Guidelines for Medical Necessity Determination for Cochlear Implantation

This edition of the *Guidelines for Medical Necessity Determination* (Guidelines) identifies the clinical information that MassHealth needs to determine medical necessity for cochlear implantation for treatment of bilateral hearing loss. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 433.000: *Physician Services*, 130 CMR 426.000: *Audiologist Services*, and 130 CMR 450.000: Administrative and Billing Regulations, and Subchapter 6 of the *Physician Manual* for information about coverage, limitations, service conditions, and other prior authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Options (SCO) plan, or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care organization's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth requires PA for initial cochlear implantation surgery (CPT 69930). The initial internal and external device (CPT L8614) does not require PA if an FDA-approved device is used. Replacement processors require PA. MassHealth reviews requests for PA based on medical necessity. Please see MassHealth regulations at 130 CMR 426.416(K) for PA requirements for replacement of external sound processors. If MassHealth approves the request, payment is still subject to all general MassHealth requirements, including member eligibility, availability of coverage through other insurance, and program restrictions.

SECTION I. GENERAL INFORMATION

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A cochlear implant is a surgically implanted electronic prosthetic device that provides electric stimulation directly to auditory nerve fibers in the cochlea. A cochlear implant is utilized when traditional acoustic amplification is not providing adequate benefit. The cochlear implant bypasses damaged inner hair cells to deliver a signal to the brain, which is then interpreted as sound. A cochlear implant consists of two components: an internal (implanted) device and an external sound processor. The surgically implanted internal components consist of a receiver/stimulator placed under the skin or within the temporal bone and an elected array inserted into the scala tympani of the cochlea. The external components consist of a microphone, sound processor, transmitter, and power supply. The microphone collects the sound and sends the input to the sound processor. The sound processor then digitally analyzes the signal, and separates the signal into frequency bands that are compressed into an electric dynamic range. The transmitter then sends the signal across the skin to the internal component. A magnet is housed in both the transmitter and receiver/stimulator so that the two components remain aligned. This allows the electric signal to be transmitted across the skin via radio frequency. The internal receiver picks up the signal from the transmitter and delivers the signal to specific electrodes within the array, which is arranged tonotopically. The selected electrode then stimulates the auditory nerve via electrical pulses. The signal is then received by the auditory nerve,

which transmits the signal to the brain as an electrical signal, perceived as sound by the recipient.

Cochlear implant internal and external components are similar across all manufacturers, although there are variations in electrode arrays, sound processor designs, processing, programming capabilities, and pairing of assistive devices across cochlear implant models and manufacturers. Since receiving approval from the Food and Drug Administration (FDA) in 1984, the criteria for cochlear implantation have expanded to include individuals of younger ages and those with more residual hearing and better speech-perception abilities. Some electroacoustic cochlear implants transmit frequencies via acoustic amplification, while others transmit frequencies via electrical stimulation. Other devices may also utilize bimodal stimulation, where a cochlear implant is in one ear and a hearing aid in the contralateral ear.

Advancements in cochlear implant technologies, along with less invasive surgical techniques, have resulted in improvements in communication outcomes. Today, the majority of individuals who use cochlear implants are able to further understand speech in multiple listening situations. Further, the majority of children who use cochlear implantation are able to develop excellent auditory skills and use spoken language. Outcomes with cochlear implantation are characterized by a wide variability that are attributed to many factors. The factors include, but are not limited to, age at onset of deafness; age of implantation; cochlear implant experience and auditory training; residual hearing; spiral ganglion cell survival in auditory pathways; cognitive abilities; patient/family personality and motivation; parental involvement and commitment; quality of device programming; consistent use; and follow-up appointments.

THE ROLE OF THE AUDIOLOGIST

The audiologist's role in the clinical management of recipients of cochlear implantation ranges from pre-implant evaluations and determination of candidacy to ongoing post-implant care. The audiologist performs the pre-implant audiological test battery for determining cochlear implant candidacy. This evaluation includes, but is not limited to, conduction assessments of auditory sensitivity, aided speech detection/reception, and spoken word recognition. The audiologist serves on a multidisciplinary team when determining candidacy. The audiologist is also responsible for post-implant care vital to positive outcomes. Consistent and timed interval follow-up care, along with device programming, are contributing factors to success with the cochlear implant. Consistent follow-up care ensures appropriate counseling, care of the device, and optimized programming of an implant. Consistent follow-up leads to increased access to the various acoustic cues needed for adequate speech perception and speech and language development.

THE ROLE OF THE OTOLARYNGOLOGIST

The otolaryngologist's role in the clinical management of cochlear implant recipients similarly begins at pre-implant evaluations and continues through determination of candidacy for surgery and ongoing, post-implant care. The otolaryngologist must be experienced in this procedure and the review of relevant patient data inclusive of scans and anatomy. The otolaryngologist must also coordinate with the care team, member, and family to set realistic expectations for functional improvement and to emphasize how post-implant care is vital to positive outcomes. The otolaryngologist must also be available for management of post-implantation issues that may arise.

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SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

1. UNILATERAL OR BILATERAL COCHLEAR IMPLANT

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;

(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;

(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;

(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);

(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.

(b) The candidate must exhibit limited benefit from appropriately fit bilateral hearing aids per the thresholds defined in 2(d);

(c) The candidate must fulfill the criteria in Section II.A.1(d) through (g);

(d) The candidate must have the following hearing thresholds:

- 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;
- 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
- 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) The candidate must have an aided consonant-nucleus-consonant word recognition score from 10% to 60% in the ear to be implanted in the preoperative aided condition;

(f) The candidate must have 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; and

(g) The proposed use of the device must be in accordance with FDA-approved labeling.

B. NONCOVERAGE

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.

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

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Requests for PA 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, as outlined in the clinical coverage requirements under Section II.A. of these Guidelines.

A. DOCUMENTATION

Documentation of medical necessity must include **all** of the following:

(a) An audiologic evaluation completed in the last six months, which provides a complete history, including date of onset of hearing loss;

(b) Progress notes documenting that any coexisting medical or mental health diagnoses are being appropriately managed and are reasonably controlled; and

(c) A letter from the clinician performing the procedure indicating **all** of the following:

- The member meets the clinical criteria for coverage described in Section II.A. of these guidelines; and
- The clinician has discussed risks and complications of the proposed procedure, including the clinician's own complication rates, and has obtained informed consent from the member.

B. CLINICAL INFORMATION

Clinical information must be submitted by the clinician performing the procedure.

Providers must electronically submit PA requests and all supporting documentation using the Provider Online Service Center (POSC), unless the provider has a currently approved electronic claims waiver. Please see All Provider Bulletin 369 for further waiver information. Questions about POSC access should be directed to MassHealth at (800) 841-2900, TDD/TTY: 711.

For PA requests that are not submitted using the POSC, providers with currently approved waivers must include the MassHealth Prior Authorization Request (PA-1 Form) and all supporting documentation. The PA-1 Form can be found at mass.gov/prior-authorization-for-mashealth-providers. Select "Request prior authorization for nonpharmacy services" and then select "By mail" for a link to the PA-1 Form.

SELECT REFERENCES

1. Academy of Audiology Cochlear Implant Practice Guidelines. https://www.audiology.org/wp-content/uploads/2021/05/CochlearImplantPracticeGuidelines.pdf

2. Academy of Speech and Language (ASHA). Cochlear Implants (asha.org)

3. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Cochlear Implants. Position Statement: Cochlear Implants - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (entnet.org)

4. Centers for Medicare & Medicaid Services. Cochlear Implants. Cochlear Implantation | CMS

5. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Cochlear Implantation (50.3). NCD - Cochlear Implantation (50.3) (cms.gov)

6. FDA. Approval Letter: Nucleus Hybrid L24 Cochlear Implant System https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130016; https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130016a.pdf

7. FDA-Approved Cochlear Implants. FDA-Approved Cochlear Implants | FDA

8. FDA Cochlear Implants. Cochlear Implants | FDA

These guidelines are based on review of the medical literature and current practice in New York, North Carolina, Texas, Maryland, and California, as well as on Medicare guidelines. MassHealth reserves the right to review and update the contents of these guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

Policy Revision Effective Date: September 5, 2024 Approved by: _____

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Policy Effective Date July 7, 2022