

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: PA.072.MH
Last Review Date: 11/03/2016
Effective Date: 01/01/2017

PA.072.MH – Cochlear Implants and Osseointegrated Bone Conduction Devices

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers **cochlear implants and osseointegrated bone conduction devices** medically necessary for the following indications:

- Cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification.

Coverage is provided only for those patients who meet all of the following selection guidelines based on their appropriate age bracket:

1. **Requirements for adults (age 18 years and over)²:**
 - a) Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition in the ear to be implanted and 60% or less in the non-implanted ear or bilaterally.
 - b) Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.
 - c) Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation and freedom from significantly compromising lesions in the auditory nerve and acoustic areas of the central nervous system.
 - d) No contraindications to surgery.
 - e) The device must be used in accordance with FDA approved labeling for that specific model.
 - f) Cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in any of the following:

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1. An FDA-approved category B investigational device exemption (IDE) clinical trial, or
2. A trial approved or under the supervision of the CMS

2. Requirements for children (ages >1 through 17 years old)⁶:

- a) Diagnosis of bilateral severe- to- profound sensorineural hearing loss AND
- b) The child has limited benefit from appropriately fitted bilateral hearing aids. Limited benefit is defined as:
 1. Less than 12% correct on the Phonetically Balanced-Kindergarten Test OR
 2. Less than 30% correct on the Hearing In Noise Test, the open-set Multisyllabic Lexical Neighborhood Test or Lexical Neighborhood Test depending on the child's cognitive ability and linguistic skills.
- c) In cases of sudden hearing loss from meningitis, all of the above indications may be waived.
- d) An absence of medical contraindications, such as chronic middle ear pathology, some lesions of the VIIIth cranial nerve, some pathologies of the central auditory pathway, and other medical issues that preclude surgical procedures;
- e) Family commitment to post-implant appointments and the re/habilitation process and realistic expectations for cochlear implant use and benefit.
- f) For children without previous experience with hearing aids and a 3-6 month hearing aid trial has been attempted and failed.
- g) The device must be used in accordance with FDA approved labeling for that specific model.

Bilateral Cochlear Implantation - Members who are approved for one implant are candidates for implants in both ears based on evidence of improved directional hearing and better hearing in background noise with binaural use.

Bilateral cochlear implant surgery may be covered when the decision to provide a second implant to a patient is based on all of the following criteria (points a through d):

- a) The physician's and cochlear implant team's expectations for improved performance in the second ear with binaural use.
- b) Reasonable and realistic expectations of the anticipated benefit from the second implant from the patient and their family.
- c) The absence of medical or surgical contradictions for the patient to undergo surgical intervention - these include:
 1. Chronic ear disease in the second ear
 2. Tympanic membrane perforation

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3. Cochlear canal anatomy precluding successful implantation
 4. Deafness in the second ear for >20 years that has been without aural amplification (A hearing aid should have been used during this time period).
- d) The device must be used in accordance with Food and Drug Administration (FDA) approved labeling for that specific model.

Bilateral cochlear implantation can be done either simultaneously or sequentially. Each type has different indications:

1. For Bilateral Simultaneous Implantation, any one of the following:
 - b) Bilateral hearing loss in the “profound” audiometric range for both ears since birth;
 - c) Normal labyrinthine, mastoid, middle ear and ear canal anatomy; or
 - d) Recent history of meningitis.
2. For Bilateral Sequential Implantation in members already unilaterally implanted, all of the following:
 - a) Second ear must meet cochlear implant candidacy criteria as described above for unilateral implants at the time of initial evaluation for the first cochlear implant.
 - b) Member should have developed reasonable abilities in the implanted ear.
 - c) The second ear is a potential candidate if the first side did not achieve sufficient function due to complications or unanticipated outcome due to it being the poorer hearing ear at time of original implantation.

BAHA Implants⁷

A bone anchored (BAHA Implant) hearing device may be considered for all of the following criteria in patients who are 5 years of age or older:

- a) The audiometric criterion of the candidate with a conductive or mixed hearing loss is a 45 dBHL bone conduction pure tone average (0.5K, 1K, 2K, 3K) and 60% monosyllabic word score in the indicated ear. The patient can have a bilateral or unilateral conductive hearing loss;
- b) Hearing loss that is not correctible in at least one ear by medical or surgical intervention;
- c) The patient is unable to use conventional air conduction hearing aid due to a congenital malformation of the external ear canal or middle ear, chronic otitis or active chronic suppurative otitis media, tumors of the external ear canal or refractory dermatitis of the external canal;

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- d) A patient with profound sensorineural hearing loss and normal hearing in the opposite ear defined as a 20 dBHL air conduction pure tone average (0.5K, 1K, 2K, and 3K) is considered a BAHA candidate; and
- e) The patient meets FDA audiologic criteria for use of the specific model requested.

Bilateral BAHA Implantation

Surgery may be covered when the decision to provide a second implant to a patient is based on the above criteria and when the symmetric bone conduction threshold is defined as either of the following:

- a) Less than 10 dB difference on average between ears (average of 0.5, 1, 2, and 3kHz); or
- b) Less than 15 dB difference at individual frequencies between ears.

Limitations

Those with cochlear implants may be at a particularly increased risk for pneumococcal meningitis. Cochlear implant recipients and all potential implant recipients must be up-to-date with age appropriate recommended vaccinations according to the CDC/Advisory Committee on Immunization Practices (ACIP) to prevent pneumococcal infections.¹

Replacement and Upgrades

Replacement:

- The currently used component is no longer functional and the component cannot be repaired;
- The currently used component renders the implant recipient unable to adequately and/or safely perform his/her age appropriate activities of daily living;
- The replacement of existing external components with upgraded components when done solely to improve appearance or to treat psychological symptomatology or complaints because it is considered not medically necessary and will not be covered.

Upgrades:

- Upgrades to existing cochlear implant systems already in place as medically necessary are covered when one of the following criteria is met:
 1. The currently used component is no longer functional and the component cannot be repaired;
 2. The currently used component renders the implant recipient unable to adequately and/or safely perform his/her age appropriate activities of daily living;

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3. The upgrade is shown to have significant improvement in the patient's listening and speech performance, or
4. Upgraded technology offers significant potential to improve functionality.

Background

It is estimated that more than 25 million Americans have hearing loss, including one out of four people older than 65.¹ Hearing loss primarily affecting the external and middle ear is referred to as conductive hearing loss. The type of loss which may be helped by a cochlear implant is known as sensorineural hearing loss or nerve deafness, which results when delicate portions of the inner ear known as hair cells have been damaged and fail to perform their normal function of converting sound waves into electrical current that stimulates the auditory nerve to transmit impulses to the brain, where they are recognized as sound.

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

The implant has 4 basic components: a microphone worn externally behind the ear, which picks up sounds; an external speech processor, which converts sounds to electrical signals; a transmitter and receiver/stimulator which forward the signals; and implanted electrodes, which stimulate the fibers of the auditory nerve.

The evidence is adequate to conclude that cochlear implantation is reasonable and necessary for treatment of bilateral pre-or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of $\leq 40\%$ correct in the best-aided listening condition on tape recorded tests of open-set sentence cognition.

The evidence is sufficient to conclude that a cochlear implant is reasonable and necessary for individuals with hearing test scores of $> 40\%$ and $\leq 60\%$ only when the provider is participating in and patients are enrolled in either an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses²

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Variations

For Medicare Members:

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Medicare coverage is provided only for those patients who meet all of the following selection guidelines:

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- 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;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling

Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective,

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controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

Codes:

CPT/HCPCS codes covered if selection criteria are met (If Appropriate):

Code	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone (Replacement procedure includes removal of old device)
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69930	Cochlear device implantation, with or without mastoidectomy
L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device, replacement
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement

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L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, replacement

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