



Medical Coverage Policy

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Cochlear and Auditory Brainstem Implants

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Related Coverage Resources

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as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses traditional cochlear implantation, hybrid cochlear implantation, auditory brainstem implantation and replacements or upgrades of these devices.

Coverage Policy

Traditional Cochlear Implant Without an External Hearing Aid

Bilateral Sensorineural Hearing Loss

A unilateral or bilateral traditional cochlear implant is considered medically necessary for the treatment of bilateral sensorineural hearing loss when there is reasonable expectation that a significant benefit will be achieved from the device and when the following age-specific criteria are met:

- For an individual age 18 years or older with **BOTH** of the following:
 - bilateral, severe-to-profound sensorineural hearing loss determined by a pure-tone average (PTA) of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz
 - limited or no benefit from appropriately fitted hearing aids, defined as $\leq 40\%$ correct in the best-aided listening condition (i.e., non-implanted ear aided or binaurally aided) using open-set sentence recognition
- For an individual age less than 18 years old with **BOTH** of the following:
 - profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz
 - limited or no benefit from a three-month trial* of appropriately fitted binaural hearing aids defined as follows:
 - age five years or younger - lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three-month period
 - over age five years - less than 20% correct on open-set sentence discrimination (e.g., Multi-syllabic Lexical Neighborhood Test [MLNT] or Lexical Neighborhood Test [LNT]), depending on the child's cognitive ability and linguistic skills

***NOTE:** a three-month trial of an appropriately fitted binaural hearing aid will be waived when a child has **EITHER** of the following:

- history of pneumococcal meningitis causing the hearing loss
- evidence of cochlear ossification on computerized tomography (CT) scan

A second traditional cochlear implant in the contralateral (opposite) ear is considered medically necessary for an individual with an existing traditional unilateral cochlear implant when the hearing aid in the contralateral ear produces limited or no benefit, there is reasonable expectation that a significant benefit will be achieved from the device and the following age-specific criteria are met:

- For an individual age 18 years or older with **BOTH** of the following:
 - bilateral, severe-to-profound sensorineural hearing loss determined by a pure-tone average (PTA) of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz
 - limited or no benefit from an appropriately fitted hearing aid, defined as ≤ 40% correct in the best-aided listening condition (i.e., non-implanted ear aided), in the second ear to be implanted on open-set sentence recognition
- For an individual age less than 18 years old with **BOTH** of the following:
 - profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz
 - limited or no benefit from a three-month trial* of an appropriately fitted hearing aid defined as follows:
 - age five years or younger - lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three month period
 - over age five years - less than 20% correct on open-set sentence discrimination in the second ear to be implanted (e.g., Multi-syllabic Lexical Neighborhood Test [MLNT] or Lexical Neighborhood Test [LNT], depending on the child's cognitive ability and linguistic skills

***NOTE:** a three-month trial of an appropriately fitted binaural hearing aid will be waived when a child has **EITHER** of the following:

- history of pneumococcal meningitis causing the hearing loss
- evidence of cochlear ossification on computerized tomography (CT) scan

Unilateral Sensorineural Hearing Loss

A traditional cochlear implant is considered medically necessary for the treatment of profound sensorineural hearing loss when an individual meets ALL of the following criteria:

- age ≥ five years
- obtains limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted
- **EITHER** of the following
 - profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear (i.e., single sided deafness [SSD])
 - profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears (i.e., asymmetric hearing loss [AHL])

NOTE:

- For an individual ≥ age 18 years, limited benefit from unilateral amplification is defined by test scores of five percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone.
- For an individual age 5–18 years, insufficient functional access to sound in the ear to be implanted determined by aided speech perception test scores of five percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

- Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.
- Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

The replacement of an existing traditional cochlear implant is considered medically necessary when EITHER of the following criteria is met:

- currently used component is no longer functional and cannot be repaired and there is no evidence to suggest that the device has been abused or neglected
- currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living

Both initial and replacement batteries (HCPCS codes L8621, L8622, L8623, L8624) are considered medically necessary for a cochlear implant.

Upgrading of a traditional cochlear implant system or component (e.g., upgrading processor from body-worn to behind-the-ear, upgrading from single- to multi-channel electrodes) of an existing, properly functioning traditional cochlear implant is considered not medically necessary.

A traditional cochlear implant for the treatment of tinnitus in an individual who does not also have profound or severe sensorineural deafness/hearing loss warranting the need for traditional cochlear implantation is considered experimental, investigational or unproven.

Hybrid Cochlear Implant With An External Hearing Aid

A hybrid cochlear implant (e.g., Nucleus® Hybrid™ L24 Cochlear Implant System) is considered medically necessary for individuals 18 years of age or older who have residual low-frequency hearing and severe to profound high-frequency sensorineural hearing loss when an individual meets ALL of the following criteria:

- limited benefit from appropriately fitted bilateral hearing aids
- normal to moderate low frequency hearing loss (i.e., thresholds no poorer than 60 dB HL up to and including 500 Hz)
- severe to profound mid- to high-frequency hearing loss in the ear to be implanted (i.e., threshold average of 2000, 3000, and 4000 Hz \geq 75 dB hearing level)
- moderately severe to profound mid to high-frequency hearing loss in the contralateral ear (threshold average of 2000, 3000, and 4000 Hz \geq 60 dB hearing level)
- consonant-nucleus-consonant (CNC) word recognition score in the ear to be implanted in the preoperative aided condition between 10% and 60%
- consonant-nucleus-consonant (CNC) word recognition score in the contralateral ear equal to or better than that of the ear to be implanted but no more than 80% correct
- individual does not have any of the following conditions:
 - deafness due to lesions of the acoustic nerve or central auditory pathway
 - active middle ear disease, with or without tympanic membrane perforation
 - absence of cochlear development
 - a duration of severe to profound hearing loss of 30 years or greater

Auditory Brainstem Implant

An auditory brainstem implant (ABI) is considered medically necessary when ALL of the following criteria are met:

- diagnosis of neurofibromatosis type 2
- age 12 years or older
- individual is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the individual will become completely deaf as a result of the surgery, or the individual had bilateral auditory nerve tumors removed and is now bilaterally deaf

Both initial and replacement batteries (HCPCS code L7367, L8621) for an auditory brainstem implant (ABI) are considered medically necessary.

Note: For an individual of any age, a post-traditional cochlear or auditory brainstem implant rehabilitation program (aural rehabilitation) is medically necessary to achieve benefit from the device. Aural rehabilitation is considered a form of speech therapy. Coverage for outpatient speech therapy is subject to the terms, conditions and limitations of the Short-Term Rehabilitative Therapy benefit as described in the applicable benefit plan's schedule of copayments.

General Background

Hearing impairment is the result of sensorineural and/or conductive malfunctions of the ear and may be congenital or secondary to trauma or disease (e.g., autoimmune disorders, auditory neuropathy, meningitis, acoustic tumors, Mondini dysplasia, enlarged vestibular aqueduct syndrome [LVAS] and cochlear otosclerosis). Sensorineural hearing loss occurs when tiny hair cells in the cochlea (inner ear) are damaged or when there is damage to the nerve pathways from the inner ear to the brain. Thus, the sensory receptors of the inner ear are dysfunctional and there is a lack of sound perception due to a defect in the cochlea, the auditory division of the vestibulocochlear nerve, or both. Hearing loss can involve low-frequency and/or high frequency sounds. Individuals with low frequency hearing loss cannot hear sounds in frequencies of 2000 hertz (Hz) and below but may still hear sounds in the higher frequencies. Low frequency sounds are low-pitched hums or drones. High frequency sounds are high-pitched noises such as ringing and whistling in frequencies greater than 2000 Hz. High-frequency hearing loss affects a person's ability to understand speech and is the most common type of sensorineural hearing loss. Complete or partial hearing impairment may begin prior to speech and language acquisition (i.e., prelingually) or after the acquisition of speech and language (i.e., postlingually). Many patients with sensorineural hearing loss can be habilitated or rehabilitated with the use of hearing aids. Patients with profound bilateral sensorineural hearing loss (i.e., greater than 70–90 decibels [dB]) who derive little or no benefit from conventional hearing aids may be appropriate candidates for a traditional cochlear implantation.

In a Health E-Stats report issued by the National Center for Health Statistics, Schoenborn and Heyman (2015) detail health disparities that exist among adults with self-reported deafness or "a lot of trouble hearing" compared with adults with self-reported "good hearing". According to the report, 3.3% of adults aged 18 and older were deaf or had a lot of trouble hearing. Of those individuals, 4.3% were men while 2.4% were women and deafness or a lot of trouble hearing increased with age affecting 11.1% of individuals >65 years old compared to 0.9% of individuals <45 years old. The highest rates of any hearing difficulty were reported in non-Hispanic white and non-Hispanic Indian or Alaska Native adults. A higher degree of hearing loss was found to be directly correlated to a higher prevalence of fair or poor health status, difficulties with physical functioning, and serious psychological distress. Compared to adults with good hearing, diabetes and hypertension were more prevalent in individuals with deafness or a lot of trouble hearing. Health risk behaviors including smoking tobacco, drinking five or more alcoholic drinks per day, sedentary behavior, obesity, and obtaining 6 or fewer hours of sleep per night were more likely in

adults with deafness or a lot of trouble hearing compared to adults with good hearing. In adults aged 18–44 years old who were deaf or had a lot of trouble hearing, >40% smoked cigarettes compared to 24% of those with good hearing. The reason for these higher rates of health risk behaviors could not be determined from the analysis. The authors concluded that a reduction of disparities among individuals with deafness or a lot of trouble hearing may be achieved with increased attention to the unique healthcare needs of these individuals and the inclusion of communication modalities appropriate for this population.

Cochlear implant has been proposed for hearing impairment secondary to auditory neuropathy spectrum disorder (ANSD). ANSD also called auditory neuropathy/auditory dyssynchrony (AN/AD), is a hearing disorder in which sound enters the inner ear normally but the signal transmission from the inner ear to the brain is impaired. Individuals with auditory neuropathy may have normal hearing or hearing loss ranging from mild to severe, with poor speech-perception abilities, meaning they have trouble understanding speech clearly. The individual may be able to respond to sounds appropriately, but their ability to decode speech and language is hindered. ANSD affects children and adults. Although the cause is not fully understood, ANSD is thought to occur at the junction of the spiral ganglion cells and the auditory nerve. Proposed etiology includes: congenital brain abnormalities, anoxia, hyperbilirubinemia, prematurity, heredity, viral diseases and seizure disorders. The condition can be associated with Charcot-Marie-Tooth syndrome, Stevens-Johnson syndrome, Ehlers-Danlos syndrome and Friedreich's ataxia. Most cases (90%–95%) are bilateral, may be present in up to 15% of all children with hearing loss and present in up to 20% of children with severe-to-profound hearing loss (Shaia, 2018; Lee, 2016; National Institute on Deafness and Other Communication Disorders [NIDCD], 2016; Ji, et al., 2015;).

The hallmark audiological signs of ANSD are the presence of outer hair cells, represented by normal otoacoustic emissions (OAEs) or normal cochlear microphonic (CM) response, and an absent/abnormal auditory brainstem response (ABR). Other diagnostic tests include: tympanometry, stapedial reflex test, air and bone conduction audiometry, and speech discrimination. It is reported that 90%–95% of all patients with ANSD will not have acoustic reflexes. ANSD can masquerade as an auditory processing disorder (APD) in children with normal hearing thresholds and poor performance with word recognition, especially in noise. In adults ANSD may masquerade as an acoustic neuroma with normal hearing thresholds, poor performance in noise, and absent/abnormal ABR are present. Hearing aids and personal listening devices may help an individual with ANSD whose speech isn't greatly distorted. If the ANSD is due to dysfunction of the inner hair cells, a cochlear implant may be beneficial. The degree of atrophy may be a factor affecting the outcome of a cochlear implant (Shaia, 2018; National Institute on Deafness and Other Communication Disorders [NIDCD], 2016; Starr and Rance, 2015; Lee, 2016).

Hearing loss is measured on a scale based on the threshold of hearing. Audiometric testing is used to measure the frequency and hearing level of an individual. Frequency is measured in hertz (Hz) which are cycles per second. The range of frequencies tested is 125 Hz to 8000 Hz. The intensity or loudness of the sound is measured in decibels (dB) which range from -10 dB to 120 dB. A summary of the audiogram for each ear is the pure-tone average (PTA) of thresholds measured at specific frequencies. One traditional PTA measure is the speech frequency average of thresholds at 500, 1000, and 2000 hertz (Hz). However, the frequencies to include in the PTA vary; for example, a high frequency such as 3000 Hz is included with the low frequency (500 Hz) and middle frequencies (1000 and 2000 Hz) in some formulations of the PTA. The most common PTA definition found in epidemiological, or population-based, studies is the four-frequency average of 500, 1000, 2000, and 4000 Hz. Normal speech and conversation occur at 40–60 dB (decibels) within a frequency range of 500–3000 Hz. Hearing loss severity is classified as follows: mild 26–40 dB HL, moderate 41–70 dB HL, severe 71–90 dB HL and profound \geq 91 dB HL (National

Institute on Deafness and Other Communication Disorders [NIDCD], 2017; American Speech and Language Association, 2004).

There are two types of FDA approved cochlear implants. The traditional cochlear implant does not have an attached external hearing aid and is intended for use by an individual with loss of high-frequency hearing with no residual low-frequency hearing in the implanted ear. The hybrid cochlear implant has an external hearing aid attached to the processor and is intended for use by an individual with high-frequency hearing loss who has low-frequency hearing capabilities.

Traditional Cochlear Implant Without an External Hearing Aid

The traditional cochlear implant (CI) without an external hearing aid is an electronic prosthesis that stimulates cells of the auditory spiral ganglion to provide a sense of high-frequency sound to individuals with bilateral, severe-to-profound sensorineural hearing impairment. Depending on the etiology and severity of the condition, a traditional CI may be worn unilaterally, or may be worn unilaterally with a hearing aid in the contralateral (opposite) ear, or when a hearing aid in the contralateral ear produces limited or no benefit, a bilateral CI may be indicated. Typically, if a contralateral hearing aid used with a traditional CI produces beneficial hearing, a bilateral CI is not indicated.

The patient selection criteria for traditional cochlear implants described in the Coverage Policy section above were adapted from the cochlear implant indications set forth by the U.S. Food and Drug Administration (FDA). The FDA criteria define "limited benefit" for adults as "test scores of 40% or less correct in best-aided listening condition on open-set sentence recognition Hearing in Noise Test sentences" (FDA, 2001). Best-aided listening condition means that the patient wears a hearing device in the non-implanted ear or both non-implanted ears (binaural aided) allowing the patient to have the best listening environment for testing.

For children, limited benefit from appropriately fitted binaural hearing aids is defined based on age as follows:

- For children age five and younger, "limited benefit" is defined as lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three month period.
- For children over age five, "limited benefit" is defined as less than 20% correct on open-set sentence discrimination on the Multi-Syllabic Lexical Neighborhood Test or Lexical Neighborhood Test, depending on the child's cognitive ability and linguistic skills (FDA, 2001).

In a child with hearing loss from pneumococcal meningitis or with evidence of cochlear ossification on computerized tomography (CT) scan, the aural rehabilitation is waived. The chance of hearing improvement following meningitis is unlikely and cochlear implantation should proceed as soon as possible when criteria are met. Ossification can begin as early as two weeks following meningitis. Early implantation with early ossification may allow for full insertion of the electrode which may not be possible with advanced ossification (Wackym and Tran, 2015; Forli, et al., 2011; American Speech-Language-Hearing Association [ASHA], 2023).

Adults and children who are a candidate for traditional CI should have a preoperative evaluation by an audiologist and otolaryngologist with experience in cochlear implantation to determine that there is a reasonable expectation that the patient will receive a significant benefit from the device and that there are no medical or surgical contraindications (e.g., acute or chronic middle ear pathology, terminal disease). The patient and/or family should be willing and motivated to participate in a post-cochlear rehabilitation program. The patient should have no psychological or cognitive deficiencies that would prohibit rehabilitation (American Academy of Audiology, 2019).

Proponents of traditional cochlear device implantation in children age less than 12 months suggest that earlier cochlear implantation allows the child to maximize this critical period of neural development, enhancing receptive and expressive language skills, speech perception, speech intelligibility, and language outcomes. It is reported that children who receive implants at an earlier age outperform those who are implanted later in life. Concerns that have been raised with implantation of traditional cochlear devices in children less than age 12 months include: the presence of an underdeveloped mastoid tip, thin skull, thin skin, anesthetic risks (e.g., respiratory complications, aspiration, bradycardia, cardiac arrest) and lack of audiological certainty in diagnosing profound hearing loss at this age (Valencia, et al., 2008; Dettman, et al., 2007; Luxford, et al., 2004; James and Papsin, 2004). Johr et al. (2008) stated that maturation of the central pathways within the first few months of life may unexpectedly improve the patient's hearing performance and stressed the importance of repeated testing. One of the challenges of studies evaluating traditional cochlear implantation in children less than age one year is the lack of available, effective tools for measuring speech perception abilities (Ertmer, et al., 2007). There is also a concern regarding the reliability of audiometric results for this age group. There are no objective means for determining the degree of hearing loss and predicting if the child age less than one year will benefit more from CI compared to traditional amplification (Johr, et al., 2008; Valencia, et al., 2008; Papsin and Gordon, 2007; Luxford, et al., 2004).

Audiological Tests and Guidelines for Traditional Cochlear Implant Candidates: Standard pure-tone and speech audiometry tests are used to screen likely traditional CI candidates. For children, the speech reception threshold and/or pure-tone average should equal or exceed 90 dB. For adults, the speech reception threshold and/or pure-tone average should equal or exceed 70 dB. If the patient can detect speech with best-fit hearing aids in place, a speech-recognition test in a sound field of 55 dB hearing level sound pressure level is performed.

In adults, limited benefit from amplification is defined as scores of $\leq 40\%$ correct in the ear to be implanted on tape-recorded tests of open-set sentence recognition (e.g., Hearing in Noise Test sentences). This definition is based on the FDA labeling of current devices. The actual value may vary, depending on specific FDA labeling. In older children, limited benefit from amplification is defined as $< 20\%$ correct on the Multi-Syllabic Lexical Neighborhood Test or Lexical Neighborhood Test, depending on the child's cognitive ability and linguistic skills. In younger children, it is generally defined as failure to develop basic auditory skills.

Holt and Svirsky (2008) noted that behavioral audiometric testing, the standard for measuring hearing sensitivity, is performed in infants using visual reinforcement audiometry and is not appropriate for infants less than age 5.5 months because they do not respond to sound with directed head turns. Because of developmental delays, this age may even be as late as eight months. If this is the case, objective measures of auditory function by audiologists is the alternative. Evoked otoacoustic emissions testing, auditory brainstem response testing (ABR), and auditory steady-state response testing are utilized to assess various elements of the auditory system. The authors stated that "there are no perfect measures for evaluating auditory status in infants" and the lack of sensitivity and specificity of each of these measures may result in inaccurate assessments of hearing capabilities and mislabeling of the degree of hearing loss in the child.

Batteries: Batteries made for the processor for a cochlear implant are either rechargeable or disposable. The most common battery for an implant is the 675 size. The cell types (what fuels the battery) include: zinc-air, silver-oxide, alkaline and rechargeable. A disposable battery can last six hours to three days depending on the cell type and the power needs of the device. Rechargeable batteries come in various sizes based on the type of processor being worn and may last for up to 365 charges. There are generic cochlear implant batteries (e.g. Rayovac, PowerOne, HearClear) and proprietary batteries made by the cochlear manufacturers. A few processors use a

standard AA or AAA battery (e.g., Neptune, Advanced Bionics, Valencia, CA) (Cochlear LTD, 2023; Advanced Bionics, 2016; Med-El, 2022).

Upgrades of Existing Device Components: In general, upgrading existing external or internal components that are functional is considered not medically necessary. Patients may seek component upgrades to make the device more aesthetically pleasing (e.g., replacing body-worn processors with behind-the-ear processors) or when they desire newer component models (e.g., upgrading from single- to multi-channel electrodes), even though a device is functioning adequately. Upgrading may be desired to obtain a processor that is smaller, more lightweight and inconspicuous, more water resistant, and/or has auto features (e.g., battery attachment auto on/off, telephone usage, detection of an FM audio system). External component replacement with the same or upgraded model is generally considered medically necessary only when the existing component is no longer functional, parts are no longer available for repair of an older device, or when it renders the implant recipient unable to perform his/her age-appropriate activities of daily living adequately or safely and cannot be repaired. Replacement due to lack of reasonable care of the device (e.g., evidence of abuse or neglect) would be considered not medically necessary. If the replacement of an existing component for a traditional CI is medically necessary and the patient has bilateral implants, replacement of the contralateral (opposite) implant is not medically necessary unless the contralateral implant is also malfunctioning, or it renders the implant recipient unable to perform his/her age-appropriate activities of daily living adequately or safely and cannot be repaired.

Tinnitus: Some patients who have received traditional cochlear implants for profound hearing loss who also have accompanying tinnitus have reported incidental tinnitus relief following implantation. There is insufficient evidence in the published peer-reviewed literature to support traditional cochlear implantation as treatment for patients with tinnitus who do not also have a profound or severe sensorineural deafness/hearing loss warranting the need for cochlear implantation.

Ramakers et al. (2015) conducted a systematic review of the literature to evaluate the effect of unilateral and bilateral cochlear implantation on tinnitus in adults with bilateral sensorineural hearing loss. Eighteen non-comparative, retrospective and prospective studies met inclusion criteria. Most of the studies included subjects with unilateral implants. The indication for CI was bilateral deafness and change in tinnitus was unintentional. The overall total tinnitus suppression rates varied from 8% to 45% of patients after cochlear implantation. Decrease of tinnitus was reported in 25%–72% of patients, 0%–36% of the patients reported that the tinnitus remained stable, and 0%–25% of patient experienced an increase in tinnitus. Newly induced tinnitus in patients with no tinnitus prior to implant ranged from 0%–10%. Studies were rated low to moderate in quality due to the lack of a comparator and heterogeneity of study designs, implant types, test conditions, follow-up duration, patient populations and outcome measures. Some studies had missing data or excluded patients because of missing data. Due to methodological weakness, no firm conclusions on the effectiveness of CI on tinnitus in adults with bilateral sensorineural hearing loss could be drawn. Because an increase of tinnitus and newly induced tinnitus were reported, a positive effect of cochlear implantation on the individual patient experiencing tinnitus could not be predicted.

Aural Rehabilitation: Aural rehabilitation following device implantation is considered an integral part of the overall management of traditional cochlear implant in both adults and children. Auditory and speech therapy may be considered rehabilitative therapy and are typically independent of the aural rehabilitation.

U.S. Food and Drug Administration (FDA): Original FDA premarket approved (PMA) speech processors and implant devices included the Nucleus® 22 and 24 Channel Systems (Cochlear

Americas, Englewood, CO), CLARION® Implants (Advanced Bionics Corp., Sylmar, CO), and the MED-EL COMBI 40+ Cochlear Implant System (Med-El Corp.; Durham, NC). These systems include an external sound processor and the internal implant. Approval of these systems was based on unilateral placement of the device. While the FDA approval language does not specifically address unilateral or bilateral use, no evidence for the safety and efficacy of bilateral traditional cochlear implants was presented to the FDA during the approval process for cochlear implant devices currently on the market. Current models of these implants include the Hiresolution Bionic Ear System (also known as HiRes™ Ultra 3D Cochlear Implant) (Advanced Bionics), the Cochlear Implant System (also known as Synchrony 2 Cochlear Implant) (Med-El Corporation) and the Nucleus 24 Cochlear Implant System (Cochlear America). The devices are intended for individuals age ≥ 18 who have bilateral, pre, peri, or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids. The Nucleus 24 Cochlear Implant System was granted PMA approval in March 2020 for “use in children 9-24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit for appropriate binaural hearing aids” (FDA, 2020).

In June of 2021, the FDA granted PMA approval for the Neuro Cochlear Implant System (Oticon Medical, Vallauris, France) “for individuals eighteen (18) years of age or older, with bilateral severe-to-profound sensorineural hearing loss, who obtain limited benefit from appropriately fitted hearing aid(s).” The device is contraindicated in the following conditions:

- “Absence of cochlear or auditory nerve development.
- Hearing loss due to lesions of acoustic nerve or central auditory pathway.
- Anatomic abnormalities, bone growth or fibrosis preventing the placement of the chosen electrode array inside the cochlea.
- Active external or middle ear infections or tympanic membrane perforation in the ear to-be- implanted.
- Presence of medical contraindications to middle-ear or inner-ear surgery or anesthesia, as required.
- Psychological instability or unrealistic expectations regarding benefits” (FDA, 2021).

In 2002, a Public Health Web Notification was issued by the FDA alerting providers “that children with cochlear implants are at a greater risk of developing bacterial meningitis caused by *Streptococcus pneumoniae* than children in the general population.” The FDA also issued a 2006 notification to healthcare providers which included updated information on the risk of bacterial meningitis in children with cochlear implants with positioners. To decrease the risk of meningitis, the FDA recommended the following: a) adherence to the CDC vaccination guidelines; b) early recognition of the signs of meningitis; c) prompt diagnosis and treatment of middle ear infections; and d) consideration of the use of prophylactic antibiotics perioperatively (FDA, 2006).

In addition to the increased risk of meningitis and the risks associated with general anesthesia, and surgical intervention to the middle or inner ear, other risks that may be associated with implantation of a cochlear device include: loss of any residual hearing in the implanted ear; injury to the facial nerve; leakage of perilymph fluid (i.e., fluid in the cochlea canal); infection of the wound; blood or fluid collection at the surgical site; episodes of dizziness or vertigo; tinnitus; taste disturbances; numbness around the ear; and localized inflammation and granuloma. In the case of failure of the internal device, the implant would have to be surgically removed. There are also concerns regarding changes in technology. External technological upgrades may not be compatible with the internal part (FDA, 2009; FDA, 2001).

Literature Review—Unilateral Implantation

Adults (i.e., age 18 years and older): Traditional unilateral cochlear implantation is a well-established treatment option for adults with severe to profound sensorineural hearing loss. Case

series and retrospective reviews reporting up to ten-years of data demonstrated improved outcomes following unilateral implantation (Gaylor, et al., 2013; Berrettini, et al., 2011; Forli, et al., 2011; Niparko, et al., 2010; Uziel, et al., 2007; Arnoldner, et al., 2005; Beadle, et al., 2005).

Children (i.e., up to age 18 years): Studies in the form of systematic reviews, case series and retrospective reviews support cochlear implantation in children including age less than 12 months (infants). It is reported that the use of a cochlear implant at a younger age exposes the child to sounds during the optimal period of development of speech and language skills and they are therefore, better able to hear and comprehend sound and develop speaking skills. (Hoff, et al., 2019; Miyamoto, et al., 2017; Bruijnzeel, et al., 2016; Forli, et al., 2011; Vlastarakos, et al., 2010a; Roland, et al., 2009; Migirov, et al., 2008; Holt and Svirsky, 2008; Dettma, et al., 2007; Tait, et al., Oct 2007; Coletti, et al., 2005; Miyamoto, et al., 2005; Waltzman and Roland, 2005; James and Papsin; 2004; Lesinski-Schiedat, et al., 2004; Schauwers, et al., 2004).

Literature Review—Bilateral Implantation

To enhance hearing capability in areas not achieved by unilateral cochlear implant (CI), bilateral traditional CI has been proposed. Some studies reported that a subsequent traditional cochlear implantation typically improved hearing when a traditional unilateral cochlear implant had been worn with a hearing aid in the contralateral ear and the hearing aid provided little or no benefit. The outcomes suggested that the use of bilateral traditional cochlear implants, implanted sequentially or simultaneously, can improve speech perception in quiet and noisy environments, as well as the listener's ability to discriminate from which side the sound is coming (i.e., sound direction), identify source position (i.e., localization), and differentiate different talkers (i.e., squelch effect). They may also benefit from the summation effect that arises from input from both ears (Smulders, et al., 2016; Brown and Blakany, 2007; Murphy and O'Donoghue, 2007; Neuman, et al., 2007; Schafer, et al., 2007; Scherf, et al., 2007; Connell and Balkany, 2006; Litovksy, et al., 2006; Das and Buchman, 2005; Tyler, et al., 2003).

Adults (i.e., age 18 years and older) and Children (i.e., less than age 18 years): Meta-analysis, randomized controlled trials, case series and retrospective reviews support the safety and efficacy of traditional bilateral cochlear implantation in adults and children reporting improved hearing and communication skills following implantation (Tyler, et al., 2002; Kuhn-Inacker, et al., 2004; Laszig, et al., 2004; Litovsky, et al., 2004; Schleich, et al., 2004; Nopp, et al., 2004; Ramsden, et al., 2005; Schoen, et al., 2005; Verschuur, et al., 2005; Rickets, et al., 2006; Litovsky, et al., 2006; Quentin Summerfield, et al., 2006; Schafer and Thibodeau, 2006; Neuman, et al., 2007; Schafer and Thibodeau, 2006; Schafer, et al., 2007; Buss, et al., 2008; Tait, et al., 2010; Dunn et al., 2010; Manrique, et al., 2004).

Technology Assessments: Health Quality Ontario (2018) conducted a health technology assessment of three randomized controlled trials (n=12–19) and twenty-one observational studies (n=10–1001) to evaluate the potential benefits and harms of bilateral cochlear implantation for children and adults with severe to profound bilateral sensorineural hearing loss. Currently, the Ontario government funds one cochlear implant for individuals with bilateral hearing loss. Their assessment was based on "evidence of moderate to high quality" and found that bilateral cochlear implantation is generally safe and resulted in improvements in hearing in noisy environments, sound localization, and quality of life.

The Agency for Healthcare Research and Quality (AHRQ) (2011, retired) conducted a technology assessment of studies (n=56) that focused on patients age ≥ 18 years with sensorineural hearing loss and concluded that unilateral traditional cochlear implants have been an effective method of hearing assistance when used alone or in addition to a hearing aid. The evidence in published studies has reported improved speech perception and health-related quality of life with the use of traditional cochlear devices. Bilateral cochlear implants provided added improvement in speech

perception outcomes in noise environments over unilateral implants. AHRQ noted that there is a need for better measures of performance and disease specific quality-of-life instruments in assessing the significance of subjective benefits. Studies with longer follow-ups are needed to compare the additional benefits of bilateral compared to unilateral implants.

A National Institute for Health Research Technology Assessment (Bond, et al., 2009) included 33 randomized and nonrandomized studies (n=848) that met inclusion criteria for the evaluation of the clinical and cost effectiveness of traditional cochlear implants for children and adults. All studies reported gains on all outcomes. Greater gains in outcomes were seen with unilateral cochlear implants compared to acoustic hearing aids. The strongest advantage for bilateral implants compared to unilateral implants was the ability to understand speech in noisy conditions. Studies with small sample sizes (n=10–30) compared bilateral implants to unilateral CI plus an acoustic hearing aid and reported improvement in the ability to detect the direction of sound and speech perception with bilateral implants. Overall, the studies were of moderate to poor quality, and a total of 62 different outcome measures were used. The authors concluded that unilateral and bilateral traditional cochlear implants were safe and effective for children and adults.

A 2007 New Zealand health technology assessment (Ali and O’Connell, 2007) evaluated the effectiveness of traditional CI at an early age compared to at a later age. The assessment evaluated studies that included some children less than two years old at the time of implantation, a mean or median implantation age less than 36 months, and a sample size of at least 20 children. Three cross sectional studies and 13 cohort studies with small heterogeneous sample sizes (n=26–216) including degree and etiology of hearing loss with a lack of detail on socio-economic and educational status of parents were included in the analysis. Outcomes included audiological performance, communication outcomes, educational achievement, and quality of life. The following conclusions were made:

- “In general, implantation at a younger age improves the effectiveness of cochlear implantation in terms of audiological performance and communication outcomes.
- This is particularly evident when cochlear implantation occurs before the age of 24 months, which is more effective than implantation after 24 months.
- It is not clear whether implantation prior to the age of 12 months improves effectiveness when compared to implantation after 12 months of age.
- Because of the short length of time that implantation has been used in large numbers of infants and young children less than 2 years of age, evidence of an increase in effectiveness is only available for immediate outcomes such as communication skills, and has only been observed up to about 5–8 years after implantation
- It is not clear what effect cochlear implantation at a younger age has on long-term outcomes such as educational achievement, and quality of life.

It is possible that those implanted at an older age (above 24 months) develop at a slower rate but eventually reach equivalent developmental milestones”.

Professional Societies/Organizations: In a position statement, the American Academy of Otolaryngology—Head and Neck Surgery (2020) stated that cochlear implantation should occur as soon as practicable, including in infants between six and 12 months of age. The Academy states that implantation below 12 months of age is associated with better language outcome and as such, implantation should not be delayed by a hearing aid trial.

In a position statement, the American Academy of Otolaryngology—Head and Neck Surgery (2014; Revised 2020) stated that traditional cochlear implantation is an appropriate treatment for adults and children with moderate to profound hearing loss. The Academy states that extensive literature demonstrates that clinically selected adults and children can perform significantly better

with two traditional cochlear implants than one. Bilateral traditional cochlear implantation is accepted medical practice.

In a 2007 position statement, the American Academy of Pediatrics Joint Committee on Infant Hearing stated that traditional cochlear implantation should be given careful consideration for children who seem to receive limited benefit from a hearing aid. Additional studies are needed on the efficacy of traditional cochlear implants in children less than age 2 years. The Committee also noted that children with traditional cochlear implants may be at a higher risk of acquiring bacterial meningitis than the normal population.

Traditional Cochlear Implant for Unilateral Hearing Loss

Unilateral hearing loss (UHL) is generally defined as a condition in which an individual has non-functioning hearing in one ear, receives little or no clinical benefit from amplification in that ear, and has normal or near-normal audiometric function in the contralateral ear. UHL includes single-sided deafness (SSD) and asymmetric hearing loss (AHL). SSD is defined as a unilateral severe-to-profound deafness (pure-tone average PTA \geq 70 dB HL), with a better, normal or near-normal ear (PTA \leq 30 dB HL). AHL is a condition in which hearing in the better ear is not normal, but can be restored using a conventional hearing aid (PTA between 30 dB HL and 55–60 dB HL). In adults, SSD can be the result of sudden idiopathic sensorineural hearing loss, vestibular schwannoma or other cerebellopontine angle tumors, meningitis, temporal bone fracture, Ménière's disease, acoustic trauma or infections. Children may experience SSD from cochlear nerve deficit, mumps, viral infections and congenital anomalies of the inner ear. Individuals with unilateral hearing loss (UHL) report difficulties in hearing despite good access to sound in one ear (Häußler, et al., 2019; Marx, et al., 2019; Peter, et al., 2019; Buss, et al., 2018; Cabral Junior et. al., 2016).

Individuals with binaural hearing (hearing in both ears) experience better speech-to-noise ratio (SNR), which improves speech understanding in noisy environments. Binaural hearing allows processing of the input sound signal by the brain from both ears allowing the brain to separate noise and speech from different locations, spectral cues and level, and refining intelligibility. It is proposed that there may be an improved summation effect, responsible for improved speech perception through the identification of identical signals arriving in both ears. Therefore, in comparison to normal hearing, unilateral deafness impairs the ability to understand speech in noise, localize sounds, and limits awareness of sounds that are located on the side of the impaired ear. In some cases SSD goes untreated or is treated with conventional hearing aids, contralateral routing of the signal (CROS) hearing aids or bone-conduction hearing aids (BCHA). CROS and BCHA devices provide increased access to sound from the side of the hearing loss by presenting sound from that side to the contralateral ear. This results in masking of sound presented on the side with better hearing. However, neither treatment option rehabilitates the impaired ear since the brain receives and processes input from one ear only. More aggressive treatment of SSD is being investigated with the goal of restoring spatial hearing abilities which is hearing based on the comparison of acoustic information perceived at one ear as compared/contrasted to acoustic information perceived at the other (Häußler, et al., 2019; Legris, et al., 2019; Buss, et al., 2018; Cabral Junior et. al., 2016; Kitterick, et al., 2016; Van deHeyning, et al., 2016). Implantation of a traditional CI is a proposed treatment option for unilateral profound hearing loss in adults and children who have tried and failed to obtain functional hearing with other types of hearing devices (e.g., CROS, BAHA).

U.S. Food and Drug Administration (FDA): The FDA expanded the approval for the Med-El Cochlear Implant System (MedEl Corp., Innsbruck, Austria) to include an indication for "revoking auditory sensations via electrical stimulation of the auditory pathways for individuals ages five years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.

- AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears.
- Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Individuals with SSD or AHL must obtain limited benefit from an appropriately fitted unilateral hearing aid in the ear to be implanted. For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For individuals between 5 and 18 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone". Per the FDA approval, "before implantation with a cochlear implant, individuals with SSD or AHL must have at least one (1) month experience wearing a Contralateral Routing of Signal (CROS) hearing aid or other relevant device and not show any subjective benefit" (FDA, Jul 2019).

Literature Review: Studies investigating cochlear implantation for the treatment of single-sided deafness (SSD) include systematic reviews, randomized and non-randomized controlled trials, case series and retrospective reviews and have reported significant improvement in various hearing outcome measures following implantation. Studies have included individuals with various etiologies for deafness and individuals with and without tinnitus. Several studies have reported that CIs reduce the severity of tinnitus in this population and are superior to CROS and BAHA devices in the areas of sound localization and speech intelligibility in noise conditions (Marx, et al., 2021; Cohen and Svirsky, 2019; Häußler Zeitler, et al., 2019; Legris, et al., 2019; Ketterer, et al., 2018; Legress, et al., 2018; Beck, et al., 2017; Dillon et. al., 2017; Döge et al., 2017; Skarzynski, et al., 2017; Thomas, et al., 2017; Kitoh et al., 2016; Tavora-Vieira, et al., 2016; Arndt, et al., 2015; Erbele et al., 2015).

Marx et al. (2021) conducted a two part prospective national multicenter study in France to evaluate the outcomes of cochlear implantation (CI) on hearing performances and quality of life in single sided deafness (SSD) (n=104) or asymmetrical hearing loss (AHL) (n=51) after failure of more conservative treatments. The study also aimed to compare CI results with contralateral routing of the signal (CROS) hearing aids, bone-anchored hearing system (BAHSs), or abstention from treatment. The first part of the study was a prospective, observational, cohort study of a six month consecutive trial of treatment with CROS and BAHSs. The second part of the study was an open-label trial allowing patients to choose one of four treatment options: abstention (n=11), CROS (n=75), BAHS (n=18), or CI (n=51). Those who chose CI were randomized to a period of observation for six months (n=26) or immediate CI (n=25). Those who underwent observation then had the option of undergoing CI once the observation period was complete. The mean age of patients (n=155) was 53.1 in the abstention group, 51.9 in the CROS group, 49.7 in the BAHS group, and 55.1 in the CI group. There were a total of 71 men and 84 women in the study. Patients were included if they were > 18 years of age, received social security, and diagnosed with SSD or AHL as documented using pure-tone average on pure-tone audiometry. Patients with cochlear anatomy not conducive to CI were excluded. The primary outcome evaluated was quality of life in the CI group compared to the observation group after six-month follow-up. The EuroQoL-5D EQ-5D was used to evaluate generic quality of life and includes a visual analog scale (EQ-VAS) and a descriptive component that evaluates mobility, autonomy, daily life activities, pain, and

anxiety/depression. The Nijmegen Cochlear Implant Questionnaire (NCIQ) and Visual Analogue Scale (VAS) for tinnitus severity were used to evaluate auditory specific quality of life including: basic perception, complex perception, speech production, self-esteem, social activities, and interactions. Secondary outcomes evaluated included speech recognition in noise evaluated using the FraMatrix test and horizontal localization evaluated using seven loudspeakers located at 30 degree intervals in a frontal semi-circle. The descriptive component of the EQ-5D did not demonstrate a statistically significant improvement in the CI group compared to the observation group. However, statistical significance was achieved in the CI group compared to the observation group using the EQ-VAS for generic quality of life. Significant improvement was noted in NCIQ scores for auditory specific quality of life in the CI group compared to the observation group ($p=0.06$). Results from the VAS for tinnitus severity scale demonstrated significant improvement in the CI group compared to the observation group ($p=0.02$). A significant difference was not observed between the CI group and observation group for hearing outcomes. When compared to abstention, CI resulted in significant improvements in NCIQ scores ($p=0.03$). When compared to CROS, CI results in significant improvements in EQ-VAS scores ($p=0.003$), NCIQ scores ($p=0.04$), FraMatrix scores ($p=0.04$), and horizontal localization ($p=0.002$). The only adverse event reported was postoperative local infection ($n=2$). One of which was managed non-surgically and the other required explantation with subsequent re-implantation of the CI. Author noted limitations included the small sample size and short-term follow-up. Additional limitations include loss to follow-up ($n=21$) and heterogeneity of underlying diagnosis (i.e., idiopathic sudden sensorineural hearing loss, Meniere's disease, Labyrinthine trauma, Labyrinthitis, other).

Legris, et al. (2019) conducted a non-randomized controlled trial to evaluate and compare the impact various types of hearing rehabilitation (i.e., cochlear implant (CI), contralateral routing of signal (CROS), bone-anchored hearing aid (BAHA)) has on speech comprehension in adults with unilateral hearing loss. There were a total of 21 adults included in the study with six using a CROS, six using a BAHA, and nine using a CI. Participants ranged in age from 34–83 years. The etiology of hearing loss was variable across participants and included: unknown, sudden, Meniere's Disease, cholesteatoma, postoperative, and otitis sequelae. Seventeen of the participants were female. Ethnicity and race were not addressed. Participants were included if their "healthy" ear had a mean pure tone threshold Pure Tone Average (PTA) of ≤ 25 dB HL at 0.5, 1, 2, and 3 kHz and their "impaired" ear had a PTA = 95 ± 18 dB. Seven additional participants with normal hearing served as the control. Patients underwent audiometry testing with and without their rehabilitative devices during the same session. Sentence recognition threshold was defined as 50% comprehension in noise. Participants were tested under three conditions: speech (S) to the normal-hearing ear (NE) and noise (N) to the impaired ear with the use of their respective rehabilitative device ($S_{NE}N_{CI/CROS/BAHA}$), speech to the impaired ear with the use of their respective rehabilitative device and N to the NE ($S_{CI/CROS/BAHA}N_{NE}$), and speech and noise via a single loudspeaker ($S0N0$). Significant improvement was reported in the comprehension threshold for participants using a CI in conditions $S_{NE}N_{CI}$ ($p = 0.02$) and $S_{CI}N_{NE}$ ($p = 0.04$) compared to without a CI, but not for participants utilizing CROS or BAHA or for any of the devices in the $S0N0$ condition. A comparison of efficacy test showed differential performance according to device in condition $S_{NE}N_{CI/CROS/BAHA}$ ($p = 0.031$), but post-hoc analysis found no significant superiority for any one device ($p > 0.05$). Participants with a BAHA or CROS performed significantly worse than the control group in condition $S0N0$ (BAHA $p = 0.01$; CROS $p = 0.01$), but no difference with respect to the CI group ($p > 0.05$). In condition $S_{CI/CROS/BAHA}N_{NE}$, the control group showed significantly better results compared to use of all rehabilitative devices: CI $p = 0.02$; CROS $p = 0.04$; BAHA $p = 0.04$. In condition $S_{NE}N_{CI/CROS/BAHA}$, there were no significant differences between the control group and patients, with or without devices ($p > 0.05$). There were no adverse events reported. Author noted limitations included the small sample sizes and heterogeneity of duration of hearing loss and which ear was impacted.

Cohen and Svirsky (2019) conducted a systematic review of the literature to assess the data on the relationship between duration of unilateral deafness and speech perception outcomes following cochlear implantation in adults with single-sided deafness. Specifically, does the duration of deafness affect the outcomes of CI in SSD individuals? Studies were included that 1) reported duration of deafness for each individual, 2) reported scores on a speech perception test with responses that were "percent correct" for each individual, 3) testing date was at least six months post-implantation, 4) subjects had normal hearing in one ear to qualify as single-sided deaf, 5) were age ≥ 18 years at the time of implantation and postlingually deaf. Eight studies (n=78), six case reports, one retrospective reviews and one conference paper met the inclusion criteria. Three studies showed a statistically significant decrease in speech perception as a function of duration of unilateral deprivation ($p=0.03$; $p=0.017$; $p=0.048$). However when a single outlier was removed from each study the results were not statistically significant in each study. No significant relationship between speech perception and duration of unilateral deprivation was found when data was pooled across studies using the same outcome measure. Overall, a negative association between speech perception scores and duration of deafness in the implanted ear) was statistically significant. When the studies were analyzed as a whole, the main conclusion was that there was a small but statistically significant decrease in speech perception outcomes ($p=0.0048$) as a function of duration of unilateral deafness. The authors concluded that the main result of the review was that the duration of unilateral deafness seemed to have a modest association with speech perception outcomes using the implanted ear. Limitations of the analysis include the small number of subjects (n=4–21), only five subjects had been deaf for ten or more years and the speech presentation method for each study varied.

Peter et al. (2019) conducted a systematic review of the literature to evaluate the effects of cochlear implantation on tinnitus in patients with single sided deafness (SSD). Studies were included if they evaluated CI in adult patients with SSD and tinnitus. Review articles, case reports, and studies with fewer than five patients, overlapping data, postimplantation scores only, and/or studies of patients with bilateral deafness and bilateral cochlear implantation were excluded. Ten prospective case series and three retrospective reviews with small patient populations (n=5–26) met the inclusion criteria. The mean patient age range was 40–53.8 years. The primary outcome measure was the results of tinnitus evaluation questionnaires. The Tinnitus Handicap Inventory (THI) questionnaire and the Visual Analog Scale (VAS) were the most commonly used questionnaires. Follow-ups ranged from 3–28 months. Analysis showed that the THI preimplantation scores varied from 25.4 (± 17.3) to 79.6 (± 7.0) compared to 2.6 (± 4.8) to 35.2 (± 27.3) postimplantation. For VAS, the mean preimplantation scores ranged from 5.0 (± 1.2) to 8.5 (± 1.1) and the postimplantation scores ranged from 1.2 (standard deviation was not extractable) to 5.7 (± 0.8). The mean maximum score reduction of VAS for tinnitus loudness/annoyance was from 8.1 (± 1.2) to 1.6 (± 2.9). Outcomes varied with some studies reporting a relatively small difference in pre- and post-operative tinnitus vs. a significant difference. In studies using the THI (n=82) as an outcome measurement, 28 patients (34.2%) demonstrated complete tinnitus suppression, 44 (53.7%) reported an improvement in tinnitus, six (7.3%) remained stable, four (4.9%) experienced an increase in tinnitus, and no patients reported a new induction of tinnitus. Regarding VAS scores (n=79), 16 patients (20.3%) reported complete suppression of tinnitus, 54 (68.4%) had improvement in tinnitus, seven (8.9%) reported no change, two patients (2.5%) experienced worsening, and no patients reported an induction of tinnitus. Overall, THI results showed 34.2% of patients demonstrated complete suppression of tinnitus, 53.7% reported an improvement, 7.3% remained stable, 4.9% experienced an increase in tinnitus and no patients reported an induction of tinnitus. Similar results were found for VAS scores but the effect was smaller than THI scores. Adverse events were not reported. Limitations of the studies included: use of various tinnitus questionnaires; heterogeneous small patient populations; short-term follow-ups; and the heterogeneity of the studies (e.g., study design; outcomes reported; evaluation and analysis methods; inclusion criteria; follow-up periods, and outcome measurements).

Cabral Junior et al. (2016) conducted a systematic review of the literature to evaluate cochlear implantation for the treatment of single-sided deafness (SSD). Studies that analyzed patients with SSD that had undergone ipsilateral cochlear implantation in the presence of normal or functional hearing in the contralateral ear and implantations due to unilateral tinnitus were included. Outcomes included speech discrimination, sound localization and tinnitus suppression. Eleven studies met the inclusion criteria (n=137). No studies were randomized controlled trials, only one study included a control group and blinding was not observed. Study populations ranged from 4–28 and follow-ups occurred at 3–24 months. One study reported on speech discrimination, sound localization and tinnitus suppression. The other studies reported on either one or two of these outcomes. Three studies analyzed sound localization in postlingual adults and reported better outcomes with CI vs. unaided ear, Contralateral Routing of Sound (CROS) or bone-anchored hearing aid (BAHA). One study reported no improvement with CI in subjects with prelingual onset of deafness. Seven studies reported on speech perception in patients with SSD and CI (n=82) and four studies reported consistent statistical data. Outcomes varied depending on where the sound was introduced (front vs CI side). Five of seven studies that analyzed the impact of CI on tinnitus (n=98) reported statistically significant reduction in tinnitus. Pooling of data was not possible due to the clinical heterogeneity among the studies. Limitations of the studies include: lack of randomization and a control group; small heterogeneous patient populations (e.g., duration of deafness, cause of deafness); short-term follow-ups; and significant heterogeneity of tests and parameters used for outcome measures.

Kitterick et al. (2016) conducted a systematic review of the evidence to determine if hearing instruments, including but not limited to rerouting devices and any device that restores input to the impaired hear (IE) (“restorative devices”), are effective in improving listening skills (speech perception and sound localization) in unilateral deafness, reducing associated listening difficulty, and improving overall health and well-being (health-related quality of life). The intent of the review was also to compare restorative and rerouting devices, and compare air- and bone conduction rerouting devices to the unaided condition. Studies were included if the subjects were adults with a pure-tone average audiometric threshold ≤ 30 dB HL in one ear (averaged across 0.5, 1, 2, and 4 kHz) and > 70 dB HL in the other ear indicating the hearing loss was severe to profound sensorineural and evaluated any hearing instrument. The minimum duration of follow-up required was one week for rerouting devices and three months for restorative devices to ensure that there was sufficient time for acclimatization. Published abstracts, articles published in non-peer reviewed publications, and unpublished studies were excluded. Thirty articles reporting 27 separate studies were included. The rerouting devices included those based on air conduction devices (ACD) and bone conduction devices (BCD). Bone conduction rerouting devices included those mounted on a head-band, on a surgically inserted abutment, on an oral prosthesis, and inserted into the ear canal. The restorative devices were the CIs. The comparators included hearing instruments, placebo devices, or no intervention. All studies that assessed ACDs compared them with BCDs. The majority of studies were before-after comparisons in which the patient acted as his/her own control. Three studies included matched control groups that did not receive a hearing instrument (two case-control studies and one cohort study). Four studies (15%) randomized the order of interventions but did not provide any information about randomization methodology or concealment according to best-practice guidelines for the reporting of randomized controlled trials. Outcomes included: speech perception in quiet and in noise, sound localization, hearing- and health-related quality of life, complications and adverse events. The minimum duration of follow-up varied considerably and was dependent on the type of intervention. Results for CI included the following:

- Speech Perception in Quiet: A statistically significant improvement in speech perception in quiet with CI was reported in two studies that compared CI with unaided hearing. Speech perception was assessed when subjects listened using their implanted ear. No study compared speech perception in quiet with a CI vs. any rerouting device. Evidence

supporting that rerouting devices or CI can provide benefits to speech perception in quiet compared with the unaided condition, or that one device may be more beneficial than another is lacking.

- **Speech Perception in Noise:** Three of the four studies reporting outcomes before and after CI vs. unaided ear found significant benefits when the implanted ear had a more favorable signal to noise ratio (SNR) (IE > NE). One study found significant benefits when both ears had a similar SNR. One study compared outcomes after CI vs. ACD or BCD devices. Speech perception was significantly better after CI compared with the preoperative use of both an ACD and BCD when either ear had a more favorable SNR. There is a lack of evidence for the effects of cochlear implant on speech perception in noise due to variations in testing methodologies. The evidence for additional benefits from one device type over another is limited.
- **Sound Lateralization and Localization:** One of three studies reported a statistically significant improvement with CI compared with unaided hearing. One study compared CI with rerouting devices and reported that localization was significantly more accurate after CI compared with ACD and BCD. The evidence suggested that rerouting signals to the NE did not improve the ability to determine the location of a sound.
- **Hearing- and Health-Related Quality of Life:** Studies reported an improved quality of life before and after CI. Three studies reported a significant decrease in self-reported difficulties with listening using the speech, spatial, and qualities of hearing (SSQ) questionnaire. One study compared CI with rerouting devices and reported significant benefits on SSQ and health-related quality of life after implantation compared with three-week trials of both an ACD and a headband-mounted BCD. No conclusion could be made regarding whether CI provides additional reductions to listening difficulty compared with rerouting devices.

Professional Societies/Organizations: The American Academy of Otolaryngology – Head and Neck Surgery (2019) issued an updated clinical practice guideline for sudden hearing loss in 2019 that addresses unilateral sudden sensorineural hearing loss (SSNHL). The guideline gives a strong recommendation for the use of cochlear implantation in the rehabilitation of patients with unrecovered severe to profound SSNHL. The Academy states that literature supports cochlear implantation for unilateral sensorineural hearing loss leading to significant improvement in hearing and quality of life.

Hybrid Cochlear Implant With An External Hearing Aid

A hybrid cochlear device uses two different technologies at the same time to provide low-frequency and high-frequency hearing. The acoustic low-frequency technology is proposed to preserve any natural residual hearing. It functions like a hearing aid by amplifying low frequency sound and sending it down the ear canal via the normal pathway of hearing. The cochlear implant technology provides high frequency hearing (electrical) by transferring digital information from the sound processor through the implant and down the electrode into the cochlea. Hybrid devices combine electrical hearing from direct stimulation of the basal cochlea with acoustical hearing from surviving apical hair cells. To allow the combined stimulation, a shorter and softer electrode array is inserted into the basal turn of the cochlea. The basal cochlea is then stimulated electrically via the implant. The apical cochlea functions via native physiology amplified as needed by an externally worn hearing aid. The external hearing aid and the implanted device are both attached to the external processor (Cochlear Ltd, 2023; Med-El, 2022; Golub, et al., 2012).

The appropriate candidate for the hybrid device would have too much residual hearing to receive a traditional cochlear implant but not enough hearing to benefit from a traditional hearing aid. Proposed advantages of the hybrid implant include improved word recognition in quiet and sentence recognition in noise, as well as enhanced music recognition abilities. Disadvantages include the risk of permanent irreversible damage to low-frequency residual hearing fibers from

the surgical placement of the shorter array after implantation. There is also lack of consensus on the correct surgical approach for array implantation and the appropriate frequency settings (Golub, et al., 2012; Dorman and Gifford, 2010; Fitzgerald, et al., 2008).

The Consonant-Nucleus-Consonant (CNC) word lists are considered the “gold standard” in the testing and management of hybrid cochlear implant users. CNC is an open-set word recognition test that consists of lists of monosyllabic words with equal phonemic distribution across lists. It is used to assess speech perception in quiet. The Test consists of 10 lists of 50 monosyllabic words per list. Scores are determined by the number of correct responses and reported as a percentage (Gantz, et al., Apr 2016; Advanced Bionics, 2011).

The Cochlear Nucleus® Hybrid™ L24 Implant (Cochlear Americas, Centennial, CO) includes the traditional Cochlear Nucleus model CI24RE (Freedom™) cochlear implant (CI) but the intracochlear electrode array, which has the same 22 active electrodes, is shorter and thinner than the traditional array. The shorter array is intended to preserve the integrity of the apical region of the cochlea (which mediates low frequencies). The Hybrid L24 is inserted to a depth of 16 mm compared to 19–25 mm of the non-hybrid implant. The Hybrid system includes the external Nucleus 6 Sound Processor with an acoustic component (external hearing device), the internal implant, and two patient remote controls. There is an intraoperative remote to be used in the operating room (Cochlear LTD, 2016; Roland, et al., 2015; FDA, 2014). According to the FDA PMA Sponsor Executive Summary document, the primary goal of implantation of the Nucleus Hybrid L24 is to improve speech recognition in patients with ski-slope hearing loss (high frequency hearing loss). The retention of low frequency hearing is necessarily a secondary objective. Ideally, speech recognition is enhanced while low frequency hearing is maintained, but Cochlear stated that making retention of low frequency hearing the primary consideration in the risk/benefit analysis misconstrues the intent of the treatment. The possibility of loss of low frequency acoustic hearing sensitivity is disclosed in the labeling and patients are informed of this risk prior to implantation. Studies have reported loss of low frequency hearing in nearly half of Hybrid implants (FDA, Jan 2016, FDA, 2013).

The Med-El Synchrony EAS™ Hearing Implant System (Med-EL Corp, Durham, NC) includes the Sonnet EAS behind-the-ear audio processor which is the same processor used for the traditional Med-EL cochlear implant. The EAS has an acoustic earhook and an ear mold that connects to the processor and is worn in the outer ear. The system is adjusted with a remote control.

U.S. Food and Drug Administration: The Nucleus® Hybrid™ L24 Cochlear Implant System was FDA approved by the PMA process in 2014 stating that the device represented a “breakthrough technology”. The implant is intended for patient’s aged 18 years and older to provide electric stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low frequency regions. Candidates have residual low-frequency hearing sensitivity, severe to profound high-frequency sensorineural hearing loss, and obtain limited benefit from appropriately fitted bilateral hearing aids. “Typical preoperative hearing of candidates ranges from normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz), with severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz \geq 75 dB HL) in the ear to be implanted, and moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz \geq 60 dB HL) in the contralateral ear. The CNC [consonant-nucleus-consonant] word recognition score will be between 10% and 60%, inclusively, in the ear to be implanted in the preoperative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct. Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids.” Appropriate candidates for the hybrid device who were not previous hearing aid users underwent a required two-week hearing aid trial prior to implantation (FDA, 2014).

The Med-EL EAS System was FDA PMA approved in September 2016. The System is “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. Typical preoperative hearing of candidates ranges from normal hearing to moderate sensorineural hearing loss in the low frequencies (thresholds no poorer than 65 dB HL up to and including 500 Hz) with severe to profound mid- to high-frequency hearing loss (no better than 70 dB HL at 2000 Hz and above) in the ear to be implanted. For the non-implanted ear, thresholds may be worse than the criteria for the implanted ear, but may not be better. The CNC word recognition score in quiet in the best-aided condition will be 60% or less, in the ear to be implanted and in the contralateral ear. Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids” (FDA, 2016).

Literature Review: Studies evaluating the safety and efficacy of hybrid cochlear implantation for the treatment of individuals (n=13–87) with high-frequency sensorineural hearing loss and residual low-frequency hearing include case series, prospective and retrospective non-randomized studies using single-arm, within-subject comparisons. Significant improvements in patient satisfaction and hearing of speech and speech recognition in both quiet and in noise have been reported utilizing up to 15 years of data. Studies have reported that hybrid CI carries a risk for the loss of residual low-frequency hearing. However, studies also suggest that a shorter electrode array is associated with preserved residual low-frequency hearing. (Gantz, et al., 2018; Roland, et al., 2018; Härkönen, et al., 2017; Kelsall, et al., 2017; Wolfe, et al., 2017; Skarynski, et al., 2014; Lenarz, et al., 2013; Szyfter, et al., 2013; Gantz, et al., 2009; Gstoettner, et al., 2008; Luetje, et al., 2007; Gantz, et al., 2004).

Gantz, et al. (2018) conducted an observational, longitudinal study to evaluate trends in low-frequency hearing and speech perception after hybrid cochlear implantation with a shorter electrode device. There were 50 participants included in the study; 14 of whom were implanted with a Nucleus Hybrid L24 (L24), 13 of whom were implanted with a Nucleus Hybrid S12 (S12), and 23 of whom were implanted with a Nucleus Hybrid S8 (S8). Twenty-nine of the participants were female and the average age at implantation was 58 years old for the S8 participants, 55 years for the S12 participants, and 46 for the L24 participants. Race and ethnicity were not addressed. Patients were included in the study if they had a minimum of two years of post-hybrid cochlear implantation data (an up to 15 years) and were ≤ 65 years of age. All participants met criteria for hybrid cochlear implant (i.e., post-lingually deafened adult with severe to profound sensorineural hearing loss for frequencies > 1500 Hz and low-frequency thresholds up to and including 500 Hz no poorer than 60 dB. Consonant-Nucleus-Consonant (CNC) monosyllabic word scores were between 10–60% in the ear to be implanted and up to 80% understanding in the contralateral ear in the best-aided condition). The type of device implanted was based upon FDA availability at the time of implantation. Testing using a battery of speech perception measures occurred pre-operatively. Soft surgery techniques were used to implant the device in an effort to preserve low-frequency hearing. The primary outcome measure was speech perception evaluated using the CNC word recognition test in quiet and the AzBio Sentence Test in noise. Follow-up testing occurred post-operatively, at three months, six months, and annually (up to 15 years) in the combined listening condition (i.e., bilateral hearing aids and the CI). If a participant did not retain functional hearing on the implanted ear post-surgery, they were tested as bimodal listeners (i.e., CI and hearing aid on the contralateral ear). Pure tone average (PTA) scores demonstrated that 83% of S8 participants, 92% of S12 participants, and 86% of L24 participants maintained longitudinally functional hearing. Seven participants experienced a non-functional PTA at some point (i.e., three months – two years) after initial activation of their device. There was no significant difference reported between bimodal and combined condition listeners for CNC performance ($p = 0.28$). Probability analysis showed that the average hybrid CI user who has an

average PTA of 50 dB HL or better at 6 months post device activation has an 88% probability to maintain functional low-frequency hearing (i.e., \geq PTA = 90dB HL) for the S8 device at nine years, 94% for the S12 device at four years, and 93% for the L24 device at four years. Significant improvements in CNC word scores compared to pre-operative bilateral hearing aid use was seen among all groups at three to six months post-activation ($p < 0.01$). Pre-operatively, the S8 group had an average CNC word score of 36% that improved to 65% in the combined condition, the S12 and S24 groups had an average pre-operative CNC word score of 54% and 34%, respectively that improved to 81% and 83% in the combined condition. This study is limited by the small patient population.

Roland et al. (2016) conducted a prospective, multicenter, single-arm, non-randomized, non-blinded clinical study ($n=50$) where each participant served as their own control to evaluate the safety and efficacy of the Cochlear Nucleus Hybrid L24 implant. Patients, age ≥ 18 years, had severe (> 75 dB HL averaged over 2000, 3000, 4000 Hz) high-frequency sensorineural hearing loss and low-frequency hearing that tested ≤ 60 dB HL at 125, 250, and 500 Hz. An aided consonant-nucleus-consonant (CNC) monosyllabic word (understanding in quiet) score of 10% through 60% using an appropriately fit hearing aid in the ear to be implanted was also required to meet inclusion criteria. Aided word recognition in the contralateral ear was required to be similar or better than the ear to be implanted, but not better than 80%. Patients were excluded if the duration of the hearing loss was greater than 30 years and/or onset of hearing loss was less than two years. The study was approved by the Food and Drug Administration. Primary outcome measures were the CNC and AzBio sentences in difficult noise for the implanted ear at six months. Follow-up occurred 3, 6 and 12 months. Overall, six-months postoperatively, patients experienced a significant improvement in CNCs ($p < 0.001$) and AzBio sentences ($p < 0.001$) in the implanted ear compared to preoperative hearing aid testing. Secondary outcomes compared individual preoperative performance with a hearing aid to performance at the six-month endpoints on CNC words and phonemes and AzBio sentences and 75% of patients demonstrated equal or improved outcomes on CNC words, phonemes, and AzBio sentences with the implant. Six-months post-activation, significant improvements were also reported with bilateral hearing (implant plus contralateral hearing aid) in CNC ($p < 0.110$) and AzBio sentences ($p < 0.001$). Results of the self-assessment Speech, Spatial, and Qualities of Hearing Questionnaire (SSQ) showed significant improvement on the Speech Hearing Scale ($p < 0.001$), the Spatial Hearing Scale ($p < 0.003$), and the Sound Quality Scale ($p < 0.001$). Thirty-four subjects had 65 adverse events including profound (> 90 dB HL) or total loss of low frequency hearing (< 90 dB HL) ($n=22$), electrode open/short circuits ($n=11$), increased tinnitus ($n=6$), and onset of tinnitus ($n=6$). Seventeen patients (34%) did not maintain functional acoustic hearing. Five hybrids (10%) were explanted and replaced with a standard cochlear implant. Author-noted limitations of the study included the lack of a comparator, small patient population and short-term follow-ups. In 2018, Roland, et al. published results on three and five year outcomes from the Roland, et al. (2016) study. The study showed that the significant improvements that were made in CNCs and AzBio sentences at the six-month endpoint were maintained at three and five years. The significant improvements in subjective satisfaction that were reported at the one year endpoint were also maintained at three and five years. In the pivotal trial, residual hearing was measured using a five-frequency (i.e., 125, 250, 500, 750, 1000Hz) low frequency pure-tone average (LF PTA). However, in the three and five year update to the study, the authors noted that more recent research has suggested that using three-frequencies (i.e., 125, 250, 500 Hz) is sufficient for measuring residual hearing with the use of a Hybrid CI. Using these updated parameters, the authors reported that at one year 87.5% of participants had functional hearing which was maintained at three and five years.

Gantz et al. (2016) conducted a prospective, multicenter case series ($n=87$) to evaluate the safety and efficacy of the Cochlear Nucleus[®] Hybrid[™] S8 implant. The study began as an FDA Investigational Device Exemption (IDE) and progressed to a phase II clinical trial. The S8 implant, also called the Iowa/Nucleus 10 mm Hybrid implant or short electrode, has six contacts across the

10 mm electrodes. Subjects were age 19.6 years to 82.3 years and used bilateral hearing aids on a daily basis or underwent at least a two-week hearing aid trial prior to implantation. Included subjects had: 1) low-frequency pure-tone acoustic thresholds between 125 Hz and 500 Hz at or better than 60 dB HL; 2) pure-tone acoustic thresholds above 1500 Hz poorer than 75 dB HL; 3) aided Consonant-Nucleus-Consonant (CNC) word scores between 10% and 60% in the ear to be implanted and up to 80% in the contralateral ear. The ear with the poorer hearing (determined by the ear with poorer word recognition score or poorer audiometric thresholds if word recognition was equivocal) received the cochlear implant device. Subject selection was based entirely on audiometric criteria. Follow-ups occurred at three, six and 12 months. The Consonant-Nucleus-Consonant (CNC) word recognition test, and the Bamford-Kowal-Bench Sentences-In-Noise (BKB-SIN) test were the primary speech perception measures. Self-assessment data were captured with the Abbreviated Profile for Hearing Aid Benefit (APHAB). The residual acoustic hearing standard pure-tone air-conduction thresholds were measured in each ear at all frequencies from 125–8000 Hz. Bone-conduction thresholds were obtained between 250 Hz and 4000 Hz to verify sensorineural hearing loss. The APHAB was conducted preoperatively at six months post-activation and was added in phase 2 of the study. Subjects were allowed to view their pre-implantation scores when assessing their post-implantation scores. All subjects (n=54) reported positive improvements in hearing in three (background noise, ease of communication, and reverberation) of the 4 subscales of the APHAB. At the twelve month follow-up (n=80; 12 month data on 75 subjects and nine month data on five subjects) results included:

- 87% significantly improved their word understanding using the acoustic + electric combination when listening with both ears;
- 60% improved their word score using the electric-only condition;
- 60% did not show a significant change in the CNC score meaning low frequency hearing was not changed;
- 16 subjects (19%) had non-functional hearing loss following implantation;
- 19.6% of subjects were unable to use their acoustic speech processing;
- 14 subjects requested that the hybrid be removed due to dissatisfaction with the device and a traditional cochlear device was implanted. Most experienced a progressive loss of acoustic hearing in the implant ear;
- five subjects had total loss of hearing;
- two subjects experienced two shifts in low-frequency hearing prior to explantation and re-implantation;
- one subject tested at 12 months was worse than their preoperative score with hearing aids only.

The authors noted that loss of functional acoustic hearing in the implant ear would reduce the ability to localize sound which is an important safety issue. Other adverse events were not addressed. Limitations of the study include the small patient population, number of subjects lost to follow-up; short-term follow-up; and number of devices that were removed.

Lenarz et al. (2013) conducted a prospective case series (n=66) to investigate preservation of residual hearing in subjects who received the Nucleus Hybrid L24 cochlear and the impact on speech recognition, sound quality and quality of life. Subjects, age ≥ 18 years, had profound high-frequency sensorineural hearing loss; ≥ 80 dB HL for frequencies > 1500 Hz and mild to moderate sensorineural hearing loss ≤ 60 dB HL for frequencies < 500 Hz. Thresholds could fall up to 10 dB outside these limits for up to two frequencies. There were no audiometric restrictions for the contralateral ears. Subjects had limited open-set word recognition even with well-fitted hearing aids. Limited was defined as aided word recognition scores between 10% and 50% inclusive in the ear to be implanted and $\leq 60\%$ in the contralateral ear when presented in quiet at 65 dB sound pressure level (SPL). Subjects had used high power hearing aids for a minimum of six weeks prior to enrollment. Follow-ups occurred for up to one year. At one year, low frequency thresholds

(125, 250, and 500 Hz) were preserved within ≤ 10 dB of pre-implant thresholds in 61% of subjects and within ≤ 30 dB in 74% of cases. Sixteen subjects had 500 Hz thresholds increased by > 30 dB. There was no systematic loss of hearing over time for the non-implant ears. Group median increase in air-conduction thresholds in the implanted ear for test frequencies 125–1000 Hz was < 15 dB. At one-year post-implant 89% of subjects were using the Hybrid processor. Significant speech recognition in quiet was reported in 65% of subjects and 73% of subjects gained speech recognition in noise. The average improvement in score for words presented in quiet was 28 percentage points, and for speech in noise at 10 dB signal-to-noise ratio (SNR) was 38 percentage points. Mean Speech Spatial and Qualities (SSQ) subscale scores and the healthy utility index (HUI3) (n=29) were significantly improved ($p<0.001$; $p<0.01$, respectively). Limitations of the study include the small patient population, short-term follow-up and number of subjects not using the hybrid processor at one year.

Auditory Brainstem Implantation (ABI)

The auditory brainstem implant (ABI) is a modified cochlear implant in which the electrode array is placed directly into the brain. ABI is approved for use in patients suffering from neurofibromatosis type 2 (NF2) who have developed tumors on both auditory nerves. NF2 is a genetic condition that is characterized by the growth of bilateral acoustic neuromas on the right and left auditory nerves. When it becomes necessary to surgically remove these benign tumors, portions of the auditory nerves must be removed along with the tumors. A cochlear implant cannot be used by a patient whose auditory nerve has been damaged by surgical removal of an acoustic neuroma. Postoperatively, ABI patients require follow-up rehabilitation, which is generally initiated one to two months following implantation (Colletti and Shannon, 2005). ABI processors use disposable batteries (e.g., zinc, lithium or alkaline) which vary in size (e.g., 675, CR2025, AA) or rechargeable batteries. The number of batteries that are needed depends on the type of batteries used, whether they are disposable or rechargeable, number of hours used and the power needs of the processor (Med-El, 2017).

U.S. Food and Drug Administration (FDA): Brainstem implants are granted a premarket approval by the FDA for use in patients with NF2 who have lost integrity of auditory nerves following vestibular schwannoma removal. The FDA approved the Nucleus 24 Auditory Brainstem Implant system (Cochlear Corp., Englewood, CO) for use in teenagers and adults who have been diagnosed with NF2. According to the labeling, implantation may occur during the first- or second-side tumor removal, or in patients with previously removed bilateral acoustic tumors (FDA, 2000). More current models of this implant are the Nucleus ABI541 Auditory Brainstem Implant and the Nucleus Auditory Brainstem Implant System.

Literature Review: Although there are a limited number of published scientific peer-reviewed studies primarily in the form of retrospective reviews and non-randomized controlled trials with small patient populations, ABI is an established treatment option for patients with NF2 (Taslimi, et al., 2019; Grayeli, et al., 2008; Kanowitz, et al., 2004; Otto, et al., 2004).

Other Indications: It has been proposed that ABI may be a treatment option for patients with non-tumor conditions including cochlear and cochlear nerve abnormalities and for patients who have failed CI. Studies have primarily been in the form of case series and retrospective reviews with small patient populations (Martins, et al., 2022; Noij, et al., 2014; Colletti, et al., 2009; Colletti and Zocante, 2008; Colletti, et al., 2005).

Colletti et al. (2009) retrospectively compared the outcomes of ABI in NF2 tumor patients (n=32) to outcomes in non-tumor (NT) patients (n=49) by reviewing open-set sentence recognition scores. The NT group included patients with cochlear malformations, auditory neuropathy, bilaterally altered cochlear patency, bilateral cochlear ossification, cochlear derangement of the turns, and cochlear fracture from head trauma. The duration of deafness ranged from 3.2–8.5

years. Sentence recognition was significantly better ($p=0.0007$) in the NT group (10–100%) compared to the tumor group (5–31%). The NT group was subdivided into four subgroups: trauma, neuropathy, cochlear malformations, and altered cochlear patency. With the exception of the neuropathy subgroup, the subgroups showed significantly better performance following ABI compared to the tumor group ($p<0.01$).

Noij et al. (2014) conducted a systematic review of the literature to evaluate ABI for non-tumor conditions in children (age < 18 years) who were not candidates for cochlear implants. No randomized controlled trials were found. Twenty-one studies ($n=172$) that involved at least one pediatric non-tumor ABI patient were included. Three studies were case reports and the remaining studies were retrospective reviews. Ten duplicate patients were identified across studies and eighteen studies discussed independent cases ($n=105$). A large proportion of patients had non-auditory disabilities, including a number of syndromes (e.g., CHARGE, Down, and Shprintzen syndromes) and cognitive and/or other developmental delays. A total of 41 patients had previously undergone cochlear implants. The most common auditory diagnosis was cochlear nerve aplasia, followed by cochlear aplasia, cochlear nerve hypoplasia, cochlear malformations, ossified cochlea, auditory neuropathy, trauma, and cochlear hypoplasia. Of the studies that reported Categories of Auditory Performance (CAP) scores, nearly 50% of ABI users reached a score >4 at five years following implantation. Median scores reached a plateau at 24 months post-operatively. Scores on the Meaningful Auditory Integration of Sound/Infant Toddler Meaningful Auditory Integration of Sound (MAIS/IT-MAIS) showed some improvement with stabilization at one year. Up to 20.8% of patients experienced major complications. The most common major morbidities reported were cerebral spinal fluid leak (11/130) and mild/transitory cerebellar edema or contusion (12/130). Limitations of the studies included: lack of a comparator; retrospective study designs; low-quality studies; small, heterogeneous patient populations; short-term follow-ups; and conflicting outcomes. According to the authors, there was also a high risk of bias because the majority of auditory perception tests were subjective in nature and the variation in auditory perception outcome measures did not allow for an analysis of objective tests.

Colletti and Zocante (2008) conducted a prospective study of 17 children, ages 14 months to 16 years, with cochlear nerve aplasia (two had NF2) who received ABIs. Six children had previously failed CI. Follow-up ranged from six months to seven years. At the last follow-up, the average Categories of Auditory Performance score was four (range 1–7, with zero being unawareness of sound). The average Meaningful Auditory Integration Scale score was 38% (range 2% to 97.5%), the Meaningful Use of Speech Scale was 49% (range 5%–100%), and the Listening Progress Profile was 45% (range 5%–100%). In the first six to 12 months following implantation, the nine children who could participate in the cognitive developmental testing showed statistically significant improvements in form completion and repeated pattern ($p<0.05$ each) when compared to four deaf non-ABI children who served as controls. Comparative studies with larger patient populations are indicated to validate the results of this trial.

Colletti et al. (2005) conducted a prospective case series in which ABIs were used on patients who had other cochlear or cochlear nerve abnormalities (e.g., congenital malformation, aplasia, head trauma, cochlear ossification, and auditory neuropathy). The study also included subjects who had a lack of hearing improvement with the use of cochlear implants. The trial was conducted over a five-year period and included adults ($n=20$) and children ($n=9$), ranging in age from 14 months to 70 years. Depending on the date of the procedure, subjects received either the Nucleus 22 or Nucleus 24 implant. Subjects treated with ABI had NF2, vestibular schwannoma, cochlear nerve aplasia, auditory neuropathy, head trauma or cochlear ossification. The control group ($n=21$) was comprised of subjects with NF2 who received a Nucleus 21 channel and was treated during a different timeframe. The one-year, closed-set word recognition average results were 55.3% and 44.3% for the study group and the control group, respectively. The one-year auditory-alone mode for sentence recognition test result averages were 38% and 6.2% for the study group and the

control group, respectively. In addition, at one year, the non-tumor study group subjects scored from 3 to 42 words/minute (normal is 70–80 words/minute) on the speech tracking test. Results of the speech tracking test for the control group were not available.

Coding Information

Notes:

1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Traditional Cochlear Implant Without External Hearing Aid

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
69930	Cochlear device implantation, with or without mastoidectomy
69949 [†]	Unlisted procedure, inner ear
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

[†]Note: Considered medically necessary when used to report removal of a cochlear implant.

HCPCS Codes	Description
L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
L8623	Lithium ion battery for use with cochlear implant device speech processor; other than ear level, replacement, each
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement

HCPCS Codes	Description
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement

Hybrid Cochlear Implant With External Hearing Aid

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
69930	Cochlear device implantation, with or without mastoidectomy
69949 [†]	Unlisted procedure, inner ear
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

[†]Note: Considered medically necessary when used to report removal of a cochlear implant.

HCPCS Codes	Description
L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
L8623	Lithium ion battery for use with cochlear implant device speech processor; other than ear level, replacement, each
L8624	Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, 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
L8699	Prosthetic implant, not otherwise specified

Auditory Brainstem Implant

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS Codes	Description
L7367	Lithium ion battery, rechargeable, replacement
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
S2235	Implantation of auditory brain stem implant

***Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<ul style="list-style-type: none">No policy statement changes.	11/15/2023

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