Medical Policy

Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

Policy Number: 3.30
Version Number: 16
Version Effective Date: 09/01/17

Product Applicability

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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers implantable bone-conduction hearing aids (including bone-anchored hearing aids or BAHA) for hearing impairment to be medically necessary when the Plan’s medical criteria are met. Prior authorization is REQUIRED for implantation surgery and the replacement of the sound processor used with an implantable bone-conduction (bone-anchored) hearing aid. It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. Review Plan policy, Cochlear Implants (policy number OCA 3.301), rather than this policy for Plan medical criteria related to cochlear implants. See Plan policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. The Plan

Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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complies with coverage guidelines for all applicable state-mandated benefits and federally-mandated benefits that are medically necessary for the member’s condition.

Prior authorization is NOT required for external hearing devices, including non-implantable bone-conduction hearing aids such as the BAHA® Softband™ (unless the external processor is related to an implantable bone-conduction/bone-anchored hearing aid). Review the member’s product-specific benefit documents (including age limitations, when applicable) to determine coverage for air-conduction and/or external, non-implantable bone-conduction hearing aids; benefit documents are available at www.bmchp.org for BMC HealthNet Plan members, posted at www.SeniorsGetMore.org for Senior Care Options members, and documented at www.wellsense.org for Well Sense Health Plan members. The hearing aid limits specified in the member’s benefit documents apply to external hearing aids and do not apply to the components of implantable hearing aids or cochlear implants. Review the following Plan reimbursement policies available at www.bmchp.org for payment guidelines for audiology testing, external (non-implantable) hearing aids, and related batteries and accessories for external (non-implantable) hearing aids: Hearing Aid Dispensing and Repairs (policy number 4.111) for BMC HealthNet Plan members (i.e., MassHealth and Qualified Health Plans members) and Hearing Aid Dispensing and Repairs (policy number SCO 4.111) for Senior Care Options members.

**Description of Item or Service**

**Bone-Conduction Hearing Aid:** Conventional external hearing aids can be generally categorized as air conduction hearing aids or bone conduction hearing aids. A hearing aid based on bone conduction may include an implanted device (e.g., BAHA® System) or use of an external device (only) to transmit sound waves with no implantation surgery. A traditional bone-conduction hearing aid requires the use of a vibrating pad held in place on the mastoid bone by a removable headband. The BAHA® Softband™ is an example of an FDA-approved device that requires no implantation surgery, since the sound processor is attached to the head using either a hard or soft headband; the BAHA® Softband™ may be used with children younger than age 5. Replacement parts include batteries and lost or damaged headbands. An implanted bone-conduction hearing aid is used for conductive hearing loss or mixed hearing loss, as well as single-sided sensorineural hearing loss.

**Implantable Bone-Conduction/Bone-Anchored Hearing Aid:** A bone-conduction hearing aid with a surgically implanted device that transmits sound waves through the bone directly to the inner ear, bypassing the external and middle ear systems. Examples of implanted bone-conduction hearing aids include the BAHA devices (by Cochlear® Corporation) and the OBC Bone Anchored Hearing Aid System (by Oticon Medical). The BAHA® System (a bone-anchored hearing aid developed by the Cochlear® Corporation) combines an external sound processor (hearing aid) with a small titanium fixture implanted in the skull in the mastoid portion of the temporal bone behind the ear; the implanted titanium fixture bonds with the surrounding tissue gradually over 6-12 weeks following implantation (through a process known as osseointegration). The abutment is like a bridge that connects the external sound processor to the titanium fixture or the implant in the skull. The external sound processor is worn on the outside of the head on the abutment. Replacement parts include batteries and the external sound processor. The processor is removed to clean around the abutment, prior to

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showering or swimming, during contact sports, before going to bed, and before undergoing MRI scans. The bone-anchored hearing aid eliminates the need for the headband used with an external bone conduction hearing aid. The system allows sound to be conducted through the bone (known as direct bone conduction) rather than via the middle ear. For the external ear prosthesis, the patient is instructed on its placement, removal, and daily care. Examples of BAHA® System (by Cochlear® Corporation) components include the BAHA® Divino™, BAHA® Intenso™ (digital signal processing), BAHA® Cordelle II™, and BAHA® BP100™. Examples of devices used with the Ponto bone-anchored hearing system (by Oticon Medical) include the Ponto Plus and Ponto Plus Power sound processors. A bone-anchored hearing aid is used for conductive hearing loss or mixed hearing loss, as well as single-sided sensorineural hearing loss.

**Medical Policy Statement**

Implantable bone-conduction (e.g., bone-anchored or BAHA) hearing aids are considered medically necessary when applicable Plan criteria are met, as specified below in item A. Replacement of the sound process for an implantable bone-conduction (bone-anchored) hearing aid is considered medically necessary when it is a covered benefit for the member (as documented in the member’s applicable document available at [www.bmchp.org](http://www.bmchp.org) for a BMC HealthNet Plan member, at [www.SeniorsGetMore.org](http://www.SeniorsGetMore.org) for a Senior Care Options member, and [www.wellsense.org](http://www.wellsense.org) for a member enrolled in a Well Sense Health Plan product) and Plan medical criteria are met, as specified below in item B.

**A. Medical Criteria for Implantation of Bone-Conduction (Bone-Anchored) Hearing Aids:**

Implantable bone-conduction (e.g., bone-anchored or BAHA) hearing aids are considered medically necessary when ONE (1) of the following applicable criteria is met and documented in the member’s medical record, as specified below in item 1 (for conductive hearing loss or mixed hearing loss) or item 2 (for single-sided sensorineural hearing loss):

1. **Conductive Hearing Loss or Mixed Hearing Loss:**

   a. **Unilateral Implantation of Bone-Conduction (Bone-Anchored) Hearing Aid for Conductive Hearing Loss or Mixed Hearing Loss:**

      ALL of the following criteria must be met for a unilateral, implantable bone-conduction hearing aid, as specified below in items (1) through (6):

      (1) Unilateral, implantable bone-conduction device will be used as an alternative to an air conduction hearing aid for the treatment of EITHER of the following types of hearing loss (with hearing loss, conductive hearing loss, and mixed hearing loss defined in the Definitions section of this policy), as specified below in item (a) or item (b):

      (a) **Unilateral or bilateral conductive hearing loss**; OR

      Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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(b) **Unilateral or bilateral mixed hearing loss** (i.e., a combination of both conductive and sensorineural hearing loss); AND

(2) The processor requested is appropriate to meet the needs of the member’s hearing loss in the ear proposed for an implantable device based on the pure tone average bone-conduction threshold, measured at 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz, as specified below in ONE (1) of the following audiologic findings determined by the type of device in items (a) through (c):

(a) Bone-conduction threshold is better than or equal to **45 dB** for implantation with the BAHA® System (by Cochlear® Corporation) using the BAHA® Divino™ device or BAHA® BP100™ device or implantation with the OBC Bone Anchoring Hearing Aid System (by Oticon Medical) with the Ponto Plus (sound processor intended to be used with either the Ponto bone-anchored hearing system by Oticon Medical or with specific compatible BAHA abutments/implants from Cochlear® Corporation according to FDA-approved labeling); OR

(b) Bone-conduction threshold is better than or equal to **55 dB** for implantation with the BAHA® System (by Cochlear® Corporation) using the BAHA® Intenso™ device or implantation with the OBC Bone Anchoring Hearing Aid System (by Oticon Medical) with the Ponto Plus Power (sound processor intended to be used with either the Ponto bone-anchored hearing system by Oticon Medical or with specific compatible BAHA abutments/implants from Cochlear® Corporation according to FDA-approved labeling); OR

(c) Bone-conduction threshold is better than or equal to **65 dB** for implantation with the BAHA® Cordelle II™ device or other FDA-approved device not specified; AND

(3) Member is 5 years of age or older on the date of service; AND

(4) Member is unable to use a conventional air conduction hearing aid or undergo surgical repair because of ANY of the following conditions, as specified below in items (a) through (e):

(a) Congenital or surgically induced malformation (e.g., atresia) of the external ear canal or middle ear; OR

(b) Severe chronic external otitis or otitis media; OR

(c) Severe dermatitis of the external canal (including hypersensitivity reactions to ear molds used in air conduction hearing aids); OR

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(d) Tumors of the external canal and/or tympanic cavity; OR

(e) Other condition that contraindicates the use of an air conduction hearing aid such as other acquired malfunction of the external or middle ear canal that includes hypersensitivity to ear molds used in air conduction hearing aids; AND

(5) Member has no contraindication to surgery; AND

(6) Device is approved by the U.S. Food and Drug Administration (FDA) and will be used in accordance with its FDA-approved labeling (including but not limited to the indications for use, directions for use, contraindications, intended patient populations, and restrictions); OR

b. Bilateral Implantation of Bone-Conduction (Bone-Anchored) Hearing Aid for Symmetrically Conductive Hearing Loss or Symmetrically Mixed Hearing Loss:

ALL of the following criteria must be met for bilateral, implantable bone-conduction hearing aids, as specified below in items (1) through (6):

(1) Bilateral, implantable bone-conduction devices will be used as an alternative to air conduction hearing aids for the treatment of EITHER of the following types of hearing loss (with hearing loss, conductive hearing loss, and mixed hearing loss defined in the Definitions section of this policy), as specified below in item (a) or item (b):

(a) Symmetrically conductive hearing loss defined as a difference between left and right side bone-conduction threshold of either of the following criteria, as specified below in item i or item ii:

i. Less than 10 dB difference (on average) between the bone-conduction threshold in each ear measured at 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz; OR

ii. Less than 15 dB difference (on average) between the bone-conduction threshold in each ear measured at individual frequencies; OR

(b) Symmetrically mixed hearing loss (i.e., mixed hearing loss is a combination of both conductive and sensorineural hearing loss) as defined as a difference between left and right side bone-conduction threshold of either of the following criteria, as specified below in item i or item ii:

i. Less than 10 dB difference (on average) between the bone-conduction threshold in each ear measured at 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz; OR

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implantable bone conduction (bone anchored) hearing aids

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ii. Less than 15 dB difference (on average) between the bone-conduction threshold in each ear measured at individual frequencies; AND

(2) The processor requested is appropriate to meet the needs of the member’s bilateral hearing loss in each ear for an implantable device based on the pure tone average bone-conduction threshold, measured at 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz, as specified below in ONE (1) of the following audiological findings determined by the type of device in items (a) through (c):

(a) Bone-conduction threshold is better than or equal to 45 dB for implantation with the BAHA® System (by Cochlear® Corporation) using the BAHA® Divino™ device or BAHA® BP100™ device or implantation with the OBC Bone Anchoring Hearing Aid System (by Oticon Medical) with the Ponto Plus (sound processor intended to be used with either the Ponto bone-anchored hearing system by Oticon Medical or with specific compatible BAHA abutments/implants from Cochlear® Corporation according to FDA-approved labeling); OR

(b) Bone-conduction threshold is better than or equal to 55 dB in each ear for implantation with the BAHA® System (by Cochlear® Corporation) using the BAHA® Intenso™ device or implantation with the OBC Bone Anchoring Hearing Aid System (by Oticon Medical) Ponto Plus Power (sound processor intended to be used with either the Ponto bone-anchored hearing system by Oticon Medical or with specific compatible BAHA abutments/implants from Cochlear® Corporation according to FDA-approved labeling); OR

(c) Bone-conduction threshold is better than or equal to 65 dB in each ear for implantation with the BAHA® Cordelle II™ device (by Cochlear® Corporation) or other FDA-approved device not specified in this section; AND

(3) Member is 5 years of age or older on the date of service; AND

(4) Member is unable to use a conventional air conduction hearing aid or undergo surgical repair because of ANY of the following conditions, as specified below in items (a) through (e):

(a) Congenital or surgically induced malformation (e.g., atresia) of the external ear canal or middle ear; OR

(b) Severe chronic external otitis or otitis media; OR

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(c) Severe dermatitis of the external canal (including hypersensitivity reactions to ear molds used in air conduction hearing aids); OR

(d) Tumors of the external canal and/or tympanic cavity; OR

(e) Other condition that contraindicates the use of an air conduction hearing aid such as other acquired malfunction of the external or middle ear canal that includes hypersensitivity to ear molds used in air conduction hearing aids; AND

(5) Member has no contraindication to surgery; AND

(6) Device is approved by the U.S. Food and Drug Administration (FDA) and will be used in accordance with its FDA-approved labeling (including but not limited to the indications for use, directions for use, contraindications, intended patient populations, and restrictions); OR

2. Single-Sided Sensorineural Hearing Loss:

A unilateral, implantable bone-conduction hearing aid will be used and ALL of the following criteria must be met, as specified below in items (a) through (g):

(a) Unilateral implantable device will be used as an alternative to an air conduction hearing aid for the treatment of single-sided sensorineural hearing loss and there is normal hearing in the other ear; AND

(b) Member’s single-sided sensorineural hearing loss is defined as severe (71 to 90 db HL) to profound (91 dB HL or greater) unilateral hearing loss at 500 hertz (Hz), 1000 Hz, and 2000 Hz; AND

(c) The pure tone average air conduction threshold of the member’s ear with normal hearing is better than 20 dB HL measured at 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz; AND

(d) Member is 5 years of age or older on the date of service; AND

(e) Member is unable to use a conventional air conduction hearing aid or undergo surgical repair because of ANY of the following conditions, as specified below in items (1) through (5):

(1) Congenital or surgically induced malformation (e.g., atresia) of the external ear canal or middle ear; OR

(2) Severe chronic external otitis or otitis media; OR
(3) Severe dermatitis of the external canal (including hypersensitivity reactions to ear molds used in air conduction hearing aids); OR

(4) Tumors of the external canal and/or tympanic cavity; OR

(5) Other condition that contraindicates the use of an air conduction hearing aid such as other acquired malfunction of the external or middle ear canal that includes hypersensitivity to ear molds used in air conduction hearing aids; AND

(f) Member has no contraindication to surgery; AND

(g) Device is approved by the U.S. Food and Drug Administration (FDA) and will be used in accordance with its FDA-approved labeling (including but not limited to the indications for use, directions for use, contraindications, intended patient populations, and restrictions); OR

B. Medical Criteria for Replacement of External Sound Processor for Bone-Anchored Hearing Aids:

Replacement of the external sound processor for an implantable bone-conduction (bone-anchored) hearing aid is considered medically necessary when it is a covered service and when ALL of the following applicable criteria are met, as specified below in items 1 through 3:

1. A treating provider (e.g., audiologist or physician) certifies that the member meets at least ONE (1) of the following criteria, as specified below in items a through f:

   a. The existing sound processor is ineffective to the point of interfering with the activities of daily living; OR

   b. There is a change in the patient’s medical condition that necessitates a different type of processor, OR

   c. The existing processor has reached the end of its reasonable useful life; the reasonable useful life of a sound processor is not less than five (5) years; OR

   d. The manufacturer of the processor no longer supports the repairs of the processor; OR

   e. The external sound processor is lost and will be replaced by the same make and model unless it is obsolete (with additional criteria met for the replacement of a lost processor when it is the requested component, as specified below in item 2, Additional Criteria for Replacement of Processor for Cochlear Implant); OR

   f. The external sound processor is unable to be repaired; AND

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2. At least ONE (1) of the criteria is met for the replacement of an external sound process, as specified below in item a for replacement of an existing processor or item b for replacement of a lost processor:

   a. **Replace Existing Processor:**

      A comprehensive report within the last six (6) calendar months with justification of the medical necessity is required for each prior authorization request for a new processor; the report must include ALL of the following documentation, as specified below in items (1) through (4):

      (1) A description of the status of the member’s current equipment; AND

      (2) Documentation of the current equipment’s obsolescence if it is the reason for the equipment replacement; AND

      (3) Member’s current sound field results and speech testing results utilizing the member’s current bone-anchored equipment; AND

      (4) Invoice stating cost of equipment requested; OR

   b. **Replace Lost Processor:**

      In the case of loss of a processor, ALL of the following information must be submitted to the Plan, as specified below in items (1) through (3):

      (1) A description of the circumstances regarding the loss; AND

      (2) An invoice stating the cost of equipment requested; AND

      (3) A list of the member’s current equipment; AND

3. The replacement device is approved by the U.S. Food and Drug Administration (FDA) and will be used in accordance with its FDA-approved labeling (including but not limited to the indications for use, directions for use, contraindications, intended patient populations, and restrictions).

See the Limitations section of this policy for Plan guidelines related to the replacement of external components of a bone conduction (bone-anchored) hearing aid to achieve aesthetic improvement. Benefit coverage varies based on the product in which the member is enrolled. Member benefit documents are available at [www.bmchp.org](http://www.bmchp.org) for members enrolled in a BMC...
Limitations

1. The Plan considers **partially-implanted**, bone-conduction implant systems (also known as middle-ear implants, partially implantable magnetic bone-conduction devices, or semi-implantable electromagnetic hearing aids) to be experimental and investigational because the effectiveness of these devices has NOT been established. This includes but is not limited to the following devices: Maxum™ System (by Ototronix and originally marketed under the name of Soundtec® Direct System™), Vibrant® Soundbridge™ System (by Med-El), BoneBridge™ (by Med-El), Otomag Bone Conduction Hearing System (by Medtronic but formerly Sophono, Inc.), BAHA® Attract System (by Cochlear® Corporation), and the Semi-Implantable Middle Ear Transducer (MET) Ossicular Stimulator System (by Otologics LLC).

2. The Plan considers the Esteem hearing device (by Envoy Medical Corp.) to be experimental and investigational because the effectiveness has NOT been established. The Esteem hearing device is a fully implantable middle ear hearing aid that is FDA-approved for individuals age 18 or older. The device requires disarticulation of the ossicular chain and partial resection of the incus bone. The device is not visible because it is implanted under the skin behind the ear and in the middle ear space. In the event that a device fails, it must be removed and leaves the individual with additional hearing loss.

3. The Plan considers an intraoral bone conduction hearing aid (e.g., SoundBite™ Hearing System by Sonitus Medical Inc.) to be experimental and investigational because their effectiveness has NOT been established for treating hearing loss.

4. The use of implantable bone-conduction (bone-anchored) hearing aids for **bilateral** sensorineural hearing loss is considered experimental and investigational.

5. Upgrade of an existing and functional external component of an implantable bone-conduction (bone-anchored) hearing aid system to achieve aesthetic improvement (such as smaller profile components) is NOT considered medically necessary.

6. A switch from a body-worn, functioning, external sound processor to a behind the ear model is NOT considered medically necessary.

7. Standard accessories directly related to the proper operation of the implantable bone-conduction (e.g., bone-anchored or BAHA) hearing aid are considered medically necessary when applicable Plan criteria are met in the Medical Policy Statement section. Additional (non-standard) accessories for the implantable bone-conduction hearing aid are NOT considered medically necessary.

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11 of 25 medically necessary and include but are not limited to the following: duplicate accessory/spare fixture for future use (e.g., baha sleeper fixture), bluetooth accessory, and/or accessory for recreational use. plan medical director review is required for prior authorization requests related to the use of non-standard accessories and the following documentation must be submitted to the plan: medical record documentation verifying that applicable criteria in the medical policy statement section are met for the implantable bone-conduction hearing aid; documentation that the non-standard accessory is approved by the u.s. food and drug administration (fda) and will be used according to fda-approved labeling; and documentation from the treating provider specifying the medical necessity of the non-standard accessory for the member’s medical condition, treatment plan, age, and comorbidities.

see the plan’s policy, experimental and investigational treatment (policy number oca 3.12), for the product-specific definitions of experimental or investigational treatment. the hearing aid limits specified in the member’s benefit documents apply to external hearing aids and do not apply to the implantable hearing aids or cochlear implants.

definitions

bone conduction threshold: an individual’s hearing threshold is defined as the softest sounds a person hears at each frequency approximately 50% of the time. the bone conduction threshold is determined with bone conduction testing. if a hearing loss exists, bone conduction thresholds, in combination with air conduction tests, help determine whether the problem is in the outer, middle, or inner ear.

contralateral routing of signals (cros): type of hearing aid that is used to treat unilateral hearing loss. the technology allows two (2) implementations: cros and bicros. the cros implementation is for an individual with relatively normal hearing on one side but has hearing that cannot be aided on the other side. the bicros implementation is for a user with little or no hearing on one side and with some hearing loss in the other ear.

decibels (db)/decibel hearing level (db hl): decibel is a unit of measure used to calculate the degree of hearing sensitivity (i.e., loudness or softness of sound detected) based on the individual’s ability to detect a variety of sounds from low to high frequency (pitch). to calculate hearing sensitivity in db, one takes the hearing threshold at different frequencies (500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz) and averages them to derive a pure tone average. the average will fall into one (1) of the following categories: normal hearing, mild hearing loss, moderate (including moderately severe) hearing loss, severe hearing loss, or profound hearing loss.

hearing loss: decreased hearing, deafness, or loss of hearing. in hearing evaluations, loudness and clarity of sound signals are reflected by numbers in two different scales, hertz (Hz) and decibel (dB). normal speech and conversation occurs at 40 to 60 decibel (DB) within a frequency range of 500-6000 Hz (Hertz). average hearing threshold levels of less than (better than) 20 dB HL do not necessarily

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According to the American Speech-Language-Hearing Association (ASHA), hearing loss can be classified into the following average hearing threshold levels (in decibel hearing level or dB HL):

1. **Mild**: 26 to 40 dB HL
2. **Moderate (Including Moderately Severe)**: 41 to 70 dB HL
3. **Severe**: 71 to 90 dB HL
4. **Profound**: 91 dB or more dB HL

**Hertz (Hz)**: Unit of measure for sound frequency (pitch) documented as one cycle per second (Hz) or per thousand of Hz (kilohertz or kHz). Hz is an absolute unit, which does not depend on external factors. The Hz scale measures the different pitches of sound the human ear can hear, a range from 50 Hz to 25,000 Hz. Hearing tests are usually limited to sounds between 250 Hz and 8000 Hz.

**Partially-implanted, Bone-conduction Implant Systems**: Also known as middle-ear implants, partially implantable magnetic bone-conduction devices, or semi-implantable electromagnetic hearing aids, these devices include an external audio processor worn behind the ear or in the ear canal, a receiver that may be housed with the audio processor or implanted, and an electromagnetic transducer that is implanted so that its tip contacts the ossicles or is close to a magnet implanted on the ossicles. The audio processor detects and converts sounds into electric currents, which are transmitted to the receiver and conveyed to the electromagnetic transducer, where they are converted into a magnetic field that vibrates the ossicles, either by direct contact with the ossicles or by acting on (attracting and repelling) the magnet implanted on the ossicles. These hearing devices are intended to improve hearing acuity in adults with moderate to severe sensorineural hearing loss who will not use or do not obtain sufficient benefit from conventional hearing aids. Examples of these devices include the following: Maxum™ System (by Ototronix and originally marketed under the name of Soundtec® Direct System™), Vibrant® Soundbridge™ System (by Med-El), BoneBridge™ (by Med-El), Otomag Bone Conduction Hearing System (by Medtronic but formerly Sophono, Inc.), BAHAB® Attract System (by Cochlear® Corporation), and the Semi-Implantable Middle Ear Transducer (MET) Ossicular Stimulator System (by Otologics LLC). (Source: Hayes, Inc.) See the Limitations section of this policy.

**Pure Tone Average**: The average decibels (dB) scores of the 4 frequencies most important for speech recognition: 500, 1000, 2000, and 3000 hertz (Hz).

**Types of Hearing Loss**: There are three (3) types of hearing loss which may be unilateral or bilateral:

1. **Conductive Hearing Loss**: Results from obstruction of the external auditory canal that can be caused by cerumen, debris and foreign bodies, swelling of the lining of the canal, atresia of the ear canal, neoplasms of the canal, breakdown of the ossicular chain, perforations of the
eardrum, trauma, infections, fluid, scarring and neoplasms of the middle ear. Conductive hearing loss is usually corrected either medically or surgically.

2. **Sensorineural Hearing Loss:** Results from damage to the inner ear (cochlea) or the 8th cranial nerve (auditory nerve) that can be caused by heredity, prenatal or birth related complications, intense noise, viral infections, ototoxic drugs, fractures of the temporal bone, meningitis, Meniere’s disease, otosclerosis, trauma, loud noise, fluid in the middle ear, benign tumor in the inner ear, and/or aging.

3. **Mixed Hearing Loss:** A combination of both conductive and sensorineural hearing loss that can result from pathology affecting the middle and inner ear together.

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adopted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

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<th>CPT Codes</th>
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<tr>
<td>69710</td>
<td>Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone (Replacement procedure includes removal of old device)</td>
</tr>
<tr>
<td>69711</td>
<td>Removal or repair of electromagnetic bone conduction hearing device in temporal bone</td>
</tr>
</tbody>
</table>

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### Clinical Background Information

Conventional hearing aids can be divided into air conduction hearing aids, bone-conduction hearing aids (external or implantable), and middle ear implants. Air conduction aids are indicated for a person with sensorineural hearing loss, mixed hearing loss, or conductive hearing loss that is not amenable to medical or surgical intervention. Bone-conduction hearing aids and bone-anchored hearing aids are indicated for a person with conductive and mixed hearing loss who is not able to use air-conduction hearing aids or has a medical condition that precludes the wearing of an air-conduction hearing aid.

A bone-anchored hearing system consists of a sound processor connected to an implant with a skin penetrating abutment. The implant is surgically anchored in the skull bone behind the ear. Vibrations generated by the sound processor are transmitted via the implant directly through the skull bone to the cochlea as bone conduction sound. The sound processor has a coupling so that it can be easily connected to and disconnected from the abutment by the user. Alternatively, it can be connected to head band accessories, to function as a conventional bone conductor. Using a computer-based filling system the sound processor can be adjusted to the patient’s individual hearing requirements.

The BAHA® System (a bone-anchored hearing aid developed by the Cochlear® Corporation) is a type of implantable bone-conduction hearing aid with a surgically implanted device that transmits sound waves through the bone directly to the inner ear, bypassing the external and middle ear systems. The U.S. Food and Drug Administration (FDA) have approved the BAHA® System with individuals aged 5 years and older for the following indications: unilateral or bilaterally symmetric conductive or mixed hearing loss (may be implanted bilaterally) and patients with sensorineural deafness in one ear and normal hearing in the other. Significant complications are uncommon after implantation of a BAHA; these complications may require local wound care, antibiotics, or revision surgery.

### HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8690</td>
<td>Auditory osseointegrated device, includes all internal and external components</td>
</tr>
<tr>
<td>L8691</td>
<td>Auditory osseointegrated device, external sound processor, replacement</td>
</tr>
<tr>
<td>L8693</td>
<td>Auditory osseointegrated device abutment, any length, replacement only</td>
</tr>
</tbody>
</table>

Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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According to the FDA 510(k) summary for Ponto Plus and Ponto Plus Power sound processors, these devices are intended to be used with either the Ponto implant system or with specific compatible BAHA abutments/implants from Cochlear® Corporation with individuals aged 5 years and older. In addition, selected Cochlear® BAHA sound processors can be used with the Ponto implant abutment. Ponto Plus and Ponto Plus Power are modifications of the previously cleared Ponto Pro and Ponto Pro Power. FDA has issued a substantial equivalence determination with 510(K) clearance which allows the manufacturer to market the Ponto Plus and Ponto Plus Power devices because they are considered comparable to devices already commercially available.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) 50.3 includes medically necessary indications for cochlear implantation for bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing aids when applicable patient eligibility criteria are met. No clinical criteria were found in an NCD or local coverage determination (LCD) for implantable bone-conduction hearing aids, semi-implantable electromagnetic hearing aids, and/or programmable and digital hearing devices such as the SoundBite Hearing System. Verify CMS criteria in the applicable NCD or LCD in effect on the date of the prior authorization request for a Senior Care Options member.

Chapter 16 of the CMS Medicare Benefit Manual (General Exclusions from Coverage) states that hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from coverage. Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices (rather than categorized as hearing aids) and include cochlear implants, auditory brainstem implants, and osseointegrated implants (i.e., implantable bone-conduction/bone-anchored hearing aids); these prosthetic devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

References


Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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Implantable Bone Conduction (Bone-Anchored) Hearing Aids

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Oticon Medical. Oticon Medical receives FDA clearance to market new Ponto Plus family of bone anchored sound processors.


Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>04/07/06 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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<tr>
<td>Internal Approval: 02/07/06</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

Note: Policy formerly titled Cochlear Implants and Bone Anchored Hearing Aids (policy number OCA 3.30). Policy renamed Implantable Bone-Conduction (Bone-Anchored) Hearing Aids, and the revised policy is effective 10/01/14. Medical criteria for cochlear implants are included in a separate medical policy, Cochlear Implants (policy number OCA: 3.301), and this policy is effective on 10/01/14.

### Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/06/07</td>
<td>Removed preauthorization requirement for most hearing aids.</td>
<td>Version 2</td>
<td>02/06/07: Q&amp;CMC</td>
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<tr>
<td>11/24/09</td>
<td>Removed all language and coding pertaining to hearing aids, updated references.</td>
<td>Version 5</td>
<td>11/24/09: MPCTAC 12/23/09: QIC</td>
</tr>
<tr>
<td>10/01/10</td>
<td>Added to the limitations section that cochlear implants are excluded from coverage for CWC members and not a covered benefit, updated coding and references.</td>
<td>Version 6</td>
<td>11/23/10: MPCTAC 12/22/10: QIC</td>
</tr>
<tr>
<td>06/01/11</td>
<td>Revised the criteria for cochlear implants from moderate to profound to severe to profound hearing</td>
<td>Version 7</td>
<td>06/29/11: MPCTAC 07/27/11: QIC</td>
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</tbody>
</table>

Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Notes</th>
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<tbody>
<tr>
<td>06/01/12</td>
<td>Updated references and revised the introductory paragraph in Applicable Coding section.</td>
<td>Version 8</td>
<td>06/20/12: MPCTAC 07/25/12: QIC</td>
</tr>
<tr>
<td>07/30/12</td>
<td>Off cycle review for Well Sense Health Plan, reformatted Medical Policy Statement. Air conduction hearing aid exclusion does not apply to Well Sense product.</td>
<td>Version 9</td>
<td>08/03/12: MPCTAC 09/15/12: QIC</td>
</tr>
<tr>
<td>06/01/14</td>
<td>Review for effective date 10/01/14. Revised Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised medical criteria in the Medical Policy Statement section and Limitations section. Revised policy title and only included documentation related to implantable bone-conduction hearing aids. Revised language in Applicable Coding section and only included applicable codes for implantable bone-conduction hearing aids. Moved policy language and coding related to cochlear implants to a new medical policy effective 10/01/14, <em>Cochlear Implants</em> (policy number OCA: 3.301).</td>
<td>10/01/14 Version 11</td>
<td>06/18/14: MPCTAC 07/09/14: QIC</td>
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<tr>
<td>05/01/15</td>
<td>Review for effective date 09/01/15. Removed Commonwealth Care,</td>
<td>09/01/15 Version 12</td>
<td>06/01/15: MPCTAC (electronic vote)</td>
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<tr>
<th>Date</th>
<th>Revision Description</th>
<th>Effective Date</th>
<th>Reviewer/Committee</th>
</tr>
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<tr>
<td>11/01/15</td>
<td>Review for effective date 01/01/16. Updated references. Added limitation for intraoral bone conduction hearing aids. Clarified age guidelines in the Medical Policy Statement section. Updated criteria for the replacement of existing or lost external sound processor and moved to the Medical Policy Statement section. Updated Policy Summary, Description of Item or Service, and Definitions sections.</td>
<td>01/01/16</td>
<td>06/10/15: QIC</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Review for effective date 09/01/16. Updated the Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised language in the Applicable Coding section.</td>
<td>09/01/16</td>
<td>05/18/16: MPCTAC</td>
</tr>
<tr>
<td>09/30/16</td>
<td>Administrative change effective 09/30/16 to remove HCPCS code L8692 from the applicable code list; this code is not related to the criteria included in the Medical Policy Statement and Limitation sections of this policy and therefore should not be included in the code list.</td>
<td>09/30/16</td>
<td>Not applicable because administrative change only.</td>
</tr>
<tr>
<td>06/01/17</td>
<td>Review for effective date 09/01/17. Administrative changes made to the Summary, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and</td>
<td>09/01/17</td>
<td>06/21/17: MPCTAC</td>
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Policy Revisions History

| Limitations sections. |

Last Review Date

06/01/17

Next Review Date

05/01/18

Authorizing Entity

MPCTAC

Other Applicable Policies

Medical Policy - Cochlear Implants, policy number OCA 3.301
Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy - Medically Necessary, policy number OCA 3.14
Reimbursement Policy - Hearing Aid Dispensing and Repairs, policy number 4.111 (MassHealth and Qualified Health Plans)
Reimbursement Policy - Hearing Aid Dispensing and Repairs, policy number SCO 4.111 (Senior Care Options products)

Reference to Applicable Laws and Regulations


The Commonwealth of Massachusetts. CMR 130.416. Hearing Aid Dispensing.

The Commonwealth of Massachusetts General Laws. Part I. Title XXII. Chapter 175. Section 47X.

The Commonwealth of Massachusetts General Laws. Part I. Title XXII. Chapter 176B. Section 4EE.


Implantable Bone-Conduction (Bone-Anchored) Hearing Aids

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Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.