STATE OF IOWA DEPARTMENT OF Health and Human Services

Cochlear Implant SRG-006

Iowa Medicaid Program:	Prior Authorization	Effective Date:	7/1/2008
Revision Number:	10	Last Rev Date:	4/19/2024
Reviewed By:	Medicaid Medical Director	Next Rev Date:	4/18/2025
Approved By:	Medicaid Clinical Advisory Committee	Approved Date:	11/2/2020

Narrative Description

Hearing loss affects approximately 16 percent of the adult population of the United States, corresponding to 29 million individuals. The impaired ability to communicate with others has been associated with poorer objective physical functioning in older adults, increased risk for disability and a poorer quality of life. In contrast with age-matched adults with unimpaired hearing, older persons with hearing loss have higher rates of hospitalization, death, falls, dementia, and depression.

The type of hearing loss which may be helped by a cochlear implant is known as sensorineural hearing loss or nerve deafness. This is the results of damage to delicate portions of the inner ear (hair cells), which no longer convert sound waves into electrical current. This current normally stimulates the auditory nerve to transmit impulses to the brain where they are recognized as sound. The cochlear implant functions by representing the auditory environment through electrical stimulation of the auditory nerve and by operating within an electrical range that is sufficient for audibility. It bypasses the impaired cochlea and directly stimulates residual neural elements in the auditory nerve.

The surgically implanted internal components consist of a receiver/stimulator placed under the skin or within the temporal bone and an electrode array inserted into 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. Within the sound processor, the signal is digitally analyzed, separated into frequency bands, and compressed into an electrical dynamic range. The transmitter then sends the signal across the skin to the internal component.

A magnet is situated in both the transmitter and receiver/stimulator so that the two components remain aligned, enabling the electrical signal to be conveyed across the skin via radiofrequency. The internal receiver picks up the signal from the transmitter and delivers the signal to specific electrodes within the array. The selected electrode then stimulates the auditory nerve via discrete electrical pulses.

Cochlear implant candidates do not need to be totally deaf. These devices should be considered for individuals whose hearing loss cannot be adequately addressed through acoustic amplification (e.g., hearing aids) alone.

Infants and Children

The minimum age for this device has dropped progressively as evidence supports implantation at an early age provides superior outcomes. In addition, bilateral implantation offers better sound localization and enhanced ability to understand speech in noisy environments. Deafened children who may face a variety of additional challenges, such as inner ear malformation, cochlear nerve deficiency, and post-meningitis cochlear ossification, can also be successfully implanted. Although candidacy must be individualized and post-implantation rehabilitation can be more challenging.

Cochlear implant devices have FDA approval for use in children as young as 12 months of age. The Cochlear[™] Nucleus[®] System received FDA approval in 2020 for infants 9 months of age and older, who have bilateral profound hearing loss and who also demonstrate limited benefit from appropriate binaural hearing aids.

Preoperative evaluation for a cochlear implant includes computed tomography (CT) or magnetic resonance imaging (MRI) of the temporal bone to evaluate the patency of the cochlea, identify congenital malformations, and assess surgical anatomy. Audiometric testing should be well documented. Other important prerequisites include access to an education program that stresses auditory and verbal skills and highly motivated parents who have realistic expectations. Because of the increased risk of meningitis in children with cochlear implants, immunization against Streptococcus pneumoniae and Haemophilus influenza is recommended.



Classification of Hearing Loss

Criteria

Adults

Cochlear implant devices are medically necessary when <u>ALL</u> the following are met:

- I. Age 18 years of age and older; **AND**
- 2. Hearing loss is EITHER:
 - a. Unilateral hearing loss:
 - Intended ear has profound hearing loss of ≥90 decibel hearing level (dB HL) at 500, 1000, 2000, and 4000 Hertz (Hz); <u>AND</u>
 - Contralateral ear has normal or mild hearing loss of ≤ 30dB HL at 500, 1000, 2000; <u>OR</u>
 - 3) Contralateral ear has mild to moderately severe hearing loss of 31 to 55 dB HL at 500, 1000, 2000, and 4000 Hz; <u>OR</u>
 - b. Bilateral hearing loss:
 - Moderately severe to profound hearing loss, as defined by ≥70 decibel hearing level at 500, 1000, and 2000 Hz; <u>AND</u>
- 3. The member is free from lesions in the auditory nerve and acoustic areas of the central auditory pathway, as determined by CT or MRI imaging; **AND**
- 4. Failure of hearing aid trial to improve hearing, or hearing aids would not be considered appropriate due to the degree of hearing loss; **AND**
- 5. The member is able to participate in a post-cochlear implant rehabilitation program in order to achieve benefit from the cochlear implant device; <u>AND</u>
- 6. The member is free from otitis media or other active middle ear infections; **AND**
- 7. All adults with cochlear implants should receive immunization against Streptococcus pneumoniae according to the current Center for Disease Control (CDC) recommendations, unless clinically contraindicated.
- 8. Approval may apply to unilateral or bilateral cochlear device implantation.

Infants and Children

Cochlear implant devices are medically necessary when <u>ALL</u> the following are met:

- Age 12 months to 17 years of age (The Cochlear[™] Nucleus[®] System is FDA approved for infants 9 months of age and older); <u>AND</u>
- 2. Hearing loss is EITHER:
 - a. Unilateral hearing loss:
 - Intended ear has profound hearing loss of ≥90 decibel hearing level (dB HL) at 500, 1000, 2000, and 4000 Hz; AND
 - Contralateral ear has normal or mild hearing loss of ≤30 dB HL at 500, 1000, 2000 Hz; OR
 - 3) Contralateral ear has mild to moderately severe hearing loss of 31 to 55 dB HL at 500, 1000, 2000, and 4000 Hz; **OR**
 - b. Bilateral hearing loss:
 - Moderately severe to profound hearing loss, as defined by ≥70 dB HL at 500, 1000, and 2000 Hz; AND
- 3. All children with cochlear implants should receive immunization against Streptococcus pneumoniae and Haemophilus influenza according to current CDC recommendations unless clinically contraindicated; <u>AND</u>

- 4. No evidence of cochlea-vestibular abnormalities by CT or MRI that would preclude implant (e.g. findings of cochlear aplasia, complete labyrinthine aplasia, lack of cochlear nerve); **AND**
- 5. Failure of hearing aid trial to improve hearing, or hearing aids would not be considered appropriate due to the degree of hearing loss or age of the member; **AND**
- 6. The member has family support and motivation to participate in post-implant rehabilitation; **AND**
- 7. The member is free from otitis media or other active middle ear infections; **AND**
- 8. Approval may apply to unilateral or bilateral cochlear device implantation.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

СРТ	Description
L8614	Cochlear device, includes all internal and external components.
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex.
69930	Cochlear device implantation, with or without mastoidectomy.

Compliance

- 1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
- 2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
- 3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

The Cochlear[™] Nucleus[®] System. Updated Pediatric Indications HE-021_F ISS1 May 2020.

Clinical Practice Guideline: Cochlear Implants, American Academy of Audiology, 2019.

EncoderPro Optum 360.

Position Statement: Pediatric Cochlear Implants, American Academy of Otolarayngology Head and Neck Surgery, Adopted April, 15, 2020.

Weber PC, Hearing amplification in Adults, UpToDate. Literature review current through Jun 2020.

Mahboubi H. Lin HW. Bhattacharyya N. Prevalence, Characteristics, and Treatment Patterns of Hearing Difficulty in the United States. JAMA Otolaryngol Head Neck Surg. 2018 Jan 1;144(1):65-70. doi: 10.1001/jamaoto.2017.2223. PMID: 29167904.

Cunningham LL. Tucci DL. Hearing Loss in Adults. N Engl J Med. 2017 Dec 21;377(25):2465-2473. doi: 10.1056/NEJMra1616601. PMID: 2926227.

Age-Related Hearing Loss. National Institute on Deafness and Other Communication Disorders. NIH Pub. No. 97-4235. March 2016. Last Updated Date: March 16, 2022. <u>https://www.nidcd.nih.gov/health/age-related-hearing-</u> <u>loss#:~:text=Approximately%20one%20in%20three%20people,%2C%20doorbells%2C%20and%</u> 20smoke%20alarms.

Cochlear Implantation. Medicare Coverage Database. CAG-00107R. Date: September 26,2022. NCA - Cochlear Implantation (CAG-00107R) - Decision Memo (cms.gov).

Cochlear Implants and Vaccination Recommendations. Center for Disease Control and Prevention. Last reviewed August 8, 2019. Content source: National Center for Immunization and Respiratory Diseases.

Use of Vaccines to Prevent Meningitis in Persons with Cochlear Implants. Center for Disease Control and Prevention. Last reviewed January 27, 2022. https://www.cdc.gov/vaccines/vpd/mening/hcp/dis-cochlear-gen.html

Weber PC. Hearing amplification in adults. UpToDate. Last updated August 18, 2022.

Cochlear Implantation. National Coverage Determination. Publication Number 100-3. Implementation date March 24, 2023.

Company website. Cochlear[™] Nucleus[®] System. Cochlear Ltd. Copyright 2023. <u>https://www.cochlear.com/us/en/home/products-and-accessories/cochlear-nucleus-system</u>. Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History						
Change Date	Changed By	Description of Change	Version			
Signature						
Change Date	Changed By	Description of Change	Version			
Signature						
Change Date	Changed By	Description of Change	Version			
4/19/2024	CAC	Annual review.	10			
Signature William (Bill) Jagiello	, DOMMAM	-				
Change Date	Changed By	Description of Change	Version			
¥	~ . ~	Added Criteria to include unilateral hearing loss				
4/21/2023	CAC	for both adults and children. Updated	9			
		References.				
Signature		\cap				
William (Bill) Jagiello	, DO ////////	Om				
Change Date	Changed By	Description of Change	Version			
1/20/2023	CAC	Annual review. Added CPT 69729. Updated	8			
	0,10	PCV requirements per CDC recommendations.	•			
Signature	0/0/000	A				
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Change Date	Changed By	Description of Change	Version			
10/21/2022	CAC	Updated Descriptive Narrative, updated	7			
	0.10	References, added Compliance section.	•			
Signature William (Bill) Jagiello	, do MMMGm					
Change Date	Changed By	Description of Change	Version			
		Updated criteria. Removed cochlear implant				
10/16/2020		replacement from this criteria to separate.	6			
		Updated References.				
Signature William (Bill) Jagiello	, do MMMG	m				
Change Date	Changed By	bescription of Change	Version			
10/20/2017	CAC	Criterion #7 added "age-appropriate".	5			
Signature C. David Smith, MD	C. David for Hu	M.D.				

Criteria Change History (continued)						
Change Date	Changed By	Description of Change	Version			
4/21/2017	Medical Director	Added section on Cochlear Implant replacement and upgrade criteria	4			
Signature						
Change Date	Changed By	Description of Change	Version			
7/15/2016	Medical Director	Criterion #1 changed "nine" months to "twelve". Added specifics for "12 to 24 months" and "older than 2 years". Added Criteron #5, #6, and #7.	3			
Signature						
Change Date	Changed By	Description of Change	Version			
7/17/2015	CAC	Added last paragraph in References.	2			
Signature						
Change Date	Changed By	Description of Change	Version			
7/14/2015	Medical Director	Added CMS references.				
Signature						