MEDICAL POLICY

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Medical Policy Title	**Cochlear Implants and Auditory Brainstem Implants**
Policy Number	**7.01.26**
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Next Review Date	March 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

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.

I. Cochlear Implants (Unilateral and Bilateral) for Bilateral Sensorineural Hearing Loss (SNHL)

A. Unilateral and bilateral* cochlear implants are considered **medically appropriate** as a prosthetic for hearing loss when **ALL** of the following criteria are met:

1. The prosthetic is approved by the U.S. Food and Drug Administration (FDA) (Refer to Regulatory section) for the individual's age;
2. Individual has bilateral severe-to-profound SNHL defined as a pure-tone average (PTA) of >70 decibels (dB HL) at 500 hertz (Hz), 1000 Hz, and 2000 Hz;
3. There has been limited or no benefit from appropriately fit hearing aids;
4. Physician attestation of the willingness of the individual or family to undergo an extended program of auditory rehabilitation.
5. None of the following contraindications for cochlear implants are present:
   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.

*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 individuals with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

II. Unilateral Cochlear implants for Single-Sided Deafness (SSD) or Asymmetric Hearing Loss (AHL)

A. Unilateral Cochlear implants are considered **medically appropriate** as a prosthetic for SSD or AHL when **ALL** of the following criteria are met:

1. Individual is 5 years of age or older (Refer to Regulatory Section);
2. There has been limited or no benefit from appropriately fit hearing aids;
3. Individual has **EITHER** of the following:
    a. Profound SNHL (defined as a PTA of >90 dB HL at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) in one ear and normal hearing or mild SNHL in the other ear (defined as a PTA up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz); or
    b. Profound SNHL (defined as a PTA of >90 dB HL at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) in one ear and mild to moderately severe SNHL (ranging from 31 dB HL up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) in the other ear, with a difference of at least 15 dB HL in PTA between ears; and
4. Individual has had a one (1) month trial wearing a Contra Lateral Routing of Signal (CROS) hearing aid and has not shown any benefit;
5. Physician attestation of the willingness of the individual or family to undergo an extended program of auditory rehabilitation;
6. None of the following contraindications for cochlear implants are present:
    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. Hybrid Cochlear Implants

A. Unilateral cochlear implantation with a device that includes the hearing aid integrated into the external sound processor (e.g., the Nucleus Hybrid L24 Cochlear Implant System) is considered **medically appropriate** when **ALL** of the following criteria are met:
    1. Individual is 5 years of age or older (Refer to Regulatory section);
    2. Individual meets **BOTH** of the of the following criteria:
        a. One ear has severe to profound SNHL (defined as a PTA of > 80 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz);
        b. In the contralateral ear, normal or near normal hearing (defined as a PTA of ≤ 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz).
    3. There has been limited benefit from an appropriately fit unilateral hearing aid (defined as a score of less than or equal to 5% on a Consonant Nucleus Consonant [CNC] word test);

4. For individuals between 5 years and 18 years of age, 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 alone;
5. Physician attestation of the willingness of the individual or family to undergo an extended program of auditory rehabilitation;
6. None of the following contraindications for cochlear implants are present:
    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.

IV. Auditory Brainstem Implants

A. Auditory brainstem implants are **medically appropriate** when **ALL** of the following criteria are met:

1. The implant is approved by the U.S. Food and Drug Administration (FDA) (Refer to Regulatory section) for the individual's age;
2. Individual has neurofibromatosis type 2;
3. Individual is rendered deaf due to bilateral resection or treatment of neurofibromas of the auditory nerve.

V. Device Repair

A. Repair of a medically necessary Cochlear Implant or Auditory Brainstem Implant or components not under warranty will be considered **medically appropriate** when the following criteria are met:

1. Physician documentation includes **ALL** of the following:
    a. date of device implantation/initiation;
    b. manufacturer warranty information, if applicable;
    c. attestation that the individual has been compliant with the use of device and will continue to benefit from the use of device;
2. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:
    a. inadequate function interferes with activities of daily living; and
    b. repair is expected to make the equipment fully functional (as defined by manufacturer).

B. Repair of equipment damaged due to individuals neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VI. Device Replacement

A. Replacement of a medically necessary Cochlear Implant or Auditory Brainstem Implant or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

1. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;
2. There is documentation that a change in the individual's condition makes the present unit non-functional and improvement is expected with a replacement unit.

B. The replacement of a properly functioning Cochlear Implant or Auditory Brainstem Implant, its components or accessories 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;

C. The replacement of equipment damaged or lost due to individual's neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

D. Accessories or components for a Cochlear Implant or Auditory Brainstem Implant that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

2.01.27 Evoked Potentials

7.01.77 Implantable Bone Conduction Hearing Aids

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

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

The American Speech-Language-Hearing Association (ASHA, n.d.) defines hearing loss (HL) within its practice portal (available from: Hearing Loss in Adults [Accessed 2025 Feb 04]).

HL 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 HL 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: 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.

HL can be bilateral or unilateral, symmetrical (degree and configuration of HL 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 HL refers to level of severity, and is measured in decibels in hearing level, or dB HL. The degree of HL 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).

The most widely accepted degree of hearing loss system utilized in the audiology field (ASHA, n.d.) is as follows:

- Normal: -10 to 15 dB HL
- Slight: 16 to 25 dB HL
- Mild: 26 to 40 dB HL
- Moderate: 41 to 55 dB HL
- Moderately severe: 56 to 70 dB HL
- Severe: 71 to 90 dB HL
- Profound: ≥ 91 dB HL

The World Health Organization (2024) identifies several causes of HL that span across the lifespan, and often occur during critical periods of life, including the following:

<u>Prenatal Period</u>

- genetic factors including hereditary and non-hereditary HL
- intrauterine infections, such as rubella and cytomegalovirus infection

<u>Perinatal Period</u>

- birth asphyxia
- hyperbilirubinemia
- low-birth weight
- other perinatal morbidities and their management

<u>Childhood and Adolescence</u>

- chronic suppurative otitis media
- chronic nonsuppurative otitis media

- meningitis and other infections

Adulthood and Older Age

- chronic diseases
- smoking
- otosclerosis
- age-related sensorineural degeneration
- sudden SNHL

Factors Across the Life Span

- cerumen impaction
- trauma to the ear or head
- loud noise/loud sounds
- ototoxic medicines
- work related ototoxic chemicals
- nutritional deficiencies
- viral infections and other ear conditions
- delayed onset or progressive genetic HL

The Minimum Speech Test Battery (MSTB) for adults has been utilized to guide clinicians for cochlear implant candidacy and document post-operative speech recognition performance. The MSTB was recently revised (MSTB-Version 3) (Dunn et al., 2024) to include the minimum battery of tests that could be utilized to provide a comprehensive assessment, which include unaided audiometric testing, hearing aid verification, functional outcomes using The Cochlear Implant Quality of Life tool (CIQOL 10), the Speech, Spatial and Qualities of Hearing Scale (SSQ-12), a Tinnitus handicap inventory when significant tinnitus is reported, and an aided speech test battery. The aided speech test battery includes the following:

- CNC Monosyllabic word test evaluating each ear separately in the best-aided condition using a list of 50-words given at different decibels to determine the better versus poorer ear to assist in the determination of which ear should be implanted.
- AzBio Sentence Test: reviews a list of words at different decibels with differing signal to noise ratios of the ear to be implanted to represent the best-aided condition.

Post-operatively, audiologic rehabilitation is recommended to help individuals understand their HL type and regain skills that they may have lost.

Technologies for the treatment of HL are dependent on the cause and severity and can include assistive listening and alerting devices, hearing aids, cochlear implants, and middle ear implants.

Hearing aids amplify sound to allow detection by damaged ears. Cochlear implants differ in that they don’t amplify, rather, they directly stimulate the auditory nerve, bypassing the damaged portions of the ear altogether. The auditory nerve recognizes the signals as sound. Hearing through a cochlear implant is different from normal hearing and takes time to learn or relearn. However, it allows many people to recognize warning signals, understand other sounds in the environment, and understand

speech in person or over the telephone. (National Institute on Deafness and Other Communication Disorders 2024)

Cochlear Implants (Unilateral and Bilateral) for Bilateral Sensorineural Hearing Loss (SNHL)

The basic structure of a cochlear implant includes both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are implanted surgically and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear. Sounds picked up by the microphone are carried to the external sound processor, which transforms sound into coded signals that are then transmitted transcutaneously to the implanted internal receiver. The receiver converts the incoming signals into electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve. Cochlear implants can worsen low-frequency hearing sensitivity (the ability to still hear low-pitched sounds) because although the inner ear is being stimulated to restore higher frequency hearing, it results in a reduced ability to perceive low-frequency sound when compared to natural hearing.

Bilateral cochlear implants are utilized for 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 HL of such magnitude that a hearing aid will not produce the required amplification). The 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. Bilateral cochlear implantation may be done sequentially or simultaneously.

Unilateral Cochlear implants for Single-Sided Deafness (SSD) and Asymmetric Hearing Loss (AHL)

AHL is when an individual has profound HL in one ear and mild to moderately severe HL in the hearing ear. The ear with the profound loss can be completely ineffective or not usable for hearing, making it unlikely the individual will benefit from an appropriately fit bilateral hearing aid. HL that only affects one ear is known as SSD, or unilateral hearing loss (UHL). The degree of impairment in the contralateral ear can range from mild to profound.

SSD occurs in both adults and children. Those with SSD 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 adults with SSD were 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, cochlear implant of the impaired ear for stimulation of both auditory pathways aims to improve performance on spatial hearing tasks, including sound source localization and speech understanding in spatially separated noise (Dillon et al., 2022).

Hybrid Cochlear Implant

Hybrid devices incorporate both a hearing aid and the external sound processor of a cochlear implant. They are indicated for individuals who have high-frequency SNHL with preserved low-

frequency hearing sensitivity (the ability to still hear low-pitched sounds even when experiencing significant hearing loss in higher frequencies). 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.

Hybrid cochlear implant electrodes are shorter and are inserted to a depth that are proposed to preserve residual low-frequency hearing that is generally lost through the use of traditional cochlear implants. The developer of the Nuclear 24 Hybrid Implant System, Cochlear (Lone Tree, Colorado), describes the hybrid mechanism of action as the following: 1) Sound processor microphones pick up the sound and convert it into digital information, 2) The acoustic component amplifies low frequency sound and sends it down the ear canal through the normal hearing pathway, 3)The high frequency information is transferred via the coil to the implant under the skin, 4)The implant sends electrical signals down the electrode into the cochlea where the hearing nerve fibers pick up the electrical signals and are combined with the amplified sounds, 5)The electrical signals are then sent to the brain to interpret the sound.

Auditory Brainstem Implant

Auditory brainstem implants are devices designed to restore some hearing in patients with neurofibromatosis type II. Neurofibromatosis type II is a genetic disorder that causes a growth of tumors. Individuals with this condition can have complete hearing loss due to the 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.

SUPPORTIVE LITERATURE

Cochlear Implants (Unilateral and Bilateral) for Bilateral Sensorineural Hearing Loss (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).

Unilateral Cochlear implants for Single-Sided Deafness (SSD) or Asymmetric Hearing Loss (AHL)

For individuals who have SSD who receive a cochlear implant(s), the evidence includes small open-label RCTs, a feasibility study, prospective and retrospective studies reporting within-subjects comparisons, and systematic reviews of observational studies. Individuals with SSD have the inability to process input from both ears, and this inability to provide a complete auditory picture negatively impacts the localization of sound, speech perception, and quality of life. Studies have been limited by population size, and heterogeneity, but several of the studies report positive outcomes for improved sound localization, speech perception in both quiet and noise, tinnitus suppression, and improved quality of life when compared to the use of Contralateral Routing of Signal and bone anchored

hearing aids in specific individuals. Because of this, the use of cochlear implants for the treatment of SSD is supported by national professional society guidelines (Refer to Professional Societies Section).

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.

Marx and colleagues aimed to assess the outcomes of cochlear implants (CI) and other treatment options in SSD or AHL on quality of life in a prospective study published in 2021. Performances for speech-in-noise recognition and localization were measured as secondary outcomes. The study included both an observational cohort of SSD/AHL who were treated using contralateral routing of the signal hearing aids (CROS) or bone-anchored systems (BAHS) or individuals who declined all treatments, and a randomized controlled trial was performed on subjects treated by cochlear implantation after failed CROS or BAHS trials. Those individuals were treated with two trials of CROS and BAHSs on headband and were then allowed to choose from the four treatment options (abstention, CROS, BAHS, or CI). Those that selected CI were then randomized into two arms, CI versus initial observation (n=51). Follow up was conducted at six months and demonstrated quality-of-life outcomes as significantly better in the CI arm versus observation, particularly in patients with associated severe tinnitus. No significant effect of the CI was found on binaural hearing results. The study was limited by the small sample size included within the RCT, and a short follow up time-frame to capture the longer-term effects of the CI on binaural hearing.

Peters et al. (2021) randomized 120 adults with single-sided deafness (median duration, 1.8 years) into three 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 HL in the best ear and a minimum 70 dB HL 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 was limited by small sample size, device heterogeneity, loss to follow-up, and lack of allocation concealment. Study follow-up through 5 years is ongoing.

Dillon et al. (2022) conducted a systematic review of the published literature on outcomes of cochlear implant use for auditory abilities, tinnitus perception, and quality of life. The review included 42 articles published between January 2008 and September 2021. Studies were screened by two

independent reviewers based on title and abstracts. Each article was assessed for the level of evidence and categorized based on the reported outcome data. Of 9 studies that were included in the assessment for speech recognition in quiet (n= 307), 100% of adults implanted with a CI had an improvement. Of the studies that evaluated outcomes for speech recognition in noise (n=256), 96% experienced improvements when the target speech was presented from the CI ear, with masking configuration presented from the normal hearing ear (13 studies noted with significant improvements).

Park et al. (2022) conducted a review of the literature and subsequently developed guidelines for the clinical assessment and management of cochlear implants in children with SSD, endorsed by the American Cochlear Implant Alliance Task Force (Refer to Professional Society Section). The guidelines recommend:

- Assurance of an accurate diagnosis of nerve deficiency through 3D-MRI of the internal auditory canals;
- Cochlear implants should be considered a priority for children who are at risk of HL progression in the better hearing ear, as well as children with SSD due to bacterial meningitis;
- Children with longer lengths of deafness may experience fewer benefits and should be appropriately counseled;
- Cochlear implant evaluation is recommended for children with a unilateral three frequency PTA of > 60 dB HL or an aided speech intelligibility score <0.65 as these children are not likely to receive adequate benefit from traditional amplification;
- Trials with rerouting devices are not recommended for children seeking binaural hearing as these devices are not able to provide the brain with bilateral input and the trial could delay a time-sensitive procedure;
- Counseling for families considering cochlear implants should include information about developmental disadvantages of SSD, the advantage of implantation at a younger age, the importance of post implant listening therapy, and reasonable expectations;
- The most appropriate post-activation test batteries and timeframes;
- Technique to utilize for evaluating audibility in the sound field;
- Device programming considerations.

The authors emphasized that this is a rapidly evolving field and readers should keep abreast of the literature and current research outcomes.

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 SSD. Pooled outcomes indicated improved scores in speech perception, localization, tinnitus, and quality of life. Study interpretation was limited by small sample sizes and heterogeneity in reported outcomes and follow-up durations.

Hybrid Cochlear Implant

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 HL 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.

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 SNHL. 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 HL 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 HL and were implanted with a Nucleus Hybrid L24 (Cochlear Ltd., Sydney, Australia) cochlear implant. The authors 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 was 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 Cochlear Implant 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 HL, 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.

In 2024, Reinhart and colleagues conducted a prospective multi-center clinical trial (NCT02379819) to assess the safety and effectiveness of a hybrid cochlear implant for delivering electric-acoustic stimulation (EAS) in patients with low- frequency acoustic hearing and severe-to-profound high-frequency HL. The study enrolled 52 adults, who were newly implanted with the hybrid cochlear implant. Post implant, testing included unaided and aided audiometric thresholds, speech perception (CNC words in Quiet and AzBio sentences +5 dB SNR), as well as patient reported outcomes using the Speech, Spatial and Qualities of Hearing Scale with a follow up timeframe of up to five years. Functionally aidable hearing, defined as low-frequency PTA (125–500 Hz) <80 dB HL, was maintained for 77% of patients through 1 year, with 66.7% maintaining through 5 years. Speech perception was significantly improved at all postoperative timepoints compared with preoperative performance with hearing aid(s), and patient-reported outcomes indicated significantly improved subjective speech understanding, spatial hearing, and sound quality. Participants with preserved acoustic hearing using EAS reported significantly higher subjective spatial hearing and sound quality than participants with electric-only hearing in the implanted ear. The results replicated the outcomes reported in the pivotal trial (Roland 2016).

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 improvemence is considered significant in this group of patients who have no other treatment options (Otto et al., 2008; Ontario Health, 2020).

The evidence on auditory brainstem implants in nontumor patients includes case series and systematic reviews. A 2014 systematic review (Merkus et al.) suggested that auditory brainstem implants might improve outcomes in bilateral complete cochlear and inner ear aplasia. Recent research includes studies of children who are deaf but would not benefit from a cochlear implant. Hearing in this age group is critical for language development, and the auditory brainstem implants have potential to substantially improve health outcomes. However, studies of early (now obsolete) auditory brainstem implants found a high rate of failure in children and high rates of adverse events in adults. Evidence from ongoing studies assessing newer device models is needed to evaluate efficacy and durability in patients with nontumor indications.

PROFESSIONAL GUIDELINE(S)

Cochlear Implants for Bilateral SNHL

In April 2021, 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 HL who have failed a trial with appropriately fit hearing aids.

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

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

In 2022, the American Cochlear Implant Alliance Task Force published guidelines on the assessment and management of adult cochlear implantation for SSD (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 cochlear implant 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 cochlear implantation outcomes.

In April 2023, the AAO-HNS issued two new position statements endorsing cochlear implantation for cases of single sided deafness (asymmetric or unilateral sensory HL) for adult patients and children. Adults with asymmetric or unilateral sensory HL struggle with speech perception in noise and sound source localization due to loss of binaural cues. They also experience disabling tinnitus and reduced quality of life and quality of hearing, stating that cochlear implants restore binaural hearing and markedly improve sound localization, speech perception in noise, reduces or eliminates tinnitus, and improves quality of life and hearing.

The AAO-HNS recommends that select children with unilateral SNHL, as early as 9 months of age, should undergo cochlear implantation as soon as HL and appropriate anatomy is verified to avoid missing a developmental window that permits integration of binaural cues. Specifically indicating that children with unilateral SNHL also 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.

The American Speech-Language Hearing Association (ASHA) publishes Evidence Maps to summarize published Clinical Practice Guidelines. Strong recommendations were made based upon guidelines published by the Brazilian Society of Otology Task Force for individuals with SSD (Tsuji, et al. 2025) and include the following:

- CIs are the most effective treatment to restore useful hearing in profound deafness in individuals with SSD. CIs are the only option to restore binaural hearing for this population (Strong Recommendation; Low-Quality Evidence).
- CIs can restore binaural hearing and produce significant improvements in speech perception, spatial localization of sound, tinnitus control, and overall quality of life (Strong Recommendation; Moderate-Quality Evidence).
- "In children with SSD due to congenital cytomegalovirus, CI is more appropriate due to the increased risk of contralateral hearing deterioration over time" (Strong Recommendation; Low-Quality Evidence).
- Family counseling should be conducted prior to the use of CI in cases of SSD in order to adjust expectations and conduct therapy (Strong Recommendation; Moderate-Quality Evidence).
- "Adult patients with SSD undergoing ipsilateral CI have statistically significant improvements in speech perception, tinnitus reduction, sound localization, and quality of life" (Strong Recommendation; Moderate-Quality Evidence).
- In cases of sporadic vestibular schwannoma (VS), CI is a treatment option for SSD. This is especially true in the presence of disabling tinnitus and preserved cochlear nerve function (Strong Recommendation; Low-Quality Evidence).

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved several cochlear implants for commercial use in the United States. Cochlear implants are Class III devices, and therefore, FDA approval is device-specific. Visit Devices@fda.gov for updates and device specific indications regarding age and degree of HL. Additionally, the FDA maintains a list of recent device recalls. For more information, please refer to: Medical Device Safety | FDA [accessed 2025 Feb 19]

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 SNHL, and who obtain limited benefit from an appropriately fitted bilateral hearing aid.

In 2022, the Nucleus Hybrid L24 received expanded approval for single-sided deafness or unilateral HL in adults and children aged 5 or older (P970051/S205). According to the FDA's summary of safety and effectiveness data, approval was based on unpublished data in 42 adults from a feasibility study (n=10) and real-world data from two cochlear implantation centers (n=32). Study interpretation is limited by small sample size in adult subjects only, unclear rationale for the efficacy threshold, and missing data. The FDA has required Cochlear Americas to conduct a post marketing study to continue to assess the safety and efficacy of the implant in a new enrollment cohort of adults and children.

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 SNHL 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 SSD or AHL who have profound sensorineural hearing loss in one ear and normal hearing or mild SNHL in the other ear.

Auditory Brainstem Implant

The Nucleus 24 Auditory Brainstem Implant System (Cochlear Corporation) is the only device that has received approval by the FDA (2016) for auditory brainstem implantation. The device is indicated for individuals 12 years of age and older who have been diagnosed with neurofibromatosis type II.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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

Code	Description
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

ICD10 Codes

Code	Description
H90.3 - H90.8	Conductive and sensorineural hearing loss (code range)
H90.A2-H90.A32	Mixed conductive and sensorineural hearing loss (code range)

Code	Description
H91.3	Deaf nonspeaking, not elsewhere classified
H93.3x1-H93.3x9	Disorders of acoustic nerve (code range)
Q85.02	Neurofibromatosis, type 2
Z96.21	Cochlear implant status

REFERENCES

Agency for Healthcare Research and Quality [Internet]. Technology assessment. Effectiveness of cochlear implants in adults with sensorineural hearing loss [2011 Apr 11; corrected 2011 Jun 17; accessed 2025 Feb 03] Available from: http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id80TA.pdf

American Academy of Audiology [Internet]. Clinical practice guideline: cochlear implants. [2019 Jul; accessed 2025 Feb 03] Available from: Position Statement: Cochlear Implants - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Position statement: cochlear implants. [Adopted 1982 Jul 10; Revised 2021 Apr 05; accessed 2025 Feb 03] Available from: https://www.entnet.org/resource/position-statement-cochlear-implants/]

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Position statement: cochlear implant candidacy for children with bilateral sensorineural hearing loss. [Adopted 2021 Jul; Revised 2021 Sep 23; accessed 2025 February 23] Available from: https://www.entnet.org/resource/position-statement-cochlear-implant-candidacy-children-bilateral-sensorineural-hearing-loss/

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Position statement: cochlear implant for single sided deafness in adults. [2023 Apr 25; accessed 2025 Feb 03] Available from: https://www.entnet.org/resource/position-statement-cochlear-implantation-for-single-sided-deafness-in-adults/

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Position statement: pediatric cochlear implantation candidacy. [2020 April 5; accessed 2025 Feb 03] Available from: https://www.entnet.org/resource/position-statement-pediatric-cochlear-implantation-candidacy/

American Speech-Language-Hearing Association (ASHA). Practice portal clinical topics: cochlear implants, hearing loss adults, and hearing loss childhood. [accessed 2025 Feb 03] Available from: https://www.asha.org/practice-portal/clinical-topics/

Baron S, et al. Sequential bilateral cochlear implants in children and adolescents: outcomes and prognostic factors. Eur Ann Otorhinolaryngol Head Neck Dis. 2019 Apr;136(2):69-73. PMID 30314876

Basura G, et al.; Aural Rehabilitation Clinical Practice Guideline Development Panel. American Speech-Language-Hearing Association clinical practice guideline on aural rehabilitation for adults with hearing loss. Am J Audiolo. 2023 Mar;32:1-51.

Benchetrit L, et al. Cochlear implantation in children with single-sided deafness: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2021 Jan 01;147(1):58-69.

Bond M, et al. Effectiveness of multi-channel unilateral cochlear implants for profoundly deaf children: a systematic review. Clin Otolaryngol. 2009 Jun;34(3):199-211. PMID 19531168

Bond M, et al. The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model. Health Technol Assess. 2009 Sep;13(44):1-330. PMID 19799825

Crathorne L, et al. A systematic review of the effectiveness and cost-effectiveness of bilateral multichannel cochlear implants in adults with severe-to-profound hearing loss. Clin Otolaryngol. 2012 Oct; 37(5): 342-54. PMID 22928754

Dillon MT, et al.; endorsed by the American Academy of Audiology. American Cochlear Implant Alliance Task Force guidelines for clinical assessment and management of adult cochlear implantation for single-sided deafness. Ear & Hearing. 2022 Aug;43:1605-1619 [accessed 2025 Feb 03.] Available from: https://www.audiology.org/practice-guideline/american-cochlear-implant-alliance-task-force-guidelines-for-clinical-assessment-and-management-of-adult-cochlear-implantation-for-single-sided-deafness/

Dunn C.C. et al. A Consensus to Revise the Minimum Speech Test Battery–Version 3. AJA. 2024 Sep;33:624-647.

Galvin JJ III, et al. Benefits of cochlear implantation for single-sided deafness: data from the house clinic-University of Southern California- University of California, Los Angeles clinical trial. Ear Hear. 2019 Jul/Aug;40(4):766-781.

Gantz BJ, et al. Multicenter clinical trial of the Nucleus Hybrid S8 cochlear implant: Final outcomes. Laryngoscope.2016 Apr;126(4):962-73.

Gaylor JM, et al. Cochlear implantation in adults: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2013 Mar;139(3):265-72. PMID 23429927

Karltorp E, et al. Cochlear implants before 9 months of age led to more natural spoken language development without increased surgical risks. Acta Paediatr. 2020 Feb;109(2):332-341.

Lenarz T, et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. Int J Audiol. 2013 Dec;52(12):838-48.

Lorens A, et al. Binaural advantages in using a cochlear implant for adults with profound unilateral hearing loss. Acta Otolaryngol. 2019 Feb;139(2):153-161.

Marx M, et al. Cochlear implantation and other treatments in single-sided deafness and asymmetric hearing loss: results of a national multicenter study including a randomized controlled trial. Audiol Neurootol. 2021 Mar 31;26(6)414-424.

McRackan TR, et al. Meta-analysis of cochlear implantation outcomes evaluated with general health-related patient-reported outcome measures. Otol Neurotol 2018 Jan;39(1):29-36.

McRackan TR, et al. Meta-analysis of quality-of-life improvement after cochlear implantation and associations with speech recognition abilities. Laryngoscope 2018 Apr; 128(4):982-990.

Merkus P, et al. Indications and contraindications of auditory brain stem implants: systematic review and illustrative cases. Eur Arch Otorhinolaryngol. 2014 Jan; 271(1): 3-13.

National Institute for Health and Care Excellence (NICE) [Internet]. Cochlear implants for children and adults with severe to profound deafness. Technology appraisal guideline (TA566) [2019 Mar; accessed 2025 Feb 03] Available from: https://www.nice.org.uk/guidance/ta566

National Institute on Deafness and Other Communication Disorders [Internet]. Cochlear Implants, NIH Publication No. 00-4798 [2016 Feb; updated 2024 Jun 13; accessed 2025 Mar 06] Available from: What Are Cochlear Implants for Hearing? | NIDCD.

Noij KS, et al. Systematic review of nontumor pediatric auditory brainstem implant outcomes. Otolaryngol Head Neck Surg. 2015 Nov;153(5):739-50.

Oh SJ, et al., Cochlear implantation in adults with single-sided deafness: a systematic review and meta-analysis. Otolaryngol Head Neck Surg. 2023 Jan 26;168(2):109-250.

Ontario Health (Quality). Auditory brainstem implantation for adults with neurofibromatosis 2 or severe inner ear abnormalities: final recommendations. Ont Health Technol Assess Ser. 2020 Mar;20(4):1-85.

Otto SR, et al. Audiologic outcomes with the penetrating electrode auditory brainstem implant. Otol Neurotol 2008 Dec;29(8):1147-54.

Park LR, et al; endorsed by the American Academy of Audiology. American Cochlear Implant Alliance Task Force guidelines for clinical assessment and management of cochlear implantation in children with single-sided deafness. Ear & Hearing. 2022 Mar;43:255-267.

Peters, JPM, et al. Short-term outcomes of cochlear implantation for single-sided deafness compared to bone conduction devices and contralateral routing of sound hearing aids-results of a randomized controlled trial (CINGLE-trial). PLoS One. 2021 Oct 13;16(10)e0257447.

Peter N, et al. The influence of cochlear implantation on tinnitus in patients with single-sided deafness: a systematic review. Otolaryngol Head Neck Surg. 2019 Oct;161(4):576-588.

Pillsbury HC, et al. Multicenter US clinical trial with an Electric-Acoustic Stimulation (EAS) System in adults: final outcomes. Otol Neurotol. 2018 Mar;39(3):299-305. PMID 29342054

Poncet-Wallet C, et al. Prospective multicentric follow-up study of cochlear implantation in adults with single-sided deafness: tinnitus and audiological outcomes. Otol Neurotol. 2020 Apr;41(4):458-466.

Reinhart P, et al. Hybrid cochlear implant outcomes and improving outcomes with electric-acoustic stimulation. Otol & Neuro. 2024 Dec;45(10): p e749-e755.

Roland JT Jr, et al; Multicenter Clinical Trial Group. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. Laryngoscope. 2016 Jan;126(1):175-81.

Roland JT Jr, et al. Long-term outcomes of cochlear implantation in patients with high-frequency hearing loss. Laryngoscope. 2018 Aug; 128(8):1939-1945.

Sladen DP, et al. Cochlear implantation for single-sided deafness: A multicenter study. Laryngoscope. 2017 Jan;127(1):223-228.

Thompson NJ, et al. Subjective benefits of bimodal listening in cochlear implant recipients with asymmetric hearing loss. Otolaryngol Head Neck Surg. 2020 Mar 17:194599820911716.

Tsugi RK, et al. Brazilian Society of Otology task force-single sided deafness-recommendations based on strength of evidence. Braz J Otorhinolaryngology. 2025 Jan-Feb;91(1):1-24.

U.S. Food and Drug Administration [Internet]. Premarket Approval: COMBI 40+ Cochlear Implant System (Med-EL)– P000025. [2021 Aug; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000025

U.S. Food and Drug Administration [Internet]. Premarket Approval: HiResolution Bionic Ear System – P960058. [2023 Jun; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P960058

U.S. Food and Drug Administration [Internet]. Premarket Approval: Med-El Cochlear Implant System with combine electrical stimulation and acoustic (ESA) amplification–P000025/S084. 2016 Sept; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000025S084

U.S. Food and Drug Administration [Internet]. Med-El Cochlear Implant System–P000025/S104. [2019 Jul; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf/P000025S104A.pdf

U.S. Food and Drug Administration [Internet]. Premarket Approval: Neuro Cochlear Implant System – P200021. [2021 Jun; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200021

U.S. Food and Drug Administration [Internet]. Premarket Approval: Nucleus Hybrid L24 Cochlear Implant System - P130016. [2014 Mar; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130016

U.S. Food and Drug Administration [Internet]. Nucleus 24 Cochlear Implant System – P970051/S172. 2020 Mar; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf/P970051S172A.pdf

U.S. Food and Drug Administration [Internet]. Premarket Approval: Nucleus 24 Cochlear Implant System – P970051/S205. 2022 Jan; accessed 2025 Feb 03] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S205

*Wilkinson EP, et al. Initial results of a safety and feasibility study of auditory brainstem implantation in congenitally deaf children. Otol Neurotol. 2017;38(2):212-220.

Warner-Czyz AD, et al.; endorsed by the American Academy of Audiology. American Cochlear Implant Alliance Task Force Guidelines for Determining Cochlear Implant Candidacy in Children. Ear & Hearing. 2022 Mar;43:268-282.

World Health Organization [Internet]. Fact sheets, deafness and hearing loss. 2024 Feb 2; accessed 2025 Feb 07] Available from: Deafness and hearing loss

Zeitler DM, et al.; endorsed by the American Academy of Audiology. American Cochlear Implant Alliance Task Force: recommendations for determining cochlear implant candidacy in adults. Laryngoscope. 2023 Jul;00:1-14.

SEARCH TERMS

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, Cochlear Implant Single-Unit Audio Processor

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cochlear Implantation (NCD 50.3) [accessed 2025 Feb 14]

Based on our review, auditory brainstem implants are not addressed in National or Regional Medicare coverage determinations or policies. Please refer to the Medicare Benefit Policy Manual [Last updated 2014 Jun 6; accessed 2025 Feb 03] Available from: Medicare Benefit Policy Manual Chapter 16-Section 100

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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.

POLICY HISTORY/REVISION

Committee Approval Dates

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, 03/20/25

Date	Summary of Changes
03/20/25	• Annual update; policy statement revised for unilateral and bilateral cochlear implants to add the treatment of individuals with single-sided hearing loss as medically appropriate; policy statement revised for unilateral cochlear implantation using hybrid cochlear implant from investigational to medically appropriate when criteria are met; policy statement revised for device repair and replacement.
01/01/25	• Summary of changes tracking implemented.
03/21/02	• Original effective date