

Policy Number: PA 21 Last Review Date: 02/3/2022 Effective Date: 07/01/2018

### **Policy**

Maryland Care, Inc., dba Maryland Physicians Care (MPC) follows the Maryland Department of Health (MDH) regulations. The services must be rendered or initiated within 6 months from the date the authorization was issued. MPC considers audiology services medically necessary for the following indications:

### 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:
    - Ear molds
    - Batteries
    - Routine follow-ups and adjustments
    - Repairs after all warranties have expired
    - Replacement of unilateral or bilateral hearing aids every 5 years when determined to be medically necessary, and
    - Other hearing aid accessories determined to be medically necessary.
- 3. Cochlear implants and related services, as listed below:
  - Unilateral or bilateral implantation of cochlear implant or implants which are medically necessary, including the cost of the device
  - Post-operative evaluation and programming of the cochlear implant or implants

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- 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, including the cost of the device
  - Non-implantable or soft band device or devices
  - 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

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 MPC
- The initial coverage of unilateral or bilateral hearing aids, cochlear implants, or auditory osseointegrated devices when the Department's medical necessity criteria have been met 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 238 disposable batteries for a unilateral cochlear implant per participant per 12 month period or 476 disposable batteries per 12 month period for a bilateral cochlear implant purchased not more frequently than every 6 months, and in quantities of 119 or fewer for a unilateral cochlear implant, or 238 or fewer for a bilateral cochlear implant;



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- Four replacement cochlear implant component rechargeable batteries per 12-month period for bilateral cochlear implants, and a maximum of two replacement rechargeable batteries per 12-month period 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 per 12-month period 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 per 12-month period 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 per 12-month period 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 unless a larger amount are determined to be medically necessary.

#### 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;

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- 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
  - o 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 MPC 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.



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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 9 months – 20 years, MPC 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 over the age of three is not previously experienced with hearing aids (radiologic evidence of cochlear ossification may justify a shorter trial with amplification); AND
- For children over the age of three, limited or no benefit from appropriate binaural hearing aids, defined as:
- o 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.
- o 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.

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<u>Clinical Coverage Criteria for Cochlear Implantation in Adults</u>
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

<u>Clinical Coverage Criteria for Bone-anchored Hearing Aids (BAHA) in Children and Adults</u> MPC 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:

o 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

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o 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:
- o Congenital or surgically induced malformations (e.g., atresia) of the external or middle ear canal; or
  - o Severe chronic external otitis or otitis media; or
  - o 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
- o Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid.

MPC 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.

### **Background**

As of July 1, 2018, audiology services for the EPSDT population will be provided through the enrollee's managed care organization (MCO). These services were placed back into the MCO system of payment. Effective July 1, 2018, audiology services are a covered Medicaid benefit for all Medicaid participants when determined to be medically necessary. The participant may have to receive a preauthorization or referral from the MCO before visiting an audiologist for evaluation and/or treatment.

This policy follows the MDH regulations and covers the following devices: hearing aids, Cochlear implants, auditory osseointegrated devices, and related services.

| Device           | Description   |
|------------------|---|
| 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.  |
| 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. |



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| Auditory osseointegrated devices | 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. |
|----------------------------------|---|
| Audiology Services               | services delivered by an audiologist to eligible participants in order to diagnose and treat hearing problems.  |

Refer to Fee Schedule for full list of codes and descriptions found at: <a href="https://mmcp.health.maryland.gov/Documents/Audiology,%20Physical%20Therapy,%20">https://mmcp.health.maryland.gov/Documents/Audiology,%20Physical%20Therapy,%20</a> and%20EPSDT%20Provider%20Manual%20Final%201%2019%202021-.pdf

### References

MDH MD MA Audiology Clinical Coverage Criteria effective 10/1/2020 found at: https://health.maryland.gov/mmcp/Documents/MD%20MA%20Audiology%20Clinical%20Cove

https://health.maryland.gov/mmcp/Documents/MD%20MA%20Audiology%20Clinical%20Coverage%20Criteria.pdf

MDH Audiology, Physical Therapy, and EPSDT Provider Manual 1/01/2022 found at: https://health.maryland.gov/mmcp/Documents/2022%20Audiology%2c%20Physical%20Therap y%2c%20and%20EPSDT%20Provider%20Manual%20FINAL%206-9-2022.pdf COMAR 10.09.51 COMAR 10.09.51.05

**Revision Log** 

| Reviewed and Revised: Minor grammatical editing. Updated template,     | February 2021 |
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| references, added links to the MDH manual and criteria. Updated all    |               |
| amounts of covered replacement batteries, transmitter cables,          |               |
| headsets, and earmolds. Updated the criteria for Cochlear              |               |
| Implantation in children to ages 9 months to 20 years. Specified child |               |
| criteria by age over age 3, younger, and older.                        |               |
| Annual review  | February 2022 |
| Reviewed and Revised: Updated the links and date effective for the     | February 2023 |
| clinical criteria and Provider Manual on the MDH website.              |               |