UnitedHealthcare®

MEDICAL POLICY

COCHLEAR IMPLANTS

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Related Policies:

- Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable
- DME, Orthotic, Ostomy Supplies, Medical Supplies and Repair and Replacement

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

If benefits exist for a cochlear implant, the external components (i.e., speech processor, microphone, and transmitter coil) are considered durable medical equipment (DME), and the implantable components are considered under the medical-surgical benefit(s). The enrollee-specific plan document must be referenced to determine the DME benefits for repair or replacement of external components.

Cochlear implant monitoring (remapping and reprogramming of implant) and rehabilitation following the cochlear implant surgery is usually billed as aural rehabilitation. This is not covered as a speech therapy benefit. The enrollee specific plan document must be referenced for any applicable limits that may apply to aural rehabilitation.

Cochlear implants are not hearing aids. Please see the Medical Policy titled Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable for benefit information on hearing aids.

Frequency modulated (FM) systems can be used as an extension or accessory of cochlear implants. FM systems do not meet the definition of Covered Health Service and are excluded from coverage. These do not prevent, diagnose or treat a sickness or injury, and are not integral to the cochlear implant itself.

COVERAGE RATIONALE

When used according to U.S. Food and Drug Administration (FDA) labeled indications, bilateral or unilateral cochlear implantation is proven and medically necessary for patients who meet all of the following criteria:

- Diagnosis of bilateral prelingual or postlingual moderate-to-profound-sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Ability to follow or participate in a program of aural rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery

See the U.S. Food and Drug Administration (FDA) section for FDA indications for each cochlear implant device. Specific criteria vary with the device.

Cochlear hybrid implants are unproven and not medically necessary for hearing loss. There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of cochlear hybrid implants in the management of patients with severe hearing loss. Published evidence has shown that there is a potential risk of low frequency hearing loss as a result of cochlear hybrid implant surgery. Studies are needed to verify that benefits are likely to outweigh the risks of cochlear hybrid implantation and to determine which group of patients would benefit most from this device.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT® Code	Description
69930	Cochlear device implantation, with or without mastoidectomy
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	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

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HCPCS Code	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, replacement
L8619	Cochlear implant external speech processor and controller, integrated system, replacement
L8621	Zinc air battery for Use with cochlear implant device, 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 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

DESCRIPTION OF SERVICES

While hearing loss may relate to abnormalities in the sound conduction system of the outer and middle ear, most severe hearing deficits in newborns and the elderly result from sensorineural abnormalities, particularly cochlear hair cell loss which limits the ability of the cochlea to convert sound vibrations into nerve impulses. This type of hearing loss is usually irreversible and has been treated with rehabilitation strategies involving hearing aids, sign language, and speech and language therapy. Amplification does not replace the function of lost cochlear hair cells and often cannot provide adequate hearing in the case of severe cochlear hair loss. If appropriate neural elements in the ear are intact and functional, it is possible to stimulate auditory nerve impulses with a cochlear implantation device to improve sound recognition.

Auditory neuropathy is described as a hearing disorder in which sound enters the inner ear normally but the transmission of signals from the inner ear to the brain is impaired. People with auditory neuropathy may have normal hearing, inconsistencies in their hearing, or sensorineural hearing loss ranging from mild to severe. Even though a person with auditory neuropathy may be able to hear sounds, they may still have trouble understanding speech clearly. It can affect people of all ages, from infancy through adulthood. The exact number of people affected by auditory neuropathy is not known, but the condition is thought to affect a relatively small percentage of people who are deaf or hearing-impaired (National Institutes of Health, 2010).

The cochlear implant is composed of three parts, which include external components and two internal surgically implanted components. Externally, a microphone, speech processor, and transmitter coil with cables are worn. The speech processor converts sound into electrical stimuli. Internal components include an antenna and electrodes. The antenna electromagnetically captures the stimuli transmitted by the speech processor and directs this information to internal electrodes. The electrodes provide direct electrical stimulation to the auditory nerve, bypassing the transducer cells which are absent or nonfunctional. Because the cochlear implant does not magnify sound, none of its components are considered a hearing aid.

Cochlear implantation (CI) is undertaken in patients with moderate to profound bilateral sensorineural hearing loss. The degree of hearing loss is defined as mild (26 to 40 decibels (dB) hearing loss), moderate (41 to 55 dB hearing loss), moderately severe (56 to 70), severe (71 to 90 dB hearing loss), and profound (91 dB or more hearing loss) (ASHA, Type, Degree and Configuration of Hearing Loss). Potential candidates for cochlear implant must obtain limited benefit from hearing aids, which typically is determined by administering age appropriate word/sentence recognition testing while the patient wears appropriately fitted hearing aids, often described as the best-aided condition. Cochlear implants may be considered for use in patients who acquired hearing loss after development of speech (postlingual), during development of speech (perilingual), or before development of speech (prelingual). After receiving cochlear implantation, devices are programmed on an individual basis and recipients must undergo training and rehabilitation to learn to use auditory cues obtained from the device. Advantages associated with cochlear implants include significantly improved speech reading ability, improved recognition of environmental sounds, and improved speech intelligibility.

Typically, patients undergo unilateral CI. However, bilateral CI is also performed with two devices implanted at the same time or sequentially. Theoretical advantages of bilateral implantation are improved localization of sound and improved speech recognition in noisy environments. Bilateral cochlear implantation in children is being investigated as a means to improve their access to phonologic inputs, thus providing the basis for oral language learning.

Cochlear hybrid implants (e.g., Duet EAS™ Hearing System or Nucleus Hybrid cochlear implant) are currently being developed to allow auditory rehabilitation of patients who are not candidates for conventional implants because their low-frequency hearing exceeds current guidelines. Short implant electrodes are placed in the cochlea through a small cochleostomy to preserve low-frequency hearing. The only cochlear hybrid implant approved by the U.S. Food and Drug Administration (FDA) is the Cochlear™ Nucleus® Hybrid Implant System.

CLINICAL EVIDENCE

Unilateral Cochlear Implantation in Adults

Overall, cochlear implantation (CI) in adults with postlingual hearing loss led to substantial or significant improvement in mean measures of sound detection and speech perception (Vermeire et al., 2005; Parkinson et al., 2002; Francis et al., 2004; Tyler et al., 2002; Hiraumi et al., 2007; Ruffin et al., 2007; Noble et al., 2009). However, the results of cochlear implantation are variable among individuals and may be influenced by age at cochlear implantation, duration of deafness, and presence of residual hearing.

A meta-analysis of data from studies of cochlear implants in adults found that 11 of 16 studies involving unilateral implantation showed a statistically significant improvement in mean speech scores as measured by open-set sentence or multi-syllable word tests. The meta-analysis revealed a significant improvement in quality of life (QOL) after unilateral implantation (Gaylor et al. 2013).

Yang et al. (2011) evaluated the results of late cochlear implantation in prelingually deaf patients with significant residual hearing loss and evaluated patient factors relevant to postoperative auditory outcomes in this patient group. Thirty-two patients with severe to profound hearing loss that developed before the age of 4 who were implanted at a mean age of 24.8 years (range, 16-44). Speech perception tests were performed preoperatively and 12 months after the operation. The results showed significant improvement in open set speech perception (sentence) scores after the implantation.

Bond et al. (2010) performed a systematic review of the effectiveness of unilateral cochlear implants for adults. Nine studies were included in the review. These were of variable quality; they concluded that some study results should be viewed with caution. The studies were too heterogeneous to pool the data. However, overall the results supported the use of unilateral cochlear implants for severe to profoundly deaf adults.

Berrettini et al. (2011) conducted a systematic review to summarize the results of scientific publications on the clinical effectiveness of cochlear implantation (CI) in adults. With regard to unilateral CI in elderly patients, the eight studies that were reviewed reported benefits with cochlear implantation despite advanced age (age 70 years or older) at time of implant. The authors also reviewed three studies that included 56 adults with pre-lingual deafness who received unilateral cochlear implants. The authors concluded that unilateral cochlear implantation provided hearing and quality-of-life benefits in adults with pre-lingual deafness, but the degree of improvement varied from study to study and some of the study sample sizes limited the conclusions that could be drawn.

In April 2011, a technology assessment was completed for the Agency for Health Care Research and Quality (AHRQ) on the effectiveness of cochlear implants in adults. The assessment reviewed 22 studies and concluded that while the studies reviewed were rated as poor to fair quality, unilateral cochlear implants are effective in adults with sensorineural hearing loss. Pre- and post-cochlear implant scores on multi-syllable tests and open-set sentence tests demonstrated significant gains in speech perception regardless of whether a contralateral hearing aid was used along with the cochlear implant. Additionally, the assessment found health-related quality of life improved with unilateral cochlear implants (Raman, 2011).

<u>Professional Societies</u>

American Speech-Language-Hearing Association (ASHA): According to a technical report approved by the ASHA, adults with long-term prelingual deafness usually do not develop open-set word recognition abilities. However, these patients may recognize environmental sounds and have improved lip reading ability following cochlear implantation (ASHA, 2004).

Unilateral Cochlear Implantation in Children

Overall, clinical studies indicate that in children with prelingual hearing loss, cochlear implantation is likely to lead to significant and rapid improvement in speech perception and speech production and more gradual but progressive improvement in complex language/grammar in most cases (Hocevar-Boltezar et al., 2005; Anderson et al., 2004; Calmels et al., 2004; Manrique et al., 2004). However, cochlear implantation results are variable; are likely to be significantly better with earlier versus later cochlear implantation, shorter versus longer duration of deafness, and oral versus total communication before cochlear implantation; but also may be influenced by other factors such as preimplant residual hearing, learning style, family structure/support, or cochlear implantation coding strategy.

Forli et al. (2011) conducted a systematic review to summarize the results of scientific publications on the clinical effectiveness of cochlear implantation (CI) in children. The authors identified seven studies comparing post-CI outcomes in children implanted within the first year of life with those of children implanted after one year of age. The findings in these studies suggested improvements in hearing and communicative outcomes in children receiving implants prior to one year of age. However, it is not clear whether any advantages of early implantation are retained over time. Studies document an advantage in children younger than 18 months of age who received a cochlear implant compared to those implanted at a later stage.

A meta-analysis was performed to review cochlear implantation in infancy and auditory perception/speech production outcomes. Five cohort-studies were identified comparing implanted infants with under 2-year-old children; three studies were identified that represented type-III and two type-II evidence. No study was supported by type I evidence. Overall, 125 implanted infants were identified. Precise follow-up period was reported in 82 infants. Median follow-up duration ranged between 6 and 12 months; only 17 children had follow-up duration equal or longer than 2 years. Reliable outcome measures were reported for 42 infants. Ten implanted infants assessed with open/closed-set measures had been compared with under 2-year-old implanted children; 4

had shown better performance, despite the accelerated rate of improvement after the first postoperative year. The reviewers found that evidence of these children's performance regarding auditory perception/speech production outcomes is limited. Wide-range comparisons between infant implantees and under 2-year-old implanted children are lacking, and longer-term follow-up outcomes should be made available (Vlastarakos, 2010).

In a prospective study, Arisi et al. (2010) examined auditory function in a group of adolescents with prelingual deafness who received cochlear implants. The study included 45 adolescents (mean age at implantation: 13.4 years) with profound congenital hearing impairment with a follow-up of three years. Significant improvements in all speech perception tests were observed after CI. However, 15 cases were considered "poor performers" (i.e., the auditory performance of these patients was less than 30 percent). The diagnosis of deafness in these subjects was significantly delayed, and their hearing threshold was significantly lower than in the good users group. According to the investigators, CI was shown to be a useful device with the ability to reverse the adverse consequences of hearing loss, particularly for prelingual adolescents who receive implantation early in life and who present a hearing threshold of 100 dB or better both at diagnosis and at surgery.

Niparko et al. (2010) conducted a prospective, longitudinal, and multidimensional assessment of spoken language development over a 3-year period in children who underwent cochlear implantation before 5 years of age (n = 188) from 6 US centers and hearing children of similar ages (n = 97) from 2 preschools. Children undergoing cochlear implantation showed greater improvement in spoken language performance than would be predicted by their preimplantation baseline scores, although mean scores were not restored to age-appropriate levels after 3 years. Younger age at cochlear implantation was associated with significantly steeper rate increases in comprehension and expression. Similarly, each 1-year shorter history of hearing deficit was associated with steeper rate increases in comprehension and expression. In multivariable analyses, greater residual hearing prior to cochlear implantation, higher ratings of parent-child interactions, and higher socioeconomic status were associated with greater rates of improvement in comprehension and expression. The investigators concluded that the use of cochlear implants in young children was associated with better spoken language learning than would be predicted from their preimplantation scores.

A National Institutes of Health (NIH) (1995) document noted that children or adults with postlingual deafness had better auditory performance after cochlear implantation than children or adults with prelingual deafness but that the difference in auditory performance between children with prelingual deafness and those with postlingual deafness lessened with time.

Professional Societies

American Speech-Language-Hearing Association (ASHA): According to a technical report approved by the ASHA, both prelingually and postlingually deafened children are candidates for cochlear implantation if they receive limited benefits from conventional amplification (ASHA, 2004).

Cochlear Implantation for Auditory Neuropathy

Humphriss et al. (2013) conducted a systematic review to summarize and synthesize current evidence of the effectiveness of cochlear implantation (CI) in improving speech recognition in children with auditory neuropathy spectrum disorder (ANSD).

A total of 27 studies were included in the review. All selected studies were observational in design, including case studies, cohort studies, and comparisons between children with ANSD and SNHL. Most children with ANSD achieved open-set speech recognition with their CI. Speech recognition ability was found to be equivalent in CI users (who previously performed poorly with hearing aids) and hearing-aid users. Outcomes following CI generally appeared similar in children with ANSD and SNHL. Assessment of study quality, however, suggested substantial methodological concerns, particularly in relation to issues of bias and confounding, limiting the robustness of any conclusions around effectiveness. The authors concluded that currently available evidence is compatible with favorable outcomes from CI in children with ANSD. However, this evidence is weak. Stronger evidence is needed to support clinical policy and practice in this area.

In a systematic review, Roush et al. (2011) summarized the current evidence related to the audiologic management of children with auditory neuropathy spectrum disorder (ANSD). The review included 15 studies that addressed cochlear implantation in these patients. Study participants demonstrated improved auditory performance; however, all studies were considered exploratory, and many had methodological limitations. The authors concluded that the clinical evidence related to intervention for ANSD is at a very preliminary stage. The authors stated that additional research is needed to address the efficacy of cochlear implantation in children with ANSD and the impact of this disorder on developmental outcomes.

Teagle et al. (2010) reported the patient characteristics, preoperative audiological profiles, surgical outcomes, and postoperative performance for children with auditory neuropathy spectrum disorder (ANSD) who ultimately received cochlear implants (CIs).The study was a prospective, longitudinal study of children with ANSD who received CIs after a stepwise management protocol when progress with the use of acoustic amplification was insufficient. Of 140 children with ANSD, 52 (37%) received CIs in their affected ears (mean duration of use of 41 months). Many of these children were born prematurely (42%) and impacted by a variety of medical comorbidities. More than one third (38%) had abnormal findings on preoperative magnetic resonance imaging of the brain and inner ear, and 81% had a greater than severe (>70 dB HL) degree of hearing loss before implantation. Although 50% of the implanted children with ANSD demonstrated open-set speech perception abilities after implantation, nearly 30% of them with greater than 6 months of implant experience were unable to participate in this type of testing because of their young age or developmental delays. No child with cochlear nerve deficiency (CND) in their implanted ear achieved open-set speech perception abilities. In a subgroup of children, good open-set speech perception skills were associated with robust responses elicited on electrical-evoked intracochlear compound action potential testing when this assessment was possible. According to the investigators, this report shows that children with ANSD who receive CIs are a heterogeneous group with a wide variety of impairments. Although many of these children may ultimately benefit from implantation, some will not, presumably because of a lack of electrical-induced neural synchronization, the detrimental effects of their other associated conditions, or a combination of factors. When preoperative magnetic resonance imaging reveals central nervous system pathology, this portends a poor prognosis for the development of open-set speech perception, particularly when CND is evident. Instead of recommending CI for all children with electrophysiologic evidence of ANSD, a stepwise management procedure allows for the identification of children who may benefit from amplification, those who are appropriate candidates for cochlear implantation, and those who, because of bilateral CND, may not be appropriate candidates for either intervention.

According to the National Institute on Deafness and Other Communication Disorders, no tests are currently available to determine whether an individual with auditory neuropathy might benefit from a hearing aid or cochlear implant. Researchers are continuing to investigate the potential benefits of cochlear implants for children with auditory neuropathy and are examining why cochlear implants may benefit some people with the condition but not others (National Institutes of Health, 2010).

Bilateral Cochlear Implantation in Adults
A meta-analysis of data from studies of cochlear implants in adults found that bilateral implantation resulted in significant improvement in at least one communication-related outcome in 12 of 15 studies included in the meta-analysis. Simultaneous bilateral implantation showed significant improvement in communication-related outcomes as compared with unilateral implantation in all but two studies. The quality of life (QOL) outcomes varied after bilateral

implantation but in general, the results showed significant improvement in QOL after implantation (Gaylor et al. 2013).

The systematic review conducted by Berrettini et al. (2011) noted above also addressed bilateral cochlear implantation (CI) in adults. The studies that were reviewed demonstrated that compared to unilateral CI, bilateral CI offers advantages in hearing in noise, in sound localization and less during hearing in a silent environment. However, there was high variability among individuals in terms of benefits from the second implant.

Bond et al. (2009) performed a systematic review to investigate whether it is clinically effective to provide (1) a unilateral cochlear implant for severely to profoundly deaf people (using or not using hearing aids), and (2) a bilateral cochlear implant for severely to profoundly deaf people with a single cochlear implant (unilateral or unilateral plus hearing aid). The clinical effectiveness review included 33 studies, of which only two were RCTs. The studies used 62 different outcome measures and overall were of moderate to poor quality. Comparison of bilateral with unilateral cochlear implants plus an acoustic hearing aid was compromised by small sample sizes and poor reporting, but benefits were seen with bilateral implants. Prelingually deafened adults benefited less than those postlingually deafened adults (mean change scores 20% versus 62%).

In April 2011, a technology assessment was completed for the Agency for Health Care Research and Quality (AHRQ) on the effectiveness of cochlear implants in adults. The assessment reviewed 16 studies on bilateral cochlear implantation of fair to moderate quality published since 2004. The assessment concluded that bilateral cochlear implants provide greater benefits in speech perception test scores, especially in noise, when compared to unilateral cochlear implants. However, it was unclear if these benefits were experienced under quiet conditions although benefits increased with longer bilateral cochlear implant usage indicating a need for longer term studies (Raman, 2011).

Bilateral Cochlear Implantation in Children

Lammers et al. (2014) evaluated the effectiveness of bilateral cochlear implantation over unilateral implantation in children with sensorineural hearing loss. Twenty-one studies were identified that compared a bilateral cochlear implant group with a unilateral group. No randomized trials were identified. Due to the clinical heterogeneity of the studies statistical pooling was not feasible and a best evidence synthesis was performed. The results of this best evidence synthesis indicate the positive effect of the second implant for especially sound localization and possibly for preverbal communication and language development. There was insufficient evidence to make a valid comparison between bilateral implantation and a bimodal fitting. The authors concluded that although randomized trials are lacking, the results of a best evidence synthesis indicate that the second cochlear implant might be especially useful in sound localization and possibly also in language development.

Boons et al. (2012) examined spoken language outcomes in children undergoing bilateral cochlear implantation (n=25) compared with matched peers undergoing unilateral implantation (n=25) in a case-control, frequency-matched, retrospective cross-sectional multicenter study. The use of bilateral cochlear implants is associated with better spoken language learning. The authors concluded that the interval between the first and second implantation correlates negatively with language scores. On expressive language development, the authors found an advantage for simultaneous compared with sequential implantation. On the receptive language tests and expressive language tests, children undergoing bilateral implantation performed significantly better than those undergoing unilateral implantation. A shorter interval between both implantations was related to higher standard scores. Children undergoing 2 simultaneous cochlear implantations performed better on the expressive Word Development Test than did children undergoing 2 sequential cochlear implantations.

The systematic review conducted by Forli et al. (2011) noted above also addressed bilateral cochlear implantation (CI) in children. Bilateral CI improved verbal perception in noise, and sound localization compared with unilateral CI in 19 of 20 studies reviewed.

Sparreboom et al. (2010) assessed the clinical effectiveness of bilateral cochlear implantation compared with unilateral cochlear implantation alone or with a contralateral hearing aid (bimodal stimulation), in children with severe-to-profound hearing loss. Studies were included if they comprised data on comparisons between bilateral cochlear implantation and unilateral cochlear implantation and/or bilateral cochlear implantation and bimodal stimulation, in children with severe-to-profound sensorineural hearing loss. Effect sizes could not be pooled because of the heterogeneity of the studies. Therefore, the results were presented qualitatively. The reviewers concluded that although the level of evidence was low, the advantages of bilateral cochlear implants corresponded with the primary benefits of bilateral hearing, that is, improved speech perception in quiet and noise. Localization results were less consistent. No data on audiologic, speech production, or educational outcomes were available.

Bond et al. (2009) performed a systematic review to investigate whether it is clinically effective to provide (1) a unilateral cochlear implant for severely to profoundly deaf people (using or not using hearing aids), and (2) a bilateral cochlear implant for severely to profoundly deaf people with a single cochlear implant (unilateral or unilateral plus hearing aid). The clinical effectiveness review included 33 studies, of which only two were RCTs. The studies used 62 different outcome measures and overall were of moderate to poor quality. Studies in children comparing one cochlear implant with non-technological support or an acoustic hearing aid reported gains on all outcome measures, some demonstrating greater gain from earlier implantation. The strongest evidence for an advantage from bilateral over unilateral implantation was for understanding speech in noisy conditions (mean improvement 13.2%); those receiving their second implant earlier made greater gains. Comparison of bilateral with unilateral cochlear implants plus an acoustic hearing aid was compromised by small sample sizes and poor reporting, but benefits were seen with bilateral implants.

According to a systemic evidence review of 37 studies conducted by Murphy and O'Donoghue (2007), the available evidence indicates that bilateral cochlear implantation confers material benefits not achievable with unilateral implantation, specifically in terms of sound localization and understanding of speech in noise. However, well-designed prospective studies of sufficient size are needed to precisely quantify these benefits, to validate outcome measures, especially in children, and to define the criteria for intervention.

Lovett et al. (2010) assessed whether bilateral cochlear implantation is associated with better listening skills, higher health-related quality of life (health utility) and higher general quality of life (QOL) than unilateral implantation in a cross-sectional observational study. Fifty severely-profoundly deaf and 56 normally-hearing children recruited via a charity, the UK National Health Service and schools were included in the study. Thirty of the deaf children had received bilateral cochlear implants; 20 had unilateral cochlear implants. On average, bilaterally-implanted children performed significantly better than unilaterally implanted children on tests of sound localization and speech perception in noise. After conservative imputation of missing data and while controlling for confounds, bilateral implantation was associated with increases of 18.5% in accuracy of sound localization and of 3.7 dB in speech perception in noise. Bilaterally-implanted children did not perform as well as normally-hearing children, on average. Bilaterally- and unilaterally-implanted children did not differ significantly in parental ratings of health utility or QOL. The investigators concluded that compared with unilateral cochlear implantation, bilateral implantation is associated with better listening skills in severely-profoundly deaf children.

Cochlear Hybrid Implants

Lenarz et al. (2013) investigated the preservation of residual hearing in subjects who received the Nucleus Hybrid L24 cochlear implant. The researchers also investigated the performance benefits up to one year post-implantation in terms of speech recognition, sound quality, and quality of life.

The study included 66 adult hearing-impaired subjects with bilateral severe-to-profound high frequency hearing loss. Post-operative performance using a Freedom Hybrid sound processor was compared with that of pre-operative hearing aids. Group median increase in air-conduction thresholds in the implanted ear for test frequencies 125-1000 Hz was less than 15 dB across the population; both immediately and one year post-operatively. Eighty-eight percent of subjects used the Hybrid processor at one year post-op. Sixty-five percent of subjects had significant gain in speech recognition in quiet, and 73% in noise (≥ 20 percentage points/2 dB SNR). Mean speech spatial qualities (SSQ) subscale scores were significantly improved. Combining residual hearing with cochlear implant (CI) gave 22-26 percentage points mean benefit in speech recognition scores over CI alone. The authors concluded that useful residual hearing was conserved in 88% of subjects. Speech perception was significantly improved over preoperative hearing aids, as was sound quality and quality of life. This study was sponsored by Cochlear AG and two of the authors are employees of Cochlear Corporation, the manufacturer of the device studied. The remaining authors report no conflicts of interest. Study limitations include short duration of follow-up (1 year). Longer follow-up is needed to assess the long-term performance of the Nucleus Hybrid L24 cochlear implant.

In a retrospective analysis, Szyfter et al. (2013) evaluated the hearing preservation rate in 21 patients with high frequency hearing loss, treated with Cochlear Nucleus Freedom Hybrid-L. Pure tone thresholds were recorded prior to the surgery and at the time of speech processor switch-on. Patients were subdivided into two groups with respect to their pure tone audiometry (PTA) thresholds: group A- classic indication for hybrid-L implant (n = 13) and group B – extended inclusion criteria (n = 8) with residual hearing loss. Average PTA for three frequencies (250, 500, 1,000 Hz) were calculated for each patient pre- and postoperatively. Preservation of hearing was observed in 17 patients (12 patients from group A, 5 patients from group B) with a mean value of 13.1 dB. In 4 out of 21 patients deafness on the implanted ear was noted. According to the authors, the results indicate that with standard procedure, hearing preservation can be obtained in majority of patients. Hearing preservation was not achieved in 19%. According to the authors, electrical acoustic stimulation (EAS) is a safe and reliable method to help patients with specific type of hearing loss. This is an uncontrolled, retrospective study with a small sample size.

In a retrospective study, Nguyen et al. (2013) reported the outcome of 32 patients implanted with electric acoustic cochlear implants with various surgical techniques and array designs. Three array models were inserted: Contour Advance implant (n = 16), Nucleus Hybrid-L (n = 12), and Med-El Flex EAS (n = 4). Postoperative pure tone audiometry was performed at 3 and 12 months after implantation. Three months postoperatively, hearing preservation within 30 dB was achieved in 50%, 50%, and 84% cases of patients implanted with a Contour Advance, Flex-EAS, and Hybrid-L, respectively. Two patients (Hybrid-L group) had a delayed sudden hearing loss (> 30 dB) 3 months postoperatively. The authors concluded that residual hearing could be preserved with various arrays ranging from 16 to 18 mm in insertion length and 0.25 to 0.5 mm tip diameter. Study limitations include a lack of controls and a small sample size.

Reiss et al. (2012) measured consonant recognition as a function of the number of stimulation channels for Hybrid short-electrode cochlear implant (CI) users, long-electrode CI users, and normal-hearing (NH) listeners in quiet and background noise. Nine adults implanted with the Hybrid short-electrode CI and nine adults implanted with the traditional long-electrode CI from Cochlear Americas participated in the study. Despite differences in intracochlear electrode spacing for equivalent channel conditions, all CI subject groups performed similarly at each channel condition and improved up to at least four channels in quiet and noise. All CI subject groups underperformed relative to NH subjects. The preliminary findings of this study suggest that consonant recognition as a function of the number of stimulation channels is similar in both quiet and noise for short-electrode CI users and long-electrode CI users in both the full condition and with only the basal electrodes activated. This study was limited by a small sample size.

Eighty-seven subjects were enrolled in an adult hybrid multicenter Food and Drug Administration clinical trial to evaluate the Iowa/Nucleus 10-mm Hybrid cochlear implant. Immediate hearing preservation was accomplished in 85 of the 87 subjects. Over time (3 months to 5 years), some hearing preservation was maintained in 91% of the group. Combined electric-acoustic processing enabled most of this group of volunteers to gain improved speech understanding, compared to their preoperative hearing, with bilateral hearing aids. Most have preservation of low-frequency acoustic hearing within 15 dB of their preoperative pure tone levels. Those with greater losses (>30 dB) also benefited from the combination of electric-acoustic speech processing. Postoperatively, in the electric-acoustic processing condition, loss of low-frequency hearing did not correlate with improvements in speech perception scores in quiet. Sixteen subjects were identified as poor performers in that they did not achieve a significant improvement through electric-acoustic processing. A multiple regression analysis determined that 91% of the variance in the poorly performing group can be explained by the preoperative speech recognition score and duration of deafness. Signal-to-noise ratios for speech understanding in noise improved more than 9 dB in some individuals in the electric-acoustic processing condition. According to the authors, the data suggest that the advantages gained for speech recognition in noise by preserving residual hearing exist, unless the hearing loss approaches profound levels. Preservation of residual low-frequency hearing should be considered when expanding candidate selection criteria for standard cochlear implants. Duration of profound high-frequency hearing loss appears to be an important variable when determining selection criteria for the Hybrid implant (Gantz et al. 2009). These findings need to be validated by additional studies to determine which group of patients would benefit most from this device.

Lenarz et al. (2009) evaluated 24 patients with low-frequency thresholds of 60 dB or better, up to 500 Hz, who were implanted with a Hybrid-L. Another group of 8 recipients with less residual hearing was included under extended inclusion criteria. Residual hearing was conserved in the majority of cases. One patient had a loss of more than 30 dB, but hearing partially recovered after 9 months. The median loss in all patients was 10 dB in both the Hybrid group and the extended group. Patients were able to use the residual hearing postoperatively to the same extent as preoperatively. In the Hybrid mode (cochlear implant + ipsilateral hearing aid), patients showed a significant improvement of 21% in speech understanding in quiet using the Freiburger Monosyllabic Word Test compared to the preoperative scores under aided conditions with their hearing aid. The Oldenburg Sentence Test in noise showed an average improvement of 10.2 dB compared to the preoperative hearing aid only mode. An additional improvement could be seen in the combined mode using an additional contralateral hearing aid. Recipients with a shorter duration of high-frequency hearing loss showed a larger benefit than those with a longer duration of hearing loss. The authors concluded that hearing conservation using the Hybrid-L electrode and a given surgical technique is possible with high probability in patients with high-frequency deafness. The use of the residual acoustic hearing offers specific advantages, especially for understanding speech in noise and for spatial hearing. This study was limited by a small sample size.

Buchner et al. (2009) investigated the effect of low-frequency hearing on speech perception performance in 22 patients being implanted with the Nucleus Hybrid-L device. The Hybrid-L study group achieved a speech reception threshold of 15.9 dB in the hearing aid alone condition, 10.8 dB in the cochlear implant alone condition, and 3.9 dB when using the combination of cochlear implant and hearing aid. Differences between the 3 conditions were statistically significant. According to the authors, results from the additional experiment on the acoustically presented frequency range suggest that very limited residual hearing below 500 Hz is already sufficient to produce a significant improvement in speech perception performance in conjunction with a cochlear implant. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes of this device.

Dorman et al. (2009) compared the effectiveness of 2 surgical interventions for improving word recognition ability in a quiet environment among patients who presented with: (1) bilateral, precipitously sloping, high-frequency hearing loss; (2) relatively good auditory thresholds at and below 500 Hz, and (3) poor speech recognition. In 1 intervention (n = 25), a conventional electrode array was inserted into 1 cochlea. As a consequence, hearing was lost in the implanted ear. In the other intervention (n = 22), a Nucleus Hybrid short-electrode array was inserted 10 mm into 1 cochlea with the aim of preserving hearing in that ear. Both groups of patients had similar low-frequency hearing and speech understanding in the ear contralateral to the implant. Following surgery, both groups had significantly higher word recognition scores than before surgery. Between-group comparisons indicated that the conventional electrode array group had higher word recognition scores than the 10-mm group when stimulation was presented to the operated ear and when stimulation was presented to both ears.

In a prospective study of patients in a manufacturer-sponsored clinical trial, Luetje et al. (2007) evaluated the benefits of hybrid cochlear implantation (CI) in 13 patients with residual low-frequency hearing. Follow-up ranged from 3 to 24 months. All 13 patients had preserved hearing immediately postoperative. However, one lost residual hearing 7 days postoperatively, and 2 patients had delayed hearing losses at 2 and 24 months, the latter apparently due to barotrauma; however, this was not conclusive. Another had a bilateral symmetrically progressive hearing loss. Six patients showed changes in low-frequency hearing less than 10 dB; 2 showed changes in the range 11 to 20 dB; 2, 21 to 30 dB; and 3, more than 50 dB. Eleven of 13 had improved consonant-nucleus-consonant words ranging up to 83% when tested with hearing aid plus CI in the operated ear. Four subjects exhibited improvement in Bamford-Kowal-Bench sentence in noise testing, although only one subject showed a significant decline associated with bilateral progression in hearing impairment. The authors concluded that combined electrical and acoustical hearing can result in significant improvement in speech understanding. Only one patient lost residual hearing as a direct result of surgery. Two others had delayed losses. There are no absolute predictive factors as to success with hybrid CI; wide variation in results may occur. According to the authors, further studies may clarify factors involved in such variation.

Gantz et al. (2006) reported on the preliminary results from an ongoing multicenter single-subject design clinical trial of the Iowa/Nucleus Hybrid 10-mm cochlear implant. The device was implanted in 48 individuals with residual low-frequency hearing. Hearing preservation was accomplished in 46 of the 48 subjects. Acoustic speech perception was also preserved. Combined acoustic plus electric speech processing enabled most of this group of volunteers to gain improved word understanding as compared to their preoperative hearing with bilateral hearing aids. A subset of subjects with 12 months or more experience demonstrated that consonant nucleus consonant (CNC) word understanding continued to improve more than 24 months after implantation. Improved word understanding in noise is also a benefit of acoustic plus electric speech processing. The authors concluded that the improvement of speech in noise and melody recognition is linked to the ability to distinguish fine pitch differences as the result of preserved residual low-frequency acoustic hearing. According to the authors, preservation of residual low-frequency hearing should be considered when expanding candidate selection criteria for standard cochlear implants. These findings require confirmation in a larger study.

In a cross-sectional study, Golub et al. (2012) compared auditory performance of Hybrid and standard cochlear implant users. Two subjects implanted with the Cochlear Nucleus Freedom-based Hybrid S8 device and three subjects implanted with the Cochlear Nucleus Freedom-based Hybrid S12 device were enrolled in the study. Subject ages ranged from 63 to 75 years. Data from forty-two standard cochlear implant subjects who underwent testing with the Speech Reception Threshold (SRT) and Clinical Assessment of Music Perception (CAMP), spectral-ripple, and Schroeder-phase discrimination tests were used for control comparison. Data from twenty-four standard cochlear implant subjects who completed the temporal modulation detection test were also used for control comparison. Hybrid cochlear implant users were followed for 12 to 33 months after implantation. Clinical Assessment of Music Perception pitch performance at 262 Hz was significantly better in Hybrid users compared with standard implant controls. There was a near significant difference on speech reception in steady-state noise. Neither Schroeder-phase discrimination at 2 frequencies nor temporal modulation detection thresholds across a range of frequencies revealed any advantage in Hybrid users. This contrasts with spectral-ripple measures that were significantly better in the Hybrid group. The spectral-ripple advantage was preserved even when using only residual hearing. According to the authors, these preliminary data confirm existing data demonstrating that residual low-frequency acoustic hearing is advantageous for pitch perception. The authors concluded that the results of the study also suggest that clinical benefits enjoyed by Hybrid recipients are due to improved spectral discrimination provided by the residual hearing. No evidence indicated that residual hearing provided temporal information beyond that provided by electric stimulation. According to the authors, subject numbers were too low to reveal a statistically significant advantage with speech recognition in steady state noise. This study was limited by a small sample size.

There is insufficient evidence to conclude that cochlear hybrid implants are beneficial for patients with hearing loss. Studies are needed to verify that benefits are likely to outweigh the risks of cochlear hybrid implantation and to determine which group of patients would benefit most from this device.

Cochlear Implantation Potential Complications

Cochlear implantation (CI) is associated with a variety of potential complications. The complication of greatest concern is the possible development of meningitis. In 2002, the FDA issued a notification regarding a possible link between CI and meningitis after receiving reports of 118 cases of meningitis in CI recipients, including 17 in whom meningitis resulted in death. Among CI users in the United States, 52 had contracted meningitis and 5 died from it. In the fatal cases, ages ranged from 13 months to 84 years but most were under 7 years of age (Callanan and Poje, 2004). Meningitis in CI recipients has been caused by the bacteria S. pneumoniae in 62% of the cases and type b or nontypeable Haemophilus (H.) influenzae strains in 21% of the cases (Rose et al., 2004). It was determined that the incidence of meningitis caused by Streptococcus (S.) pneumoniae in pediatric CI recipients was over 30 times that in similarly aged children in the general population (Callanan and Poje, 2004). Initially, it was believed that an electrode positioner used in some CI devices was at fault, since use of the positioner required a larger cochleostomy, caused more trauma and damage to the inner ear, and was associated with a higher incidence of meningitis than other CI devices. However, the positioner was voluntarily taken off the market and the meningitis cases in subsequent CI recipients still occurred, although at a substantially lower and declining rate. The development of bacterial meningitis also is related to middle and inner ear infections, inner ear malformations, and cerebrospinal fluid (CSF) leaks. (Callanan and Poje, 2004) Middle ear infections (otitis media) are prevalent in young children and can spread to the inner ear (Callanan and Poje, 2004), and inner ear malformations and CSF leaks often are present in patients receiving CI (Bhatia et al., 2004; Arnoldner et al., 2005). These data emphasize the importance of ensuring that all pediatric CI users are appropriately vaccinated against S. pneumoniae and are monitored and promptly treated for bacterial infections (Callanan and Poje, 2004). See the following Web site for more information: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/ucm062892.htm Accessed April 2014.

According to the Advisory Committee on Immunization Practices (ACIP), children and adults with cochlear implants should receive 23-valent pneumococcal polysaccharide vaccine (PPV23) (Pneumovax®) according to the schedule used for persons with chronic illnesses; a single dose is indicated. See the following Web sites for more information:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a5.htm
Accessed April 2014.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm
Accessed April 2014.
http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf
Accessed April 2014.

Cochlear implants are contraindicated in patients with acoustic nerve or central auditory pathway lesions, or active middle ear infection. Relative contraindications to cochlear implants include large tympanic membrane perforations. The size, location and etiology of the tympanic membrane perforation influence the safety for proceeding with implant surgery. Children with recurrent otitis media and myringotomy tubes remain candidates for cochlear implant surgery.

Success may be influenced by the degree of intracochlear fibrosis and/or ossification.

Professional Societies

American Speech-Language-Hearing Association (ASHA): According to a 2004 technical report approved by the ASHA, bilateral implantation is currently being studied in a limited number of cochlear implant recipients with mixed results. In some cases, recipients experience enhanced speech understanding, especially in noise; in other users the improvement in speech understanding compared with unilateral performance is minimal or absent and the primary advantage of binaural implantation is sound localization. Bilateral implantation outcomes to date are encouraging but inconclusive due to the limited number of participants and the scope of the projects. There is a clear need for further exploration of the many variables that can affect the performance of people with binaural implants before widespread use is warranted. Many of these studies are currently underway and the results will help to define prognosis and optimization of binaural implant usage. Such studies will determine the ultimate benefit and cost effectiveness of bilateral cochlear implantation (ASHA, 2004).

American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)*:* The AAO-HNS considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can perform significantly better with two cochlear implants than one, bilateral cochlear implantation is accepted medical practice (AAO-HNS, 2014).

American Academy of Audiology (AAA): In a policy statement regarding Cochlear Implants in Children, the AAA states recognizes multichannel cochlear implants as sensory aid options for children with profound hearing impairments who demonstrate limited or no functional benefit from conventional hearing aid amplification. The audiological criteria for implantation are a congenital or acquired profound sensorineural hearing loss and limited or no functional benefit from electroacoustic hearing aid amplification. Generally, a pure tone average (500, 1000, 2000 Hz) of 90dB HL or greater in both ears is indicated (AAA, 2008).

American Academy of Pediatrics (AAP): In a 2007 position statement on the Principles and Guidelines for Early Hearing Detection and Intervention Programs, the AAP states that cochlear implantation should be given careful consideration for any child who seems to receive limited benefit from a trial with appropriately fitted hearing aids. The AAP also states that the presence of developmental conditions (e.g., developmental delay, autism) in addition to hearing loss should not, as a rule, preclude the consideration of cochlear implantation for an infant or child who is deaf (AAP, 2007).

The American Academy of Pediatrics (AAP) has issued a statement on cochlear implants in children. The new policy statement covers surgical site infections and prevention and treatment of acute otitis media (AOM) and meningitis. The policy statement indicates that children with profound deafness who are candidates for cochlear implants should receive all age-appropriate doses of pneumococcal conjugate and *Haemophilus influenzae* type b conjugate vaccines and appropriate annual immunization against influenza (Rubin et al. 2010). See the following for more information: http://pediatrics.aappublications.org/cgi/reprint/126/2/381. Accessed April 2014.

The National Institute for Health and CareExcellence (NICE) has published guidance on the use of cochlear implants for severe to profound deafness in children and adults. Unilateral cochlear implantation is recommended as an option for those with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids. Simultaneous bilateral cochlear implantation is recommended as an option for 1) children and 2) adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness. Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness (NICE,2011).

To provide clinicians and healthcare providers information on the benefits, limitations, and other relevant issues of cochlear implantation, the National Institutes of Health NIH sponsored a consensus development conference in 1995. This conference involved a 14-member consensus panel of experts and concluded that cochlear implantation improves communication ability, often leading to positive psychological and social benefits, in adults with severe to profound, postlingual hearing loss; provides more limited improvement in speech perception but allows important environmental sound awareness in adults with prelingual hearing loss; and results in more variable outcomes but may lead to gradual improvement in speech perception, speech production, and language in hearing-impaired children (NIH, 1995).

Additional Search Terms
Cochlear prosthesis

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

See the end of this section for a summary list of FDA labeled indications for currently marketed cochlear implants.

At the present time, there are several manufacturers of FDA-approved cochlear implant devices, including Cochlear™ (previously Cochlear Corp.), Advanced Bionics Corp., and MED-EL Corp. Since the first cochlear implant device was approved in the 1980s, these devices have undergone progressive technological refinement, and approved indications for their use gradually have expanded and have become more specific. The currently marketed cochlear implant devices are indicated for 1) adults (age 18 years or older) with severe-to-profound or moderate-to-profound, bilateral, sensorineural hearing loss or 2) children age 12 months or older with bilateral, sensorineural hearing loss who obtain limited benefit from appropriately fitted hearing aids. Specific criteria vary with the device. See the following web site for more information (use product code MCM): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Accessed April 2014. FDA approval language does not address unilateral or bilateral use.

Cochlear™ manufactures the Nucleus® series of cochlear implant devices, including the Nucleus Freedom, Nucleus 5 System, Nucleus 22 Channel Cochlear Implant System and the Nucleus 24 and Nucleus 24 Contour Systems. The original premarket approval (PMA) for the Nucleus 22 system occurred in 1985. Indications for the Nucleus 22 system include adults with severe-to-profound, bilateral, sensorineural hearing loss who obtain 30% or less speech recognition on tests of recorded sentence materials in the best-aided condition and children aged 18 months or older with profound, bilateral, sensorineural hearing loss who obtain little or no benefit from conventional amplification in the best-aided condition. Subsequent technological refinements led to the Nucleus 24 Cochlear Implant System and, later, the Nucleus 24 Contour Cochlear Implant System. In 2000, the Nucleus 24 Contour System was approved for adults with moderate-to-profound, bilateral, sensorineural, hearing loss who obtain test scores of 50% or less in the ear to be implanted, or 60% or less in the best-listening condition on tape recorded tests of open-set sentence recognition and approved for children aged 12 months or older with profound, bilateral, sensorineural hearing loss who obtain little or no benefit from appropriate binaural hearing aids. See the following web site for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=8605&lpcd=MCM. Accessed April 2014.

Cochlear Americas received approval from the FDA to market Nucleus® Freedom™ (Nucleus 24) in 2005. The Nucleus Freedom features both an internal component and an external speech processor. See the following web site for more information: http://www.cochlear.com/wps/wcm/connect/us/for-professionals/cochlear-implants/Products/sound-processors/cochlear-freedom-sound-processor Accessed April 2014.

The Nucleus® 6 System was approved by the FDA on August 2, 2013. This system is a new suite of external accessories including external sound processors (cp910 and cp920) and programming software to be used with the Nucleus 24 Cochlear Implant.
See the following Web sites for more information:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm377425.htm Accessed April 2014
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=11378 Accessed April 2014.

The Cochlear™ Nucleus® Hybrid Implant System was approved by the FDA on March 20, 2014. According to the approval order statement, the hybrid l24 cochlear implant system is intended to provide electric stimulation to the mid-to-high frequency region of the cochlea and acoustic amplification to the low frequency regions, for patients with residual low frequency hearing sensitivity. The system is indicated for unilateral use in patients aged 18 years and older who have residual low-frequency hearing sensitivity and severe to profound high frequency sensorineural hearing loss, and who obtain limited benefit from appropriately fit 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 Consonant Nucleus Consonant (CNC) 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.
See the following for more information:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P130016
Accessed May 2014.

The FDA approval was based on a clinical study involving 50 patients with severe to profound high-frequency hearing loss who still had significant levels of low-frequency hearing. The patients were tested before and after being implanted with the device. A majority of the patients reported statistically significant improvements in word and sentence recognition at 6 months after activation of the device compared with their baseline pre-implant performance using a conventional hearing aid. Of the 50 individuals participating in the study, two thirds experienced low-frequency hearing loss, tinnitus (ringing in the ear), electrode malfunction, and dizziness. Almost 50% developed profound or total low-frequency hearing loss in the implanted ear; 6 patients underwent an additional surgery to replace the device with a standard cochlear implant. The FDA noted that while the risk of low-frequency hearing loss is of concern, the overall benefits of the device outweigh this risk for those who do not benefit from traditional hearing aids.
See the following Web sites for more information:
http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm389860.htm Accessed April 2014.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=21471 Accessed April 2014.
http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/EarNoseandThroatDevicesPanel/UCM373792.pdf
Accessed April 2104.

MED-EL Corp. produces the MED-EL COMBI 40+ Cochlear Implant System® includes a series of devices, including the SONATATI100 or PULSARci100 Cochlear Implant System and the Combi 40+ (C40+) S (compressed), C40+ Gb (split), and C40+ M (medium) electrode arrays. In 2001, the COMBI 40+ device was approved for adults (age 18 years or older) with severe-to-profound, bilateral, sensorineural hearing impairment (determined a pure tone average of 70 decibels [dB] or more at 500 Hertz [Hz], 1000 Hz, and 2000 Hz) and children aged 18 months to 17 years 11 months with profound, bilateral, sensorineural hearing loss (with thresholds of 90 dB or more at 1000 Hz) who obtain limited benefit from appropriately fitted binaural hearing aids. Limited benefit for adults was defined as scores of 40% or less in the best-aided listening condition on CD recorded tests of open-set sentence recognition, or the Hearing in Noise Test (HINT). Limited benefit in younger children (maximum age not specified) was 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 3- to 6-month period. Limited benefit in older children was defined as less than 20% correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or the Lexical Neighborhood Test (LNT), depending on cognitive ability and linguistic skills. In children without prior hearing aid experience, a 3- to 6-month hearing aid trial is required, although this trial may be shortened in patients with radiological evidence of cochlear ossification. See the following web site for more information (use product code MCM): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Accessed April2014. In 2003, approval was broadened to include children age 12 months or older.

Advanced Bionics Corp. manufactures CLARION® and Hi Resolution™ cochlear implant devices. The initial device, the CLARION Multi-Strategy Cochlear Implant, was approved in March 1996 for adults (age 18 years or older) with severe to profound, bilateral, sensorineural hearing loss. In December 1996, approval expanded to include children aged 2 years to 17 years, or 18 months if there was radiological evidence of ossification, with profound, bilateral, sensorineural deafness who do not benefit from appropriately fitted hearing aids. Lack of benefit in younger children (age maximum not specified) was defined as failure to attain basic auditory milestones (e.g., inconsistent response to own name or environmental sounds) and in older children was defined as a score of 0% on open-set word recognition (phonetically balanced kindergarten test - word list) administered with monitored live-voice (70 dB sound pressure level). Approval specified that all children must demonstrate only minimal ability on age-appropriate open-set sentence measures and a plateau in auditory development. See the following web site for more information (use product code MCM): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm Accessed April 2014.

In 1997, approval was broadened to include children 18 months of age or older. Equipment modifications led to the CLARION Bionic Ear and the Hi Resolution Bionic Ear systems, which were approved in 2002 for adults with postlingual onset of severe-to-profound (pure tone average of 70 dB or more hearing level), bilateral, sensorineural hearing impairment who obtain limited benefit, defined as test scores of 50% or less correct on a test of open-sentence recognition (HINT sentences) from appropriately fitted hearing aids and children aged 12 months to 17 years 11 months with profound, bilateral, sensorineural hearing loss who lack benefit from appropriately fitted hearing aids. The Harmony Hi Resolution Bionic Ear System™ subsequently received approval for the same indications. See the following web site for more information (use product code MCM): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Accessed April 2014.

The available literature occasionally mentioned other cochlear implantation devices, including the Digisonic® device (MXM Company, Vallauris, France), the Laura device (Cochlear CTEC, Mechelen, Belgium), the 3M device (Cochlear Corp.), and the Ineraid device (Smith & Nephew Richards). However, these devices have not received approval from the FDA (Digisonic, Laura), or are no longer manufactured (3M, Ineraid).

The FDA labeled indications for currently marketed cochlear implants are summarized in the following table.

FDA-Approved Cochlear Implant (CI)	FDA Labeled Indications
Advanced Bionics® http://www.bionicear.com/ -HiResolution® Bionic Ear System (HiRes	**Adults** • 18 years of age or older • Severe-to-profound, bilateral sensorineural hearing

90K)
-Predecessors: Clarion Multi-Strategy and-Clarion HiFocus
	loss [≥70 decibels (dB)]
	• Postlingual onset of severe or profound hearing loss
	• Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences)
	
	Children
	• 12 months through 17 years of age
	• Profound, bilateral sensorineural deafness (≥90 dB)
	• Use of appropriately fitted hearing aids for at least 6 months in children 2 through 17 years of age, or at least 3 months in children 12 through 23 months of age. The minimum duration of hearing aid use is waived if x-rays indicate ossification of the cochlea
	• Little or no benefit from appropriately fitted hearing aids
	  o In younger children (<4 years of age), lack of benefit is defined as a failure to reach developmentally appropriate auditory milestones (such as spontaneous response to name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or ≤20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice (70 dB SPL)
	  o In older children (≥4 years of age), lack of hearing aid benefit is defined as scoring ≤12% on a difficult open-set word recognition test (Phonetically Balanced-Kindergarten Test) or ≤30% on an open-set sentence test (Hearing in Noise Test for Children) administered using recorded materials in the soundfield (70 dB SPL)
	
	See the following for more information:
	http://thehearingblog.com/wp-content/uploads/Advanced-Bionics-HiRes90K-Harmony-System-Physicians-Package-Insert-9055522-001-RevA2.pdf
	
	http://www.advancedbionics.com/content/dam/ab/Global/en_ce/documents/libraries/Professional%20Library/AB%20Product%20Literature/System_Indications_Precautions/Indications_and_Contraindications.pdf
	Accessed April 2014

Cochlear™ Nucleus® http://www.cochlear.com -Nucleus® 5 and 6 series of CI devices -Predecessors: Nucleus 22 Channel Cochlear Implant System, Nucleus 24 Contour systems, and Nucleus Freedom	**Adults** • 18 years of age or older • Bilateral, pre, peri or post-linguistic sensorineural hearing impairment • Moderate-to-profound hearing loss in the low frequencies and profound (≥90 dB HL) hearing loss in the mid to high speech frequencies. • Limited benefit from appropriate binaural hearing aids. Limited benefit from amplification is defined by test

	scores of 50% correct or less in the ear to be implanted (60% or less in the best-aided listening condition) on tape-recorded tests of open set sentence recognition. **Children 12 to 24 months of age** • Bilateral profound sensorineural hearing loss • Limited benefit from appropriate binaural hearing aids. In younger children, 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 to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test. **Children 25 months through 17 years of age** • Bilateral severe-to-profound sensorineural hearing loss. • Limited benefit from appropriate binaural hearing aids. In older children, limited benefit is defined as ≤ 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A 3 to 6 month hearing aid trial is recommended for children without previous aided experience. See the following for more information: http://products.cochlearamericas.com/sites/default/files/Nucleus_Insert_web.pdf Accessed April 2014.

Med El®
http://www.medel.com/ENG/US/
-Maestro® (Sonata or Pulsar)
-Predecessor: Combi 40+
	Adults
	• 18 years of age of older
	• Severe-to-profound bilateral sensorineural hearing loss (≥ 70dB)
	• Limited benefit from appropriate binaural hearing aids defined as 40% correct or less in Hearing In Noise Test (HINT) sentences with best-aided listening condition
	
	Children
	• 12 months through 17 years of age with profound bilateral sensorineural hearing loss (≥ 90dB)
	• Limited benefit from appropriate binaural hearing aids
	  o In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills with hearing aids over a 3-6 month period
	  o In older children, lack of aided benefit is defined as < 20% correct on the Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical

	Neighborhood Test (LNT) depending upon the child's cognitive ability and linguistic skills o A 3 to 6 month trial with hearing aids is required if not previously experienced with hearing aids. Radiologic evidence of cochlear ossification may justify a shorter trial with amplification. See the following for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/P000025b.pdf Accessed April 2014.

For a current list of indications for each device, refer to the FDA web site for medical devices (Product code MCM [implant, cochlear]): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Accessed April 2014.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers cochlear implants when criteria are met. Refer to the National Coverage Determination (NCD) for Cochlear Implantation (50.3). There are Local Coverage Determinations (LCDs) that address the diagnostic analysis of cochlear or brain stem implant and programming. Refer to the LCDs for Vestibular and Audiologic Function Studies.

Also see the Medicare Benefit Policy Manual Chapter 16 §100 Hearing Aids and Auditory Implants at: http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf for additional information.

(Accessed May 5, 2014)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
08/01/2014	• Revised coverage rationale: o Changed coverage status for *cochlear hybrid implants for hearing loss* from "investigational" to "unproven and not medically necessary" • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references • Archived previous policy version 2014T0070M