

MEDICAL POLICY



SUBJECT: COCHLEAR IMPLANTS AND AUDITORY BRAINSTEM IMPLANTS	EFFECTIVE DATE: 03/21/02 REVISED DATE: 02/20/03, 01/15/04, 02/17/05, 01/19/06, 12/21/06, 06/21/07, 03/20/08, 06/18/09, 07/15/10, 07/21/11, 07/19/12, 07/18/13, 10/16/14, 07/16/15, 07/21/16, 07/20/17, 05/17/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

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 BAHTM System, Esteem[®] Implanted Hearing System, Vibrant SoundbridgeTM 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 prosthetic 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[®] HybridTM 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.

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POLICY GUIDELINES:

- 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.

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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 2017, Sladen et al retrospectively reviewed prospectively collected data of short-term (6-month) follow-up for 23 adults and children with single-sided deafness from a variety of mechanisms who received a cochlear implant. In the implanted ear, CNC word recognition improved significantly from preimplantation to 3 months postactivation (p=0.001). However, for AzBio sentence understanding in noise (+5 dB signal-to-noise), there was no significant improvement from preimplantation to 6 months postactivation. Level of Evidence 4, Case series; case control study (diagnostic studies); poor reference standard; analyses with no sensitivity analyses.

In 2016, Sladen et al in a prospective repeated-measures cohort study that included 20 subjects with single-sided deafness implanted with cochlear implants (15 of whom had reached 6-month follow-up), Sladen et al reported on speech recognition and QOL.44 Pure-tone audiometry improved with air conduction in the implanted ear. CNC scores in quiet improved from 4.8% in the preoperative period to 42.3% at the 6-month postactivation check in patients who reached that follow-up. Level of Evidence 4, Case series; case control study (diagnostic studies); poor reference standard; analyses with no sensitivity analyses.

Also in 2016, Rahne et al reported on a retrospective review of 4 children and 17 adults with single-sided deafness treated with cochlear implants and followed for 12 months. Sound localization with aided hearing improved from preimplantation for all individuals. The speech recognition threshold in noise (signal-to-noise) ratio improved from -1.95 dB (CI off, SD=2.7 dB) to -4.0 dB after 3 months (SD=1.3 dB; p<0.05), with continued improvements through 6 months.

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.

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

For individuals who have unilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes prospective and retrospective studies reporting within-subjects comparisons and systematic reviews of these studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Given the natural history of hearing loss, pre- and postimplantation comparisons may be appropriate for objectively measured outcomes. However, the available evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, is limited by small sample sizes, short follow-up times, and heterogeneity in evaluation protocols and outcome measurements. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. Additional published studies regarding the hybrid device are generally non-randomized, uncontrolled studies with small patient populations and short term follow-up.

For individuals who have high-frequency sensorineural hearing loss with preserved low-frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound processor, the evidence includes prospective and retrospective studies using single-arm, within-subjects comparison pre- and postintervention and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available evidence has suggested that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. The available evidence has also suggested that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation after a hybrid cochlear implantation if there is loss of residual hearing. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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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).

In January 2016, Roland, et. al. reported a prospective, single-arm repeated measures, single-subject design study undertaken to evaluate the safety and efficacy of acoustic and electric sound processing for individuals with significant residual low-frequency hearing and severe-to-profound high-frequency sensorineural hearing loss. Fifty individuals, aged 18 years and older, with low-frequency hearing and severe high-frequency loss were implanted with the Cochlear Nucleus Hybrid L24 implant at 10 investigational sites. Preoperatively, subjects demonstrated consonant-nucleus-consonant word scores of 10% through 60% in the ear to be implanted. Subjects were assessed prospectively, preoperatively, and postoperatively on co-primary endpoints of consonant-nucleus-consonant words, AzBio sentences in noise, and self-assessment measures. Significant mean improvements were observed for co-primary endpoints: consonant-nucleus-consonant words (35.8 percentage points) and AzBio sentences in noise (32.0 percentage points), both at P<0.001. 96% of subjects performed equal or better on speech in quiet and 90% in noise. 82% of subjects showed improved performance on speech in quiet and 74% in noise. Self-assessments were positive, corroborating speech perception results. 65 adverse events involving 34 of the 50 subjects were reported. The type and frequency of events were consistent with those reported in cochlear implantation (e.g., electrode open or short circuits, postoperative dizziness, changes in tinnitus) or other mastoid operations; no unanticipated adverse events were reported. The authors concluded the Nucleus Hybrid System provides significant improvements in speech intelligibility in quiet and noise for individuals with severe high-frequency loss and some low-frequency hearing and expands indications to hearing-impaired individuals who perform poorly with amplification due to bilateral high-frequency hearing loss and who previously were not implant candidates. ***However, they also noted additional longer term follow-up for safety and study of the device in larger and diverse subgroups is important.***

The 2018 results by Roland, et al, of three related clinical studies compiled to provide outcome data after 1, 3 and 5 years of implant use in a group of subjects who presented with preoperative high-frequency hearing loss and were implanted with a Nucleus Hybrid L24 (Cochlear Ltd., Sydney, Australia) cochlear implant concluded the results demonstrate long-term success and benefits significantly better than those in the preoperative best-aided condition. The level of evidence given to these studies is 2b.

A final outcomes study by the same authors was reported by Gantz, et. al. in April 2016. 87 subjects received a Nucleus Hybrid S8 CI in their poorer ear. Speech perception in quiet (Consonant-Nucleus-Consonant [CNC] words) and in noise (Bamford-Kowal-Bench Sentences-In-Noise [BKB-SIN]) were collected pre- and postoperatively at 3, 6, and 12 months. Subjective questionnaire data using the Abbreviated Profile for Hearing Aid Benefit (APHAB) were also collected. Some level of hearing preservation was accomplished in 98% subjects, with 90% maintaining a functional low-frequency pure-tone average (LFPTA) at initial activation. By 12 months, five subjects had total hearing loss and 80% of the subjects maintained functional hearing. CNC words demonstrated that 82.5% and 87.5% of subjects had significant improvements in the hybrid and combined conditions, respectively. The majority had improvements with BKB-SIN. Results also indicated that as long as subjects maintained at least a severe LFPTA, there was significant improvement in speech understanding. Furthermore, all subjects reported positive improvements in hearing in three of the four subscales of the APHAB. 14 subjects requested the Hybrid S8 implant be removed for various reasons of dissatisfaction with the device and had a standard length Nucleus Freedom CI placed. Most experienced a progressive loss of acoustic hearing in the implant ear. 2 subjects who opted to have the Hybrid S8 device removed did not experience a significant ipsilateral threshold shift, but did not have good speech perception outcomes with the hybrid device. The authors concluded the concept of hybrid speech processing has significant advantages for subjects with residual low-frequency hearing, the Nucleus Hybrid S8 provided improved word understanding in quiet and noise, and there appears to be stability of the residual hearing after initial activation of the device. They also stated the reasons for loss of hearing after activation of the implant and acoustic amplification requires more research.

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Q85.02 Neurofibromatosis, type 2

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*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=gAAAABAAAAA&A&A&>

Neither a National Coverage Determination nor a Local Coverage Determination has been identified for auditory brainstem implants. However, the Medicare Benefit Policy Manual addresses auditory brainstem implants under Chapter

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16, Section 100 of the manual and states auditory brainstem implants can be considered as prosthetic devices when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery. Please refer to the following website for Medicare Members:
<http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf>.