Medical Policy

Cochlear Implants

Policy Number: OCA 3.301
Version Number: 15
Version Effective Date: 07/01/17

Product Applicability

All Plan Products

- Well Sense Health Plan
  - New Hampshire Medicaid
  - NH Health Protection Program
- Boston Medical Center HealthNet Plan
  - MassHealth
  - Qualified Health Plans/ConnectorCare/Employer Choice Direct
  - Senior Care Options

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 cochlear implants for hearing impairment to be medically necessary when the Plan’s medical criteria are met. Prior authorization is required. It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. See Plan policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. The Plan complies with coverage guidelines for all applicable state-mandated benefits and federally-mandated benefits that are medically necessary for the member’s condition.
See the Plan’s *Implantable Bone-Conduction (Bone-Anchored) Hearing Aids* medical policy (policy number OCA 3.30) for Plan medical criteria related to implantable bone-conduction hearing aids. 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](http://www.bmchp.org) for BMC HealthNet Plan members, posted at [www.SeniorsGetMore.org](http://www.SeniorsGetMore.org) for Senior Care Options members, and documented at [www.wellsense.org](http://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](http://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**

**Cochlear Implant**: An electronic medical device that converts received sounds from its external components into electrical impulses, resulting in the direct electrical stimulation of auditory spiral ganglion cells that form the auditory nerve. Cochlear implants do not restore normal hearing to a person with a hearing impairment but instead provide a sense of sound and facilitate speech recognition. The cochlear implant device consists of a surgically implanted instrument to stimulate nerve fibers (i.e., implanted components include a receiver and electrodes) and a device that is worn externally to capture, analyze, and code sound (i.e., external components include a microphone, speech processor, transmitter). Cochlear implants detour the damaged structures in the inner ear (and bypass damaged regions of the cochlea) and instead directly stimulate the auditory nerve. The implant is capable of electronically arranging useful sounds, transforming them into electrical impulses, and delivering these signals to the nerves leading to the brain where they are interpreted as sound. It is indicated for cases of severe to profound bilateral sensorineural hearing loss in members who receive only limited benefit from amplification with air conducting hearing aids.

**Medical Policy Statement**

Unilateral and bilateral cochlear implants are considered medically necessary when applicable Plan criteria are met, as specified below in item A. Replacement of external components for cochlear implants 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, or at [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 Unilateral and Bilateral Cochlear Implants:

Unilateral and bilateral cochlear implant(s) are considered medically necessary for the treatment of a bilateral sensorineural hearing impairment when EITHER of the following applicable criteria is met and documented in the member’s medical record, as specified below in item 1 or item 2:

1. Unilateral Cochlear Implant for Bilateral Severe-to-Profound Sensorineural Hearing Loss:

   ALL of the following criteria must be met for a unilateral cochlear implant, as specified below in items a through j:

   a. Member is diagnosed with bilateral severe-to-profound sensorineural hearing impairment; AND

   b. The member’s bilateral pre or post linguistic, sensorineural hearing loss is documented as severe or profound, with documentation of ONE of the following applicable criteria, as specified below in item (1) for an adult member or item (2) for a pediatric member:

      (1) For an adult member age 18 or older on the date of service, pure tone average is 70 decibels hearing level (dB HL) or greater at 500 hertz (Hz), 1000 Hz, and 2000 Hz in both ears; OR

      (2) For a pediatric member age 2 to age 17 on the date of service, pure tone average is 70 dB HL or greater at 500 Hz, 1000 Hz, and 2000 Hz in both ears; OR

      (3) For a pediatric member 12 months of age to 23 months of age on the date of service, pure tone average is 90 dB HL or greater at 500 Hz, 1000 Hz, and 2000 Hz in both ears; AND

   c. Member is 12 months of age or older on the date of service; AND

   d. The treating provider has determined that the member has limited or no benefit from appropriate amplification with hearing aids (or vibrotactile aids) and has some specific cases of bilateral auditory dys-synchrony with limited ability to recognize words or sentences or limitations in speech, language, and listening skills typically considered appropriate to the member’s age, developmental stage, and cognitive ability; AND

   e. Member possesses the cognitive ability to use auditory clues and a willingness to undergo an extended program of age-appropriate, postoperative cochlear implant rehabilitation and training on the device; AND
f. Member is free from middle ear infection and free from lesions in the auditory nerve and acoustic areas of the central nervous system; AND

g. Member has an accessible cochlear lumen that is structurally suited to implantation; AND

h. Member has no contraindication to surgery; AND

i. Device must be used in accordance with U. S. Food and Drug Administration (FDA)-approved labeling; AND

j. Member has received age-appropriate pneumococcal vaccination under the same schedules that apply to other individuals at high risk for invasive pneumococcal disease; OR

2. **Bilateral Cochlear Implant for Bilateral Severe-to-Profound Sensorineural Hearing Loss:**

   ALL of the following criteria must be met for bilateral cochlear implants, as specified below in items a and b:

   a. All of the criteria are met for unilateral cochlear implant, as specified above in items 1a through 1j of this section; AND

   b. The treating provider has determined that a unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit for the member (i.e., hearing aid will not produce the required amplification); OR

B. **Medical Criteria for Replacement of External Components for Cochlear Implants:**

   Replacement of external components for cochlear implants (e.g., sound processor, transmitting coil, microphone, or connecting cords) is considered medically necessary when it is a covered service for the specified indication and when applicable criteria are met, as specified below in item 1 (criteria for the replacement of all external components) or item 2 (additional criteria for the replacement of the processor).

1. **Criteria for Replacement of All External Components for Cochlear Implants:**

   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 component 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 component, OR

c. The existing component 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 component no longer supports the repairs of the device; OR

e. The external component 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 component is unable to be repaired, with additional criteria met for the replacement of an existing processor when it is the requested component, as specified below in item 2, Additional Criteria for Replacement of Processor for Cochlear Implant; OR

2. Additional Criteria for Replacement of Processor for Cochlear Implant:

BOTH of the following criteria are met, as specified below in item a and item b:

a. At least ONE (1) of the criteria is met for replacement of external components specifically related to the processor, as stated above in item 1 of this section (Criteria for Replacement of All External Components for Cochlear Implants); AND

b. When the request is for a replacement of a cochlear implant processor, the following ADDITIONAL documentation must be submitted to the Plan with the prior authorization request, as specified below in item (1) for a replacement request of an existing processor or item (2) for a replacement request when the processor is lost:

(1) 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 (a) through (d):

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

(b) Documentation of the current equipment’s obsolescence if it is the reason for the equipment replacement; AND
(c) Member’s current sound field results and speech testing results utilizing the member’s current cochlear implant equipment; AND

(d) Invoice stating cost of equipment requested; OR

(2) 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 (a) through (c):

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

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

(c) A list of the member’s current equipment

See the Limitations section of this policy for Plan guidelines related to the replacement of external components of a cochlear implant and a switch from a body-worn sound processor to a behind-the-ear sound processor. Benefit coverage varies based on the product in which the member is enrolled. Member benefit documents are available at www.bmchp.org for members enrolled in a BMC HealthNet Plan product, at www.SeniorsGetMore.org for Senior Care Options members, or at www.wellsense.org for members enrolled in a Well Sense Health Plan product.

Limitations

1. Contraindications to cochlear implants include at least ONE (1) of the following, as specified below in items a through f:

   a. Absence of cochlear development as demonstrated on CT scan; OR

   b. Active or chronic infection of the external or middle ear and mastoid cavity; OR

   c. Tympanic membrane perforation; OR

   d. Cochlear ossification that prevents electrode insertion; OR

   e. Deafness due to lesion(s) of the 8th cranial nerve (acoustic nerve), central auditory pathway, or brain stem; OR

Cochlear Implants

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f. Lack of motivation preoperatively by the adult member to participate in the rehabilitation process or lack of family support or family interest in participating in the rehabilitation process for pediatric member. (Participation in the rehabilitation process is essential for optimal benefit from the cochlear implant; rehabilitation may include telephone use, communication strategies, speech reading and auditory training after cochlear implantation.)

2. Upgrade of an existing and functional external component of a cochlear implant system to achieve aesthetic improvement (such as smaller profile components) is not considered medically necessary.

3. A switch from a body-worn, functioning, external sound processor to a behind the ear model to achieve aesthetic improvement is not considered medically necessary.

4. The Plan considers unilateral or bilateral cochlear implantation to be experimental and investigational when used as a treatment for a member with unilateral hearing loss (with or without tinnitus).

5. The Plan considers hybrid cochlear implants to be experimental and investigational because the long-term safety, effectiveness, and impact on quality of life have not been established; this includes the MED-EL EAS Hearing Implant System (by MED-EL Corporation) or the Nucleus® Hybrid™ L24 Cochlear Implant System (by Cochlear Americas).

6. The Plan considers cochlear implants with Bluetooth technology integrated within the device itself or accessories that allow for Bluetooth technology’s wireless streaming of sound to the device to be experimental and investigational because the effectiveness has not been established.

7. Currently, there are no cochlear implant systems FDA approved for children less than 12 months of age. A request for a cochlear implantation for a member younger than 12 months of age with active infection (to prevent closure of the cochlear space with new bone growth or fibrous tissue ingrowth) requires Plan Medical Director review.

See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

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.

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. Decibel Hearing Level

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 imply normal hearing. According to the American Speech-Language-Hearing Association (ASHA), hearing loss can be classified as 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.

Hybrid Cochlear Implants: Hybrid cochlear implants use electroacoustic technology to improve hearing loss for individuals with bilateral, severe to profound sensorineural hearing loss of high-frequency sounds but who still have the ability to hear lower frequencies in the contralateral ear. The hybrid device combines the electrostimulation technology used in traditional cochlear implants with the acoustic amplification technology found in hearing aids. Some individuals with severe to profound sensorineural hearing loss may still hear low-frequency sounds, and this residual hearing is at risk during standard cochlear implantation due to the surgical technique and to the dimensions of the traditional cochlear implant electrode array. Since low frequencies are detected in the innermost regions of the cochlea, hybrid cochlear implant arrays are shorter and narrower than standard cochlear implant arrays, and therefore are implanted only partway into the cochlea to avoid damaging areas still capable of detecting low-frequency sound. The typical candidate for a hybrid cochlear implant has

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normal to moderate sensorineural hearing loss in the low frequencies (thresholds no poorer than 60-65 dB HL up to and including 500 Hz) with severe to profound mid- to high-frequency hearing loss (no better than 70dB HL to 75 dB HL at threshold average 2000, 3000, and 4000 Hz) in the ear to be implanted; for the contralateral (non-implanted) ear, thresholds may be worse than for the implanted ear but not better. Examples of FDA-approved hybrid cochlear implants include the MED-EL EAS Hearing Implant System (by MED-EL Corporation) and the Nucleus® Hybrid™ L24 Cochlear Implant System (by Cochlear Americas). Treatment options for sensorineural hearing loss as an alternative to hybrid cochlear implants include the use of bone-conducting and bone-anchored hearing aids (BAHAs), assisted listening devices, air conduction hearing aids, auditory brainstem implants, and electromagnetic middle-ear implants (semi-implantable and totally implantable devices such as cochlear implants).

**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, 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 adapted 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 notice.

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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.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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</thead>
<tbody>
<tr>
<td>69930</td>
<td>Cochlear device implantation, with or without mastoidectomy</td>
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**HCPCS Codes**

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>L8614</td>
<td>Cochlear device, includes all internal and external components</td>
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<tr>
<td>L8615</td>
<td>Headset/headpiece for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>L8616</td>
<td>Microphone for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>L8617</td>
<td>Transmitting coil for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>L8618</td>
<td>Transmitter cable for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>L8619</td>
<td>Cochlear implant, external speech processor and controller, integrated system, replacement</td>
</tr>
<tr>
<td>L8627</td>
<td>Cochlear implant, external speech processor, component, replacement</td>
</tr>
<tr>
<td>L8628</td>
<td>Cochlear implant, external controller component, replacement</td>
</tr>
<tr>
<td>L8629</td>
<td>Transmitting coil and cable, integrated, for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>V5273</td>
<td>Assistive listening device, for use with cochlear implant</td>
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</table>

**Clinical Background Information**

Conventional hearing aids can be divided into the following categories: 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.

Cochlear implants are indicated for adults and children with bilateral severe-to-profound sensorineural hearing loss and associated poor speech discrimination. Cochlear implant surgery is performed under general anesthesia; the surgery typically takes about 1 to 3 hours and can be done

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10 of 22
either in the inpatient or outpatient setting. Contraindications to surgery include poor anesthetic risk, severe mental retardation, severe psychiatric disorders, and/or organic brain syndromes. The standard radiologic evaluation includes computed tomography (CT) scanning to detect mixed fibrous and bony occlusions and anatomical abnormalities. MRI provides better resolution of soft tissue structures and should supplement the CT scan when indicated.

The cochlear implant device consists of a surgically implanted instrument to stimulate nerve fibers and a device that is worn externally to capture, analyze, and code sound. The external parts include a microphone, a speech processor, and a transmitter. The microphone looks like a behind-the-ear hearing aid; it picks up sounds like a hearing aid microphone does and sends them to the speech processor. The speech processor may be housed with the microphone behind the ear, or it may be a small box-like unit typically worn in a chest pocket. The speech processor is a computer that analyzes and digitizes the sound signals and sends them to a transmitter worn on the head just behind the ear. The transmitter sends the coded signals to an implanted receiver just under the skin. The internal (implanted) parts include a receiver and electrodes. The receiver is just under the skin behind the ear. The receiver takes the coded electrical signals from the transmitter and delivers them to the array of electrodes that have been surgically inserted in the cochlea. The electrodes stimulate the fibers of the auditory nerve, and sound sensations are perceived.

Children age 12 months or older with severe-to-profound sensorineural hearing loss bilaterally and minimal speech perception may be considered for cochlear implantation. In the young child, auditory brainstem response, auditory steady state response testing, stapedial reflex testing, and otoacoustic emission testing may be useful when combined with auditory behavioral responses to determine hearing status. Prior to implantation, a trial period with appropriate amplification combined with intensive auditory training should be attempted to ensure that maximal benefit is achieved. Children should also undergo a complete medical evaluation to rule out the presence of active systemic disease that would contraindicate implantation. The child must be otologically stable and free of active middle ear disease prior to cochlear implantation. Preoperative assessment should involve evaluation of the child by an experienced cochlear implant team in home, social, and educational settings to ensure that implantation is the proper intervention. Parental expectations must be addressed, and compliance to habilitation is essential. Because the rate for pneumococcal meningitis is higher in children with cochlear implants and *Streptococcus pneumoniae* is the most common pathogen causing bacterial meningitis in cochlear implant recipients of all ages with meningitis of known etiology, the Advisory Committee on Immunization Practices (ACIP) recommends the age-appropriate pneumococcal vaccine for all individuals who have or are scheduled to receive a cochlear implant.

The U.S. Food and Drug Administration (FDA) first approved cochlear implant devices for adults in 1985 and for children in 1990. According to the National Institute on Deafness and Other Communication Disorders, as of December 2010 approximately 70,000 individuals (over half of whom were children) had received cochlear implants in the United States and over 219,000 individuals received cochlear implants worldwide. Initially, cochlear implants were performed unilaterally; however, bilateral implantation is becoming more common. Dual-ear stimulation allows left-right discrimination of sound location, provides optimum hearing benefits from implantation, and services as a backup in case of

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device malfunction. Bilateral cochlear implantation can be performed simultaneously or sequential implantation procedures.

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. Verify CMS criteria in the applicable NCD or local coverage determination (LCD) and coverage guidelines in the CMS Medicare Benefit Policy for auditory osseointegrated and auditory brainstem devices 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


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15 of 22


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<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
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<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>Q&amp;CMMC</td>
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<tr>
<td>Internal Approval: 02/07/06 Quality and Clinical Management Committee (Q&amp;CMMC)</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 Cochlear Implants (and renumbered policy number OCA 3.301), and the revised policy is effective 10/01/14. Medical criteria for implantable bone-conduction hearing aids are included in a separate medical policy, Implantable Bone-Conduction (Bone-Anchored) Hearing Aids (policy number OCA 3.30), and this revised policy is effective on 10/01/14.

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
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<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;CMMC</td>
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<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>
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<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 impairment (71 and greater dB HL). Added criteria for the bone anchored hearing aids (BAHA), added limitations for the cochlear implant speech processors, updated coding and references.</td>
<td>Version 7</td>
<td>06/29/11: MPCTAC 07/27/11: QIC</td>
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<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</td>
<td>Version 11</td>
<td>10/01/14 06/18/14: MPCTAC 07/09/14: QIC</td>
</tr>
</tbody>
</table>

*Cohlear Implants* (Plan) refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>04/01/15</td>
<td>Review for effective date 08/01/15. Updated Limitations section. Updated</td>
<td>08/01/15</td>
<td>04/15/15: MPCTAC</td>
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<tr>
<td></td>
<td>criteria for the replacement of external components and moved to the Medical</td>
<td></td>
<td>05/13/15: QIC</td>
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<tr>
<td></td>
<td>Policy Statement section. Removed Commonwealth Care, Commonwealth Choice, and</td>
<td></td>
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<tr>
<td></td>
<td>Employer Choice from the list of applicable products because the products</td>
<td></td>
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<tr>
<td></td>
<td>are no longer available. Updated References and Definitions sections.</td>
<td></td>
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<tr>
<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable</td>
<td>01/01/16</td>
<td>11/18/15: MPCTAC</td>
</tr>
<tr>
<td></td>
<td>products and notes. Administrative changes made to the Medical Policy</td>
<td></td>
<td>11/25/15: MPCTAC</td>
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<tr>
<td></td>
<td>Statement section without changing criteria. Revised language in the</td>
<td></td>
<td>(electronic vote)</td>
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<td></td>
<td>Applicable Coding section.</td>
<td></td>
<td>12/09/15: QIC</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Review for effective date 09/01/16. Revised criteria in the Medical Policy</td>
<td>09/01/16</td>
<td>05/18/16: MPCTAC</td>
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<td>Statement and Limitations sections. Updated the Clinical Background</td>
<td></td>
<td>06/08/16: QIC</td>
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<tr>
<td></td>
<td>Information and References sections.</td>
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<tr>
<td>06/01/17</td>
<td>Review for effective date 07/01/17. Administrative changes made to the</td>
<td>07/01/17</td>
<td>06/21/17: MPCTAC</td>
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<td></td>
<td>Summary, Description of Item or Service, Definitions, References, Other</td>
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Cochlear Implants

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<table>
<thead>
<tr>
<th>Policy Revisions History</th>
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<tbody>
<tr>
<td>Applicable Policies, and Reference to Applicable Laws and Regulations sections.</td>
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<table>
<thead>
<tr>
<th>Last Review Date</th>
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<td>06/01/17</td>
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<tr>
<th>Next Review Date</th>
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<td>05/01/18</td>
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<tr>
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<td>MPCTAC</td>
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<tr>
<th>Other Applicable Policies</th>
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<tbody>
<tr>
<td>Medical Policy - <em>Experimental and Investigational Treatment</em>, policy number OCA 3.12</td>
</tr>
<tr>
<td>Medical Policy - <em>Implantable Bone-Conduction (Bone-Anchored) Hearing Aids</em>, policy number OCA 3.30</td>
</tr>
<tr>
<td>Medical Policy - <em>Medically Necessary</em>, policy number OCA 3.14</td>
</tr>
<tr>
<td>Reimbursement Policy - <em>General Billing and Coding Guidelines</em>, policy number 4.31</td>
</tr>
<tr>
<td>Reimbursement Policy - <em>General Clinical Editing and Payment Accuracy Review Guidelines</em>, policy number 4.108</td>
</tr>
<tr>
<td>Reimbursement Policy - <em>Hearing Aid Dispensing and Repairs</em>, policy number 4.111 (MassHealth and Qualified Health Plans)</td>
</tr>
<tr>
<td>Reimbursement Policy - <em>Hearing Aid Dispensing and Repairs</em>, policy number SCO 4.111 (Senior Care Options products)</td>
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<tr>
<td>Reimbursement Policy - <em>Outpatient Hospital</em>, policy number 4.17</td>
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<tr>
<td>Reimbursement Policy - <em>Physician and Non Physician Practitioner Services</em>, policy number 4.608</td>
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<tr>
<td>The Commonwealth of Massachusetts. CMR 130.416. Hearing Aid Dispensing.</td>
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<tr>
<td>The Commonwealth of Massachusetts General Laws, Part I, Title XXII, Chapter 175. Section 47X.</td>
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The Commonwealth of Massachusetts General Laws. Part I. Title XXII. Chapter 176B. Section 4EE.


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.

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