KAISER PERMANENTE®

Northwest Utilization Review

UR 41: Cochlear Implants Medical Necessity Criteria

Department: KPNW Utilization Review
Applies to: KPNW Region
Review Responsibility: UROC
SME: John Goddard, MD (ENT)

Number: UR 41
Issued: 4/07
Last Reviewed: 5/22
Last Reviewed/Revised: 6/23, 5/24

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage are determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR COCLEAR IMPLANT

DEFINITIONS

A. Cochlea: a spirally wound, tube-like structure that forms part of the inner ear and is essential for hearing. It is composed of a network of liquid filled tubing and tiny hairs. When sound is sent to the cochlea, it causes ripples in the liquid and the hairs to bend. This movement triggers electrical impulses which are transmitted to the auditory nerve.

B. Cochlear implant device: 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. The purpose is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired. A cochlear implant consists of two (2) main components:
   1. The implant package and electrode array (or receiver-stimulator) – this controls the flow of electrical pulses into the ear and is inserted into the shell-like structure in the inner ear known as the cochlea; and
   2. The external speech processor and headset – a coil is held in position against the skin by a magnet and the microphone is worn behind the ear; the body-worn speech processor can be worn in a pocket, in a belt pouch, or in a harness (the other option is an ear-level speech processor).

C. dB: decibel, unit for expressing loudness of sound

D. Hz: hertz, unit for expressing frequency of sound

E. The Lexical Neighborhood Test and the Multi-syllabic Lexical Neighborhood Test, designed for children who may be cochlear implant candidates, assess recognition of words and individual sounds. The results are used as a benchmark for children with hearing impairment.

F. Middle ear: the hollow portion of the ear behind the eardrum. The middle ear contains one or more ossicles, which amplify vibration of the eardrum into pressure waves in the fluid in the inner ear.

POLICY AND CRITERIA

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	NCD 50.3 "Cochlear Implantation"
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	For Medicare lines of business, apply the criteria in the NCD.

For Non-Medicare Members

MEDICAL NECESSITY CRITERIA

A. Adults (age 18 or older) with 1 or 2 below in addition to 3 through 5:
   1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing aids.
      a. Limited benefit from binaural amplification: defined by test scores of ≤50% correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and ≤60% in the opposite ear (See Special Group Considerations below for Medicare criteria).
      b. Profound sensorineural hearing loss: for individuals older than 24 months, the pure tone average for both ears should equal or exceed 70dB at 500Hz, 1000Hz, and 2000Hz.
   2. Single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in the ear to be implanted and normal hearing or mild to moderate sensorineural hearing loss in the other ear.
   3. For single sided deafness, cochlear implant is not recommended if profound hearing loss for over 10 years.
   4. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.
   5. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.

B. Children (age 9 months through 17 years) with 1 or 2 below in addition to 3 through 9:
   1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from binaural amplification, defined by test scores of ≤50% correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and ≤60% in the opposite ear.
   2. For patients 5 years and older with single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in the ear to be implanted and normal hearing or mild to moderate sensorineural hearing loss in the other ear.
   3. For single sided deafness, cochlear implant is not recommended if profound hearing loss for over 10 years.
   4. For children age 12-24 months, profound sensorineural hearing loss: thresholds of 90dB or greater at 1000Hz.

5. For children age 24 months to 17 years, pure tone average of 70dB or greater at 500Hz, 1000Hz, and 2000Hz.
6. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six-month period.
   In older children, lack of aided benefit is defined as ≤30% correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills.
7. A three to six-month hearing aid trial is required for children without previous experience with hearing aids. Radiographic evidence of labyrinthine fibrosis that would lead to ossification will justify implantation without a trial of amplification.
8. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.
9. Freedom from lesions in the auditory nerve and acoustic areas of the central nervous system.

OTHER REQUIREMENTS or CONSIDERATIONS

Replacement of battery charger is not covered; replacement of batteries is covered for all members. Replacement of a cochlear implant and/or its external components is considered medically necessary when the existing device cannot be repaired or when replacement is required because a change in the member's condition makes the present unit non-functional and improvement is expected with a replacement unit. Must be performed in an ambulatory surgery center (ASC) or an inpatient or outpatient hospital facility.

CONTRAINDICATIONS

A. Agenesis of the 8th cranial nerve
B. Complete CN aplasia
C. Pathologies of the central auditory pathway
D. Michel deformity (complete labyrinthine aplasia/non-development) present
E. Known intolerance to materials used in the implant
F. Perforated tympanic membrane
G. Deafness attributed to central damage of the acoustic nerve or central auditory pathway
H. External or middle ear infection present

SPECIAL GROUP CONSIDERATIONS

Oregon Medicaid: See Prioritized List

OREGON: Senate Bill 491 requires that bilateral cochlear implants be provided when medically necessary.

RATIONALE

EVIDENCE BASIS

MCG reviewed the evidence on cochlear implants in 2022. Their findings are provided below:

For adults with hearing loss, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review and meta-analysis of 14 studies (679 adult patients) evaluating quality of life improvement after cochlear implantation found that cochlear implantation was associated with significant

improvement in quality of life measured by hearing-specific or cochlear implant-specific quality of life patient-reported outcomes.[1] A systematic review of 3 randomized controlled trials and 7 observational studies (308 adult patients) with severe to profound sensorineural hearing loss found that compared with unilateral cochlear implantation, bilateral cochlear implantation was associated with improved speech perception in noise, sound localization, and subjective improvements in speech and spatial hearing.[2] A systematic review of unilateral vs bilateral cochlear implantation in adults concluded that unilateral implantation with or without the use of hearing aids was effective for improving speech perception in adults with severe to profound sensorineural hearing loss; both simultaneous and sequential bilateral cochlear implantation provided additional improvement in speech perception.[3] A systematic review of 14 studies comparing unilateral cochlear implant with or without hearing aid on the non-implant ear vs bilateral cochlear implant found benefit for bilateral implants in noise conditions and in several self-reported outcome measures.[4] A systematic review of sequential cochlear implants in adults and children found that although the quality of the studies was poor, the evidence suggested that a second implant can be beneficial even if there is a substantial interval between implants.[5] An industry-sponsored randomized controlled trial of 38 adults with postlingual, severe to profound hearing loss compared simultaneous and sequential (2 years between procedures) bilateral cochlear implants and found, 1 year after both implants were in place, comparable results between the groups in terms of speech intelligibility in noise from straight ahead, from spatially separated sources, and in silence. The authors concluded that patients who receive sequential implants derive the same benefit as those who receive them simultaneously.[6] A national guideline recommends simultaneous bilateral cochlear implantation only for adults with severe to profound deafness who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism of spatial awareness.[7] Most adult patients who receive a cochlear implant have improvement in both hearing threshold and ability to lip-read. Postlingual deaf adults attain scores of 90% to 100% for speech-reading capabilities on everyday sentence material and above 80% for high-content sentences after cochlear implant. Over half of postlingual deaf adults can achieve some degree of telephone conversational ability after cochlear implant.[8] A prospective study of 94 postlingual deaf patients (65 to 85 years of age) who were treated with cochlear implants for sensorineural hearing loss found a mean improvement in speech perception scores of 52% at 6 months, with continued improvement at 12 months; there was also significant improvement in quality of life. Patients with depression, as assessed by the Geriatric Depression Scale-4 (GDS-4), decreased from 41% to 24% at 12 months after implantation.[9] A literature review of patients 65 years and older who were treated with cochlear implants found that patients showed improvement in speech outcomes and quality of life and had similar device complication rates as compared with younger patients. The authors concluded that elderly age should not exclude appropriate candidates for a cochlear implant.[10] A prospective study of 20 patients with asymmetric hearing loss found, at 1-month follow-up, that cochlear implantation in the affected ear was associated with decreased tinnitus severity and improved sound localization and hearing-specific quality of life, as compared with preoperative measurements; the improvements were sustained at 12-month follow-up.[11] A technology assessment found moderate-quality evidence that cochlear implants improve sound localization, speech perception in noise, tinnitus symptoms, and quality of life in adults and children with single-sided deafness or asymmetric hearing loss.[12]

For infants or children with hearing loss, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review of prognostic factors for cochlear implant in children found that improved outcomes were associated with early implant, congenital deafness due to GJB-2 gene mutation, less severe inner ear malformations, and early implant of postmeningitic or congenitally deaf children.[13] Multiple studies of

unilateral cochlear implant in children demonstrate that functional outcomes are improved when the surgery is performed at a younger age. Eligible children should receive a cochlear implant as soon as bilateral profound hearing impairment is diagnosed to maximize speech and language achievement and integration into an oral communication environment. Children who are implanted when younger than 2 years can experience normal or near-normal rates of auditory skill and oral language development. However, even in older children, the oral language and speech benefits of implant are substantial for those who have some residual hearing because they are able to hear more speech and sound information with the cochlear implant than with a hearing aid.[14-18] A systematic review of 14 studies evaluating the effect of early (before 12 months) cochlear implantation found better scores on speech production, auditory performance, and some receptive language tests in children implanted before 12 months compared with those implanted later. However, the authors noted that the available evidence consisted of cohort studies with moderate to high risk of bias, and recommended long-term follow-up studies.[19] A systematic review of 4 studies with a total of 103 pediatric patients found that simultaneous bilateral implantation, as compared with sequential bilateral implantation, resulted in statistically significant higher speech and language development scores 3 years after the first cochlear implantation.[20] Children with bilateral cochlear implants that are activated at earlier ages and with shorter gaps between surgeries appear to receive greater benefit than those implanted later and with longer gaps between surgeries.[21] Other systematic reviews that compared bilateral cochlear implant with unilateral implant in children found that, although the data are limited, bilateral cochlear implant appeared to be more effective in terms of sound localization and improved speech perception in quiet and noise.[22-24] A systematic review and meta-analysis of 12 observational studies with 119 pediatric patients (mean age 6.6 years) with single-sided deafness (unaided pure-tone average of 90 dB or greater in one ear) found that cochlear implants improved speech perception in noise in 79.6% of patients and speech perception in quiet in 81% of patients; cochlear implants were also associated with improved sound localization.[25] A technology assessment found moderate-quality evidence that cochlear implants improve sound localization, speech perception in noise, tinnitus symptoms, speech and language development, and quality of life in children with single-sided deafness or asymmetric hearing loss.[12] A systematic review of 13 studies with a total of 1073 pediatric patients compared the outcome of cochlear implantation in children with normal development to those with mild to severe developmental disability; children with mild developmental delay had similar receptive and expressive language outcomes as compared with children without developmental delay, but children with severe developmental delay had worse outcomes. Careful preoperative and postoperative counseling may be particularly important in this patient population.[26] A retrospective study of factors associated with limited use and nonuse of cochlear implants in children found that disabilities (eg, cerebral palsy, autism, moderate mental retardation, attention-deficit hyperactivity disorder, learning disability) and lack of family interest were factors that required more support to ensure adequate use.[27]

REFERENCES

1. McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of quality-of-life improvement after cochlear implantation and associations with speech recognition abilities. *Laryngoscope*. Apr 2018;128(4):982-990.
2. Bilateral Cochlear Implantation: A Health Technology Assessment. *Ont Health Technol Assess Ser*. 2018;18(6):1-139.
3. 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):265-72.

4. 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*. Feb 2013;34(2):190-8.
5. Smulders YE, Rinia AB, Rovers MM, van Zanten GA, Grolman W. What is the effect of time between sequential cochlear implantations on hearing in adults and children? A systematic review of the literature. *Laryngoscope*. Sep 2011;121(9):1942-9.
6. Kraaijenga VJC, Ramakers GGJ, Smulders YE, et al. Objective and Subjective Measures of Simultaneous vs Sequential Bilateral Cochlear Implants in Adults: A Randomized Clinical Trial. *JAMA Otolaryngol Head Neck Surg*. Sep 1 2017;143(9):881-890.
7. NICE. Cochlear Implants for Children and Adults With Severe to Profound Deafness. National Institute for Health and Care Excellence. Accessed May 15, 2023.
8. Koch DB, Staller S, Jaax K, Martin E. Bioengineering solutions for hearing loss and related disorders. *Otolaryngol Clin North Am*. Apr 2005;38(2):255-72.
9. Mosnier I, Bebear JP, Marx M, et al. Improvement of cognitive function after cochlear implantation in elderly patients. *JAMA Otolaryngol Head Neck Surg*. May 1 2015;141(5):442-50.
10. Cosetti MK, Lalwani AK. Is cochlear implantation safe and effective in the elderly? *Laryngoscope*. Jun 2015;125(6):1279-81.
11. Dillon MT, Buss E, Rooth MA, et al. Effect of Cochlear Implantation on Quality of Life in Adults with Unilateral Hearing Loss. *Audiol Neurootol*. 2017;22(4-5):259-271.
12. Implantable Devices for Single-Sided Deafness and Conductive or Mixed Hearing Loss: A Health Technology Assessment. *Ont Health Technol Assess Ser*. 2020;20(1):1-165.
13. Black J, Hickson L, Black B, Perry C. Prognostic indicators in paediatric cochlear implant surgery: a systematic literature review. *Cochlear Implants Int*. May 2011;12(2):67-93.
14. Niparko JK, Tobey EA, Thal DJ, et al. Spoken language development in children following cochlear implantation. *Jama*. Apr 21 2010;303(15):1498-506.
15. Peterson NR, Pisoni DB, Miyamoto RT. Cochlear implants and spoken language processing abilities: review and assessment of the literature. *Restor Neurol Neurosci*. 2010;28(2):237-50.
16. Sharma SD, Cushing SL, Papsin BC, Gordon KA. Hearing and speech benefits of cochlear implantation in children: A review of the literature. *Int J Pediatr Otorhinolaryngol*. Jun 2020;133:109984.
17. Tait ME, Nikolopoulos TP, Lutman ME. Age at implantation and development of vocal and auditory preverbal skills in implanted deaf children. *Int J Pediatr Otorhinolaryngol*. Apr 2007;71(4):603-10.
18. White JR, Preciado DA, Reilly BK. Special Populations in Implantable Auditory Devices: Pediatric. *Otolaryngol Clin North Am*. Apr 2019;52(2):323-330.
19. Bruijnzeel H, Ziylan F, Stegeman I, Topsakal V, Grolman W. A Systematic Review to Define the Speech and Language Benefit of Early (<12 Months) Pediatric Cochlear Implantation. *Audiol Neurootol*. 2016;21(2):113-26.
20. Lammers MJ, Venekamp RP, Grolman W, van der Heijden GJ. Bilateral cochlear implantation in children and the impact of the inter-implant interval. *Laryngoscope*. Apr 2014;124(4):993-9.
21. Simon F, Roman S, Truy E, et al. Guidelines (short version) of the French Society of Otorhinolaryngology (SFORL) on pediatric cochlear implant indications. *Eur Ann Otorhinolaryngol Head Neck Dis*. Oct 2019;136(5):385-391.
22. Lammers MJ, van der Heijden GJ, Pourier VE, Grolman W. Bilateral cochlear implantation in children: a systematic review and best-evidence synthesis. *Laryngoscope*. Jul 2014;124(7):1694-9. doi:10.1002/lary.24582
23. Murphy J, O'Donoghue G. Bilateral cochlear implantation: an evidence-based medicine evaluation. *Laryngoscope*. Aug 2007;117(8):1412-8.
24. 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*. Sep 2010;31(7):1062-71.
25. Benchetrit L, Ronner EA, Anne S, Cohen MS. Cochlear Implantation in Children With Single-Sided Deafness: A Systematic Review and Meta-analysis. *JAMA Otolaryngol Head Neck Surg*. Jan 1 2021;147(1):58-69.

26. Eze N, Ofo E, Jiang D, O'Connor AF. Systematic review of cochlear implantation in children with developmental disability. *Otol Neurotol*. Oct 2013;34(8):1385-93.
27. Özdemir S, Tuncer Ü, Tarkan Ö, Kıroğlu M, Çetik F, Akar F. Factors contributing to limited or non-use in the cochlear implant systems in children: 11 years experience. *Int J Pediatr Otorhinolaryngol*. Mar 2013;77(3):407-9.
28. https://www.cochlear.com/us/en/professionals/products-and-candidacy/candidacy/cochlear-implant