MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Cochlear Implants and Auditory Brainstem Implants**
Policy Number	**7.01.26**
Category	**Technology Assessment**
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Committee Approval 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, 05/16/19, 05/21/20, 05/20/21, 05/19/22, 03/23/23, 03/21/24**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

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) are not addressed in this policy.

POLICY STATEMENT

Cochlear Implant

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, therefore, are considered **medically appropriate** as a prosthetic for hearing loss approved by the U.S. Food and Drug Administration (FDA) (*see Rationale section*) for the patient's age and the patient meets **ALL** of the following criteria:
   A. Bilateral, severe-to-profound sensorineural hearing loss (defined as a pure-tone average [PTA] of >70 decibels at 500 hertz [Hz], 1000 Hz, and 2000 Hz); who have shown limited or no benefit from hearing aids;
   B. Physician attestation of the willingness of the patient and/or family 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, cochlear implants are contraindicated for the following conditions and, therefore, are considered **not medically necessary**:
   A. cochlear aplasia (absence of cochlear development);
   B. deafness due to lesions of the eighth cranial (acoustic) nerve or central auditory pathway;

C. infection of the external or middle ear (e.g., otitis media) or other active aural disease processes.

III. Based upon our criteria and assessment of the peer-reviewed literature, cochlear implantation with a hybrid cochlear implant/hearing aid device, in which the hearing aid is integrated into the external sound processor of the cochlear implant (e.g., Nucleus Hybrid L24 Cochlear Implant System) is considered **investigational.**

Auditory Brainstem Implants

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, therefore, are considered **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.

Repair and Replacement

V. Repair and/or replacement of a medically necessary cochlear implant, auditory brainstem implant and/or external components not under warranty will be considered **medically appropriate** when the following criteria are met:
   A. Physician documentation to include all the following:
      1. date of device implantation,
      2. manufacturer warranty information, **and**
      3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; **AND ONE OF THE FOLLOWING APPLY:**
   B. Repair of the currently used device when **ALL** of the following are met:
      1. it is no longer functioning adequately,
      2. inadequate function interferes with activities of daily living, **and**
      3. repair is expected to make the equipment fully functional (as defined by manufacturer); **OR**
   C. Replacement of the currently used device when the following are met:
      1. it is no longer functioning adequately, **AND EITHER:**
      2. it has been determined to be non-repairable; **or**
      3. the cost of the repair is in excess of the replacement cost; **OR**
   D. Replacement of the currently used device when **BOTH** of the following are met:
      1. there is documentation that a change in the patient's condition makes the present unit non-functional (e.g., greater loss of hearing); **and**
      2. improvement is expected with a replacement unit.

VI. The replacement of properly functioning cochlear implant(s), auditory brainstem implant(s), and/or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

Refer to Corporate Medical Policy #7.01.77 Implantable Bone Conduction Hearing Aids

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Cochlear implants and auditory brainstem implants are prosthetic devices. Coverage for prosthetic devices is contract dependent.

II. A post cochlear implant rehabilitation program is essential to achieve benefit from the cochlear implant. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

DESCRIPTION

According to the American Speech-Language-Hearing Association (ASHA, n.d.) hearing loss refers to an audiologic diagnosis of hearing thresholds outside the range of typical hearing, and can be described by variation in type, degree, and configuration. The three basic types of hearing loss are:

- Sensorineural hearing loss (SNHL): cochlear (sensory) or vestibulocochlear nerve/CN VIII (neural) auditory dysfunction.
- Conductive hearing loss: a problem conducting sound waves through the outer ear canal, tympanic membrane, or middle ear (ossicles).
- Mixed hearing loss is the result of damage to conductive pathways of the outer and/or middle ear and to the nerves or sensory hair cells of the inner ear.

Hearing loss can be bilateral or unilateral, symmetrical (degree and configuration of hearing loss are the same in each ear) or asymmetrical, progressive, or sudden in onset, fluctuating or stable, and present at birth or acquired. The degree of hearing loss refers to level of severity. The degree of hearing loss can have significant implications for an individual (e.g., limiting the ability to understand speech in background noise, decreasing the enjoyment of music, impacting overall quality of life).

Traditional Cochlear Implant

A traditional cochlear implant (CI) is a surgically implanted electronic prosthetic hearing device for advanced bilateral high-frequency SNHL with preserved low-frequency hearing. The device provides electric stimulation directly to auditory nerve fibers in the cochlea, effectively bypassing damaged inner ear hair cells to deliver a signal to the brain, which is interpreted as sound. The basic system consists of:

- a microphone, which picks up sound from the environment;
- an external signal/speech processor, which selects and arranges sounds picked up by the microphone;
- an external transmitter and an internal receiver, implanted in the temporal bone, which receives signals from the speech processor and converts them into electrical impulses; and
- an electrode array implanted in the cochlea, which 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.

Bilateral cochlear implants have been proposed for use in patients who meet the criteria for unilateral cochlear implant, when it has been determined that 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 such magnitude that 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.

Individuals with single-sided deafness (SSD) have severe to profound hearing loss in one ear and normal or near-normal hearing in the other ear. Individuals with unilateral hearing loss (UHL) have hearing loss in one ear and near-normal hearing in the opposite ear. Those with SSD/UHL experience poorer spatial hearing abilities and diminished speech understanding in the presence of competing noise when compared to listeners with normal hearing bilaterally. Historically, clinical recommendations for these adults were either to remain in an unaided condition or listen with a hearing technology that reroutes the acoustic signal from the impaired ear to the normal hearing ear (e.g., bone conduction device or contralateral routing of the signal (CROS) hearing aid). Given the limitations of these options, CI of the impaired ear for stimulation of both auditory pathways has been investigated to potentially improve performance on spatial hearing tasks, including sound source localization and speech understanding in spatially separated noise (Dillon et al., 2022).

Hybrid Cochlear Implant

Developed for individuals who have a high-frequency SNHL with preserved low-frequency hearing, the device includes a hearing aid integrated into the external sound processor of the cochlear implant. Hybrid cochlear implant electrodes are shorter and are inserted to a depth that are proposed to preserve residual low-frequency hearing. Candidates for a hybrid device have too much residual hearing to receive a traditional cochlear implant yet not enough hearing to benefit from using a hearing aid.

Auditory Brainstem Implant

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, which 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.

RATIONALE

The U.S. Food and Drug Administration (FDA) has approved, through the premarket approval (PMA) process, several cochlear implants for commercial use in the United States. Labeled indications have expanded over the years and currently approved devices are summarized in the sections below. FDA product codes: CMC and PGQ.

Traditional Cochlear Implant for Bilateral SNHL

Cochlear implants, unilateral and bilateral, for adults and children with bilateral SNHL are a well-established intervention. Published studies show consistent improvement in speech reception, especially in noise, and in sound localization with bilateral devices (Baron et al., 2018; McRacken et al., 2018; Gaylor et al., 2013; Crathorne et al., 2012; Bond et al., 2009).

In July 2021, AAO-HNS issued a new position statement specifically addressing cochlear implant candidacy for children with bilateral sensorineural hearing loss. The position reconfirms that cochlear implantation should be considered for children with bilateral sensorineural hearing loss who are not making expected progress despite appropriately fit amplification.

In November 2020, the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) revised the position statement on cochlear implants to endorse unilateral and bilateral cochlear implantation as appropriate treatment for adults and children over 9 months of age with moderate to profound hearing loss who have failed a trial with appropriately fit hearing aids.

Traditional Cochlear Implant for Single-sided Deafness (SSD)/Unilateral Hearing Loss (SSD/UHL)

In April 2023, the American Academy of Otolaryngology–Head and Neck Surgery issued two new position statements endorsing cochlear implantation for cases of single sided deafness (asymmetric or unilateral sensory hearing loss) for adult patients and children. Indicating, cochlear implants restore binaural hearing in these patients and markedly improves sound localization, speech perception in noise, reduces or eliminates tinnitus, and improves quality of life and hearing.

The AAO-HNS endorses that in selected children with unilateral SNH, as early as 9 months of age, should undergo cochlear implantation as soon as hearing loss and appropriate anatomy is verified to avoid missing a developmental window that permits integration of binaural cues. Specifically indicating that children with unilateral SNHL experience problems with sound localization, speech perception in noise, and increased auditory effort due to loss of binaural cues. Restoration of true binaural hearing can only be accomplished with a cochlear implant, and use of a cochlear implant has demonstrated marked improvements in localization, speech perception in noise and auditory effort.

In 2022, the American Cochlear Implant Alliance Task Force published guidelines on the assessment and management of adult cochlear implantation for single-sided deafness (Dillon et al., 2022) The guidance recommendations were based on expert consensus and systematic review of the current literature. The task force concluded that although further research

investigating the patient and device variables that may influence the performance of adult CI users with SSD, cochlear implantation is an effective treatment option for adults with SSD. Noted potential contraindications include advanced cochlear ossification, severe labyrinthine dysplasia, and cochlear nerve aplasia; however, advanced age is not a contraindication. Prolonged duration of deafness combined with congenital SSD onset may result in limited CI outcomes.

For individuals with unilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes prospective and retrospective studies and systematic reviews of these studies. Given the natural history of hearing loss, pre- and post-implantation 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 at this time.

Oh et al. (2023) published a systematic review and meta-analysis of 50 studies, including prospective and retrospective observational studies and case series, evaluating cochlear implantation in adults (n=674) with single-sided deafness. Pooled outcomes indicated improved scores in speech perception, localization, tinnitus, and quality of life. Study interpretation is limited by small sample sizes and heterogeneity in reported outcomes and follow-up durations.

Peters et al. (2021) randomized 120 adults with single-sided deafness (median duration, 1.8 years) into 3 treatment groups for the "Cochlear Implantation for siNGLE-sided deafness" (CINGLE) trial: cochlear implant (n=29); first bone-conduction devices, then CROS (n=45); and first CROS, then bone-conduction devices (n=46). Patients with a maximum 30 dB hearing loss in the best ear and a minimum 70 dB hearing loss in the poor ear with duration of single-sided deafness between 3 months and 10 years were eligible for inclusion. After the initial cross-over period, 25 patients were allocated to bone-conduction devices, 34 patients were allocated to CROS, and 26 patients preferred no treatment. Seven patients did not receive their allocated treatment. For the primary outcome, speech perception in noise from the front, a statistically significant improvement was noted for the cochlear implant group at 3 and 6 months compared to baseline. At 3 months follow-up, the cochlear implant group performed significantly better than all other groups. At 6 months, the cochlear implant group performed significantly better than the bone-conduction devices and no treatment groups, but no significant difference was observed between the cochlear implant group and the CROS group. Sound localization improved in the cochlear implant group only. All treatment groups improved on disease-specific quality of life compared to baseline. The study is limited by small sample size, device heterogeneity, loss to follow-up, and lack of allocation concealment. Study follow-up through 5 years is ongoing.

In 2017, Sladen et al. retrospectively reviewed prospectively collected data of short-term (six-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, consonant-nucleus-consonant (CNC) word recognition improved significantly from preimplantation to three months post activation (p=0.001). However, for AzBio sentence understanding in noise (+5 dB signal-to-noise), there was no significant improvement from preimplantation to six months post activation. (Level of Evidence 4, Case series; case control study (diagnostic studies); poor reference standard; analyses with no sensitivity analyses.)

Regulatory (FDA):

	Traditional (non-hybrid) Cochlear Implants			
Device	HiResolution Bionic Ear System (Advanced Bionics)	Cochlear Nucleus 22 and 24 (Cochlear America)	Cochlear Implant System (Synchrony) (Med-EL)	Neuro Cochlear Implant System (Oticon Medical)
PMA	P960058	P840024, P970051	P000025	P200021
Indications **Adults ≥18 years**	Postlingual onset of severe-to-profound SNHL (>70dB) Limited benefit from appropriately fitted hearing aids, defined as	Pre-, peri-, or postlingual onset of bilateral SNHL usually characterized by:	Severe-to-profound bilateral SNHL (≥70dB)	Severe-to-profound bilateral SNHL (≥70dB at 500,1000, and 2000 Hz). Limited benefit from appropriately fit

	scoring ≤50% on a test of open-set HINT sentence recognition	o Moderate-to-profound HL in low frequencies o Profound (≥90 dB) HL in mid-to-high speech frequencies Severe to profound unilateral SNHL (SSD or AHL) o PTA at 500Hz, 1000 Hz, 2000 Hz, and 4000 Hzof ≥ 80 dBHL o Normal or near normal hearing in the contralateral ear defined as PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of ≤ 30 dBHL o Limited benefit from an appropriately fitted unilateral hearing device		hearing aids, defined as scoring ≤50% correct HINT sentences in quiet or noise with best-sided listening condition
Indications **Children**	12 mon to 17yr of age: Profound bilateral SNHL (≥90 dB) Use of appropriately fitted hearing aids for at least 6 mon in children 2yr-17yr or at least 3 mon in children 12-23 mon Lack of benefit in children <4 yr defined as a failure to reach developmentally appropriate auditory milestones (e.g., spontaneous response to name in quiet or to environmental sounds) measured using IT-MAIS or MAIS or <20% correct on a simple open-set word recognition test (MLNT) administer reducing monitored live voice (70dB SPL).	25 mon to 17yr: Severe-to-profound bilateral SNHL MLNT scores ≤30% in best-aided condition in children LNT scores ≤30% in best-aided conclusion in children 9 mon to 24 mon: Profound SNHL bilaterally Limited benefit from appropriate binaural hearing aid. 5yr to 18yr: Severe to profound unilateral SNHL (SSD or AHL) o PTA ≥80db HL o Normal or near normal hearing in	12 mon to 18yr: Profound sensorineural HL (≥90 dB) o In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills with hearing aids over 3 to 6 mon o In older children, lack of aided benefit is defined as ≤20% correct on the MLNT or LNT, depending on child's cognitive ability and linguistic skills. o A 3- to 6-mon trial with hearing aids is required if not previously experienced.	Not applicable

	Lack of hearing aid benefit in children ≥4 yr defined as scoring <12% on a difficult open-set word recognition test (PBK test) or<30% on an open-set sentence test (HINT for Children) administered using recorded materials in the sound field (70dB SPL).	the contralateral ear defined at PTA of ≤30dB HL. Limited benefit from an appropriately fitted unilateral hearing device.	5 yr to 18 yr of age: SSD (≥90 dB) or AHL(Δ15 dB PTA) o Insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted. o Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit.	

KEY: AHL: asymmetric hearing loss; CNC: consonant-nucleus-consonant; CROS: contralateral routing of signal; HINT: Hearing in Noise Test; HL: hearing loss; IT-MAIS: Infant-Toddler Meaningful Auditory Integration Scale; LNT: Lexical Neighborhood Test; MAIS: Meaningful Auditory Integration Scale; MLNT: Multisyllabic Lexical Neighborhood Test; PBK: Phonetically Balanced-Kindergarten; PMA: premarket approval; PTA: pure tone average; SNHL: sensorineural hearing loss; SPL: sound pressure level; SSD: single-sided deafness.

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 a 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 full vaccination of those recipients, as two patients had recently died from infection, and neither one was fully vaccinated.

Hybrid Cochlear Implant

The Nucleus Hybrid L24 Cochlear Implant System (Cochlear Americas) received FDA approval on March 20, 2014, through the premarket approval (PMA) process (P130016). The implant was intended for unilateral use in patients aged 18 years and older who have residual low-frequency hearing sensitivity and severe-to-profound high-frequency sensorineural hearing loss, and who obtain limited benefit from an appropriately fitted bilateral hearing aid.

The MED-EL Cochlear Implant System combined with electrical stimulation and acoustic amplification (EAS) received FDA approval in September 2016 (P000025/S084) and was indicated for partially deaf individuals aged 18 years and older who have residual hearing sensitivity in the low frequencies sloping to a severe/profound sensorineural hearing loss in the mid to high frequencies, and who obtain minimal benefit from conventional acoustic amplification. The FDA expanded the indication for the MED-EL Cochlear Implant System in July 2019 (P000025/S104) to include individuals aged five years and older with single-sided deafness (SSD) or asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.

A concern with traditional cochlear implants is that the implantation process typically destroys any residual hearing, particularly for hearing in the low-frequency ranges. Newer devices have used a shorter cochlear electrode in combination with a hearing aid-like amplification device to mitigate the damage to the cochlea and preserve residual hearing. 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, pre- and postintervention comparisons and systematic reviews.

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.

The pivotal trial results for the Cochlear Nucleus Hybrid L24 were published in January 2016 (Roland et al.). A prospective, single-arm, repeated measures, single-arm, multicenter, nonrandomized 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 (50) 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. Significant mean improvements were observed for co-primary endpoints: consonant-nucleus-consonant words and AzBio sentences in noise 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.

Five-year outcomes for the pivotal trial were reported by Roland et al. (2018). The results of three related clinical studies compiled to provide outcome data after one, three and five 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. A total of 87 subjects received a Nucleus Hybrid S8 CI in their poorer ear. Speech perception in quiet (CNC words) and in noise (Bamford-Kowal-Bench Sentences-In-Noise [BKB-SIN]) were collected pre- and postoperatively at three, six, 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. 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. Most experienced a progressive loss of acoustic hearing in the implant ear. The authors concluded that 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 appeared to be stability of the residual hearing after initial activation of the device. They also stated that the reasons for loss of hearing after activation of the implant and acoustic amplification required more research.

Lenarz et al. (2013) reported on results of a prospective multicenter European study evaluating the Nucleus Hybrid L24 system. The study enrolled 66 adults with bilateral severe-to-profound high-frequency hearing loss to investigate the preservation of residual hearing the performance benefits (e.g., speech recognition, sound quality, and quality of life) up to one-year post-implantation. 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. At 1 year postoperatively, 89% of the patients were still using the Hybrid processor, 65% of subjects had significant gains in speech recognition in quiet, and 73% had significant gains in noisy environments. Compared with the cochlear implant hearing alone, residual hearing significantly increased speech recognition scores. The authors concluded that useful residual hearing was conserved in 88% of subjects, and speech perception was significantly improved over pre-operative hearing aids, as was sound quality and quality of life. Study limitations include short-term follow-up, small patient population, and fewer number of subjects still using the hybrid processor at the one-year mark.

Auditory Brainstem Implant

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 (Otto et al., 2008; Ontario Health, 2020).

The use of auditory brainstem implants (ABI) for nontumor etiologies has been investigated; however, studies of early (now obsolete) ABI devices found a high rate of failure in children and high rates of adverse events in adults (Merkus et al., 2014; Noij et al., 2015). FDA approval has not been granted for other indications.

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 of age and older who have been diagnosed with neurofibromatosis type II.

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
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
92605	Evaluation for prescription of non-speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour
92618	each additional 30 minutes (List separately in addition to code for primary procedure)
92640	Diagnostic analysis with programming of auditory brain stem implant, per hour

HCPCS Codes

Code	Description
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)
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
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

ICD-10 Codes

Code	Description
H90.3 - H90.8	Conductive and sensorineural hearing loss (code range)
H91.3	Deaf nonspeaking, not elsewhere classified
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 50.3) for cochlear implantation. Please refer to the following NCD 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=gAAAABAAAAAA&.] accessed 02/27/24.

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) identified for auditory brainstem implants. However, the Medicare Benefit Policy Manual addresses auditory brainstem implants under Chapter 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.] accessed 02/27/24.