COCHLEAR IMPLANTS

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INSTRUCTIONS FOR USE

This protocol 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 Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

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.

COMMERCIAL COVERAGE RATIONALE

When used according to U.S. Food and Drug Administration (FDA) labeled indications, bilateral or unilateral cochlear implantation is 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 **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.

**MEDICARE COVERAGE RATIONALE**

Medicare covers cochlear implants when criteria are met. Refer to the National Coverage Determination (NCD) for Cochlear Implantation (50.3) below. There are no Local Coverage Determinations (LCDs) for Nevada at this time. Accessed April 2016.

**Cochlear Implantation (50.3)**

**General**

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

**Indications and Limitations of Coverage**

Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition.

Medicare **coverage is provided** only for those patients who meet all of the following selection guidelines.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids, and
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation, and
- 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, and
- No contraindications to surgery, and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.
Effective for services performed on or after April 4, 2005, cochlear implantation **may be covered** for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

**Note:** Medicare beneficiaries not meeting **all** of the coverage criteria for cochlear implantation listed are **deemed not eligible** for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act. All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered above remain at local contractor discretion.

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**
Please review Local Coverage Determinations that apply to other states outside of Nevada.
http://www.cms.hhs.gov/mcd/search

**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

**MEDICAID COVERAGE RATIONALE**


1. Bilateral and unilateral cochlear implants are a Nevada Medicaid covered benefit when determined to be medically necessary for eligible recipients with profound hearing impairment. **Covered services include** but are not limited to:
   a. otologic examination
   b. audiological evaluation
   c. physical examination
   d. psychological evaluation
   e. surgical implantation of the device
   f. postoperative follow-up evaluation and rehabilitation.

2. Coverage is restricted to those recipients, who meet the following audiologic/medical criteria as determined by a physician or audiologist:
   a. recipient must be referred by an M.D. or Ear, Nose and Throat specialist with documentation to determine medical candidacy for such a device. This is to include recent (within 6 months) results of a CT or MRI scan to evaluate the anatomy of the inner ear; and
   b. must be at least 12 months of age or older; and
   c. must suffer from severe to profound pre-or post-lingual hearing loss (70 decibels or greater) confirmed by audilogic testing that obtains limited or no benefit from appropriate hearing aids for six months or greater; and
d. must have the cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation; and

e. must be free of middle ear infection; and

f. must have an accessible cochlear lumen that is structurally suited to implantation; and

g. be free of lesions in the auditory nerve and acoustic areas of the central nervous system; and

h. have no contraindications for the surgery.

3. Use of the device must be in accordance with the Food and Drug Administration (FDA) approved labeling.

4. There must be good family support with self motivation, as determined by a physician or audiologist. Education of families/caregiver and the recipient must be conducted to ensure understanding of the benefits and limitations of the device, appropriate expectations, commitment to the development of auditory and verbal skills, dedication to the therapeutic program and the ability to adequately care for the external equipment.

5. Adults:
Cochlear implants may be covered for pre-linguistically (before the development of language), pre-linguistically (during the development of language), and post-linguistically (after language has fully developed) deafened adults (over age 21). Post-linguistically deafened adults must demonstrate test scores of 40% or less on sentence recognition scores from tape recorded tests in the recipient’s best listening condition.

6. Children:
Cochlear implants may be covered for pre-linguistically and post-linguistically deafened children from 12 months through 20 years of age. Bilateral profound sensorineural deafness must be demonstrated by the inability to improve on age appropriate closed set word identification tasks with amplification.

7. Rehabilitation Program
A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant for both children and adults. The program is performed by an audiologist and speech-language pathologists. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants, vowels and tests of speech perception ability. Refer to Chapter 1700 for Therapy Services of the Medicaid Service Manual.

8. Warranty
The limited warranty must be included in the documentation from the product manufacturer. Services beyond the warranty must be prior authorized.

9. Damage and Loss
Damage and loss insurance is required at the time of implant. Insurance must be all inclusive for replacement and loss, no deductibles or co-pays are allowed. There must be continuous insurance coverage for five years. Insurance is not to exceed $250/year.
PRIOR AUTHORIZATION
Prior authorization is required with medical documentation to substantiate the request for the cochlear implant.

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 evidence of coverage (EOC) or certificate of coverage (COC) must be referenced to determine the DME benefits for upgrade 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 benefit document must be referenced for any applicable limits that may apply to aural rehabilitation.

Cochlear implants are not hearing aids. Please see the appropriate evidence of coverage (EOC) or the medical protocol 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.

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, 2011).
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 slight (16 to 25 decibels (dB) hearing loss), mild (26 to 40 dB hearing loss), moderate (41 to 55 dB hearing loss), moderately severe (56 to 70 dB hearing loss), 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™ L24 Cochlear Implant System) 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 Nucleus Hybrid L24 Cochlear 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).

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).

**Professional Societies**

**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).

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.

**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**

Humphris 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.

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, 2011).

**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
deafered 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.

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.

In a systematic review, 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.

Sarant et al. (2014) compared language abilities of children having unilateral and bilateral cochlear
implants (CIs) to quantify the rate of any improvement in language attributable to bilateral CIs and to
document other predictors of language development in 91 children with CIs. Children using bilateral
CIs achieved significantly better vocabulary outcomes and significantly higher scores on the Core and
Expressive Language subscales of the Clinical Evaluation of Language Fundamentals than did
comparable children with unilateral CIs. Bilateral CI use was found to predict significantly faster rates of vocabulary and language development than unilateral CI use; the magnitude of this effect was moderated by child age at activation of the bilateral CI. The authors concluded that children with bilateral CIs achieved significantly better vocabulary outcomes, and 8-year-old children with bilateral CIs had significantly better language outcomes than did children with unilateral CIs. These improvements were moderated by children's ages at both first and second CIs. The outcomes were also significantly predicted by a number of factors related to parenting, child characteristics, and family background.

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 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

In a prospective single-arm trial, Roland et al. (2015) evaluated the safety and efficacy of acoustic and electric sound processing for individuals with significant residual low-frequency hearing and severe-to-profound high-frequency sensorineural hearing loss. Fifty individuals, ≥ 18 years old, with low-frequency hearing and severe high-frequency loss were implanted with the Cochlear Nucleus Hybrid L24 implant at 10 investigational sites. Preoperatively, subjects demonstrated consonant-nucleus-consonant word scores of 10% through 60% in the ear to be implanted. Subjects were assessed prospectively, preoperatively, and postoperatively on coprimary endpoints of consonant-nucleus-consonant words, AzBio sentences in noise, and self-assessment measures. Significant mean improvements were observed for coprimary endpoints: consonant-nucleus-consonant words (35.8 percentage points) and AzBio sentences in noise (32.0 percentage points). Ninety-six percent of subjects performed equal or better on speech in quiet and 90% in noise. Eighty-two percent of subjects showed improved performance on speech in quiet and 74% in noise. Self-assessments were positive, corroborating speech perception results. The authors concluded that the Nucleus Hybrid System provides significant improvements in speech intelligibility in quiet and noise for individuals with severe high-frequency loss and some low-frequency hearing. According to the authors, the study limitations include nonrandomized design, limited sample size, and limited duration of follow-up. The authors recommend that there be additional longer term follow-up for safety and study of the device in larger and diverse subgroups.

Jurawitz et al. (2014) investigated the degree and progression of hearing preservation over a longitudinal postoperative period in a consecutive cohort of implanted patients with preoperative residual hearing who received either the Nucleus Hybrid-L24 or the Nucleus Freedom CI422 implant.
The intention was to examine potential characteristics and triggers of resulting postoperative hearing loss which may support a differentiation of CI candidacy criteria for a certain implant type. A retrospective data analysis of patient files on consecutively implanted subjects presenting with a severe-to-profound sensorineural hearing loss at frequencies >1,500 Hz and substantial residual hearing at frequencies ≤1,500 Hz, implanted with a Nucleus Hybrid-L24 (n=97) or a CI422 implant (n=100), was undertaken. A single-subject repeated-measure design comparing the mean threshold shift for pure-tone thresholds under headphones up to 24 months after implantation was used. Hearing preservation is observed in the majority of subjects with either implant (250-1,500 Hz frequency range). Hybrid-L24 patients exhibited a median hearing loss of 10 dB at initial fitting (n=97) and of 15 dB after 24 months (n=51). A 14.4-dB decrease in median hearing loss at initial fitting (n=100) and a 30-dB decrease after 24 months (n=28) was observed with the CI422 electrode. At initial fitting, 54.6% of the Hybrid-L24 (n=97) and 49.0% of the CI422 (n=100) subjects showed a mean threshold shift <15 dB. After 24 months, 58.8% (Hybrid-L24, n=51) and 28.6% (CI422, n=28) of the patients showed a mean threshold shift <15 dB. According to the authors, the study results indicate that residual hearing was preserved for the majority of implanted patients with the Hybrid-L24 and the CI422 implant. Patients implanted with the Hybrid-L24 implant demonstrate greater stability and less median hearing loss over time than those with the CI422 implant. The authors stated that assessments of onset and stability of hearing loss prior to implantation are important factors to consider during candidacy evaluation for electrode selection to potentially maximize the performance outcome for each patient. Additional studies are needed to determine which group of patients would benefit most from 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.

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.

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 Food and Drug Administration (FDA) issued a notification 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 emphasized the importance of ensuring that all pediatric CI users are appropriately vaccinated against Streptococcus pneumoniae and are monitored and promptly treated for bacterial infections. See the following Web site for more information: [http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/ucm062892.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/ucm062892.htm). Accessed April 2016.

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 2016.

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).

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 2016. 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/cfr/rl/rl.cfm?lid=8605&lpcd=MCM. Accessed April 2016.


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 site for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=12357. Accessed April 2016.

The Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Limited; Cochlear Americas) was approved by the FDA on March 20, 2014. According to the approval order statement, the Nucleus 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:

The FDA approval of the Nucleus® Hybrid L24 Cochlear Implant System 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:

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):
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):

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.

<table>
<thead>
<tr>
<th>FDA Approved Cochlear Implant (CI)</th>
<th>FDA Labeled Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Bionics®</td>
<td>Adults:</td>
</tr>
<tr>
<td><a href="http://www.advancedbionics.com/us/en/home.html">http://www.advancedbionics.com/us/en/home.html</a></td>
<td>- 18 years of age or older</td>
</tr>
<tr>
<td>HiResolution® Bionic Ear System (HiRes90K) -Predecessors: Clarion Multi-Strategy and Clarion HiFocus</td>
<td>- Severe-to-profound, bilateral sensorineural hearing loss [≥70 decibels (dB)]</td>
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<td></td>
<td>- Postlingual onset of severe or profound hearing loss</td>
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<tr>
<td></td>
<td>- Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences)</td>
</tr>
</tbody>
</table>
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
  - 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).
  - 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:

Accessed April 2016.

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.
<table>
<thead>
<tr>
<th>Age Group</th>
<th>Conditions/Definitions</th>
</tr>
</thead>
</table>
| 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. |
| 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  
  - 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  
  - 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  
  - 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:  
Accessed April 2016.

Med El®  
-Maestro® (Sonata or Pulsar)  
-Predecessor : Combi 40+

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_docs/pdf/P000025b.pdf](http://www.accessdata.fda.gov/scripts/cdrh_docs/pdf/P000025b.pdf)  
Accessed April 2016.
**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan 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 claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<th>CPT® Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>69930</td>
<td>Cochlear device implantation, with or without mastoidectomy</td>
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*CPT® is a registered trademark of the American Medical Association.*

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<th>HCPCS Code</th>
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<td>Cochlear device, includes all internal and external components</td>
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<tr>
<td>L8615</td>
<td>Headset/headpiece for Use with cochlear implant device, replacement</td>
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<tr>
<td>L8616</td>
<td>Microphone for Use with cochlear implant device, replacement</td>
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<td>L8617</td>
<td>Transmitting coil for Use with cochlear implant device, replacement</td>
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<tr>
<td>L8618</td>
<td>Transmitter cable for Use with cochlear implant device, replacement</td>
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<tr>
<td>L8619</td>
<td>Cochlear implant external speech processor and controller, integrated system, replacement</td>
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<td>Cochlear implant, external controller component, replacement</td>
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<td>L8629</td>
<td>Transmitting coil and cable, integrated, for use with cochlear implant device, replacement</td>
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**REFERENCES**


## PROTOCOL HISTORY/REVISION INFORMATION

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The foregoing Health Plan of Nevada/Sierra Health & Life Healthcare Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.