### MEDICAL POLICY

**SUBJECT: COCHLEAR IMPLANTS AND AUDITORY BRAINSTEM IMPLANTS**

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<th>POLICY NUMBER: 7.01.26</th>
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<td>EFFECTIVE DATE: 03/21/02</td>
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- **If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.**
- **Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.**
- **Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.**

This policy addresses cochlear implants and auditory brainstem implants only. Bone conduction, semi-implantable, and fully implantable hearing aids (e.g., Branemark Bone-Anchored Hearing Aid or BAHA™ System, Esteem® Implanted Hearing System, Vibrant Soundbridge™ System, and RetroX Hearing System) and the associated surgery are alternatives to conventional acoustic hearing aids and are not addressed in this policy.

### POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer-reviewed literature, unilateral and bilateral* cochlear implants have been medically proven to be effective and are **medically appropriate** as a prosthesis for hearing loss when approved by the U.S. Food and Drug Administration (FDA) and ALL the following criteria are met:
   A. At least 1 year of age;
   B. Severe to profound bilateral sensorineural hearing loss (defined as a hearing threshold of 70 decibels or above) that cannot benefit from hearing aids, and
   C. Cognitive ability to use auditory clues and a willingness to undergo an extended program of auditory rehabilitation.

   *Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit (e.g., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

II. **Contraindications:** Based upon our criteria and assessment of the peer-reviewed literature, the following are contraindications for *cochlear implants* and therefore, these devices are **not medically appropriate** in the presence of the following conditions:
   A. Deafness due to lesions of the acoustic nerve or central auditory pathway;
   B. Otitis media or other active, aural disease processes; or
   C. Complete cochlear aplasia.

III. Based upon our criteria and assessment of the peer-reviewed literature, cochlear implantation with a hybrid cochlear implant/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) is considered **investigational.**

IV. Based upon our criteria and assessment of the peer-reviewed literature, FDA approved *auditory brainstem implants* have been medically proven to be effective and are **medically appropriate** for individuals 12 years of age or older with neurofibromatosis type II who are rendered deaf due to bilateral resection or treatment of neurofibromas of the auditory nerve.

V. The replacement of properly functioning cochlear implants, auditory brainstem implants, and/or external components are considered **not medically necessary.** This includes, but is not limited to, when:
   A. the implant or components are desired due to advanced technology, or
   B. in order to make the device more aesthetically pleasing.

*Refer to Corporate Medical Policy #1.01.18 regarding Prosthetic Devices.*

*Refer to Corporate Medical Policy # 7.07.77 regarding Implantable Bone Conduction Hearing Aids.*

Proprietary Information of YourCare Health Plan
I. Cochlear implants and auditory brainstem implants are prosthetic devices. Coverage for prosthetic devices is contract dependent.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Profound deafness in childhood affects the development of auditory speech perception, speech production and language skills. Failure to develop adequate oral communication skills can have a significant negative effect for these individuals.

The cochlear implant is intended to restore a level of auditory sensation to individuals with severe to profound sensorineural hearing loss by electrical stimulation of the acoustic nerve. The basic system consists of:

I. A microphone, which picks up sound from the environment;

II. An external signal/speech processor, which selects and arranges sounds picked up by the microphone;

III. An external transmitter and an internal receiver, implanted in the temporal bone, that receives signals from the speech processor and converts them into electrical impulses; and

IV. An electrode array implanted in the cochlea that collects the impulses from the stimulator and sends them to the brain.

Electrical stimulation of the cochlea by the electrode enables many profoundly deaf people to experience the sensation of sound.

The 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 profoundly postlingual deaf adults who cannot significantly benefit from a hearing aid, the cochlear implant provides awareness of environmental sounds and facilitates lip reading.

Cochlear implant devices are available in single and multi-channel models. However, current therapy warrants a multi-channel device if one is implanted. (The multi-channel devices appear to facilitate some speech discrimination without lip-reading). Some examples of cochlear implants that have been approved by the U.S. Food and Drug Administration (FDA) and are currently marketed include the Advanced Bionics® HiResolution Bionic Ear System (HiRes 90k), the Cochlear® Nucleus 5, and the Med El® Maestro (Sonata or Pulsar).

Bilateral cochlear implants have been proposed for use in patients who meet the criteria for unilateral cochlear implant for whom it has been determined a unilateral cochlear implant plus a hearing aid in the contralateral ear will not result in a binaural benefit (e.g., patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification). The proposed benefits of bilateral cochlear implants are to improve understanding of speech in noise, localization of sounds and speech intelligibility. Bilateral implantation may be performed independently with separate implants and speech processors in each ear or with a single processor. However, no single processor for bilateral implantation has been approved by the FDA. Bilateral cochlear implantation may be done sequentially or simultaneously.

On March 20, 2014, the US Food and Drug Administration (FDA) approved a hybrid cochlear implant, the Nucleus® Hybrid™ L24 cochlear implant. The implant is intended for patients 18 and older with severe or profound sensorineural hearing loss of high-frequency sounds in both ears, but who can still hear low-frequency sounds with or without a hearing aid. The device combines the function of a cochlear implant and a conventional hearing aid.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program consists of 6 to 10 sessions that last approximately 2½ hours each. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

Auditory brainstem implants are devices designed to restore some hearing in patients with neurofibromatosis type II who are rendered deaf by bilateral removal of the characteristic neurofibromas involving the auditory nerve. The device consists of an externally worn speech processor that provides auditory information to an electrical signal that is transferred to a receiver/stimulator that is implanted in the temporal bone. The receiver stimulator is attached to an electrode array that
is implanted on the surface of the cochlear nerve in the brainstem, thus bypassing the inner ear and auditory nerve. The electrode stimulates multiple sites on the cochlear nucleus, which is then processed normally by the brain. The Nucleus 24® Auditory Brainstem Implant System (Cochlear Corporation) is the only device that has received approval by the FDA for auditory brainstem implantation. The device is indicated for individuals 12 years or age and older who have been diagnosed with neurofibromatosis type II.

RATIONALE:

Pre- and post-implantation testing demonstrate that in appropriately selected individuals with severe to profound sensorineural hearing loss, an FDA approved cochlear implant along with auditory rehabilitation therapy can restore a level of auditory sensation to individuals.

In 2002 the FDA issued an alert stating that children with cochlear implants were at greater risk of developing bacterial meningitis caused by Streptococcus pneumoniae than children in the general population. Their investigation showed that cochlear implants with electrode positioners were associated with greater risk of developing meningitis than implants without positioners. The only model with a positioner was withdrawn from the market in July 2002. In 2006 an alert was issued discussing results of two year follow-up of the children identified in the earlier investigation. To decrease the risk of meningitis, the FDA recommends: adherence to the CDC vaccination guidelines, early recognition of the signs of meningitis, prompt diagnosis and treatment of middle ear infections, and consideration of the use of prophylactic antibiotics perioperatively. In October 2007 the FDA issued a Public Health Notification: Importance of Vaccination in Cochlear Implant Recipients, and Advice for Patients with Cochlear Implants: New Information on Meningitis Risk. Both reminded of the increased, life-threatening risk of bacterial meningitis in cochlear implant recipients, especially those with a positioner, and the importance of these recipients being fully vaccinated, since two patients recently died from infections and neither one was fully vaccinated.

Published case reports support the efficacy of the cochlear implant in children under the age of one year. Larger studies are needed that demonstrate improved outcomes in children under the age of one year.

Published studies addressing bilateral cochlear implantation show consistent improvement in speech reception, especially in noise, and in sound localization with bilateral devices.

Hybrid cochlear implant devices are considered investigational as peer-reviewed, published literature has not demonstrated improved outcomes with these devices over standard cochlear implant devices. Few studies have been published addressing these devices.

A prospective multicenter study of 66 adult hearing-impaired subjects with bilateral severe-to-profound high frequency hearing loss was undertaken to investigate the preservation of residual hearing in subjects who received Nucleus® Hybrid™ L24 Cochlear Implant System and to investigate the performance benefits up to one year post-implantation in terms of speech recognition, sound quality, and quality of life. The group median increase in air-conduction thresholds in the implanted ear for test frequencies 125-1000 Hz was less than 15 dB across the population; both immediately and one year post-operatively. 88% of the patients used the Hybrid processor at one year post-op. 65% of the patients had significant gain in speech recognition in quiet, and 73% in noise (greater than or equal to 20% points/2 dB signal to noise ratio). Mean Speech, Spatial and Other Qualities (SSQ) subscale scores were significantly improved (+ 1.2, + 1.3, + 1.8 points, p less than 0.001), as was mean Health Utilities Index Mark 3 (HUI3) score (+ 0.117, p less than 0.01). Combining residual hearing with CI gave 22-26 percentage points mean benefit in speech recognition scores over CI alone (p less than 0.01). The authors concluded useful residual hearing was conserved in 88% of subjects and speech perception was significantly improved over preoperative hearing aids, as was sound quality and quality of life. (Lenarz, et al. 2013)

A small, retrospective, single-center study of 21 patients investigating the Nucleus® Hybrid™ L24 Cochlear Implant System was undertaken to evaluate the hearing preservation rate in patients with high frequency hearing loss who have the Hybrid device implanted. Pure tone thresholds were recorded prior to the surgery and at the time of speech processor switch-on. Patients were subdivided into two groups with respect to their pure tone audiometry (PTA) thresholds: group A - classic indications and group B - extended indications. Average PTA for three frequencies (250, 500, 1,000 Hz) were calculated for each patient pre- and postoperatively. In the group of 21 implanted patients in 17 cases preservation of
hearing (12 patients from group A, 5 patients from group B) with a mean value of 13.1 dB was observed. In 4 out of 21 patients deafness on the implanted ear was noted. The authors concluded the results indicate standard procedure hearing preservation can be obtained in majority of patients. Hearing preservation was not achieved in 19%, but owing to design of the electrode of the Cochlear Nucleus Hybrid-L that enables to work as cochlear implant platform alone, in patients who lost their hearing after surgery re-implantations were not required. The authors stated the device is a safe and reliable method to help patients with specific type of hearing loss. (Szyfter, et al, 2013).

The American Academy of Otolaryngology-Head and Neck Surgery position statement on cochlear implants was revised in 2014 and “considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can significantly perform better with two cochlear implants rather than one, bilateral cochlear implantation is accepted medical practice.”

The Nucleus 24® Auditory Brainstem Implant System (Cochlear Corporation) received FDA premarket approval in 2000 for neurofibromatosis type II patients, 12 years of age and older, who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve. Studies have shown that while the use of an auditory brainstem implant is associated with a very modest improvement in hearing, this level of improvement is considered significant in this group of patients who have no other treatment options. Its use for other cochlear and cochlear nerve abnormalities has been investigated, however FDA approval has not been granted for other indications.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:
- 69930 Cochlear device implantation, with or without mastoidectomy
- 92601 Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
- 92602 subsequent reprogramming
- 92603 Diagnostic analysis of cochlear implant, age 7 years or older; with programming
- 92604 subsequent reprogramming
- 92640 Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS:
- L8614 Cochlear device, includes all internal and external components
- L8615-L8619 Replacement components of cochlear implant device/system (code range)
- L8621-L8624 Replacement batteries used with cochlear implant device/system (code range)
- 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
- S2235 Implantation of auditory brainstem implant

ICD9:
- 237.72 Neurofibromatosis, type 2
Sensorineural hearing loss (code range) 389.10-389.18
Mixed conductive and sensorineural hearing loss (code range) 389.20-389.22
Deaf, non-speaking, NEC 389.7
Conductive and sensorineural hearing loss (code range) H90.3-H90.8
Deaf nonspeaking, not elsewhere classified H91.3
Neurofibromatosis, type 2 Q85.02


*key article

KEY WORDS:
Hearing implant, Advanced Bionics® HiResolution Bionic Ear System (HiRes 90k), Cochlear® Nucleus 5, Med El® Maestro (Sonata or Pulsar), Nucleus 24® Auditory Brainstem Implant System, Nucleus® Hybrid™ L24 Cochlear Implant System.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Cochlear Implantation. Please refer to the following website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+&+Upstate&KeyWord=cochlear+implant&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAABAAAAAA&.

Neither a National Coverage Determination nor a Local Coverage Determination has been identified for auditory brainstem implants.