COCHLEAR IMPLANTS

Policy Number: ENT 004.28 T2 **Effective Date**: January 1, 2019

Instructions for Use

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Related Policies

- Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements
- Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package
Referral Required (Does not apply to non-gatekeeper products)	Yes[1,2]
Authorization Required (Precertification always required for inpatient admission)	No - Office, Outpatient[1] Yes - Inpatient
Precertification with Medical Director Review Required	No[1]
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Inpatient, Outpatient, Office
Special Considerations	[1]Precertification with review by a Medical Director or their designee is required only for surgical implantation and initial provision of the cochlear device and components (CPT codes 69930, L8614 and L8619). [2]A referral is required for all other services listed in the policy in both the office and outpatient setting.

COVERAGE RATIONALE

See Benefit Considerations

The following are proven and medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions:

- **Non-hybrid cochlear implantation (unilateral or bilateral) for treating individuals who meet ALL of the following criteria:**
  - Diagnosis of bilateral prelingual or postlingual moderate-to-profound-Sensorineural Hearing Loss; and
  - Limited benefit (Refer to the FDA section) from appropriate hearing (or vibrotactile) aids. A hearing aid trial is not required in an individual with a concern for meningitis-related cochlear ossification; and
  - Ability to follow or participate in a program of aural 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

- **Hybrid cochlear implantation for treating individuals who meet ALL of the following criteria:**
  - Diagnosis of bilateral severe to profound Sensorineural Hearing Loss in the mid to high frequencies with residual low-frequency hearing sensitivity; and
  - Ability to follow or participate in a program of aural 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

DEFINITIONS

Degree of Hearing Loss:

Degree of Hearing Loss	Range (dbHL = decibels hearing level)
Normal hearing	-10 to15 dBHL
Slight Loss	16 to 25 dBHL
Mild Loss	26 to 40 dBHL
Moderate Loss	41 to 55 dBHL
Moderately Severe Loss	56 to 70 dBHL
Severe Loss	71 to 90 dBHL
Profound Loss	91 dBHL or more

(ASHA, Type, Degree and Configuration of Hearing Loss; Clark, 1981)

Sensorineural Hearing Loss (SNHL): Occurs when there is damage to the inner ear (cochlea), or to the nerve pathways from the inner ear to the brain. Most of the time, SNHL cannot be medically or surgically corrected. This is the most common type of permanent hearing loss (American Speech-Language-Hearing Association (ASHA). Sensorineural Hearing Loss).

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 may apply.

CPT Code	Description
69930*	Cochlear device implantation; with or without mastoidectomy

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*Precertification is required in all sites of service.

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 or auditory osseointegrated device, replacement
L8619*	Cochlear implant external speech processor and controller, integrated system, replacement
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement
V5273	Assistive listening device, for use with cochlear implant

*Precertification is required in all sites of service.

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 (CI) 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 (CI) 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 CI does not magnify sound, none of its components are considered a hearing aid.

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 individual wears appropriately fitted hearing aids, often described as the best-aided condition. Cochlear implants may be considered for use in individuals 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 lip reading ability, improved recognition of environmental sounds and improved speech intelligibility.

Typically, individuals 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.

Hybrid cochlear implants use electric-acoustic stimulation (EAS) that simultaneously combines electro-stimulation technology used in traditional cochlear implants with acoustic amplification technology used in hearing aids. Hybrid cochlear devices are intended to be used in individuals with severe to profound Sensorineural Hearing Loss with residual low-frequency hearing sensitivity. To preserve low-frequency hearing, implant electrodes are designed to minimize cochlear trauma and are placed in the cochlea using an optimum surgical approach. (Friedland and Runge-Samuelson, 2009)

BENEFIT CONSIDERATIONS

Cochlear implant monitoring (remapping and reprogramming of implant) and rehabilitation following the cochlear implant surgery is usually billed as aural rehabilitation and is covered as an outpatient rehabilitation therapy benefit. The member specific benefit plan document must be referenced for any applicable limits that may apply to aural rehabilitation.

Cochlear implants are not hearing aids. Please refer to the 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 Care Service and are excluded from coverage. These do not prevent, diagnose or treat a sickness or injury, and are not integral to the function of the cochlear implant itself.

CLINICAL EVIDENCE

Unilateral Cochlear Implantation in Adults

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. Cochlear implant recipients with greater amounts of preimplant residual hearing demonstrate superior postimplant spoken word recognition. Presumably, persons with greater residual hearing have a more intact auditory system with a larger number of surviving neural elements to stimulate. (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. Cochlear implantation in the early preschool years and possibly in infancy followed by high quality aural rehabilitation and speech training should improve the proportion of children with good speech and language outcomes. (ASHA, 2004)

Cochlear Implantation for Auditory Neuropathy

Fernandes et al. (2015) conducted a systematic review of the literature to summarize the evidence regarding the performance of hearing skills in children with auditory neuropathy spectrum disorder (ANSD) using cochlear implants (CIs). Eighteen articles and two dissertations met the criteria and were included in this systematic review. Of those studies, five were non-randomized controlled trials of high quality, five were characterized as randomized controlled trials of low quality, and ten were clinical outcome studies. The results suggest that after CI use, individuals with ANSD improve in the detection of speech sounds, speech discrimination, and the recognition of words and sentences, but still have difficulty in speech perception in noisy conditions, and that there is no difference in the test scores of the hearing skills of ANSD/CI children and CI children with sensorineural hearing loss, with respect to speech detection, discrimination, and recognition of words and sentences. The authors concluded that additional long-term studies of ANSD/CI children are needed in order to guide the rehabilitation process in this population.

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.

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, updated 2017)

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)

A systematic review conducted by Berrettini et al. (2011) 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.

van Zon et al. (2017) conducted a multicenter randomized controlled trial to investigate hearing capabilities and self-reported benefits of simultaneous bilateral cochlear implantation (BiCI) compared with unilateral cochlear implantation (UCI) after a 2-year follow-up and evaluated the learning effect of cochlear implantees over time. Thirty-eight postlingually deafened adults were included in this study and randomly assigned to either UCI or simultaneous BiCI. The primary outcome was speech intelligibility in noise, with speech and noise coming from straight ahead (Utrecht-Sentence Test with Adaptive Randomized Roving levels). Secondary outcomes were speech intelligibility in noise with spatially separated sources, speech intelligibility in silence (Dutch phoneme test), localization capabilities and self-reported benefits assessed with different quality of hearing and quality of life (QoL) questionnaires. The patients were followed for two years and results showed comparable results for the UCI and simultaneous BiCI group, when speech and noise were both presented from straight ahead, however patients in the BiCI group performed significantly better than patients in the UCI group, when speech and noise came from different directions, and were better able to localize sounds. These results were consistent with patients' self-reported hearing capabilities, but not with the questionnaires regarding QoL. The authors found no significant differences on any of the subjective and objective reported outcomes between the 1-year and 2-year follow-up. The authors concluded that this study demonstrates important benefits of simultaneous BiCI compared with UCI that remain stable over time. Bilaterally implanted patients benefit significantly in difficult everyday listening situations such as when speech and noise come from different directions, and are able to localize sounds, which is impossible for unilaterally implanted patients.

In a multicenter randomized clinical trial, Smulders et al. (2016) determined the benefits of simultaneous bilateral cochlear implantation (BCI) compared with unilateral cochlear implantation (UCI) in adults with postlingual deafness. Thirty-eight patients were included in the trial. Nineteen participants were randomized to undergo UCI and 19 to undergo BCI. Fifteen patients in the BCI group used hearing aids before implantation compared with 19 in the UCI group. Otherwise, there were no significant differences between the groups' baseline characteristics. At 1-year follow-up, there were no significant differences between groups on the Utrecht Sentence Test with Adaptive Randomized Roving levels or the consonant-vowel-consonant test. The BCI group performed significantly better than the UCI group when noise came from different directions. The BCI group was better able to localize sounds. These results were consistent with the patients' self-reported hearing capabilities. According to the authors, this randomized clinical trial demonstrates a significant benefit of simultaneous BCI above UCI in daily listening situations for adults with postlingual deafness.

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.

A systematic review conducted by Forli et al. (2011) 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. The following outcome measures were analyzed: audiological, speech perception, speech production, functional capacities, health related quality of life, and/or educational outcomes. 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.

Hybrid Cochlear Implants

Pillsbury et al. (2018) evaluated the safety and effectiveness of the MED-EL Electric-Acoustic Stimulation (EAS) System (a hybrid cochlear implant), for adults with residual low-frequency hearing and severe-to-profound hearing loss in the mid to high frequencies in a prospective, repeated measures study. Subjects implanted with PULSAR or SONATA cochlear implants with FLEX electrode arrays were included in the study. Subjects were fit postoperatively with an audio processor, combining electric stimulation and acoustic amplification. Unaided thresholds were measured preoperatively and at 3, 6, and 12 months postactivation. Speech perception was assessed at these intervals using City University of New York sentences in noise and consonant-nucleus-consonant words in quiet. Subjective benefit was assessed at these intervals via the Abbreviated Profile of Hearing Aid Benefit and Hearing Device Satisfaction Scale questionnaires. Sixty-seven of 73 subjects (92%) completed outcome measures for all study intervals. Of those 67 subjects, 79% experienced less than a 30 dB HL low-frequency pure-tone average (250-1000 Hz) shift, and 97% were able to use the acoustic unit at 12 months postactivation. In the EAS condition, 94% of subjects performed similarly to or better than their preoperative performance on City University of New York sentences in noise at 12 months postactivation, with 85% demonstrating improvement. Ninety-seven percent of subjects performed similarly or better on consonant-nucleus-consonant words in quiet, with 84% demonstrating improvement. The investigators concluded that the MED-EL EAS System is a safe and effective treatment option for adults with normal hearing to moderate sensorineural hearing loss in the low frequencies and severe-to-profound sensorineural hearing loss in the high frequencies who do not benefit from traditional amplification.

Roland et al. (2018) assessed the long-term benefits of implantation in patients with high-frequency sensorineural hearing loss by reviewing the 5-year follow-up on a group of implant recipients who were subjects of the Cochlear™ Nucleus® Hybrid™ L24 Implant System pivotal clinical study (Roland et al., 2016). The results of three related clinical studies were compiled to provide outcome data after 1, 3, and 5 years of implant use in a group of subjects who presented with preoperative high-frequency hearing loss and were implanted with a Nucleus Hybrid L24 cochlear implant. A subset of the 50 adult subjects (N = 32) who participated in the Hybrid L24 pivotal Investigational Device Exemption (IDE) completed comprehensive evaluations at 12 months postactivation, 3 years postactivation, and then as part of a postapproval study at 5 years postactivation. Testing included audiometric, speech perception, and subjective satisfaction measures. Mean unilateral speech perception performance was significantly improved at all postoperative intervals compared to preoperative best-aided results and has remained stable to 5 years postactivation. Ninety-four percent of subjects had measurable hearing, and 72% continued to use electric-acoustic stimulation in the

implanted ear after 5 years of implant use. Subjective satisfaction results support objective performance improvements. The authors concluded that the study results demonstrate long-term success of patients with high-frequency hearing loss following Hybrid L24 (Cochlear) cochlear implantation. According to the authors, benefits include speech perception abilities significantly better than those in the preoperative best-aided condition, with additional benefit in those using electric-acoustic stimulation in the implanted ear.

In a prospective single-arm trial, Roland et al. (2016) 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.

Kelsall et. al (2017) conducted a prospective, multicenter, nonrandomized, single-arm repeated measures, single-subject design study on the patient-reported outcomes (PROs) from the above clinical trial (Roland et al., 2016) for individuals with significant residual low-frequency hearing and severe-to-profound high-frequency sensorineural hearing loss (SNHL) who received the hybrid cochlear implant (CI). Fifty adults seen in tertiary ambulatory care centers, with severe-to-profound high-frequency SNHL and residual low-frequency hearing with aided word recognition scores between 10 and 60% in the ear to be implanted, and in the contralateral ear greater than or equal to implant ear less than or equal to 80% were evaluated. Speech, spatial and qualities of hearing scale (SSQ), device use questionnaire (DUQ), University of Washington Clinical Assessment of Music Perception (UW-CAMP) were assessed preoperatively and after 6 and 12 months of hybrid CI use. The results showed significant improvements in mean SSQ ratings were demonstrated at 6 and 12 months postactivation overall and for domains related to speech hearing, spatial hearing, and sound quality. Significant improvement was also found for overall satisfaction on the DUQ and across a number of specific listening situations in addition to aspects related to social engagement. UW-CAMP pitch discrimination and melody and timbre recognition abilities were not compromised postoperatively, allowing hybrid subjects to maintain superior music perception abilities than typically observed with standard CIs. The authors concluded that patients who received the hybrid CI demonstrated significant PRO benefits on the SSQ and the DUQ after 6 and 12 months of CI use. In addition, given the opportunity to maintain useful low-frequency acoustic hearing, patients retained music listening abilities, as assessed by the UW-CAMP.

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. 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.

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)

Gantz et al. (2016) describe the final outcomes of a multicenter, longitudinal, single-subject design study of the Nucleus Hybrid S8 CI that took place between 2002 and 2011. Eighty-seven subjects received a Nucleus Hybrid S8 CI in their poorer ear. Speech perception in quiet (Consonant-Nucleus-Consonant [CNC] words) and in noise (Bamford-Kowal-Bench Sentences-In-Noise [BKB-SIN]) were collected pre- and postoperatively at 3, 6, and 12 months. Subjective questionnaire data using the Abbreviated Profile for Hearing Aid Benefit (APHAB) were also collected. Some level of hearing preservation was accomplished in 98% subjects, with 90% maintaining a functional low-frequency pure-tone average (LFPTA) at initial activation. By 12 months, five subjects had total hearing loss, and 80% of subjects maintained functional hearing. CNC words demonstrated that 82.5% and 87.5% of subjects had significant improvements in the hybrid and combined conditions, respectively. The majority had improvements with BKB-SIN. Results also indicated that as long as subjects maintained at least a severe LFPTA, there was significant improvement in speech understanding. Furthermore, all subjects reported positive improvements in hearing in three of the four subscales of the APHAB. According to the authors, the concept of hybrid speech processing has significant advantages for subjects with residual low-frequency hearing. Fourteen subjects requested the Hybrid S8 implant be removed because of dissatisfaction with the device. Most experienced a progressive loss of acoustic hearing in the implant ear.

Friedmann et al. (2015) conducted a retrospective chart review to compare rates of hearing preservation and effects on performance of loss of low-frequency acoustic hearing with two different length electrodes. Twelve patients were implanted with the CI422 a slim-straight electrode; the second group consisted of 10 patients implanted with the Hybrid-L, a shorter hearing preservation electrode. At 1 year, 3/10 (30%) patients with the Hybrid-L and 7/12 (58%) patients with the CI422 lost residual acoustic hearing resulting in a profound hearing loss in the implanted ear. In comparing these patients in particular, mean Consonant-Nucleus-Consonant (CNC) words in the implanted ear were 72% in the CI422 electrode group and 15% in the Hybrid-L electrode group at 1 year. While hearing preservation rates with the Hybrid-L tended to be better, among recipients who lost residual hearing, speech perception was better in those with the longer CI422 electrode. The authors stated that patients need to be counseled regarding possible outcomes and options should loss of residual hearing occur following implantation. While shorter electrodes may have better rates of hearing preservation, the patients with the longer straight electrode in the study had significantly better speech understanding following the loss of residual hearing.

Erixon et al. (2015) measured patient satisfaction and correlated to hearing results in partially deaf patients, after hearing preservation cochlear implant surgery with hybrid hearing strategy, and evaluated the stability of residual low-frequency hearing (LFH) over time. The study design consisted of a patient satisfaction survey and a retrospective, 2-year follow-up journal study. Nineteen partially deaf patients intended for hybrid hearing responded to a questionnaire when they had used their cochlear implants for at least a year. The questionnaire consisted of the International Outcome Inventory for Hearing Aids, EuroQol Group visual analogue scale and nine questions about hybrid hearing. Pure-tone audiometry, monosyllables, and hearing in noise test results from the patients' medical records were evaluated and compared with the results from the patient satisfaction survey. All of the patients were satisfied with their CIs. The mean International Outcome Inventory for Hearing Aids score was 29. The CIs provided a

major contribution to the speech comprehension of these partially deaf patients. Two years after surgery, the patients' mean binaural score on tests of monosyllables was 58%, and the mean signal to noise ratio was 4.6 dB. We observed ongoing deteriorations in the residual hearing of the operated ears that surpassed the deteriorations observed in the contralateral ears. One month after surgery, the LFH loss (125-500 Hz) was 17 dB, and after 2 years, this loss was 24 dB compared with 5 dB in the nonoperated ear. There were no significant correlations between preserved LFH and patient satisfaction or speech perception results. The authors concluded that electric stimulation provided a major contribution to speech comprehension of partially deaf patients. According to the authors, the gain reached in speech understanding widely exceeded the downside in losing some residual hearing.

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.

Meningitis-Related Cochlear Ossification

Durisin et al. (2015) determined the impedance values and charge consumption following cochlear implantation post-meningitic deaf children depending on the grade of cochlear ossification and obliteration. Post-meningitic deaf (n=49) and control (n=43) children treated with cochlear implants were included in the study. Impedance and charge values were calculated for each group. The degree of ossification of the cochlea was evaluated from a high-resolution computed tomography (HRCT) scan whereas the degree of obliteration was determined intraoperatively by the surgeon. Pneumococci were the principal pathogen responsible for bacterial meningitis, followed by meningococci. In HRCT scans, the degree of ossification was 1 and 2 in 29% of patients. The results of the intraoperative assessment of the cochlea showed obliteration grade 1 in 38% and grade 2 in 23% of cases. Children in the meningitis group showed significant higher impedances comparing to the control group. A significantly increased charge consumption was observed in patients with a grade 2 ossification when compared to those without ossification. Discussion Cochlea implanted children with meningitis-related deafness exhibit higher impedances, especially in the region of the basal and middle turn, however, not depending on the degree of cochlear ossification. High impedances and charge in the meningitis group may be explained by alterations in the central auditory pathway or on the electrode surface. The authors concluded that to optimize the outcome in post-meningitic deaf children, surgery is advisable at an early stage prior to the onset of cochlear ossification.

Philippon et al. (2010) proposed guidelines in the management of a profound bilateral sensorineural hearing loss after bacterial meningitis. The study was designed as a retrospective chart review that included 40 patients who had postmeningitic cochlear implantation surgeries. Twenty-seven children and 13 adults with postmeningitic deafness were implanted. Mean age was 3 years 8 months for the children and 44 years and 10 months for the adults. The mean time delay between meningitis and surgery was 2 years 1 month for children and 28 years for adults. Eighteen children (67%) were implanted within a year. Labyrinthitis ossificans was evidenced at surgery in 62% of patients. Intraoperative cochlear ossification was classified according to the scale described by Smullen and Balkany (2005). Stage II ossification was seen in 3 patients within 49 days, with 1 of them as soon as 21 days. There was a partial insertion in 9 patients secondary to ossification. Open-set speech discrimination was achieved by 37% of the children (10 of 27) and 23% of the adults (3 of 13). The authors recommend early cochlear implantation for patients with bilateral profound deafness secondary to meningitis.

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 (AAO): 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. Multichannel cochlear implants are appropriate for children with prelingual or postlingual deafness. Generally, a pure tone average (500, 1000, 2000 Hz) of 90dB HL or greater in both ears is indicated. (American Academy of Audiology (AAA): Cochlear Implants in Children)

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)

Additional Search Terms

Cochlear prosthesis

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Hybrid Cochlear Implants

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. Refer to the following website for more information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P130016. (Accessed April 19 2018)

In September 2016, the FDA approved the Med EL EAS™ (Electric Acoustic Stimulation) Hearing Implant System (Med EL Corp.). This system is a hybrid cochlear implant and hearing aid, with the hearing aid integrated into the external sound processor of the cochlear implant. It is the combination of the SYNCHRONY cochlear implant and the SONNET EAS audio processor. The MED-EL EAS System is indicated for partially deaf individuals aged 18 years and older who have residual hearing sensitivity in the low frequencies sloping to a severe/profound sensorineural hearing loss in the mid to high frequencies, and who obtain minimal benefit from conventional acoustic amplification. Typical

preoperative hearing of candidates ranges from normal hearing to moderate sensorineural hearing loss in the low frequencies (thresholds no poorer than 65 dB HL up to and including 500 Hz) with severe to profound mid- to high-frequency hearing loss (no better than 70 dB HL at 2000 Hz and above) in the ear to be implanted. For the non-implanted ear, thresholds may be worse than the criteria for the implanted ear, but may not be better. The CNC word recognition score in quiet in the best-aided condition will be 60% or less, in the ear to be implanted and in the contralateral ear. Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids. Refer to the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/p000025s084b.pdf. (Accessed April 19, 2018)

Cochlear Implants (Non-Hybrid)

At the present time, FDA-approved cochlear implant devices are manufactured by 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. FDA approval language does not address unilateral or bilateral use.

The FDA labeled indications for currently marketed non-hybrid cochlear implants are summarized in the following table:

FDA-Approved Cochlear Implants (Non-Hybrid)	FDA Labeled Indications

Advanced Bionics®
• http://www.advancedbionics.com/us/en/home.html
• HiResolution® Bionic Ear System (HiRes 90K)
• Predecessors:
  ○ Clarion Multi-Strategy
  ○ Clarion HiFocus
	Adults
	• 18 years of age or older
	• Severe-to-profound, bilateral sensorineural hearing 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.
	  ○ 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).

Cochlear™ Nucleus® • http://www.cochlear.com • Nucleus® 5 and 6 series of CI devices • Predecessors: ○ Nucleus 22 Channel Cochlear Implant	**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

FDA-Approved Cochlear Implants (Non-Hybrid)	FDA Labeled Indications
System ○ Nucleus 24 Contour systems ○ Nucleus Freedom	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://www.cochlear.com/wps/wcm/connect/us/for-professionals/products/cochlear-implants/candidacy • http://www.cochlear.com/wps/wcm/connect/us/recipients/nucleus-5/nucleus-5-basics (Accessed May 1, 2018)
Med El® • http://www.medel.com/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 ○ 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:

FDA-Approved Cochlear Implants (Non-Hybrid)	FDA Labeled Indications
	• http://www.accessdata.fda.gov/cdrh_docs/pdf/P000025b.pdf • http://www.medel.com/indications/ (Accessed May 18, 2018)

For a current list of indications for each device, refer to the following FDA web sites [use product code MCM (implant, cochlear)]:

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

(Accessed May 1, 2018)

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).

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*2019T0070W*]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description

01/01/2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section
	• Updated and reformatted coverage rationale:
	  ○ Simplified content
	  ○ Removed criterion requiring "no contraindications to surgery"
	• Added definition of "Sensorineural Hearing Loss (SNHL)"
	• Updated list of applicable HCPCS codes; revised description for V5273
	• Updated supporting information to reflect the most current references
	• Archived previous policy version ENT 004.27 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies 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.