KAISER PERMANENTE®	Cochlear Implants and Auditory Brain Stem Implants
Mid-Atlantic States	Medical Coverage Policy

### Utilization \*ALERT\*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- This medical coverage policy includes cochlear implants only
- For auditory brainstem implant devices and services, please consult the current edition of MCG.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.

#### I. Procedure / Service Cochlear Implants

II. Diagnosis Moderate-to-profound sensorineural hearing loss

III. Specialties Otolaryngology, Audiology

### IV. Adult Criteria Cochlear Implants

Kaiser Permanente Mid-Atlantic States considers implantation of a cochlear implant medically necessary when the following criteria are met for adults aged 18 years of age or older.

- **A.** The patient must have moderate to profound sensorineural hearing loss (SNHL).
  - 1. The hearing loss may be pre-lingual or post-lingual.
  - 2. The hearing loss is determined by a pure tone average (PTA) of at least 70 dB at 500 Hz, 1000 Hz, and 2000 Hz.
- B. The patient must have obtained limited benefit from a trial of appropriately fitted binaural hearing aids, worn on a full-time basis (at least 8 hours per day) for a minimum of 6 weeks. Limited benefit from amplification is defined by scoring 50% or less correct in optimum listening conditions on open-set sentence recognition testing (AzBios sentence lists or other appropriate sentence-level speech testing).

<sup>&</sup>lt;sup>1</sup> FDA approval for hybrid cochlear implants is for unilateral only.

Hybrid criteria aligns with CMS Medicare coverage requirements.

<sup>&</sup>lt;sup>2</sup> Based on manufacturers' recommended screening methods for cochlear implants.

<sup>&</sup>lt;sup>3</sup> CROS/BICROS hearing aids: With a CROS system hearing aids are worn on both ears. The sound detected by the aid on the "bad ear" is transmitted directly to the aid on the "good ear". This allows for signals to be perceived on both sides of the head to be heard in one ear. BICROS hearing aids are designed for people who have hearing loss in their "good ear" too. With the BICROS system the aid in the "good ear" will be programmed for any amplification needed.

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- **C.** Hybrid cochlear implants may be considered for unilateral implantation<sup>1</sup> in individuals with all of the following auditory measurements
  - 1. Bilateral severe-to-profound sensorineural hearing loss in the high frequencies (defined by a PTA at 2000, 3000 and 4000 Hz of ≥ 60 dB HL)
  - 2. The ear to be implanted, an aided consonant nucleus consonant (CNC) word recognition score between 10% and 60% (inclusive)
  - 3. For the contralateral (non-implant) ear, not better than 80% correct on aided CNC word recognition testing.
- **D.** There should be no contraindications for surgery.
- **E.** The patient also must be able and willing to undergo post-surgical program of aural rehabilitation.

# V. Pediatric Criteria Cochlear Implants

- A. For ALL children between 9 months and 18 years of age
  - 1. The patient must have severe to profound bilateral sensorineural hearing loss (determined by PTA of at least 90 dB at 500 Hz, 1000 Hz, and 2000 Hz.)
  - 2. In addition, the patient must receive limited benefit from a 3-month trial of appropriately fitted hearing aids.
  - 3. If there is a diagnosis of cochlear ossification, the requirement for a hearing aid trial may be waived.

# B. For children under age 4 years

The following defines and quantifies the child's limited benefit from hearing aids

1. Limited benefit is defined as failure to reach developmentally appropriate auditory milestones in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3–6-month period.

<sup>&</sup>lt;sup>1</sup> FDA approval for hybrid cochlear implants is for unilateral only.

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 Quantification of "limited benefit" should be measured using the Meaningful Auditory Integration Scale or the Early Speech Perception Test or obtaining <20% correct on the Multi-Syllabic Lexical Neighborhood Test (MLNT).

### C. For children 5 years of age and older

The following defines and quantifies the child's limited benefit from hearing aids

- 1. Limited benefit is described as scoring <20% on open-set sentence discrimination
- 2. Quantification of "limited benefit" should be measured using the
  - a. Multi-Syllabic Lexical Neighborhood Test or the Lexical Neighborhood Test; or,
  - b. 12% or less on the Phonetically Balanced Kindergarten (PBK) Test<sup>2</sup>: or,
  - **c.** The pediatric AzBios sentence test.<sup>2</sup>

### VI. Unilateral Cochlear Implantation for Single-Sided Deafness and Asymmetric Hearing Loss

- A. For ALL children between 9 months and 18 years of age
  - 1. The patient must have severe to profound unilateral sensorineural hearing loss (determined by PTA of at least 90 dB at 500 Hz, 1000 Hz, and 2000 Hz.)
  - 2. In addition, the patient must receive limited benefit from a 3-month trial of appropriately fitted hearing aids.
  - 3. If there is a diagnosis of cochlear ossification, the requirement for a hearing aid trial Bimay be waived.

## B. For children under age 4 years

The following defines and quantifies the child's limited benefit from hearing aids

 Limited benefit is defined as failure to reach developmentally appropriate auditory milestones in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3–6-month period.

<sup>&</sup>lt;sup>1</sup> FDA approval for hybrid cochlear implants is for unilateral only.

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 Quantification of "limited benefit" should be measured using the Meaningful Auditory Integration Scale or the Early Speech Perception Test or obtaining <20% correct on the Multi-Syllabic Lexical Neighborhood Test (MLNT).

## C. For children 5 years of age and older

The following defines and quantifies the child's limited benefit from hearing aids

- 1. Limited benefit is described as scoring <20% on open-set sentence discrimination
- 2. Quantification of "limited benefit" should be measured using the
  - a. Multi-Syllabic Lexical Neighborhood Test or the Lexical Neighborhood Test; or,
  - b. 12% or less on the Phonetically Balanced Kindergarten (PBK) Test3: or,
  - **c.** The pediatric AzBios sentence test.<sup>2</sup>

# D. Unilateral Cochlear Implantation for Single-Sided Deafness and Asymmetric Hearing Loss - Candidacy Criteria

- 1. Aged 5 years and older
- 2. Profound sensorineural hearing loss (SHNL) in one ear
  - a. Pure tone average of 90 dB hearing loss or greater at 500 Hz, 1000 HZ, 2000 Hz and 4000 Hz
  - b. Duration of loss in affected ear must be between 0.5-10 years
- 3. Adults with short duration profound hearing loss and severe Tinnitus
  - a. Based on Tinnitus Functional Index (TKI) and Tinnitus Handicap Inventory (THI)
  - b. No improvement with non-surgical tinnitus management including but not limited to pharmaceutical or psychiatric treatment.
- 4. Poor unaided word recognition
  - a. <= 30% unaided word recognition score (WRS) needed for referral criteria
- 5. Limited benefit from an appropriately fitted unilateral hearing aid
  - a. <= 50% aided performance on an appropriate measure of speech perception

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- 6. Patients must complete a minimum one month trial of hearing aid, CROS, BICROS<sup>3</sup> or Baha<sup>4</sup> in the affected ear without subjective benefit.
- 7. Stable psychological status

### VII. Bilateral and Unilateral Implants, Replacements and Upgrades

### A. Internal Components

- 1. A second, contralateral cochlear implant is considered medically necessary when a patient who has an existing single implant, derives little or no benefit from an appropriately-fitted hearing aid to the non-operated ear;
- 2. Persons with a unilateral cochlear implant may qualify for subsequent bilateral implantation without having to be retested if medical records document that they had met the criteria at the time of the initial (first) cochlear implantation); and
- **3.** A replacement of an existing internal implant is considered medically necessary when the current implant is at or near the end of functional life and cannot be repaired.

## B. External Component(s)

External component (speech processor) replaced/upgraded when the current speech processor is no longer under warranty **<u>and</u>** is considered obsolete by the manufacturer, i.e. not supported for parts or repair.

We will cover upgrades in the 6 months prior to the obsolescence date. It is not medically necessary to upgrade prior to this time.

We will cover upgrades in the 6 months prior to the obsolescence date. It is not medically necessary to upgrade prior to this time. Medicare considers the reasonable useful life of a speech processor to be no less than 5 years. We will cover upgrades for KP Medicare patients, after a minimum of 5 years of use, 6 months prior to the obsolescence date as determined by the manufacturer.

## VIII. Contraindications for bilateral and unilateral implants

- A. Absent Cochlea or absent Cochlear nerve/auditory pathway;
- B. Anatomic abnormalities of the skull which could interfere with housing placement;
- **C.** Unstable psychological status as determined by a focused psychological assessment;

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- D. Profound hearing loss for over 10 years.;
- E. Acoustic neuroma;
- F. Medical contraindications against surgery of the middle and inner ear and/or anesthesia; and
- **G.** Known intolerance of cochlear implant materials.

### IX. Exclusions and Limitations

- A. Upgrading or replacement of components is NOT medically necessary if the request is made for convenience or to upgrade to newer technology (e.g., upgrading processor from body-worn to behind-the-ear, newer speech processor or wireless technologies or waterproof technologies) and the current components are functional;
- **B.** Device replacement is not solely based on the expiration of device warranty;
- **C.** Cochlear implantation is not covered for a diagnosis of tinnitus unless the individual also meets the sensorineural hearing loss criteria;
- **D.** Replacement or repair of lost parts is not covered;
- E. KP follows Medicare rules in considering cochlear implants and auditory brainstem implants as prosthetics. Medicare considers as prosthetics "cochlear implants and auditory brainstem implants i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays".

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Adult Hearing Aid Users 65 Years or Older: A Secondary Analysis of a Nonrandomized Clinical Trial. *JAMA otolaryngology-- head & neck surgery*, *146*(10), 925–932. <u>https://doi.org/10.1001/jamaoto.2020.1585</u>

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## **Approval History**

Date approved by RUMC*	Date filed with the State of Maryland	Date of Implementation (Ten days after filing)
08/09/2012	08/14/2012	08/25/2012
08/28/2013	08/29/2013	09/10/2013
08/26/2014	08/28/2014	09/08/2014
08/27/2015	08/28/2015	09/08/2015

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#### **Approval History**

Effective June 01, 2016, state filing no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
08/29/2016	08/29/2016
08/29/2017	08/29/2017
08/30/2018	08/30/2018
08/28/2019	08/28/2019
08/26/2020	08/26/2020
08/17/2021	08/17/2021
07/26/2022	07/26/2022
06/26/2023	06/26/2023
06/25/2024	06/25/2024

\*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

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Hybrid criteria aligns with CMS Medicare coverage requirements.

<sup>2</sup> Based on manufacturers' recommended screening methods for cochlear implants.

<sup>3</sup> CROS/BICROS hearing aids: With a CROS system hearing aids are worn on both ears. The sound detected by the aid on the "bad ear" is transmitted directly to the aid on the "good ear". This allows for signals to be perceived on both sides of the head to be heard in one ear. BICROS hearing aids are designed for people who have hearing loss in their "good ear" too. With the BICROS system the aid in the "good ear" will be programmed for any amplification needed.