Cochlear Implant Replacement *

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NOTICE: This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Cochlear Implants (CI)

While hearing loss may relate to abnormalities in the sound conduction system of the outer and middle ear, most severe hearing deficits in newborns and the elderly result from sensorineural abnormalities, particularly cochlear hair cell loss which limits the ability of the cochlea to convert sound vibrations into nerve impulses. This type of hearing loss is usually irreversible and has been treated with rehabilitation strategies involving hearing aids, sign language, and speech and language therapy. Amplification does not replace the function of lost cochlear hair cells and often cannot provide adequate hearing in the case of severe cochlear hair loss. If appropriate neural elements in the ear are intact and functional, it is possible to stimulate auditory nerve impulses with a cochlear implantation device to improve sound recognition.

The cochlear implant (CI) is composed of three parts which include external components and two internal surgically implanted components.

External
External components include a microphone, speech processor, and transmitter coil with cables are worn.

- The speech processor converts sound into electrical stimuli.

Internal
Internal components include an antenna and electrodes.

- The antenna electromagnetically captures the stimuli transmitted by the external speech processor and directs this information to internal electrodes.
- The electrodes provide direct electrical stimulation to the auditory nerve, bypassing the transducer cells which are absent or nonfunctional.

Because the cochlear implant does **not** magnify sound, none of its components are considered a hearing aid.

CI revision surgery is uncommon, a small percentage of 3% - 8% of all CI procedures require revisional surgery and cochlear reimplantation may be necessary for a variety of reasons to include but not limited to:

- Electrode extrusions
- Hardware failure
- Improper initial placement
- Receiver-stimulator repositioning due to device migration
- Software failure
- Wound complications
    - In cases of infection the receiver-stimulator is removed there is a delayed reimplantation of a new device.

Regulatory Status
Several cochlear implants are commercially available in the United States and are manufactured by Cochlear Americas, Advanced Bionics, and the MED - EL Corporation. Over time, subsequent generations of the various components of the devices have been approved by the U.S. Food and Drug Administration (FDA) focusing on improved electrode design and speech-processing capabilities.

Warranty coverage is subject to the manufacturer's warranty for the individual's specific device.

PRIOR APPROVAL

Prior approval is required.

POLICY

Medically Necessary
The replacement of a cochlear implant (external components) is considered **medically necessary** when documentation is provided to support **all** of the following criteria:

- Date the device was received; **and**
- Manufacturer warranty information including the currently used device is **not** under warranty; **and**
- Determination of the device to be non-repairable including objective documentation from the audiologist on how the device is non-repairable/malfunctioning; **and**
- The device currently used is no longer functional as evidenced by interfering with the individuals' activities of daily living (ADLs); **and**
- There is no evidence to suggest that the device has been lost, abused, or neglected; **and**
- The individual has been compliant with the use of the device and will continue to benefit from the device; **and**
- The device was being used daily until malfunction.

The replacement of a cochlear implant (external components) is considered **medically necessary** if there is a change in the individual's medical condition making the present unit non-functional and improvement is expected with a replacement unit.

Not Medically Necessary
The replacement of cochlear implants (external components) is considered **not medically necessary** including but not limited to the following:

- The replacement is solely for better technology or improved aesthetics.
- When the above criteria are not met.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- L8619 Cochlear implant external speech processor and controller, integrated system, replacement
- L8627 Cochlear implant, external speech processor, component, replacement
- L8628 Cochlear implant, external controller component, replacement

SELECTED REFERENCES

- Sterkers F, Merklen F, Piron JP, et al. Outcomes after cochlear reimplantation in children. Int J Pediatr Otorhinolaryngol. Mar 23 2015. PMID 25843784
- Fernandes NF, Morettin M, Yamaguti EH, et al. Performance of hearing skills in children with auditory neuropathy spectrum disorder using cochlear implant: a systematic review. Braz J Otorhinolaryngol. Jan-Feb 2015;81(1):85-96. PMID 25458263
- Centers for Medicare and Medicaid (CMS). National Coverage Determination (NCD) Pub. 100.3, section 50.3 Cochlear Implantation.
- American Academy of Otolarygology-Head and Neck Surgery Foudation. Position Statement on Bilateral Cochlear Implants. 2014 revision
- Gaylor JM, Raman G, Chung M, et al. Cochlear implantation in adults: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. Mar 2013;139(3):265-272. PMID 23429927
- Institute for Health and Clinical Excellence (NICE). Technology Appraisal Guidance 166. Cochlear implants for children and adults with severe to profound deafness. 2009 January 28.
- Cochlear Implants in Adults and Children. NIH Consensus Statement Online 1995 May 15-17; 13(2):1-30.
- Jurawitz MC, Büchner A, Harpel T, et al. Hearing preservation outcomes with different cochlear implant electrodes: Nucleus® Hybrid™-L24 and Nucleus Freedom™ CI422. Audiol Neurootol. 2014;19(5):293-309.
- National Institutes of Health. National Institute on Deafness and Other Communication Disorders. Auditory Neuropathy. 2011.
- Roland JT Jr, Gantz BJ, Waltzman SB, et al.; Multicenter Clinical Trial Group. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. Laryngoscope. 2016 Jan;126(1):175-81.
- Gantz BJ, Dunn C, Oleson J, et al. Multicenter clinical trial of the Nucleus Hybrid S8 cochlear implant: Final outcomes. Laryngoscope. 2016 Apr;126(4):962-73.
- Abbas, P., Brown, C. Clinicaltrials.org (NCT02203305) Cochlear Implantation in Cases of Single-Sided Deafness; planned enrollment 30; completion date December 2018.
- Woodson, E. A., Reiss, L. A. J., Turner, C. W., Gfeller, K., & Gantz, B. J. (2010). The Hybrid cochlear implant: A review. Advances in Oto-Rhino-Laryngology, 67, 125–134.
- Brown, K.D., Connell, S.S., Balkany, T.J., Eshraghi, A.E., Telischi, F.F. and Angeli, S.A. (2009) Incidence and Indications for Revision Cochlear Implant Surgery in Adults and Children. Laryngoscope, 119, 152-157.

POLICY HISTORY		
Date	**Reason**	**Action**
September 2022	Annual Review	Policy Renewed
September 2021	Annual Review	Policy Revised
September 2020	Annual Review	Policy Revised
September 2019	Annual Review	Policy Renewed
September 2018	Annual Review	Policy Renewed
September 2017	Annual Review	Policy Renewed
September 2016	Annual Review	Policy Renewed
October 2015		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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