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# Medical Policy Cochlear Implant

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Policy Number: 478

BCBSA Reference Number: 7.01.05

#### **Related Policies**

- Auditory Brainstem Implant, #481
- Implantable Bone-Conduction and Bone-Anchored Hearing Aids, #479
- Semi-Implantable and Fully Implantable Middle Ear Hearing Aid #480

#### **Policy**

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be <u>MEDICALLY NECESSARY</u> in patients age 12 months and older with bilateral severe-to-profound pre-or postlingual (sensorineural) hearing loss defined as a hearing threshold of pure-tone average of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz, and 2,000 Hz, and have shown limited or no benefit from hearing aids.

Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is **INVESTIGATIONAL**.

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 <a href="Motor Medical Ly Necessary">NOT MEDICALLY NECESSARY</a>.

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, is <a href="INVESTIGATIONAL">INVESTIGATIONAL</a>.

## Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Indications and Limitations of Coverage Nationally Covered Indications

- 1. Effective for services performed on or after April 4, 2005, 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 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Medicare coverage is provided only for those patients who meet all of the following selection guidelines:
  - 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.
- 2. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

#### **Nationally Non-Covered Indications**

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed are deemed not eligible for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act.

#### Other

All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered above remain at local Medicare Administrator Contractor discretion.

#### National Coverage Determination (NCD) for Cochlear Implantation (50.3)

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&bc=AgAAgAAAAAA&

#### **Prior Authorization Information**

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

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Commercial Managed Care (HMO and POS)	No
Commercial PPO and Indemnity	No
Medicare HMO Blue <sup>SM</sup>	No
Medicare PPO Blue <sup>SM</sup>	No

#### **CPT Codes / HCPCS Codes / ICD-9 Codes**

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's

contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

#### **CPT Codes:**

CPT codes:	Code Description
69930	Cochlear device implantation, with or without mastoidectomy

#### **HCPCS Codes**

HCPCS	
codes:	Code Description
L8614	Cochlear device; includes all internal and external components

#### **ICD-9 Diagnosis Codes**

ICD-9-CM diagnosis codes:	Code Description
389.10	Sensorineural hearing loss, unspecified
389.11	Sensory hearing loss, bilateral
389.12	Neural hearing loss, bilateral
389.14	Central hearing loss
389.16	Sensorineural hearing loss, asymmetrical
389.18	Sensorineural hearing loss, bilateral

### ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis	
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codes:	Code Description
H90.3	Sensorineural hearing loss, bilateral
H90.5	Unspecified sensorineural hearing loss

#### **Description**

A cochlear implant is a device for people with severe-to-profound hearing loss 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.

#### **Background**

The basic components of a cochlear implant include both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are implanted surgically 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 sound into coded signals that are then transmitted transcutaneously 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.

#### **Summary**

A cochlear implant is a device for people with severe-to-profound hearing loss 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.

The available evidence, summarized in multiple systematic reviews and technology assessments, is sufficient to conclude that cochlear implants improve hearing outcomes for both adults and children. Studies show consistent improvement in speech reception (especially in noise) and in sound localization with bilateral devices. Studies also suggest that earlier implantation may be preferred. Based on these studies, and several systematic reviews that have provided additional evidence in support of unilateral and bilateral cochlear implantation, cochlear implants have been shown to provide benefits sufficient to improve net health outcomes in patients with bilateral hearing loss. Therefore, unilateral and bilateral cochlear implants are considered medically necessary for individuals with bilateral hearing loss in individuals aged 12 months and older.

The available 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.

Future controlled studies with appropriate patient selection comparing cochlear implants with alternative treatment options are needed. Therefore, cochlear implantation as a treatment for patients with unilateral hearing loss is considered to be investigational.

Hybrid cochlear implant/hearing aid systems have not been demonstrated to improve outcomes compared with either a cochlear implant alone; therefore, they are considered to be investigational.

#### **Policy History**

Date	Action
10/2014	BCBSA National medical policy review.
	New investigational indications described. Coding information clarified. Effective
	10/1/2014.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
1/2014	Coding information clarified. Updated to add new CPT codes 92521-92524.
12/2013	BCBSA National medical policy review.
	New investigational indications described. Effective 12/1/2013. Coding information
	clarified.
5/2013	New references from BCBSA National medical policy.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
4/2012	No changes to policy statements.
12/2011	BCBSA National medical policy review.
	Changes to policy statements.
3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology.
	No changes to policy statements.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology.
	No changes to policy statements.
3/2009	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology.
	No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology.
	No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology.
	No changes to policy statements.
7/2007	BCBSA National medical policy review.
	No changes to policy statements.

5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology.
	No changes to policy statements.
3/2007	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology.
	No changes to policy statements.

#### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

**Clinical Exception Process** 

Medical Technology Assessment Guidelines

#### References

- FDA. Approval Letter: Nucleus Hybrid L24 Cochlear Implant System -- P130016. 2014. Available online at: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130016a.pdf. Last accessed April 16, 2014
- 2. Food and Drug Administration (FDA). AdreView: Highlights of Prescribing Information. Available online at: http://www.accessdata.fda.gov/drugsatfda\_docs/label/2013/022290s001lbl.pdf. Last accessed May, 2013.
- 3. 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 2009; 13(44):1-330.
- 4. Bond M, Elston J, Mealing S et al. Effectiveness of multi-channel unilateral cochlear implants for profoundly deaf children: a systematic review. Clin Otolaryngol 2009; 34(3):199-211.
- 5. Bond M, Elston J, Mealing S et al. Systematic reviews of the effectiveness and cost-effectiveness of multi-channel unilateral cochlear implants for adults. Clin Otolaryngol 2010; 35(2):87-96.
- 6. M JB, C EV, J JB. Cardiac autonomic nervous system in heart failure: imaging technique and clinical implications. Current cardiology reviews 2011; 7(1):35-42.
- 7. Tamaki N, Yoshinaga K. Novel iodinated tracers, MIBG and BMIPP, for nuclear cardiology. Journal of nuclear cardiology: official publication of the American Society of Nuclear Cardiology 2011; 18(1):135-43.
- 8. Gaylor JM, Raman G, Chung M et al. Cochlear implantation in adults: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg 2013; 139(3):265-72.
- 9. Bittencourt AG, Ikari LS, Della Torre AA et al. Post-lingual deafness: benefits of cochlear implants vs. conventional hearing aids. Braz J Otorhinolaryngol 2012; 78(2):124-7.
- 10. Berrettini S, Baggiani A, Bruschini L et al. Systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in adult patients. Acta Otorhinolaryngol Ital 2011; 31(5):299-310.
- 11. 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 2012; 37(5):342-54.
- 12. van Schoonhoven J, Sparreboom M, van Zanten BG et al. The effectiveness of bilateral cochlear implants for severe-to-profound deafness in adults: a systematic review. Otol Neurotol 2013; 34(2):190-8.
- 13. Smulders YE, Rinia AB, Rovers MM et al. What is the effect of time between sequential cochlear implantations on hearing in adults and children? A systematic review of the literature. Laryngoscope 2011; 121(9):1942-9.
- 14. Sharma A, Dorman MF. Central auditory development in children with cochlear implants: clinical implications. Adv Otorhinolaryngol 2006; 64:66-88.
- 15. Sharma A, Dorman MF, Kral A. The influence of a sensitive period on central auditory development in children with unilateral and bilateral cochlear implants. Hear Res 2005; 203(1-2):134-43.

- 16. 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 2011; 31(5):281-98.
- 17. Black J, Hickson L, Black B et al. Prognostic indicators in paediatric cochlear implant surgery: a systematic literature review. Cochlear Implants Int 2011; 12(2):67-93.
- 18. Pakdaman MN, Herrmann BS, Curtin HD et al. Cochlear Implantation in Children with Anomalous Cochleovestibular Anatomy: A Systematic Review. Otolaryngol Head Neck Surg 2011.
- 19. Roush P, Frymark T, Venediktov R et al. Audiologic management of auditory neuropathy spectrum disorder in children: a systematic review of the literature. Am J Audiol 2011; 20(2):159-70.
- 20. Eze N, Ofo E, Jiang D et al. Systematic review of cochlear implantation in children with developmental disability. Otol Neurotol 2013; 34(8):1385-93.
- 21. Humphriss R, Hall A, Maddocks J et al. Does cochlear implantation improve speech recognition in children with auditory neuropathy spectrum disorder? A systematic review. Int J Audiol 2013; 52(7):442-54.
- 22. 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 2009; 10 Suppl 1:28-32.
- 23. Colletti L. Long-term follow-up of infants (4-11 months) fitted with cochlear implants. Acta Otolaryngol 2009; 129(4):361-6.
- 24. Colletti L, Mandala M, Zoccante L et al. Infants versus older children fitted with cochlear implants: performance over 10 years. Int J Pediatr Otorhinolaryngol 2011; 75(4):504-9.
- 25. Johr M, Ho A, Wagner CS et al. Ear surgery in infants under one year of age: its risks and implications for cochlear implant surgery. Otol Neurotol 2008; 29(3):310-3.
- 26. 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 2010; 74(2):119-26.
- 27. Lammers MJ, van der Heijden GJ, Pourier VE et al. Bilateral cochlear implantation in children: a systematic review and best evidence synthesis. Laryngoscope 2014.
- 28. Sparreboom M, van Schoonhoven J, van Zanten BG et al. The effectiveness of bilateral cochlear implants for severe-to-profound deafness in children: a systematic review. Otol Neurotol 2010; 31(7):1062-71.
- 29. 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 2013; 14 Suppl 4:S19-21.
- 30. Sarant J, Harris D, Bennet L et al. Bilateral Versus Unilateral Cochlear Implants in Children: A Study of Spoken Language Outcomes. Ear Hear 2014.
- 31. 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 2013; 34(4):682-9.
- 32. Vlastarakos PV, Nazos K, Tavoulari EF et al. Cochlear implantation for single-sided deafness: the outcomes. An evidence-based approach. Eur Arch Otorhinolaryngol 2013.
- 33. Arndt S, Aschendorff A, Laszig R et al. Comparison of pseudobinaural hearing to real binaural hearing rehabilitation after cochlear implantation in patients with unilateral deafness and tinnitus. Otol Neurotol 2011; 32(1):39-47.
- 34. Van de Heyning P, Vermeire K, Diebl M et al. Incapacitating unilateral tinnitus in single-sided deafness treated by cochlear implantation. Ann Otol Rhinol Laryngol 2008; 117(9):645-52.
- 35. Arts RA, George EL, Stokroos RJ et al. Review: cochlear implants as a treatment of tinnitus in single-sided deafness. Curr Opin Otolaryngol Head Neck Surg 2012; 20(5):398-403.
- 36. Hansen MR, Gantz BJ, Dunn C. Outcomes after cochlear implantation for patients with single-sided deafness, including those with recalcitrant Meniere's disease. Otol Neurotol 2013; 34(9):1681-7.
- 37. Tavora-Vieira D, Marino R, Krishnaswamy J et al. Cochlear implantation for unilateral deafness with and without tinnitus: a case series. Laryngoscope 2013; 123(5):1251-5.
- 38. Lenarz T, James C, Cuda D et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. Int J Audiol 2013; 52(12):838-48.
- 39. Gifford RH, Dorman MF, Skarzynski H et al. Cochlear implantation with hearing preservation yields significant benefit for speech recognition in complex listening environments. Ear Hear 2013; 34(4):413-25.

- 40. American Academy of Otolarygology-Head and Neck Surgery Foudation. Position Statement on Bilateral Cochlear Implants. 2014 revision. Available online at: http://www.entnet.org/Practice/policyCochlearImplants.cfm. Last accessed March, 2014.
- 41. Blakely B. Hearing: when surgery is appropriate for age-related hearing loss. In Geriatric Care Otolaryngology. American Academy of Otolaryngology-Head and Neck Surgery Foundation, 2006. Pages 11- 14. Available online at: http://www.entnet.org/EducationAndResearch/upload/Chapter-1.pdf. Last accessed March, 2014.
- 42. Chugh SS. Early identification of risk factors for sudden cardiac death. Nature reviews. Cardiology 2010; 7(6):318-26.
- 43. Kuramoto Y, Yamada T, Tamaki S et al. Usefulness of cardiac iodine-123 meta-iodobenzylguanidine imaging to improve prognostic power of Seattle heart failure model in patients with chronic heart failure. The American journal of cardiology 2011; 107(8):1185-90.