

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: MP.072
REVISION DATE: 05/2009
ANNUAL APPROVAL DATE: 07/2009
PAGE NUMBER: 1 of 10

SUBJECT: Cochlear Implants and Osseointegrated Bone Conduction Devices (Baha)
INDEX TITLE: Medical Management
ORIGINAL DATE: April 2007

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()	POS ()	PPO ()	OOA ()		
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)		
Medicare Select ()	Medicare Supplement ()				
DPW-MA:					
Health Choices ()	Voluntary ()		All (X)		
CMS-MA:					
OH ()	WV ()	PA ()	All (X)	Other ()	
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS ()	All ()
PID-CHIP:					
Free ()	Sub ()	Full ()	All (X)		
APPLICABLE TO:					
Community Care ()	Work Partners ()				

I. POLICY

It is the policy of UPMC Health Plan to recognize coverage of cochlear implants and osseointegrated bone stimulators (Baha) as appropriate and consistent with good medical practice when performed according to the clinical criteria described below. It is the policy of UPMC Health Plan to authorize payment for services that are medically necessary and covered under the member's benefit plan.

This policy addresses cochlear implants and the Baha implant only. This review excludes hearing aids which generally are not a covered benefit.

All denials are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director (Medical Director).

II. DEFINITIONS

Baha Implant (implantable osseointegrated bone conduction hearing device): is a surgically implantable system for treatment of hearing loss that works through direct bone conduction. A titanium post, or fixture, is surgically implanted into the skull on the side of the head with hearing impairment. An abutment is coupled to the fixture which exits through a small opening through the skin. After a period of time allowing for healing and osseointegration a sound processor is attached to the abutment and transmits sound vibrations to the skull and inner ear which stimulates the cochlear hair cells of the

ipsilateral ear for patients with conductive or mixed hearing loss or the contralateral normal hearing inner ear for patients with single sided deafness (unilateral severe to profound sensorineural hearing loss). The purpose of the Baha implant for patients with conductive hearing loss is to bypass the function of the external ear canal, tympanic membrane and the middle ear and provide energy to the cochlea via a transducer. Patients with unilateral complete sensorineural hearing loss (single sided deafness) benefit from placement of the Baha device on the anacoustic side which allows the vibratory sound energy to be transmitted through the skull to the contralateral cochlea. Stereo hearing results in patients being able to “hear” from the anacoustic side without turning their good ear to the sound source, improved understanding of speech especially in background noise and assists in the localization of sound.

Cochlear Implant: is an electronic instrument, part of which is surgically implanted to stimulate auditory nerve fibers, and part of which is externally worn or carried by the individual to capture, analyze, and code sound and then deliver the signal to the internal receiver. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons with severe to profound bilateral sensorineural hearing loss. The purpose of the cochlear implant is to replace or bypass the function of the cochlear hair cells and provide electrical energy to cochlear (auditory) nerve fibers via an implanted electrode array.

Hearing Aid: is an electronic device which helps people with hearing impairment hear sound and speech better. The components of a traditional hearing aid include an externally worn microphone, circuitry for amplification and a receiver (speaker). External hearing aids can be divided into air conduction hearing aids or bone conduction hearing aids. Air conduction devices provide amplified acoustic energy to the cochlea through the external auditory canal. Bone conduction devices provide mechanical energy to the cochlea via stimulation of the skull with amplified mechanical vibration. Certain devices that produce perception of sound by replacing or enhancing the function of the tympanic membrane, middle ear, and cochlea are considered prosthetic hearing devices eligible for financial coverage. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic ear disease, or severe-to-profound sensorineural hearing loss. Cochlear implants and the Baha implant are considered prosthetic devices.

III. PURPOSE

The purpose of this policy is to establish pre-authorization criteria for coverage of cochlear implants, and the Baha implant.

IV. SCOPE

This policy applies to various UPMC Health Plan Departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Background/Medical Description

Hearing impairment is a reduction in the ability to perceive sound and/or speech. Hearing impairment can vary from mild to profound and is classified as conductive hearing loss, sensorineural hearing loss or mixed hearing loss. There are various interventions, devices and procedures available for treating each type of hearing loss. Prior to determining treatment options, a comprehensive otologic history and physical examination are obtained and an audiological evaluation should be completed to determine the type and severity of the hearing loss. The physician, in conjunction with the audiologist, determines the most appropriate treatment plan.

A cochlear implant is a small, complex electronic device that can provide a sense of sound to a person with severe to profound sensorineural hearing loss. The basic components of a cochlear implant include both internal and external components. The internal device contains a magnet and internal antenna for transcutaneous attraction of the external headpiece and to receive its FM signal, respectively. The internal receiver transforms the signal into electrical impulses that are sent to the auditory nerve through a multi-channel electrode surgically inserted into the inner ear through a very small opening drilled into the cochlea.

The external components consist of:

- A microphone, which picks up sound and speech from the environment;
- An external sound processor, which then selects and processes sounds and speech into a meaningful encoded electrical signal;
- A magnet within the center of the transmitter which provides attraction over the internal receiver;
- A transmitter which receives encoded signals from the sound processor and sends the signal across the skin to the internal receiver.

The internal components consist of:

- A magnet within the internal receiver which attracts and orients the external headpiece over the internal receiver;
- A receiver/stimulator, which converts the incoming signals to electrical impulses that are then conveyed to the electrode array;
- An electrode array implanted in the cochlea, which transmits the impulses from the stimulator and stimulates the auditory nerve which delivers the encoded message to the hearing pathway in the brain. The cochlea is the part of the inner ear that is responsible for hearing.

A cochlear implant does not restore or create normal hearing, but can give a deaf person a useful auditory understanding of the environment and help them understand speech. For those profoundly postlingual deaf adults who cannot significantly benefit from a hearing

aid, the cochlear implant provides not only awareness of environmental sounds but can provide understanding of speech with and without speech (lip) reading.

Patients who are eligible for a cochlear implant have severe to profound sensorineural hearing loss and auditory amplification is insufficient. Once a patient has been deemed eligible for a unilateral implant, by definition the hearing loss is of sufficient magnitude to be eligible for bilateral cochlear implantation. Bilateral cochlear implants are performed either simultaneously (at the same operative encounter) or sequentially (two separate procedures performed over an interval of time). Simultaneous bilateral cochlear implants are more often performed in young children. This may occur in a circumstance where maximal benefit is desired with profound hearing loss since birth or in a case where the patient becomes deaf following meningitis. The propensity for the otic capsule to develop labyrinthitis ossificans warrants more rapid intervention to facilitate electrode placement.

Bone anchored hearing devices (Baha) are designed for individuals who have conductive, mixed, or sensorineural hearing loss. The device is composed of three components- a titanium implant called the fixture, an external abutment, and a sound processor. The system works by transmitting sound directly to the hearing nerve without involving the external ear or middle ear. Patients having problems with the external auditory canal (absence, stenosis or chronic infection) can benefit from the Baha since it is not inserted into the ear canal. A Baha sound processor offers sound quality at least as good as a conventional air conduction device. In people with sufficient thickness of the skull (usually patients greater than 9 years of age) the operative procedure can be done in one stage. The titanium fixture and abutment are implanted into the mastoid bone. The abutment protrudes a few millimeters through the skin which has been thinned to remove underlying hair follicles. After three to four months the fixture should have strong osseointegration into the bone permitting use of the sound processor. This is connected by an attachment that is snapped off and on. In children the bone may be too thin to permit a one-stage procedure. In this situation the fixture is implanted into the bone and covered with a small cap. During a second stage procedure 4-6 months later, an opening through the skin over the fixture is made and the abutment is attached. After a healing period of 1-3 months, the processor can then be used.

B. Specific 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:

For adults (age 18 years and over):

- 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 50% correct in the best-aided listening condition on tape-recorded tests of open-set

- sentence recognition in the ear to be implanted and 60 percent or less in the non-implanted ear or bilaterally.
- 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 significantly compromising lesions in the auditory nerve and acoustic areas of the central nervous system.
 - No contraindications to surgery.
 - The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling for that specific model.
 - Cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 50% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in any of the following:
 - An FDA-approved category B investigational device exemption (IDE) clinical trial **OR**
 - A trial approved or under the supervision of the Centers for Medicare & Medicaid Services (CMS).

For children under the age of 2 years:

- Diagnosis of bilateral profound sensorineural hearing loss **and**
- The child has limited benefit from appropriately fitted bilateral hearing aids. Limited benefit is defined as the lack of improvement in auditory skills with hearing aid amplification for 3-6 months using any of the following:
 1. Infant-Toddler Meaningful Auditory Integration Scale
 2. The Meaningful Auditory Integration Scale
 3. Lack of progress on The Early Speech Perception test

In cases of sudden hearing loss from meningitis, all of the above indications may be waived.

For children age 2 years and over:

- Diagnosis of bilateral severe- to- profound sensorineural hearing loss **and**
- 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 Multi-syllabic Lexical Neighborhood Test or Lexical Neighborhood Test depending on the child's cognitive ability and linguistic skills.
- In cases of sudden hearing loss from meningitis, all of the above indications may be waived
- For children without previous experience with hearing aids and a 3-6 month hearing aid trial has been attempted and failed.

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:

- The physician's and cochlear implant team's expectations for improved performance in the second ear with binaural use.
- Reasonable and realistic expectations of the anticipated benefit from the second implant from the patient and their family.
- 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
 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)

AND

For **Bilateral Simultaneous** Implantation:

- Bilateral hearing loss in the "profound" audiometric range for both ears since birth
 - Normal labyrinthine, mastoid, middle ear and ear canal anatomy
- OR**
- Recent history of meningitis

For **Bilateral Sequential** Implantation in members already unilaterally implanted:

- 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.
- Member should have developed reasonable abilities in the implanted ear.
- 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.

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:

- The audiometric criterion of the candidate with a conductive or mixed hearing loss is a 45 dBHL bone conduction pure tone average (.5K, 1K, 2K, 3K) and 60% monosyllabic word score in the indicated ear. The patient can have a bilateral or unilateral conductive hearing loss
- Hearing loss that is not correctible in at least one ear by medical or surgical intervention; **and**
- 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.
- Patients with profound sensorineural hearing loss and normal hearing in the opposite ear defined as a 20 dBHL air conduction pure tone average (.5K, 1K, 2K, and 3K) is considered a Baha candidate.
 - 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:

- less than 10 dB difference on average between ears (average of 0.5, 1, 2, and 3kHz) **OR**
- less than 15 dB difference at individual frequencies between ears

C. Limitations

Cochlear implants are contraindicated for:

- Deafness due to lesions of the acoustic nerve or central auditory pathway; (an exception may exist in patients diagnosed with auditory neuropathy where cochlear implantation may provide benefit by delivering a synchronized stimulus to the cochlear nerve);
- Otitis media or other active, aural disease processes; or
- Complete cochlear aplasia.

Following implantation the successful achievement of effective oral communication depends heavily on postoperative speech rehabilitation. This is especially pertinent to children. This is done through an audiologist or speech-language pathologist with special training at the implant center or through the child's institution for education. This rehabilitation period usually consists of 6-10 sessions of 2 ½ hours each.

D. Replacement and Upgrades

Replacement:

- UPMC Health Plan will not cover 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.

Upgrade:

- UPMC Health Plan covers upgrades to existing cochlear implant systems already in place as medically necessary when one of the following criteria is met:
 1. the currently used component is no longer functional and the component can not be repaired; or

2. the currently used component renders the implant recipient unable to adequately and/or safely perform his/her age appropriate activities of daily living; or
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.

E. Information Required for Review

In order to assess medical necessity for cochlear implants or the Baha implant adequate information must be furnished by the treating physician. Necessary documentation includes, but is not limited to, the physician's evaluation of the member's condition to determine medical necessity of the procedure, including results of the audiological evaluation and testing.

F. Review Process

1. The Medical Management staff assigned to review the clinical information according to the Prior Authorization/Pre-Service Review policy - CRM.001 determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to the Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate according to CRM.005 - Medical Director Referral and CRM .015- Medical Necessity policy.
3. The Medical Management staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan (CRM.004 – Timeliness of Utilization Management Decisions – Medicaid; CRM.007 – Timeliness of Utilization Management Decisions – Commercial and CHIP, CRM.022 – Timeliness of Utilization Management Decisions – Medicare).

H. Variations

N/A

I. References:

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7. Centers for Medicare and Medicaid Services, MLN Matters # 4038, Auditory Osseointegrated and Auditory Brainstem devices. Nov 10,2005
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12. Aetna Clinical Policy Bulletin:Cochlear Implants and Auditory Brainstem Implants, Number 0013, 02/12/2008,
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14. Cigna HealthCare, Coverage Position Number 0190, Cochlear and Auditory Brainstem Implants. 05/15/2008
15. Cigna HealthCare, Coverage Position Number 0093, Hearing Aids. 05/15/2008
16. Centers for Medicare & Medicaid Services, NCD for Cochlear Implantation 50.3, 07/25/2005

Disclaimer:

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

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