant word recognition score in the contralateral ear equal to or greater than the ear to be implanted, but not greater than 80% correct.
   g. The proposed use of the device must be in accordance with FDA-approved labeling.

3. Replacement of cochlear implant processor - 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.

4. Replacement of cochlear implant external components, other than the cochlear implant external processor - 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.

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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3. The American Academy of Otolaryngology (AAO) Head and Neck Surgery, Position Statement: Cochlear Implants, Revised 11/10/2020. Available at: https://www.entnet.org/resource/position-statement-cochlear-implants/#:~:text=The%20American%20Academy%20of%20Otolaryngology,with%20appropriately%20fit%20hearing%20aids. Accessed 05/22/2023.
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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.
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Policy history

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(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 (updated coverage criteria for Community Care members effective for dates of service on or after March 1, 2024).

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.