## Subject: Cochlear Implants

**Background:** Cochlear implants are surgically implanted prosthetic devices that use electrical stimulation to provide hearing. The criteria for implantation include moderate to severe bilateral sensorineural hearing loss and an individual who still struggles to hear and understand despite appropriately fit hearing aids. The goal of cochlear implantation is to restore hearing by converting received sounds into electrical impulses that stimulate the auditory nerve, thereby performing the function normally performed by cochlear hair cells.

Bone-anchored hearing aids (BAHAs) are surgically implanted hearing devices that transmit sound directly to the inner ear through bone, bypassing the external auditory canal and middle ear. A titanium screw implanted into the skull allows removable coupling of the sound processor to the bone. BAHAs are intended to improve hearing acuity in individuals who have moderate to severe conductive or mixed hearing loss.

An auditory brainstem implants (ABI) is a surgically implanted electronic device where the electrode is placed into the brain on the first auditory relay station in the brainstem and cochlear nucleus. ABIs may be used for those who have severe hearing loss.

## Authorization:

Prior authorization is required for unilateral, bilateral and hybrid implants requested for members enrolled in commercial (HMO, POS, and PPO) products.

## Policy and Coverage Criteria:

**Cochlear Implants - Unilateral or Bilateral Implants for Adults**

Harvard Pilgrim Health Care (HPHC) considers unilateral or bilateral U.S. Food and Drug Administration (FDA)-approved cochlear implants as reasonable and medically necessary for individuals age 18 years or older when documentation confirms ALL the following criteria:

- Member has pre- or post-lingual hearing loss and has limited benefit from hearing (or vibrotactile) aids; AND
- Member demonstrates limited benefit from amplification, which 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; AND
- Member has cognitive ability to use auditory clues and a willingness to participate in an extended rehabilitation program; AND
- Member has freedom from middle ear infection and from lesions in the auditory nerve and acoustic areas of the central nervous system; AND
- Member has no contraindications to surgery; AND
- Member must be current on age-appropriate pneumococcal vaccinations per Centers for Disease Control and Prevention (CDC) guidelines.

**Cochlear Implants - Unilateral or Bilateral Implants for Children**
Harvard Pilgrim Health Care (HPHC) considers unilateral or bilateral U.S. Food and Drug Administration (FDA)-approved cochlear implants as reasonable and medically necessary for children up to age 17 when documentation confirms bilateral profound sensorineural hearing impairment, member is current on age-appropriate pneumococcal vaccinations per CDC guidelines, and hearing aids provide no benefit.

**Cochlear Implants - Hybrid Implants for Adults**
Harvard Pilgrim Health Care (HPHC) considers hybrid cochlear implant or hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant (e.g. Nucleus® Hybrid™ L24 Cochlear Implant System) as medically necessary when documentation confirms ALL the following criteria:

- Member is 18 years or older; AND
- Member has bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; AND
- Member has obtained limited benefit from appropriately fitted bilateral hearing aids; AND
- Member must be current on age-appropriate pneumococcal disease vaccinations per CDC guidelines; AND
- Member has ANY of the following hearing thresholds:
    - Low frequency hearing threshold no poorer than 60 decibel hearing level (dbHL) up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation, OR
    - Severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 75 dbHL) in the ear to be implanted, OR
    - Moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, 4000 HZ greater than or equal to 60 dbHL) in the contralateral ear, OR
    - Aided consonant-nucleus-consonant (CNC) word recognition score from 10-60% in the ear to be implanted in the preoperative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct.

NOTE: Special consideration of urgent cochlear implantation without a trial of hearing aids may be given to individuals with meningitis and hearing loss or radiologic evidence of cochlear ossification.

**Bone-Anchored Hearing Aids**
Harvard Pilgrim Health Care (HPHC) considers fully or partially implanted bone-anchored hearing aids that are U.S. Food and Drug Administration (FDA)-approved (e.g. Bonebridge Bone Conduction Implant) as reasonable and medically necessary for individuals 5 years of age or older when documentation confirms ALL the following criteria:

- Member has at least ONE of the following conditions:
    - Dermatitis of the external canal, OR
    - Tumors of the external canal and/or tympanic cavity, OR
      Congenital or surgically induced malformations of the external or middle ear, OR
    - Severe chronic external otitis or otitis media
- Member must be current on age-appropriate pneumococcal disease vaccinations per CDC guidelines; AND
- Member has failed conventional treatment and ANY of the following:
    - For members with unilateral hearing loss, individual has conductive or mixed hearing loss and can still benefit from amplification of the sound. Pure tone average (PTA) bone conduction (BC)

threshold for the indicated ear should be better than 45 dBHL (measured at 0.5, 1, 2 and 3 kHz), OR
    - For members with bilateral hearing loss, individual has symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5. 1, 2 and 4 kHz, or less than 15 dB at individual frequencies, OR
    - For members with sensorineural hearing loss, individual has profound hearing loss in one ear and normal hearing in the opposite ear and cannot use an air conduction contralateral routing of signal (AC CROS). Pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than 20 dBHL (measured at 0.5, 1, 2 and 3 kHz).

Harvard Pilgrim Health Care (HPHC) considers Baha® Softband as reasonable and medically necessary as an alternative to fully or partially implanted bone-anchored hearing aids for children under 5 years.

NOTE: Bone-anchored hearing aids are only covered when hearing aid coverage is included in a member's benefit plan. Refer to the member's specific benefit plan to determine if coverage applies.

**Auditory Brainstem Implant**
Harvard Pilgrim Health Care (HPHC) considers an auditory brainstem implant (ABI) as reasonable and medically necessary for members age 12 years or older when documentation confirms ALL the following:

- Individual has diagnosis of neurofibromatosis type 2; AND
- Individual is expected to become completely deaf due to bilateral removal of tumors of the auditory nerves

**Replacements**
Harvard Pilgrim Health Care (HPHC) considers the replacement of cochlear implants as medically necessary when documentation confirms ALL the following:

- The present implant has been rendered ineffective or inoperable due to either:
    - A change in member condition that the current implant is unable to accommodate OR
    - Being damaged by events outside the control of the user
- Continued use of the device is supported; AND
- Device replacement is not solely based the expiration of device warranty; AND
- Loss/damage is not attributable to abuse, sabotage, or neglect on the part of the user; AND
- The cost of replacement rather than repair is justified by the nature of damage and useful lifetime of the device; AND
- The replacement is not an additional/backup implant; AND
- The replacement implant is synonymous to the implant being replaced unless replacement has been necessitated by a change in member condition the old device is unable to accommodate.

Note: In cases where neither the make and model of the device being replaced nor directly competitive devices from other brands are available, selection of a new device must be based on meeting the requirements associated with member condition.

**Exclusions:** Harvard Pilgrim Health Care (HPHC) considers cochlear implants as not medically necessary for all other indications. In addition, HPHC does not cover:

- Bone-anchored hearing aids for individuals below the age of 5
- Intraoral bone conduction hearing aids

- Bone-anchored hearing aids for individuals with bilateral pure sensorineural hearing loss
- Auditory neuropathy
- SoundBite Hearing System

## Supporting Information:

Cochlear hair cell vibration stimulates the auditory nerve, thereby converting sound vibrations into nerve impulses, which travel along the auditory nerve pathway to the auditory cortex of the brain, where they are interpreted as sound. While hearing loss may be related to abnormalities in the sound conduction system of the outer and middle ear, most hearing deficits in newborns and the elderly result from sensorineural abnormalities, particularly cochlear hair cell loss, which limits cochlear ability to convert sound vibrations into nerve impulses. Cochlear hair cell loss may be caused by a variety of disorders and mechanisms and cannot be remedied by any known means. This type of hearing loss has typically been treated with rehabilitation strategies involving hearing aids, vibrotactile aids, lip reading, and/or sign language, as well as speech and language therapy. Of these techniques, all assist communication ability, but only hearing aids can improve hearing. This is achieved by amplifying incoming sounds, which amplifies vibrations received by remaining cochlear hair cells. However, amplification does not replace the function of lost cochlear hair cells and often cannot provide adequate hearing in the case of severe cochlear hair cell loss. If neural elements that transmit information from the cochlea to the auditory cortex remain intact and functional, it is possible to stimulate auditory nerve impulses with a prosthetic cochlear implantation (CI) device. With CI, externally worn components, including a microphone, a speech processor, and a transmitter, capture sounds from the environment, transform sounds into electronic impulses, and send electronic impulses to an implanted receiver/stimulator, which conveys electronic impulses to the auditory nerve via electrodes implanted in the cochlea. By electrically stimulating the auditory nerve, CI performs the function normally performed by cochlear hair cells, thereby restoring some degree of hearing.

Tang et al. 2018 conducted a multicenter, prospective case series for 20 patients (age 7 to 67) with conductive hearing loss (n=13), mixed hearing loss (n=3) or single-sided deafness (SSD) (n=4). The reports showed significant improvement with greater than 30dB from 500 to 4000kHz ($p<0.05$). All individuals were satisfied (>80%) with the implant and the authors concluded hearing among patients was safely restored for those with conductive or mixed hearing loss and SSD.

Sprinzl and Wolf-Magele et al. 2016 conducted a systematic review to evaluate the safety and efficacy of Bonebridge for those with conductive or mixed hearing loss as well as single-sided deafness (SSD). The authors reviewed findings from 217 patients within the span of 29 total studies (17 published and 12 presentations). The studies revealed improved hearing thresholds and speech recognition with the Bonebridge for adults and children with either type of hearing loss. The authors concluded the bone conduction implant provided a valuable benefit to those experiencing conductive or mixed hearing loss and SSD.

Lammers et al. 2014 summarized the evidence on the effectiveness of bilateral cochlear implantation compared with unilateral implantation among children with sensorineural hearing loss. A total of 21 studies evaluated bilateral implantation in children, with no randomized controlled trials identified. One study demonstrated improvements in language development, although other studies found no significant improvements. The currently available evidence consists solely of cohort studies that compare a bilaterally implanted group with a unilaterally implanted control group, with only one study providing a clear description of matching techniques to reduce bias.

Kiringoda et al. 2013 summarized peer-reviewed literature to describe the range and rate of complications related to osseointegrated hearing aids in adult and pediatric individuals. The review states that after excluding articles

that did not meet criteria, 20 articles were identified, comprising 2,134 patients who underwent a total of 2,310 osseoimplants. Complications reported in the literature were typically minor in nature. Skin reactions from Holgers Grade 2 to 4 ranged from 2.4% to 38.1%. Failure of osseointegration ranged from 0% to 18% in adult and mixed populations, and 0% to 14.3% in pediatric populations. The rate of revision surgery ranges from 1.7% to 34.5% in adult and mixed populations and 0.0% to 44.4% in pediatric patients, whereas the total rate of implant loss ranged from 1.6% to 17.4% in adult and mixed populations and from 0.0% to 25% in pediatric patients.

Nadaraja et al. 2013 performed a systematic review to compare hearing outcomes of atresiaplasty versus osseointegrated bone conduction devices (OBCD) in congenital aural atresia (CAA) patients. Results showed that of the atresiaplasty ears, 73.8% (95% CI, 62.2%-85.4%), had a SRT [speech reception threshold] less than 30 dB (338 ears), 60.3% (95% CI, 45.8%-74.8%) had a PTA [pure tone average] less than 30 dB (390 ears), and 68.9% (95% CI, 59.4%-78.3%) had an ABG [air-bone gap] less than 30 dB (852 ears). The average hearing gain was 24.1 dB (95% CI, 21.62-26.51) for 516 ears, however hearing outcomes deteriorated with time. Of OBCD patients, 95.9% (95% CI, 91.5%-100.0%) had a PTA less than 30 dB (77 ears), and 98.2% (95% CI, 94.5%-100.0%) had an ABG less than 30 dB (47 ears); the average hearing gain was 38.0 dB (95% CI, 33.14-45.22) in 100 ears.

Jansenn et al. 2012 conducted a systematic review of the outcomes of bilateral versus unilateral (BAHA) for individuals with bilateral permanent conductive hearing loss (CHL) with the goal of deriving clinically oriented insights into the advantages and disadvantages of bilateral fitting and to identify gaps in knowledge to stimulate future research. Based on their research, 628 abstracts were generated from the literature searches; 11 studies met the criteria for data extraction and analysis. All 11 studies were observational. In most studies, comparisons between unilateral and bilateral BAHA were intra-subject. Bilateral BAHA provided audiologic benefit compared to unilateral BAHA (improved thresholds for tones [2 studies], speech in quiet [5 studies] and in noise [3 studies], and improved localization/lateralization [3 studies]) and patients' perceived subjective benefit from bilateral BAHA (3 studies). Disadvantages of bilateral BAHAs included listening in noise in some conditions (3 studies), presumed additional cost, and presumed increase in adverse event risk.

## Guidelines:

The National Institute for Health and Care Excellence (NICE, 2009) guidelines recommend unilateral cochlear implantation as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.

Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids:

- Children
- Adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.

**American Speech-Language-Hearing Association (ASHA)**
**Degree and Configuration of Hearing Loss**

| Degree of Hearing Loss | Range of Hearing Loss (dbHL = Decibels Hearing Level) |
|---|---|
| Normal | -10 to 15 dbHL |
| Slight | 16 to 25 dbHL |

| | |
|---|---|
| Mild | 26 to 40 dbHL |
| Moderate | 41 to 55 dbHL |
| Moderately Severe | 56 to 70 dbHL |
| Severe | 71 to 90 dbHL |
| Profound | 91+ dbHL |

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2016) considers bone conduction hearing devices, including implantation of a percutaneous or transcutaneous device and use of a bone conduction oral appliance or bone conduction scalp device to be acceptable, and in many cases preferred, procedures in the treatment of conductive or mixed hearing loss and single-sided deafness when performed by-a qualified otolaryngologist-head and neck surgeon. Use of these devices, which have been Food and Drug Administration (FDA)-approved for these indications, should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and other similar regulatory agencies in countries other than the United States.

Based on the 2002 Centers for Disease Control and Prevention (CDC) Guidelines, members who are recipients of cochlear implants must receive age-appropriate vaccinations against pneumococcal diseases. The Advisory Committee on Immunization Practices (ACIP) recommends the following:

- Children with cochlear implants age <24 months should receive PCV7, as is universally recommended; children with a lapse in vaccination should be vaccinated according to the catch-up schedule issued after the PCV7 shortage resolved (4,5).
- Children age 24-59 months with cochlear implants who have not received PCV7 should be vaccinated according to the high-risk schedule; children with a lapse in vaccination should be vaccinated according to the catch-up schedule for persons at high risk issued after the PCV7 shortage resolved (3,4). Children who have completed the PCV7 series should receive PPV23 >2 months after vaccination with PCV7 (3).
- Persons age 5-64 years with cochlear implants should receive PPV23 according to the schedule used for persons with chronic illnesses; a single dose is indicated (6).

Persons planning to receive a cochlear implant should be up-to-date on age-appropriate pneumococcal vaccination >2 weeks before surgery, if possible.

## Coding:

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

| CPT® Codes | Description |
|---|---|
| **69710** | Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone |
| **69711** | Removal or repair of electromagnetic bone conduction hearing device in temporal bone |
| **69715** | Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy |
| **69930** | Cochlear device implantation, with or without mastoidectomy |
| **92601** | Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming |

| | |
|---|---|
| **92602** | Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming |
| **92603** | Diagnostic analysis of cochlear implant, age 7 years or older; with programming |
| **92604** | Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming |
| **92640** | Diagnostic analysis with programming of auditory brainstem implant, per hour |

| HCPCS Codes | Description |
|---|---|
| **L8614** | Cochlear device/system, 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 |
| **L8619** | Cochlear implant external speech processor, replacement |
| **L8628** | Cochlear implant, external controller component, replacement |
| **L8690** | Auditory osseointegrated device, includes all internal and external components |
| **L8691** | Auditory osseointegrated device, external sound processor, replacement |
| **L8692** | Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment |
| **L8693** | Auditory osseointegrated device abutment, any length, replacement only |

## Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

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**Summary of Changes:**

| Date | Changes: |
|---|---|
| **7/21** | Annual review; no changes |
| **7/20** | Annual review; exclusions, references and supporting information updated |
| **7/19** | Annual review; criteria and coding updated |

| | |
|---|---|
| **2/18** | Policy coverage criteria refined; Unilateral, bilateral and hybrid implants now require prior authorization |

**Approved by Medical Policy Committee: 7/20/21**
**Approved by Clinical Policy Operational Committee: 9/07; 10/09; 10/11; 10/13; 10/15; 4/17; 2/18; 7/19; 8/20; 8/21**
**Policy Effective Date: 8/6/21**
**Initiated: 9/07**