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Coverage Policy

Traditional Cochlear Implant Without An External Hearing Aid
A unilateral or bilateral traditional cochlear implant is considered medically necessary for an individual with 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 adult (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 ≤ 40% correct in the best-aided listening condition (i.e., non-implanted ear aided or binaurally aided) using open-set Hearing in Noise Test (HINT) sentence recognition

- For a child (age 12 months to 17 years, 11 months) 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 in 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 adult (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 Hearing in Noise Test (HINT) sentence recognition

- For a child (age 12 months to 17 years, 11 months) 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

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., Cochlear Nucleus® Hybrid™ Implant System) is considered experimental, investigational or unproven.
**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 adult or child, 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.

**Overview**
This Coverage Policy addresses cochlear implantation, including the hybrid cochlear implant, auditory brainstem implantation, and replacements or upgrades of these devices.

**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.

Cochlear implant has been proposed for hearing impairment secondary to auditory neuropathy spectrum disorder (ANSD). ANSD also called auditory neuropathy/auditory dysynchrony (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; Ji, et al., 2015; National Institute on Deafness and Other Communication Disorders [NIDCD], 2011).

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; Starr and Rance, 2015; Lee, 2014; National Institute on Deafness and Other Communication Disorders [NIDCD], 2011).

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 ≥ 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 also has low-frequency hearing capabilities. There is insufficient evidence in the published peer-reviewed literature to support the efficacy of a hybrid cochlear implant.

**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], 2004).

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, 2014; Centers for Medicare and Medicaid, 2005).

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).

Holt and Svirsly (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.

**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 ≤ 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.

**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, 2017; Advanced Bionics, 2016; Med-El, 2017).

**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 in order 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 (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 Advanced Bionics’ HiRes 90K, the MedEl Synchrony Cochlear Implant System and the Cochlear C124RE Contour Advance or Straight System.

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:** No single test can predict which patients will achieve success with traditional cochlear implantation. Evidence supporting the efficacy of traditional unilateral cochlear implants in sensorineural deafness exists primarily in the form of data from a number of uncontrolled prospective and retrospective case series, comparative case series, and matched-pair case series.

**Adults (i.e., age 18 years and older) and Children (i.e., age 1–18 years):** Traditional unilateral cochlear implantation is a well-established treatment option for adults (i.e., age 18 years and older) and children (i.e., age 1–18 years) 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., age less than one year):** There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of a traditional cochlear implant (CI) in children age less than one year. Studies are primarily in the form of case series and retrospective reviews with small patient populations of various age groups, and short-term follow-ups. The studies are also limited by author-developed assessment tools, subjective parental responses on questionnaires, number of infants unable to complete testing, and the number of infants lost to follow-up. Implantation of a traditional cochlear implant in children less than age one year is not an established treatment option.

Bruijnzeel et al. (2016) conducted a systematic review to evaluate the effects of cochlear implantation on speech and language development and auditory performance in children age <12 months. Studies that included a comparison between different age groups at the time of pediatric cochlear implant (CI) and a minimal follow-up of five years were included. Fourteen studies (case series and retrospective reviews) met inclusion criteria. Speech perception (n=5 studies) was assessed using consonant-nucleus-consonant (CNC), phonetically balanced
kindergarten (PB-K) and/or Glendonald auditory screening procedure (GASP) scores. Five studies reported outcomes for speech production. Speech production was assessed using the diagnostic evaluation of articulation and phonology (DEAP), speech intelligibility rate (SIR) and/or Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS). Nine studies reported receptive language outcomes. Receptive language was measured on oral and written language skills (OWLS), Clinical Evaluation of Language Fundamentals (CELF), Preschool Language Scale (PLS), Peabody Picture Vocabulary Test (PPVT) and/or Reynell Developmental Language Scale (RDLS) scores. In three studies auditory performance was assessed using Categories of Auditory Performance (CAP) scores only. Outcomes were conflicting with some studies reporting improvement following CI and others reporting that no significant differences were found in the outcome measure(s). Three studies reported that CI can be performed without increased risk of anesthetic and surgical complications in this younger population. The authors concluded that the additional speech and language benefits of CI before the age of 12 months have not been established. The best available evidence is based on independent, subjective outcome measures. There were several limitations to this analysis. Age ranges within the studies started at zero months and went up to five years and the data on less than age 12 months was extracted from each study. Long-term follow-ups are lacking. A limited number of children were implanted at this early age and current study samples may have been too small to show significant differences between different age-at-CI groups. The majority of studies consisted of retrospective designs with inconsistent or incomplete language measures and lacked multivariate analysis.

Forli et al. (2011) conducted a systematic review to evaluate the effectiveness of traditional CI in children. Studies reporting audiological, language and/or communication results were included. A total of 49 studies met inclusion criteria. Seven studies addressed CI in children age less than 12 months. Statistical significance of the data was not confirmed in all studies and statistical analysis did not always provide statistically significant outcomes. According to the authors, “the data was insufficient to assess whether the advantages identified in children implanted in their first year of life is retained over time and to what extent they are influenced by a longer period of usage of the implant”. The included studies were heterogeneous in age ranges and outcome measures. The long-term results of traditional CI in this age group are unknown.

Vlastarakos et al. (2010a) conducted a systematic review and meta-analysis to evaluate traditional cochlear implantation in infants less than age one year. Fifty-one publications met inclusion criteria and 125 children receiving cochlear implant prior to age one year were identified. Follow-up ranged from 6–12 months with 17 children followed for at least two years. No randomized controlled trials were found. Ten children receiving implants before the first year of life were compared to children implanted between the first and second year of life. “Reliable outcomes” were available on 42 infants (i.e., open- and/or closed-set testing [n=15], developmental rating scales [n=14], prelexical speech discrimination tools [n=13]). A meta-analysis of the 42 infants revealed that only four infants had shown statistically better performance. The authors concluded that “robust and reliable outcome measures of monitoring implanted infants are lacking” and “evidence that supports infant implantation, with regard to speech perception and production outcomes, is still limited and of lower quality.”

Roland et al. (2009) conducted a retrospective review on 50 children, age less than one year, who underwent either a traditional Nucleus or Advanced Bionics cochlear implantation. Age at implant ranged from 5–11 months (mean 9.9). Upon diagnosis, all infants wore hearing aids. Three patients had simultaneous bilateral implants. There were no perioperative anesthetic complications. Minor complications (10%) included hematoma, cellulites, and skin flap erythema (n=1 each) and two wound problems. Major complications (6%) included cerebral spinal fluid leak, device failure, and infection/exposed implant (n=1 each). Forty-two patients were available for postoperative speech perception testing. Various testing tools were used including Multisyllable Lexical Neighborhood Test (MLNT), Phonetically Balanced Kindergarten Test (PBK), Lexical Neighborhood Test (LNT), and the Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS). Eighteen patients scored a mean 93% on LNT/PBK, and similar scores were seen on five MLNT patients. Eight patients had postoperative GASP scores of 57% and IT-MAIS scores of 32 (out of a possible 40). Prospective long-term monitoring of outcomes is needed to validate the outcomes of this study.

Retrospective reviews have evaluated the risks and complication rates of CI. Migirov et al. (2008) compared the complication rate of unilateral CI in infants to CI in older children with a minimal follow-up of 12 months. Group 1 included 15 infants, ages 10–12 months. Group 2 included 57 children, ages one to two years. There were no statistically significant differences in major (requiring explantation or revision surgery) (p=0.297) or minor
complications ($p=0.502$) between the two groups. Valencia et al. (2008) conducted a retrospective review to evaluate the risks of traditional cochlear implantation in children ($n=15$), ages 6.67–11.6 months, with severe and profound hearing loss. Follow-ups ranged from two months to five years. There were no anesthetic complications. One child developed a leakage of spinal fluid around the electrode otorrhea. Late complications included two device failures and one infection requiring removal of the CI and re-implantation. At the 1–3 month follow-ups, the post-stimulation range of pure tone average was a mean 27dB compared to 25dB at the 5–8 months follow-up. These results were borderline normal to mild hearing loss.

Holt and Svirsky (2008) conducted a case series of 96 children who were a subgroup of children who received traditional cochlear implantation for profound bilateral sensorineural hearing loss to determine if significant gains were made by CI at age less than 12 months. The subjects were subdivided into four groups. Group 1 ($n=6$) underwent CI between ages six and 12 months, group 2 ($n=32$) between ages 13 and 24 months, group 3 ($n=37$) between ages 25 and 36 months, and group 4 ($n=21$) between ages 37 and 48 months. Children were tested preoperatively and every six months following activation of CI for up to 2.5 years. The Average Developmental Difference values between groups 1 and 2 were not significantly different, but they were significantly different between groups 1 and 3, groups 2 and 3, and groups 3 and 4. The significant mean Average Developmental Difference values varied between 15 to 18 percentage points indicating that children who received CI at earlier ages scored higher than children who received CI at older ages. Comparisons within each group of the Average Developmental Difference values for receptive language were significant ($p<0.05$). Word recognition results and expressive language performance were not significantly different between groups 1 and 2, but were significantly different between groups 1 and 3, groups 2 and 3, and groups 3 and 4 ($p<0.05$ for each). Group 1 demonstrated no significant difference in two of three outcomes (i.e., word recognition and expressive language) compared to group 2, but did demonstrate scores significantly higher than groups 3 and 4 ($p<0.05$ for each). No significant gains in expressive language development and spoken word recognition were accomplished by implantation prior to age 2 years. There was an advantage for receptive language development for group 1 compared to group 2 ($p=0.034$) and group 3 ($p=0.023$).

Dettman et al. (2007) conducted a retrospective review of 106 infants, who received a unilateral multichannel Cochlear Ltd. implant for profound bilateral sensorineural hearing loss. The children were divided into group 1 (age range 0.61–1.07 months; $n=19$), and group 2 (age range 1.13–2.00 years; $n=87$), and a comparison was made between the receptive and expressive language growth of the two groups. Follow-ups ranged from one to three years. There was a significant difference between the average rate of language comprehension growth scores for group 1 ($n=11$), compared to group 2 ($p<0.001$), as well as a significant difference in the language expression rate of growth over time in group 1 compared to group 2 ($p<0.002$). Complications included one case of mastoiditis and three explantations in group 2.

Tait et al. (Oct 2007) conducted a two-center prospective study comparing 10 normal-hearing children, age range 8–11 months to 10 profoundly deaf children who received unilateral traditional cochlear implantation at ages 8–11 months. There were no significant differences in vocal turn scores six months postoperatively between the two groups, but one year postoperatively the study group score was 59.5 compared to 84.5 for the control group ($p=0.003$). At one year the study group had a mean gestural turn of 27.5 compared to 12.0 for the control group ($p=0.01$) and a mean gestural autonomy of 15.5 vs. 2.5 ($p=0.01$). There were no significant differences between the two groups in mean and median vocal autonomy or non-looking vocal turns at six and 12 months following implantation. Following implantation, the deaf children communicated more vocally than silently.

Colletti et al. (2005) reported on 10 children, ages 4–11 months, who were fitted with a traditional cochlear implant for deafness. Auditory performance was measured based upon the Categories of Auditory Performance (CAP). All children had zero CAP scores prior to implantation. At the 12-month follow-up, five infants had a 4–5 CAP score. At the 24-month follow-up, CAP scores were 6–7 for the three children left in the study. In children age less than one year, the CAP median score of 7 compared to a CAP median score of 3.5 for children who received CI at ages 12–23 months was statistically significant ($p=0.01$). The three youngest implant infants, ages 5–6 months, started babbling two months after cochlear implant activation compared to children implanted at 10–11 months who had onset of babbling at 1–3 months post-implant. The difference between the study group and normal-hearing control group as it relates to babbling onset and babbling spurs was not statistically significant. No complications were reported.
Miyamoto et al. (2005) compared the outcomes of unilateral traditional cochlear implantation using Med-EL, Nucleus 24 and Clarion devices, in eight children (group 1) under age one year (range 6.38–10.85 months) to a group of 17 infants (group 2) age one year or older (range 12.39–23.24 months). The authors developed assessment tools to quantify outcomes of group 1. Following implantation testing was divided into three intervals. Interval 1 was evaluated at one day, one week, and one month following implantation; interval 2 was assessed at two months, three months, and six months; and interval 3 was tested at nine months, 12 months and 18 months. Approximately 20% of the testing sessions could not be completed due to crying, fussiness, or equipment malfunction. Video analysis revealed longer looking times to the novel trial compared to the old trial for group 1 (p=0.02), as well as group 2 (p=0.03) suggesting that the infants could discriminate between a continuous and a discontinuous sound. Preferential Looking Paradigm (PLP) testing yielded significantly longer looking times to the target, representing a video-sound association, versus the nontarget in group 1 (p=0.04), but not in group 2 (p=0.7). Infants in group 1 were able to learn association between speech sound and objects, while group 2 did not exhibit this ability. No surgical or anesthetic complications were reported.

Waltzman and Roland 2005 conducted a prospective study of 18 children who underwent unilateral Nucleus cochlear implantation. Subjects, implantation age range 6-11 months, had severe to profound sensorineural hearing loss. The mean preoperative Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) was 0.7 (1.75%). At six months postoperative (n=18) the IT-MAIS score was 30.4 out of a possible 40 (76%). Of the nine subjects available for the one year follow-up, the mean IT-MAIS score was 34.8 (87%) at one year compared to a score of 30.6 (76.5%) at the six-month follow-up. Speech perception scores (n=4) at the last evaluation included: Multi-Syllabic Lexical Neighborhood Test word score range 83–100% and Multi-Syllabic Lexical Neighborhood Test phoneme score range 95–100%; Lexical Neighborhood Test word score range 84–97% and Lexical Neighborhood Test phoneme score range 93–98%. Common phrases scores ranged from 60%–100%. One year postoperatively, one patient developed a breakdown on the antenna edge and eventually underwent reimplantation.

James and Papsin (2004) retrospectively reviewed the medical records of 25 infants (group 1) who had received unilateral traditional cochlear implantation (i.e., Nucleus 24) between the ages of 6–12 months. Review of records included computed tomography scan (CT) comparisons of mastoid bone anatomy to children who had received cochlear implant at ages 13 months to 3.5 years (group 2; n=25). The ages of Group 1 at the time of the CT scan ranged from 2.7–12 months compared to 13–42 months in group 2. The differences in mastoid bone size between the two age groups were not statistically significant. In group 1, three subjects had virtually no pneumatization at 12 months. Overall the proportion of pneumatization, which allows safe identification of surgical landmarks, was equal to marrow content in group 1. Pneumatization increased to approximately 60% by age 2 years, leaving very little marrow (p<0.001). With a maximum follow-up of 42 months, no surgical or anesthetic complications were reported. One child, who had a history of meningitis, required a double array CI.

Lesinski-Schiedat et al. (2004) conducted a retrospective study to compare the outcomes of profound bilaterally deaf children who received traditional unilateral CI (i.e., Nucleus, Clarion) at ages 0.4–12 months (mean 0.8 years) (group 1) (n=27) and ages 1–2 years (mean 1.6 years) (group 2) (n=89). Response to noise three months postoperatively was observed in 75% of group 1 and 69% in group 2. Group 1 response improved to 97% (n=6) at 18 months. Fifty-nine percent (n=20) of group 1 and 48% of group 2 (n=56) were able to identify different noises after three months which increased to 91% (n=8) in group 1 and 87% (n=44) in group 2 at the 24-month follow-up. At 12 months following CI, group 1 was performing at the same level as group 2 at 24 months. At three months, spoken language was utilized more by group 2 (14.3%) than group 1 (4.2%). Following implantation group 2 demonstrated stronger oral competence up until month 18. In open-set testing, group 2 had better Test of Auditory Perception of Speech scores and monosyllable test scores at 12 months, then group 1 exceeded group 2 at 18 and 24 months. After 24 months, group 1 scored 50% in the Glendonald Auditory Screening test compared to 30% by group 2 and 66% on the Common Phrases test compared to 53% by group 2. The 0.4 year-old child required intensive care due to severe lack of blood volume.

Schauwers et al. (2004) conducted a prospective study to analyze the onset of prelexical babbling and audiologic outcome in 10 congenitally deaf children who received a unilateral Nucleus 24 multichannel cochlear implant. Five children received implants between ages 5.5–10 months and five between ages 1.1–1.7 months. Ten normal hearing children, ages six to 11 months, functioned as the control group. The two youngest implant
children (ages 8–10 months) were considered within normal hearing range (ages 6–8 months) at age of onset of babbling with two additional early implant children babbling at 11 months of age. The median onset of babbling was one month following activation of the implant. Compared to the normal hearing children (ages 8.5–10.5 months), the youngest CI child fell within the normal range for babbling spurs (p<0.05). Of the children implanted prior to 12 months of age, four reached normal Categories of Auditory Performance scores three months following activation of the CI compared to zero to 12 months for children implanted after 12 months of age.

**Literature Review—Bilateral Implantation:** To enhance hearing capability in areas not achieved by unilateral CI, bilateral traditional cochlear implantation 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., age 1–18 years):** Meta-analysis, randomized controlled trials, case series and retrospective reviews support the safety and efficacy of traditional bilateral cochlear implantation in adults (i.e., age 18 years and older) and children (i.e., age 1–18 years) (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; Scherf, et al., 2007; Buss, et al., 2008; Tail, et al., 2010; Dunn et al., 2010).

**Children (i.e., age less than one year):** Evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of bilateral implantation of a traditional CI in children age less than 12 months. Manrique et al. (2004) conducted a prospective study of 130 children who received bilateral CI for profound congenital bilateral sensorineural hearing impairment. Group 1 included 36 children, age range 0–1 year (mean 0.94 months). Ten children had not used hearing aids prior to implantation. Group 2 included 94 children age range 2–6 years (mean 3.3 years). Prior to implantation hearing aids had not been used by 11 of the group 2 children. With the exception of one child who received a Med-El Combi 40+, all children received a Nucleus device. Follow-up occurred for up to five years. In comparison to preoperative values, a statistically significant difference in mean pure-tone average thresholds was seen in each group (p<0.05) postoperatively. During the five-year follow-up, group 1 experienced an improvement in closed-set tests (i.e., vowels, series of daily words) and open-set logoaudiometric tests. Following implantation, mean vowel testing results were significantly better at years one and three, and series of daily words testing at years 2 and 4. A significant difference was noted with Central Institute for the Deaf (CID) sentences (p<0.05). Group 2 also experienced a significant improvement in the closed-set tests (p<0.001), as well as in the open-set logoaudiometric tests during the five years of follow-up. Following implantation, group 1 demonstrated a slightly lower pure-tone average than group 2 with significantly lower differences in group 1 at years two and three following implantation (p<0.05). Group 1 performed better in the closed-set tests and CID test, being statistically significant in years three and five postoperatively (p<0.05). Group 1 experienced a relatively normal development of language compared to group 2 who demonstrated a two-year lag. During the five-year follow-up period, no complications were experienced by Group 1 compared to four complications (i.e., ulceration of cutaneous flap [n=1], device failures requiring reimplantation [n=3]) in group 2. Limitations of the study include the small patient population and lack of a control group.

**Technology Assessments:** 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 at 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”.

The Agency for Healthcare Research and Quality (AHRQ) (2011) 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.

Professional Societies/Organizations: In a position statement, the American Academy of Otolaryngology—Head and Neck Surgery (2014) stated that traditional cochlear implantation is an appropriate treatment for adults and children with severe 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 seems 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.

Hybrid Cochlear Implant With An External Hearing Aid
A hybrid or electric-acoustic stimulation (EAS) cochlear device uses two different technologies at the same time to provide low-frequency and high-frequency hearing. The low-frequency technology (acoustic) is proposed to
preserve any natural residual hearing while the traditional cochlear implant provides high frequency hearing (electrical). 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, 2017; Med-El, 2017; 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 residual hearing fibers from the surgical placement of the shorter array and loss of low-frequency residual hearing 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 inserter 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 Cochlear 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 age 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 ≥ 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 ≥ 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: There is insufficient evidence in the published peer-reviewed literature to support the efficacy of hybrid cochlear implants. Studies are primarily in the form of case reports and case series with small patient populations (n=13–87) and short term follow-ups of six months to two years (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). Outcomes varied regarding number of patients who experienced significant hearing and the type of hearing gained (e.g., speech recognition in noise and quiet, word score and speech reception thresholds). The long-term success of the hybrid devices, the number of users who lose low-frequency hearing following implantation and the long-term conversion rate of hybrid device users to traditional cochlear implants needs to be established. It is also unknown if the hearing improvements will be maintained over time.

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 was 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.

Roland et al. (2016) conducted a prospective, multicenter case series (n=50) 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.

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 ≤ 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.
A Hayes 2015 Technology Brief (reviewed 2017) on the Nucleus Hybrid L24 system reported that the evidence included "very poor" quality case series and retrospective studies with small patient populations. The studies suggested that the majority of patients experienced residual hearing and increased mid- to high-frequency hearing. Hayes noted that device implantation carries a risk of loss of residual hearing, but no other reported major safety issues were noted. In addition to the retrospective study design, limitations of the individual studies included the lack of control groups; small sample sizes; short-term follow-ups; and inadequate statistical analyses.

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 (American Speech-Language-Hearing Association, 2004; 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, 2015).

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).

Literature Review: Although there are a limited number of published scientific peer-reviewed studies primarily in the form of prospective reviews, ABI is an established treatment option for this patient population (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. 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 Zoccante (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.

Professional Societies/Organizations: The American Speech-Language-Hearing Association (2004) stated that an ABI is indicated in individuals whose auditory nerve has been damaged during acoustic tumor removal and cannot benefit from the use of a cochlear implant. Substantial improvement in the quality of life can be obtained in patients with ABI.

Use Outside of the US
Traditional cochlear and auditory brainstem implants are available throughout the world including Canada, Australia, China, Belgium, France, Germany and/or Asia.

The National Institute for Health and Clinical Excellence (NICE) (United Kingdom) (2009) technology appraisal on traditional cochlear implants recommended unilateral cochlear implantation for individuals with “severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.” Simultaneous bilateral implantation is indicated for individuals with “severe to profound deafness who do not receive adequate benefit from acoustic hearing aids” and “adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.” NICE also noted that some children and adults may be considered for a simultaneous implant when they meet the criteria for implantation and the second implant would provide sufficient benefit.

The National Institute for Clinical Excellence (NICE) (2005) issued an interventional procedure guidance supporting the evidence on the safety and efficacy of ABI for the treatment of bilateral deafness caused by vestibulocochlear nerve damage as a result of surgery or tumors.
Coding/Billing Information

Note: 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:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>69930</td>
<td>Cochlear device implantation, with or without mastoidectomy</td>
</tr>
<tr>
<td>69949†</td>
<td>Unlisted procedure, inner ear</td>
</tr>
<tr>
<td>92601</td>
<td>Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming</td>
</tr>
<tr>
<td>92602</td>
<td>Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming</td>
</tr>
<tr>
<td>92603</td>
<td>Diagnostic analysis of cochlear implant, age 7 years or older; with programming</td>
</tr>
<tr>
<td>92604</td>
<td>Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming</td>
</tr>
</tbody>
</table>

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

Hybrid Cochlear Implant With External Hearing Aid

Considered Experimental/Investigational/Unproven when used to report a hybrid cochlear implant:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8614</td>
<td>Cochlear device, includes all internal and external components</td>
</tr>
<tr>
<td>L8615</td>
<td>Headset/headpiece for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>L8616</td>
<td>Microphone for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>L8617</td>
<td>Transmitting coil for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td>L8618</td>
<td>Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement</td>
</tr>
<tr>
<td>L8619</td>
<td>Cochlear implant, external speech processor and controller, integrated system, replacement</td>
</tr>
<tr>
<td>L8621</td>
<td>Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each</td>
</tr>
<tr>
<td>L8622</td>
<td>Alkaline battery for use with cochlear implant device, any size, replacement, each</td>
</tr>
<tr>
<td>L8623</td>
<td>Lithium ion battery for use with cochlear implant device speech processor; other than ear level, replacement, each</td>
</tr>
<tr>
<td>L8624</td>
<td>Lithium ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each</td>
</tr>
<tr>
<td>L8627</td>
<td>Cochlear implant; external speech processor, component, replacement</td>
</tr>
<tr>
<td>L8628</td>
<td>Cochlear implant; external controller component, replacement</td>
</tr>
<tr>
<td>L8629</td>
<td>Transmitting coil and cable, integrated, for use with cochlear implant device, replacement</td>
</tr>
</tbody>
</table>
Medical Coverage Policy:0190

Cochlear device implantation, with or without mastoidectomy

†Unlisted procedure, inner ear

Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming

Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming

Diagnostic analysis of cochlear implant, age 7 years or older; with programming

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 | Transmitter 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


References


112. Tyler RS, Dunn CC, Witt SA, Noble WG. Speech perception and localization with adults with bilateral sequential cochlear implants. Ear Hear. 2007 Apr;28(2 Suppl):86S-90S.


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