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OVERVIEW
A cochlear implant is a device for treatment of severe-to-profound hearing loss in individuals who only receive limited benefit from amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea. This policy documents the coverage guidelines for cochlear implants.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Prior authorization is not required.

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Cochlear Implantation
Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be considered medically necessary in patients age 12 months and older with bilateral severe to profound pre- or post-lingual (sensorineural) hearing loss and who have shown limited or no benefit from hearing aids.

Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear (BTE) model, are considered not covered, as this is considered a convenience. Additionally, replacement of internal and/or external components solely for the purpose of upgrading to a system with advanced technology or to a next-generation device is considered not covered, as this is considered a convenience.

Replacement of internal and/or external components is considered medically necessary only in a small subset of members who have inadequate response to existing component(s) to the point of interfering with the individual's activities of daily living, or the component(s) is/are no longer functional and cannot be repaired.

Hybrid Cochlear Implant/Hearing Aid
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 (eg, the Nucleus® Hybrid™ L24 Cochlear Implant System) may be considered medically necessary for patients ages 18 years and older who have bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low frequency hearing sensitivity and receive limited benefit from appropriately fit bilateral hearing aids.

BlueCHiP for Medicare
Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Surgery Services and Medical Equipment, Medical Supplies, and Prosthetic Devices/Diagnostic Imaging, Lab, Machine Tests/Speech Therapy, and Personal Appearance and/or Items coverage/benefits.

BACKGROUND

A cochlear implant, classified by Centers for Medicare and Medicaid Services (CMS) as a prosthetic device, is an electronic instrument, 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.

The basic structure of a cochlear implant includes both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are surgically implanted and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear.

Sounds that are picked up by the microphone are carried to the external sound processor, which transforms the sound into coded signals that are then transmitted through the skin to the implanted internal receiver. The receiver converts the incoming signals to electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. A typical rehabilitation program consists of 6 to 10 sessions that last approximately 2½ hours each. A rehabilitation program would include development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

Typically, severe hearing loss is defined as a bilateral hearing threshold of 70 to 90 dB, and profound hearing loss is defined as a bilateral hearing threshold of 90 dB and above. In adults, limited benefit from hearing aids is defined as scores 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.

Several cochlear implants are commercially available in the United States and are manufactured by Cochlear Americas, Advanced Bionics, and the MED-EL Corp. 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. Furthermore, smaller devices and the accumulating experience in children have resulted in broadening of the selection criteria to include children as young as 12 months.

In 2014, the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Americas) was approved by FDA through the premarket approval process. This system is a hybrid cochlear implant and hearing aid, with the hearing aid integrated into the external sound processor of the cochlear implant. It is indicated for unilateral use in patients ages 18 years and older who have residual low-frequency hearing sensitivity and severe-to-profound high-frequency sensorineural hearing loss, and who obtain limited benefit from an appropriately fit

bilateral hearing aid. The electrode array inserted into the cochlea is shorter than conventional cochlear implants. According to FDA's premarket approval notification, labeled indications for the device include:

- Preoperative hearing in the range from "normal to moderate hearing loss [HL] in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz)"
- Preoperative hearing with "severe to profound mid to high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥75 dB HL) in the ear to be implanted"
- Preoperative hearing with "moderately severe to profound mid to high frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥60 dB HL) in the contralateral ear"
- "The CNC [Consonant-Nucleus-Consonant] word recognition score will be between 10% and 60%, inclusively, in the ear to be implanted in the preoperative aided condition and in the contralateral ear equal to or better than that of the ear to be implanted but not more than 80% correct."

Other hybrid hearing devices have been developed but do not have FDA approval, including the Med El® EAS Hearing Implant System.

For individuals who have unilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, is limited by small sample sizes, short follow-up times, and heterogeneity in evaluation protocols and outcome measurements. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

In addition to the codes identified in this policy under the diagnostic imaging, lab, and machine tests benefit, there may be other therapeutic service codes related to cochlear implants (such as auditory rehabilitation) which would be applied to the member's speech therapy benefit.

BlueCHiP for Medicare and Commercial Products

The following code is covered under the member's **surgery services** benefit:

69930 Cochlear device implantation, with or without mastoidectomy

The following codes are covered under the member's **speech therapy** benefit:

92626 Evaluation of auditory rehabilitation status; first hour
92627 Evaluation of auditory rehabilitation status; each additional 15 minutes
92630 Auditory rehabilitation; pre-lingual hearing loss
92633 Auditory rehabilitation; post-lingual hearing loss

The following codes are covered under the **diagnostic imaging, lab, and machine tests** benefit:

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 reprogramming
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 reprogramming

The following codes are covered under the **prosthetic devices** benefit:

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 and controller, integrated system, 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
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

The following codes are covered under the **durable medical equipment** benefit:
Note: There are no participating providers for batteries for cochlear devices. Therefore, batteries are paid as an in-network benefit.
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
L8625 External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each

RELATED POLICIES
Clinical Trials BlueCHiP for Medicare
Clinical Trials Mandate Commercial
Durable Medical Equipment
Speech Therapy

PUBLISHED
Provider Update, May 2020
Provider Update, September 2019
Provider Update, November 2018
Provider Update, October 2017
Provider Update, November 2016

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Cochlear Implantation (50.3).
2. Food and Drug Administration. Approval Letter: Nucleus Hybrid L24 Cochlear Implant System (P130016). 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130016a.pdf. Accessed January 25, 2018.
3. Cochlear Implants in Adults and Children. NIH Consens Statement Online. 1995;13(2):1-30.
4. Bond M, Mealing S, Anderson R, et al. The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model. Health Technol Assess. Sep 2009;13(44):1-330. PMID 19799825
5. 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
6. Crathorne L, Bond M, Cooper C, et al. A systematic review of the effectiveness and cost-effectiveness of bilateral multichannel cochlear implants in adults with severe-to-profound hearing loss. Clin Otolaryngol. Oct 2012;37(5):342-354. PMID 22928754
7. Choi JS, Betz J, Li L, et al. Association of using hearing aids or cochlear implants with changes in depressive symptoms in older adults. JAMA Otolaryngol Head Neck Surg. Jul 01 2016;142(7):652-657. PMID 27258813
8. van Zon A, Smulders YE, Ramakers GG, et al. Effect of unilateral and simultaneous bilateral cochlear implantation on tinnitus: a prospective study. Laryngoscope. Apr 2016;126(4):956-961. PMID 26255618

9. Bond M, Elston J, Mealing S, et al. Effectiveness of multi-channel unilateral cochlear implants for profoundly deaf children: a systematic review. Clin Otolaryngol. Jun 2009;34(3):199-211. PMID 19531168
10. Sharma A, Dorman MF. Central auditory development in children with cochlear implants: clinical implications. Adv Otorhinolaryngol. Aug 2006;64:66-88. PMID 16891837
11. Forli F, Arslan E, Bellelli S, et al. Systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in paediatric patients. Acta Otorhinolaryngol Ital. Oct 2011;31(5):281-298. PMID 22287820
12. Sterkers F, Merklen F, Piron JP, et al. Outcomes after cochlear reimplantation in children. Int J Pediatr Otorhinolaryngol. Jun 2015;79(6):840-843. PMID 25843784
13. Black J, Hickson L, Black B, et al. Prognostic indicators in paediatric cochlear implant surgery: a systematic literature review. Cochlear Implants Int. May 2011;12(2):67-93. PMID 21756501
14. Pakdaman MN, Herrmann BS, Curtin HD, et al. Cochlear implantation in children with anomalous cochleovestibular anatomy: a systematic review. Otolaryngol Head Neck Surg. Feb 2012;146(2):180-190. PMID 22140206
15. 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
16. Vlastarakos PV, Proikas K, Papacharalampous G, et al. Cochlear implantation under the first year of age—the outcomes. A critical systematic review and meta-analysis. Int J Pediatr Otorhinolaryngol. Feb 2010; 74(2):119126. PMID 19896223
17. Ching TY, Dillon H, Day J, et al. Early language outcomes of children with cochlear implants: interim findings of the NAL study on longitudinal outcomes of children with hearing impairment. Cochlear Implants Int. Dec 2009;10 Suppl 1:28-32. PMID 19067433
18. Colletti L, Mandala M, Zoccante L, et al. Infants versus older children fitted with cochlear implants: performance over 10 years. Int J Pediatr Otorhinolaryngol. Apr 2011;75(4):504-509. PMID 21277638
19. Guerzoni L, Murri A, Fabrizi E, et al. Social conversational skills development in early implanted children. Laryngoscope. Sep 2016;126(9):2098-2105. PMID 26649815
20. Lammers MJ, van der Heijden GJ, Pourier VE, et al. Bilateral cochlear implantation in children: a systematic review and best-evidence synthesis. Laryngoscope. Jul 2014;124(7):1694-1699. PMID 24390811
21. Broomfield SJ, Murphy J, Emmett S, et al. Results of a prospective surgical audit of bilateral paediatric cochlear implantation in the UK. Cochlear Implants Int. Nov 2013;14 Suppl 4:S19-21. PMID 24533758
22. Sarant J, Harris D, Bennet L, et al. Bilateral versus unilateral cochlear implants in children: a study of spoken language outcomes. Ear Hear. Jul-Aug 2014;35(4):396-409. PMID 24557003
23. Escorihuela Garcia V, Pitarch Ribas MI, Llopez Carratala I, et al. Comparative study between unilateral and bilateral cochlear implantation in children of 1 and 2 years of age. Acta Otorrinolaringol Esp. May-Jun 2016;67(3):148-155. PMID 26632253
24. Friedmann DR, Green J, Fang Y, et al. Sequential bilateral cochlear implantation in the adolescent population. Laryngoscope. Aug 2015;125(8):1952-1958. PMID 25946482
25. Illg A, Giourgas A, Kral A, et al. Speech comprehension in children and adolescents after sequential bilateral cochlear implantation with long interimplant interval. Otol Neurotol. Jun 2013;34(4):682-689. PMID 23640090
26. van Zon A, Peters JP, Stegeman I, et al. Cochlear implantation for patients with single-sided deafness or asymmetrical hearing loss: a systematic review of the evidence. Otol Neurotol. Feb 2015;36(2):209-219. PMID 25502451

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