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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cochlear Implant

- Cochlear Implant Device
- Hybrid Cochlear Implant

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Cochlear Implantation (50.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Service	Criteria Used
Cochlear Implant	Kaiser Permanente has elected to use the Cochlear Implant (KP-0177 12012022v2) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • Most recent audiogram/hearing test • Most recent clinical notes from requesting provider &/or specialist (otolaryngology, ENT)
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	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

***MCG Manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

A cochlear implant is an electronic device that can enable patients with severe to profound hearing loss to perceive sound. Cochlear implants have two main parts:

1) An internal device that is implanted under the skin behind the ear; and
2) A speech processor that is worn or carried (externally) by the individual.

Sounds are detected by a microphone and transformed into an electrical signal. The speech processor codes the signals into a particular pattern of electrical pulses. The pulses are sent to the implant, which in turn transmits them via the auditory nerve to the brain, which recognizes them as sound. Use of a cochlear implant requires both a surgical procedure to implant the device, and substantial post-implantation therapy to learn or re-learn the sense of hearing. In the United States, approximately 22,000 adults have cochlear implants and about 15,000 children have received them (NIDCD, 2006).

Provision of unilateral cochlear implants is currently standard practice. Although results are often positive, particularly in the ability to understand speech in a quiet situation, normal hearing is not restored. There is increasing interest in bilateral cochlear implants to further improve the ability to patients to detect sound. Potential advantages of bilateral implantation include improvements in:

- Hearing in noise, due to the ability to benefit from a “head shadow effect
- Speech perception, due to the availability of sound information from both ears;
- Sound localization, the ability to correctly identify the directional location of sounds surrounding the listener (Litovsky et al., 2006; Tyler et al., 2003).

A potential problem with bilateral cochlear implants is that bilateral coordination of pulsed signals is not yet possible. Instead, the two implants function independently. This is not likely to be as effective as normal binaural hearing which takes advantages of the integration of binaural acoustical cues. In addition, patients with severe hearing loss may have different patterns of loss on each side, and also may have developed abnormal binaural brain maps (Tyler et al., 2003). Response to bilateral cochlear implants, especially localization ability, may also depend on previous experience with hearing. Adults who have had exposure to binaural stimulation early in life appear to perform better with bilateral cochlear implants than adults who were born without hearing or lost hearing at a very young age (Litovsky et al., 2006).

Experts have pointed out that a challenge in studying the effectiveness of bilateral cochlear implants is that learning may influence an individual’s ability to detect aural cues, either unilateral or bilateral. Studies that evaluate users of bilateral implants without comparing them to experienced users of unilateral users may be limited because they do not include patients who have been able to adapt to listening through one device.

Medical Technology Assessment Committee (MTAC)

Hybrid Cochlear Implant

BACKGROUND

Sensorineural hearing loss (SHL) is the most common form of hearing loss occurring when there is damage to the inner ear or the nerve pathway from the inner ear to the brain. Causes are variable and range from aging and heredity, all the way to exposure to loud noises and drugs toxic to the inner ear. SHL typically results in difficulty hearing faint sounds, understanding people with higher-pitched voices, hearing certain speech sounds, and in some cases, hearing high-pitched emergency vehicle sirens or common safety alarms, such as smoke detectors. Any type of hearing loss can be debilitating and can affect people in various ways.

Conventional treatment options for hearing loss are dependent on the type and source of hearing loss. While hearing loss cannot be fully restored, a wide variety of technologies are currently available to improve hearing. These technologies utilize either air or bone conduction to transmit sound. Air conduction hearing aids (ACHA), for example, receive sound waves through a microphone which are then converted to electrical signals and amplified through a speaker in the ear. Alternatively, bone anchored hearing aids (BAHA) transmit sound vibrations directly to the inner ear through the skull, bypassing the outer and middle ear completely. In any case, both technologies come with strengths and limitations.

The Nucleus® Hybrid™ L24 Cochlear Implant System, developed by Cochlear® (Centennial, CO), combines the functions of both ACHA and BAHA in a single device. The device specifically uses acoustic amplification to amplify low frequency hearing, while taking advantage of cochlear implant technology to restore access to the high-frequency hearing allowing a near normal hearing experience. The hybrid technology requires surgical

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implantation, similar to that of a standard cochlear implant with the main difference being that the array is shorter and therefore not inserted as far into the cochlear.
The United States Food and Drug Administration (FDA) approved the first hybrid cochlear implant in March of 2014. The Medical Technology and Assessment Committee (MTAC) has not previously assessed hybrid cochlear implants and is currently reviewing the topic to support a coverage decision.

08/17/2015: MTAC REVIEW
Hybrid Cochlear Implant
Evidence Conclusion: *Effectiveness*: A multi-centered European study, carried out by Lenarz and colleagues, investigated hearing conservation in 66 patients with significant low-frequency residual hearing using the Nucleus Hybrid L24 cochlear implant. The investigators compared pre- and post-operative performance in speech recognition scores in both quiet and noisy environments were significantly improved for 65% and 73% of subjects, respectively. In addition, the mean speech spatial and quality subscale ratings were significantly improved by 1.2, 1.3 and 1.8 points, respectively ($p<0.001$). Ultimately, the investigators concluded that the hybrid cochlear implant preserved low-frequency residual hearing and improved speech perception (Lenarz, James et al. 2013). [Evidence Table 1] A similar study, conducted by Roland et al. in multiple centers across the US, included 50 individuals with severe to profound high-frequency hearing loss. In the same way as the European trial, pre- and post-operative performance was measured on consonant-nucleus-consonant words, AzBio sentence noise as well as self-assessment. At six months, the investigators reported that a majority of the patients had statistically significant improvements in word and sentence recognition leading the investigators to conclude that the Nucleus Hybrid L24 cochlear implant provides significant improvements to hearing (Roland, Gantz et al. 2015). [Evidence Table 2]
Safety: The safety profile on these devices is not entirely clear. Both of the included studies detail a number of adverse effects including dizziness, irritation and tinnitus to name a few. Beyond that, the literature reports risk of permanent damage to residual hearing fibers from the surgery and placement of the electrode itself. A larger long-term concern is associated with future changes in hearing in the implanted ear. Specifically, should the patient experience additional hearing loss, will they need additional surgery using a longer standard electrode.
Collectively, the evidence is limited by small sample sizes, lack of randomization and inadequate comparison groups. To add to this, neither of the studies provide a sufficient follow-up period. Finally, both of the studies are sponsored by the device manufacturer leaving the studies open to potential bias. Ultimately, the evidence does not adequately support the safety and effectiveness of the hybrid cochlear implant. The evidence base would benefit from large RCTs with extended follow-up to establish long-term performance and safety.
Conclusions: There is insufficient evidence to support the effectiveness of a hybrid cochlear implant with external hearing aid compared with a standard cochlear implant. There is insufficient to establish the safety of hybrid cochlear implant with standard cochlear implant.
Articles: The search returned a small variety of publications including retrospective analyses, small single arm prospective studies and one cross-sectional study (Golub, Won et al. 2012; Nguyen, Mosnier et al. 2012; Reiss, Turner et al. 2012; Szyfter, Wróbel et al. 2013; Jurawitz, Büchner et al. 2014). The literature was specifically screened for randomized controlled trials (RCTs) with the overall aim to compare hybrid cochlear implants with conventional cochlear implants. In the absence of RCTs with appropriate comparators, the best available evidence came from two prospective, single arm studies (one of which supported the 2014 FDA approval) were selected for critical appraisal. The following articles were selected for review: Lenarz T, James C, Cuda D, et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. *International Journal of Audiology*. 2013; 52:838-848. See Evidence Table 1. Roland JT, Gantz BJ, Waltzman SB, et al. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. *Laryngoscope.* 2015. See Evidence Table 2.

The use of hybrid cochlear implants does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Cochlear Implant - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69930	Cochlear device implantation, with or without mastoidectomy
HCPC Codes	**Description**
L8614	Cochlear device, includes all internal and external components
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement

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L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement

Hybrid Cochlear Implant - Considered Not Covered:

Same as listed above and billed with HCPC Code	Description
L8614	Cochlear device, includes all internal and external components

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
03/20/1995	09/07/2010 MDCRPC, 10/05/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013 MDCRPC, 01/07/2014 MPC, 11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC, 02/01/2022MPC, 02/07/2023MPC, 07/02/2024MPC	02/06/2025

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt updates to the Cochlear Implant criteria (KP-0177) Specific changes include but not limited to: • No longer indicates a need to place one implant at a time and that evidence supports concurrent bilateral implants specifically for adults • Added “replacement exclusion” language from commercial contracts Removed non-applicable CPT codes: 69714, 69715, 69717, 69718
03/02/2021	MPC approved the updated recommendations to the current hybrid criteria for Cochlear Implant to include indications for unilateral sensorineural hearing loss for ages 5 years old and older. Requires 60-day notice, effective date 08/01/2021.
07/05/2022	MPC approved to update the hybrid criteria (KP-0177) to include indications for single-sided deafness and include clarifying language for obsolescence/warranty. Requires 60-day notice, effective date 12/01/2022.
07/02/2024	MPC approved Cochlear Implant into the Care Delivery Medical Necessity Review program.
02/06/2025	Removed MTAC Reviews on Bilateral Cochlear Implants from 2004 and 2006 as it is no longer applicable and covered using KP/MCG Guidelines.

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