PURPOSE:
The purpose of this policy is to define Maryland Care, Inc., dba Maryland Physicians Care (MPC) clinical guidelines for the review and coverage of audiology services using the MDH criteria for coverage.

POLICY:
Effective July 1, 2018 Maryland Physicians Care authorizes medically necessary audiology services and devices as outlined in COMAR. The services must be provided in accordance with the regulations for Maryland Medical Assistance Audiology Services. The prior authorization department will utilize the MDH criteria when reviewing for audiology services and devices.

The following devices are covered under this policy: hearing aids, Cochlear implants, auditory osseointegrated devices, and related services. Prior authorization is required for these services. The services must be rendered or initiated within 6 months from the date the authorization was issued. The patient must be eligible at the time the service is rendered.

Maryland Physicians Care covers the following medically necessary services if the clinical coverage criteria are met:

1. Audiology services
   - Audiology assessments using procedures appropriate for the member’s developmental age and abilities; and
   - Hearing-aid evaluations and routine follow-up for members with an identified hearing impairment, who currently use or are being considered for hearing aids.

2. Hearing amplification services
   - Unilateral or bilateral hearing aids which are medically necessary and are:
     - Not used or rebuilt, and which meet the current standards set forth in 21 CFR §§801.420 and 801.421, which are incorporated by reference;
     - Recommended and fitted by an audiologist when in conjunction with written medical clearance from a physician who has performed a medical examination within the past 6 months;
     - Sold on a 30-day trial basis; and
     - Fully covered by a manufacturer’s warranty for a minimum of 2 years at no cost to the Program
   - Hearing aid accessories and services, as listed below:
3. Cochlear implants and related services, as listed below:

- Unilateral or bilateral implantation of cochlear implant or implants which are medically necessary
- Post-operative evaluation and programming of the cochlear implant or implants
- Aural rehabilitation services, and
- Repair or replacement of cochlear implant device components subject to the limitations in COMAR 10.09.51.05

4. Auditory osseointegrated device or devices and related services, as listed below:

- Unilateral or bilateral implantation of auditory osseointegrated devices which are medically necessary
- Non-implantable or soft band device or devices for members younger than 5 years old
- Evaluation and programming of the auditory osseointegrated device or devices and
- Repair or replacement, or both of auditory osseointegrated device components subject to the limitations in COMAR 10.09.51.05.

Limitations of covered audiology services including hearing aids, cochlear implants and auditory osseointegrated devices:

- One audiology assessment per year, unless the time limitation is waived by MDH
- The initial coverage of:
  - Unilateral and bilateral hearing aids for children younger than 21 years old
  - Unilateral hearing aids for members 21 years old or older unless otherwise approved by the Department or its designee
  - Bilateral cochlear implants for members younger than 21 years old
  - Unilateral cochlear implants for members 21 years old or older
  - Bilateral auditory osseointegrated devices for members younger than 21 years old, and
  - Unilateral auditory osseointegrated devices for members 21 years old or older
- Replacement of unilateral or bilateral hearing aids once every 5 years unless MDH approves more frequent replacement
• Replacement of hearing aids, cochlear implants and auditory osseointegrated device components that have been lost, stolen, or damaged beyond repair, after all warranties policies have expired;

• Repairs and replacements that take place after all warranties policies have expired;

• A maximum of 76 batteries per participant per 12 month period for a unilateral hearing aid or osseointegrated devices, or 152 batteries per participant per 12 month period for a bilateral hearing aid or osseointegrated devices purchased from the Department not more frequently than every 6 months, and in quantities of 38 or fewer for a unilateral hearing aid or osseointegrated, or 76 or fewer for a bilateral hearing aid or osseointegrated device;

• A maximum of 180 disposable batteries for a unilateral cochlear implant per participant per 12 month period or 360 disposable batteries per 12 month period for a bilateral cochlear implant purchased not more frequently than every 6 months, and in quantities of 90 or fewer for a unilateral cochlear implant, or 180 or fewer for a bilateral cochlear implant;

• Two replacement cochlear implant component rechargeable batteries per 12-month period for bilateral cochlear implants, and a maximum of one replacement rechargeable battery for a unilateral cochlear implant;

• Two cochlear implant replacement transmitter cables per 12-month period for bilateral cochlear implants, and a maximum of one replacement transmitter cable for a unilateral cochlear implant;

• Two cochlear implant replacement headset cables per 12-month period for bilateral cochlear implants, and a maximum of one replacement headset cable for a unilateral cochlear implant; and

• Two cochlear implant replacement transmitting coils per 12-month period for bilateral cochlear implants, and a maximum of one replacement transmitting coil for a unilateral cochlear implant

• Charges for routine follow-ups and adjustments which occur more than 60 days after the dispensing of a new hearing aid;

• A maximum of two unilateral earmolds or four bilateral earmolds per 12-month period for participants younger than 21 years old; and

• A maximum of one unilateral earmold or two bilateral earmolds per 12-month period for participants 21 years old or older.
Services which are not covered are:

- Services not medically necessary
- Hearing aids and accessories not medically necessary;
- Cochlear implant services and external components not medically necessary;
- Cochlear implant audiology services and external components provided less than 90 days after the surgery or covered through initial reimbursement for the implant and the surgery;
- Spare or backup cochlear implant components;
- Spare or backup auditory osseointegrated device components;
- Replacement of hearing aids, equipment, cochlear implant components, and auditory osseointegrated device components if the existing devices are functional, repairable, and appropriately correct or ameliorate the problem or condition;
- Spare or backup hearing aids, equipment, or supplies;
- Repairs to spare or backup hearing aids, cochlear implants, auditory osseointegrated devices, equipment, or supplies;
- Investigational or ineffective services or devices, or both;
- Additional professional fees and overhead charges for a new hearing aid when a dispensing fee claim has been made to the MPC; and
- Loaner hearing aids
- Replacement of improperly fitted ear mold or ear molds unless the:
  - Replacement service is administered by someone other than the original provider, and
  - Replacement service has not been claimed before
Clinical Coverage Criteria for Audiology Devices
The clinical documentation submitted with the request must include clinical information to justify the following medical necessity criteria.

Clinical Coverage Criteria for Hearing Aid Coverage in Children
The Maryland Medicaid Program considers bilateral or unilateral hearing aids medically necessary for participants up to age 21 years when the following criteria are met:
- The participant has a hearing loss of 25 dB or greater; AND
- Hearing aid(s) recommended and fitted by an audiologist; AND
- For initial hearing aid(s), written medical clearance is obtained from a physician who has performed a medical examination within the past 6 months

Clinical Coverage Criteria for Hearing Aids in Adults
Unilateral hearing aids are considered medically necessary for participants 21 years of age and older when the following criteria are met:
- The participant has a pure tone average threshold of 40 dB or greater at 500, 1000, 2000 and 3000 Hz in the better ear; AND
- Documentation that patient is alert and able to utilize their aid appropriately; AND
- Hearing aid is recommended and fitted by an audiologist; AND
- For initial hearing aid, written medical clearance from a physician who has performed a medical examination within the past 6 months.

Bilateral hearing aids are considered medically necessary in recipients 21 years of age and older who meet the criteria for unilateral hearing aids and when one of the following criteria is met:
- The participant has visual impairment meeting the definition of statutory blindness; OR
- The participant is a previous successful bilateral hearing aid user and meaningful objective benefit to the participant over unilateral amplification can be documented; OR
- The participant demonstrates significant hearing-related disability in educational, vocational, or community settings with a unilateral aid and meaningful objective benefit from bilateral aids can be documented.
Clinical Coverage Criteria for Cochlear Implantation in Children
For children 12 months – 20 years, the Maryland Medicaid Program considers unilateral or bilateral implantation of a cochlear implant medically necessary when the following criteria are met:

- Bilateral severe to profound pre- or post-lingual sensorineural hearing loss, defined as a pure tone average threshold of 70 dB or greater at 500, 1000, and 2000 Hz; AND
- A minimum 3 to 6-month trial with appropriate binaural hearing aids has occurred if child is not previously experienced with hearing aids (radiologic evidence of cochlear ossification may justify a shorter trial with amplification); AND
- Limited or no benefit from appropriate binaural hearing aids, defined as:
  - In younger children, lack of progress in the development of simple auditory skills in conjunction with hearing aids over a 3 to 6-month period, quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.
  - In older children,  < 30% correct on the Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT) depending upon the child’s cognitive ability and linguistic skills; AND
- Documentation that the child and parent/guardian are willing and able to participate in a post-cochlear implant rehabilitation program in order to achieve benefit from the cochlear implant device; AND
- 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; AND
- No contraindications to surgery.

Clinical Coverage Criteria for Cochlear Implantation in Adults
For participants 21 years and older, unilateral implantation of a cochlear implant is considered medically necessary when the following criteria are met:

- Bilateral severe to profound pre- or post-lingual sensorineural hearing loss, defined as a pure tone average threshold of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz; AND
- Limited benefit from appropriate hearing aids, defined as scoring 50% or less in best-aided listening condition on a test of open-set sentence recognition (ex. HINT Sentences); AND
- The participant is willing and able to participate in a post-cochlear implant rehabilitation program in order to achieve benefit from the cochlear implant device; AND
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; AND

- No contraindications to surgery.

Bilateral cochlear implants are considered medically necessary in recipients aged 21 years and older who meet the criteria for unilateral cochlear implants and when one of the following criteria is met:

- The participant is a previous successful bilateral cochlear implant user; OR
- It has been determined that a unilateral cochlear implant plus a hearing aid in the contralateral ear will not result in adequate amplification

Clinical Coverage Criteria for Bone-anchored Hearing Aids (BAHA) in Children and Adults

The Maryland Medicaid Program considers bone-anchored hearing aids medically necessary for participants 5 years and older (and non-implantable or soft band devices for participants less than 5 years or as clinically indicated) when the following criteria are met:

- Unilateral implant: conductive or mixed hearing loss with a pure tone average bone conduction threshold at 500, 1000, 2000, and 3000 Hz that is less than or equal to 45 dB (BAHA Attract, BAHA Divino, BAHA BP100, Baha 4 and Sophono Alpha System), 55 dB (BAHA 5 Power, BAHA Intenso, Ponto Plus Power) or 65 dB (BAHA Cordelle II); or
- Bilateral implants: moderate-to-severe bilateral symmetric conductive or mixed hearing loss, meeting above-listed bone conduction thresholds in both ears; symmetric bone conduction threshold is defined as less than:
  - 10 dB average difference between ears (measured at 500, 1000, 2000 and 4000 Hz) or less than 15 dB difference at individual frequencies (BAHA Divino, Ponto Plus, Ponto Plus Power, Ponto Pro, Sophono Alpha System); or
  - 10 dB average difference between ears (measured at 500, 1000, 2000 and 3000 Hz), or less than a 15-dB difference at individual frequencies (BAHA Attract, BAHA BP100, BAHA 4, BAHA 5 Power, BAHA Cordelle II, BAHA Intenso); AND
- For unilateral or bilateral implants, participant has one of the following medical conditions preventing use of a conventional air conduction hearing aid:
  - Congenital or surgically induced malformations (e.g., atresia) of the external or middle ear canal; or
  - Severe chronic external otitis or otitis media; or
  - Tumors of the external ear canal and/or tympanic cavity; or
Dermatitis of the external ear canal, including hypersensitivity to ear molds used in air conduction hearing aids; or
Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid.

The Maryland Medicaid Program considers a bone-anchored hearing aid medically necessary for participants 5 years and older with unilateral sensorineural hearing loss (single-sided deafness) and normal hearing (a pure tone average hearing threshold of <20 dB) in the other ear.

**OPERATING PROTOCOL:**

**Systems**
The business application system prior authorization module is used to document the request for audiology services and devices.

**Measurement**

**Reporting**

**INTER-/INTRADEPENDENCIES:**

**Internal**

**External**

**LEGAL/CONTRACT REFERENCES:**

COMAR 10.09.51,
10.09.67.20, 26-4, 27 transferred to 10.67.06.26-4
10.09.70.03 transferred to 10.67.08
DEFINITIONS:

**Audiology Services**: services delivered by an audiologist to eligible participants in order to diagnose and treat hearing problems.

**Auditory osseointegrated device**: a device implanted in the skull that replaces the function of the middle ear and provides mechanical energy to the cochlea via a mechanical transducer.

**Cochlear implant**: a device that is implanted under the skin that picks up sounds and converts them to impulses transmitted to electrodes placed in the cochlea, restoring some hearing to people with a hearing impairment.

**Hearing aid**: an instrument or device that is designed for improving or correcting impaired human hearing, or any part or accessory of the instrument or device.

**Medically necessary**: the service or benefit is directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition; consistent with currently accepted standards of good medical practice; the most cost efficient service that can be provided without sacrificing effectiveness or access to care; and not primarily for the convenience of the consumer, family, or provider.

**Affiliate**: Medicaid business conducted by the direct and indirect subsidiaries of the management company.

**Board of Directors**: MPC board of directors has ultimate accountability for the health plan processes, activities, and systems. This includes responsibility for implementing systems and processes for monitoring and evaluating the care and services members receive through the health delivery network.


**COMAR**: Code of Maryland Regulation

**Contractor and Agent**: Any entity or person, including a sub-contractor, that, on behalf of MPC or its affiliates, furnishes of administrative and/or operational services.
**Member:** A person enrolled by the State of Maryland Medicaid/MDH to MPC, a Medicaid managed care organization.

**Personnel:** Employees of MPC management company, its affiliates, consultants, temporary or seasonal employees, student interns, volunteers, and any other class or type of full or part time employee who participate in MPC administrative operations.

**REVISION LOG:**

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<td>Reviewed revised updated COMAR citations</td>
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<tr>
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**POLICY AND PROCEDURE APPROVAL:**
The electronic approval retained in P&P management software is considered equivalent to a signature.