Cochlear Implants (for New Jersey Only)

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Instructions for Use

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Related Policies

- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for New Jersey Only)
- Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable (for New Jersey Only)

Application

This Medical Policy only applies to the state of New Jersey.

Coverage Rationale

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
  - 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

Hybrid and non-hybrid cochlear implantation are unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:

- Single sided deafness or unilateral Sensorineural Hearing Loss
- All other conditions that do not meet the above criteria

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, 2015; 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 federal, state, or contractual requirements 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 Guidelines may apply.

CPT Code	Description
69930	Cochlear device implantation, with or without mastoidectomy

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HCPCS Code	Description
L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device 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

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. Cochlear implantation has traditionally been

used to treat bilateral moderate-to-profound-Sensorineural Hearing Loss. Cochlear implantation is being studied for treating single sided deafness (SSD) or unilateral Sensorineural Hearing Loss in individuals who have profound sensorineural hearing loss in one ear and normal hearing or mild Sensorineural Hearing Loss in the other ear.

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 cochlear implant 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 in individuals with bilateral moderate-to-profound-Sensorineural Hearing Loss. 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 optimal surgical approach (Friedland and Runge-Samuelson, 2009).

Clinical Evidence

Non-Hybrid Cochlear Implantation in Adults for Bilateral Hearing Loss

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 a meta-analysis, Gaylor et al. (2013) evaluated the communication-related outcomes and health-related QOL outcomes after unilateral or bilateral cochlear implantation in adults with sensorineural hearing loss. A total of 42 studies met the inclusion criteria. Most unilateral implant studies showed a statistically significant improvement in mean speech scores as measured by open-set sentence or multisyllable word tests; meta-analysis revealed a significant improvement in QOL after unilateral implantation. Most included studies compared pre- to post-implantation results, except one that compared cochlear implants to hearing aids and demonstrated a benefit in communication-related outcomes. Results from studies assessing bilateral implantation showed improvement in communication-related outcomes compared with unilateral implantation and additional improvements in sound localization compared with unilateral device use or implantation only.

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 included a review of 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. The assessment also included a review of 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).

Clinical Practice Guidelines

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).

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).

Non-Hybrid Cochlear Implantation in Children for Bilateral Hearing Loss

Hoff et al. (2019) evaluated the safety and effectiveness of cochlear implantation of 219 children under age 37 months in a retrospective cohort study comparing early (age < 12 months) to later (age 12 months or older) implantation. A total of 39 children implanted below age 12 months and 180 children implanted at age 12-36 months were included in the study. The main outcome measures included surgical and anesthesia complications, measurable open-set speech discrimination, primary communication mode(s). Few surgical complications occurred, with no difference by age group. No major anesthetic morbidity occurred, with no critical events requiring intervention in the younger group while four older children experienced desaturations or bradycardia/hypotension. Children implanted under 12 months developed open-set earlier (3.3 years vs. 4.3 years, $p \leq 0.001$) and were more likely to develop oral-only communication (88.2% vs. 48.8%, $p \leq 0.001$). A significant decline in rate of oral-only

communication was present if implanted over 24 months, especially when comparing children with and without additional conditions associated with language delay (8.3% and 35%, respectively). The authors concluded that implantation of children under 37 months of age can be done safely, including those below age 12 months. According to the authors, implantation below 12 months is positively associated with earlier open-set ability and oral-only communication. Children implanted after age 24 months were much less likely to use oral communication exclusively, especially those with complex medical history or additional conditions associated with language delay. Comparisons using level of speech perception ability were not possible in this study due to the young ages and range of developmental status which required clinical use of different test measures and procedures. Strengths of the study included comparisons of patient-centered outcomes between groups receiving intervention at different ages. Weakness included lack of clarify on whether the two groups were contemporaneous and lack of randomization, which could have introduced biases in the findings.

In a retrospective cohort study, Kim et al. (2017) determined the perioperative morbidity of 186 children ≤ 12 months undergoing cochlear implantation (CI) compared to a large contemporaneous group of children older than 12 months at the time of the CI (n = 2,725) and using the American College of Surgeons National Surgical Quality Improvement Program Pediatric Database (ACS-NSQIP-P). Risk factors analyzed included age, prematurity, and presence of congenital disorders. Outcomes analyzed included operative time, length of stay, general surgical complications, readmissions, and related reoperations. Over the database accrual period, the percentage of children ≤ 12 months at the time of surgery increased from 2012 to 2015 (6.08-7.78%, p = 0.0752). Total operative time, length of stay (≥ 1 d), and readmissions for those ≤ 12 months were significantly greater compared with those >12 months at the time of surgery ($p < 0.001$, $p = 0.0037$, and $p < 0.0001$, respectively). The study failed to demonstrate statistically significant differences in general surgical complications (i.e., superficial incisional surgical site infections, organ/space surgical site infections, and/or unplanned reoperations) in cases ≤ 12 months as compared to cases > 12 months (3.2% vs. 1.6%, p = 0.12) with a low overall complication rate. Complications specific to CI such as facial nerve paralysis, cerebrospinal fluid leak, and mastoiditis were not recorded in the ACS-NSQIP-P. The authors concluded that infants had no more general surgical complications in the immediate postoperative period compared with older children, although total operative time, length of stay, and readmissions were found to be significantly greater in frequency. Strengths of the study included comparisons between contemporaneous groups receiving intervention at different ages. Weakness included lack of randomization, which could have introduced biases in the findings.

In a systematic review, Bruijnzeel et al. (2016) evaluated the additional benefit of pediatric cochlear implantation before 12 months of age considering improved speech and language development and auditory performance. Ten studies with a high directness of evidence (DoE) were included in the review. Four articles with medium DoE were discussed in addition. Six cohort studies compared infants implanted before 12 months with children implanted between 12 and 24 months. Follow-up ranged from 6 months to 9 years. The authors subdivided the results into four categories: receptive language, speech perception, speech production, and auditory performance. Speech production outcomes indicated that children implanted under 12 months scored higher on speech production tests (diagnostic evaluation of articulation and phonology-DEAP and IT-MAIS). Speech and language outcome measures indicated that early implanted children (< 12 months) score better on speech production (DEAP and IT-MAIS scores), auditory performance (CAP-II score) and on two out of the five receptive language scores (combined PLS-4 and OWLS and PPVT scores) compared to their later implanted peers (> 12 months). The authors concluded that the current best evidence lacks level 1 evidence studies and consists mainly of cohort studies with a moderate to high risk of bias. Included studies showed consistent evidence that cochlear implantation should be performed early in life, but evidence is inconsistent on all speech and language outcome measures regarding the additional benefit of implantation before the age of 12 months. Long-term follow-up studies are necessary to provide insight on additional benefits of early pediatric cochlear implantation.

Dettman et al. (2016) examined the influence of age at implant on speech perception, language, and speech production outcomes in a large unselected pediatric cohort. The cohort study pooled available assessment data (collected prospectively and entered into respective databases from 1990 to 2014) from three Australian centers and compared groups of patients implanted at different ages. Children (n = 403) with congenital bilateral severe to profound hearing loss who received cochlear implants under 6 years of age (excluding those with acquired onset of profound hearing loss after 12 months, those with progressive hearing loss and those with mild/moderate/severe additional cognitive delay/disability) were included in the study. The main outcome measure in the study included speech perception; open-set words (scored for words and phonemes correct) and sentence understanding at school entry and late primary school time points. Language; PLS and PPVT standard score equivalents at school entry, CELF standard scores. Speech Production; DEAP percentage accuracy of vowels, consonants, phonemes-total and clusters, and percentage word-intelligibility at school entry. Regression analysis indicated a significant effect for age-at-implant for all outcome measures. Cognitive skills also accounted for significant variance in all

outcome measures except open-set phoneme scores. ANOVA with Tukey pairwise comparisons examined group differences for children implanted younger than 12 months (Group 1), between 13 and 18 months (Group 2), between 19 and 24 months (Group 3), between 25 and 42 months (Group 4), and between 43 and 72 months (Group 5). Open-set speech perception scores for Groups 1, 2, and 3 were significantly higher than Groups 4 and 5. Language standard scores for Group 1 were significantly higher than Groups 2, 3, 4, and 5. Speech production outcomes for Group 1 were significantly higher than scores obtained for Groups 2, 3, and 4 combined. Cross tabulation and $\chi 2$ tests supported the hypothesis that a greater percentage of Group 1 children (than Groups 2, 3, 4, or 5) demonstrated language performance within the normative range by school entry. The authors concluded that these results support provision of cochlear implants younger than 12 months of age for children with severe to profound hearing loss to optimize speech perception and subsequent language acquisition and speech production accuracy. Strengths of the study included comparisons between groups receiving intervention at different ages. Weakness included lack of clarify on whether the groups were contemporaneous and lack of randomization, which could have introduced biases in the findings.

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.

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. The authors indicated that the level of evidence does not justify systematic implantation in the first year of life. This indication should be limited to cochlear ossification or to selected cases reliably evaluated by experienced teams, with a definite diagnosis with regard to hearing threshold, etiology, and site of lesion.

Clinical Practice Guidelines

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).

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 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). This position statement indicates that research is currently underway to determine how to best manage unilateral hearing loss in infants and young children.

The AAP statement on cochlear implants in children discusses 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).

Hybrid Cochlear Implants

Neben et al. (2018) conducted a single-center prospective study with repeated measures to evaluate the performance outcome of Freedom™ Hybrid™ versus the CP900 series sound processor with Hybrid Hearing. In addition, a preliminary evaluation was conducted to consider the feasibility of upgrading experienced electric-only CI users who had substantial residual hearing to Hybrid Hearing. The randomized AABB cross-over design to compensate for learning effects included two test groups. Group 1 compared two systems for Hybrid Hearing (Freedom Hybrid sound processor versus CP900 series sound processor) and Group 2 compared CP900 series sound processor (electric-only) versus the CP900 with Hybrid Hearing in experienced CI users who had confirmed residual low-frequency hearing. Groups 1 and 2 were composed of different participants. Group 1 (n = 24) performance on speech perception tests was equivalent or superior with the CP900 series sound processor showing a statistically significant mean improvement of 1.87 dB in background noise ($p < 0.001$). The mean speech understanding in quiet showed a better performance by 5% ($p = 0.064$) for participants tested with the CP900. The patient-reported outcome questionnaire confirmed the beneficial performance with the CP900 series sound processor with Hybrid Hearing. The feasibility portion of the study (Group 2, n = 14) showed an average benefit of 0.54 dB in background noise when using the CP900 with Hybrid Hearing function versus electric-only stimulation. According to the investigators, the outcome presents sufficient evidence to show the effectiveness of the CP900 series sound processor with Hybrid Hearing over the Freedom Hybrid for participants with substantial residual hearing. Positive outcomes were observed for improved speech understanding and subjective hearing performance. Further, a trend was demonstrated in the data towards better performance with CP900 with Hybrid Hearing versus electric-only stimulation. The investigators found that Hybrid Hearing users showed a clinically relevant and statistically a significant benefit from the current CP900 series sound processor generation supporting its recommendation, on a case-by-case basis, to current electric-only users.

Gantz et al. (2018) investigated the stability of residual hearing and speech perception outcomes in individuals who were implanted with a shorter electrode device. Fifty subjects who received a Nucleus Hybrid short electrode cochlear implant (CI) and had a minimum of 2 years (and up to 15 years) of postoperative longitudinal experience were included in the study. Twenty-three subjects received a Nucleus Hybrid S8 (S8); 14 subjects received a Nucleus Hybrid L24 (L24); and 13 received a Nucleus Hybrid S12 (S12). Audiometric thresholds and consonant-nucleus-consonant (CNC) words were collected pre- and postoperatively for up to 15 years for the S8 subjects and for up to 7 years for the S12 and L24 subjects. AzBio Sentences in multi-talker babble was collected for up to 7 years on the S12 and L24 subjects. Longitudinally, 83% of the S8 subjects, 92% of the S12 subjects, and 86% of the L24 subjects maintained a functional hearing pure-tone average (PTA) (125-500 Hz). Predicted change using a piecewise linear mixed model in PTA over time showed a postoperative linear decrease in hearing for each group until 0.5 years, after which the PTA stabilizes and is maintained. The averaged individual data for CNC and AzBio sentences show a significant improvement in scores by 0.25 to 0.5 years post implantation, after which scores start to reach their maximum. The authors concluded that this long-term study demonstrates that acoustic-electric processing hearing and improvement in speech understanding in quiet and in noise can be accomplished and sustained for many years with a short electrode CI.

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 post activation. 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 post activation. 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 post activation, 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 post activation, 3 years post activation, and then as part of a post approval study at 5 years post activation. 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 post activation. 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.

Harkonen et al. (2017) evaluated the effect of hybrid cochlear implantation (hCI) on quality of life (QoL), quality of hearing (QoH), and working performance in adult patients, and compared the long-term results of patients with hCI to those of patients with conventional unilateral cochlear implantation (CI), bilateral CI, and single-sided deafness (SSD) with CI. Sound localization accuracy and speech-in-noise test were also compared between these groups. Eight patients with high-frequency sensorineural hearing loss of unknown etiology were selected for the study. Patients with hCI had better long-term speech perception in noise than uni- or bilateral CI patients, but the difference was not statistically significant. The sound localization accuracy was equal in the hCI, bilateral CI, and SSD patients. QoH was statistically significantly better in bilateral CI patients than in the others. In hCI patients, residual hearing was preserved in all patients after the surgery. During the 3.6-year follow-up, the mean hearing threshold at 125-500 Hz decreased on average by 15 dB HL in the implanted ear. QoL and working performance improved significantly in all CI patients. The investigators concluded that hearing outcomes with hCI are comparable to the results of bilateral CI or CI with SSD, but hearing in noise and sound localization are statistically significantly better than with unilateral CI. The impact of CI on QoL, QoH, and working performance was similar in all groups. This study shows that patients with hybrid and conventional CIs experienced a positive impact from cochlear implantation on their well-being and working performance.

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 post activation 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.

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.

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.

Cochlear Implantation for Single Sided Deafness (SSD)

The evidence is insufficient to support the use of CI for SSD. No firm conclusions can be drawn about the efficacy and safety of CI for SSD since published studies are limited by lack of comparison groups using other approaches to SSD treatment, heterogeneous findings, and small sample sizes.

In a prospective case series, Hwa et al. (2020) compared outcomes in speech and quality of life in individuals undergoing cochlear implantation for SSD, with the aim to characterize the clinical impact of underlying diagnosis in the affected ear and pre-operative hearing status. A total of 42 adult patients with the diagnosis of SSD who underwent CI were included in the study. Patients were evaluated at 3-, 6-, and 12-months post-operatively using AZBio sentence and speech, and consonant-nucleus-consonant (CNC) depending on appropriate testing level. The authors previously validated Comprehensive Cochlear Implant Quality of Life (CCIQ) questionnaire was administered. Subjects were stratified by the underlying diagnosis: Meniere's Disease (MD; n = 10), sudden sensorineural hearing loss (SSNHL; n = 13), and Other (e.g., TBI, acoustic neuroma, progressive, noise-induced; n = 19). Mean preoperative pure tone average (PTA) of the implanted ear was 82dB ±17; that of the nonimplanted ear was 32dB ±17. SSNHL and MD demonstrated the highest speech perception score at 3 months (93 and 95%), and "Other" demonstrated the lowest scores at 88%. All three groups demonstrated nadir in speech scores at 6 months before improving at 12 months, but the "Other" diagnoses maintained the lowest speech testing across all time points. All three groups reported improved quality of life on CCIQ. The authors concluded that subjects with SSNHL and MD demonstrate excellent speech perception and quality of life outcomes after cochlear implantation for SSD. Subjects with "Other" diagnoses underlying their SSD demonstrated lower scores on speech testing but nonetheless reported improved quality of life. This study is limited by lack of comparison group.

In a multicentered prospective case series, Poncet-Wallet et al. (2020) investigated the audiological and tinnitus outcomes of cochlear implantation (CI) in adults with SSD and tinnitus. Twenty-six patients with SSD and incapacitating tinnitus (Tinnitus Handicap Inventory [THI] > 58) underwent cochlear implantation. CIs delivered only masking white noise stimulation for one month and then standard CI stimulation. Before and after CI surgery, patients completed the THI, Tinnitus Reaction Questionnaire (TRQ), Subjective Tinnitus Severity Scale (STSS), and two visual analogue scales quantifying tinnitus loudness and annoyance. Speech perception in spatialized noise was tested at 13 months. The first month of white noise stimulation triggered a significant improvement in THI scores (72 ± 9 to 55 ± 20, $p < 0.05$). No change was observed for the other measures. After 1 year of standard CI stimulation, 23 patients (92%) reported a significant improvement in tinnitus. This improvement started 1 to 2 months after CI and exceeded 40% improvement for 14 patients (54%). Average speech-in-noise perception after 1 year significantly improved for the 23 patients who completed these measures. The authors concluded that CI is efficacious to reduce the handicap of patient with SSD and incapacitating tinnitus, leading to a decrease in reported

tinnitus and partial restoration of binaural hearing abilities. This study is however limited to lack of comparison group and to the subpopulation of patients with SSD and tinnitus.

In a systematic review, Cohen and Svirsky (2019) examined the relationship between duration of unilateral deafness and speech perception outcomes after cochlear implantation in adults with SSD. A statistically significant negative effect of duration of unilateral deafness on speech perception was found, but there was substantial uncertainty regarding the strength of the effect. The authors indicated that existing data make it difficult to either support or reject a hard 5- or 10-year unilateral auditory deprivation limit on CI candidacy for patients with single-sided deafness. This is because the totality of available data is consistent with a very small effect, perhaps negligible in practical terms, and just as consistent with a very large effect. Regardless of effect size, the present results have important basic implications. They suggest that unilateral sound deprivation may have a deleterious effect on auditory processing even though more central parts of the auditory system have continued to receive input from a contralateral normal ear. The authors concluded that speech perception scores in SSD patients are negatively correlated with duration of deafness, but the limited amount of data from CI users with long-term single-sided deafness leads to substantial uncertainly, which in turn precludes any strong clinical recommendations. The authors indicated that further study of SSD CI users with long-term deafness will be necessary to generate evidence-based guidelines for implantation criteria in this population.

Peter et al. (2019) conducted a systematic review to evaluate the influence of cochlear implantation on tinnitus in patients with SSD. Thirteen studies (n = 153 patients), all observational, that evaluated the influence of cochlear implantation on tinnitus in patients with SSD were included in the review. The pre- and post-implantation tinnitus scores of the included studies were extracted for the further systematic review. Due to the nature of cochlear implantation in SSD, no randomized trials exist, which limits the evaluation in a systematic review. Generally, the mean tinnitus questionnaire scores decreased after cochlear implantation in these 13 studies. The most widely used tinnitus questionnaire was the Tinnitus Handicap Inventory. In these studies, 34.2% of patients demonstrated complete suppression, 53.7% an improvement, 7.3% a stable value, and 4.9% an increase of tinnitus, and none of the patients reported an induction of tinnitus. The authors concluded that this review shows a clear improvement of tinnitus complaints after cochlear implantation in patients with SSD. The findings are limited by the observational nature of the studies, lack of comparison groups with other approaches to SSD and tinnitus treatment, and to the subsample of patient with tinnitus.

Lorens et al. (2019) conducted a prospective study to evaluate three possible advantages of binaural hearing in CIs adult users with unilateral hearing loss including SSD and asymmetric hearing loss (AHL) subgroups. The study included 70 sequentially implanted patients. Subgroups of these subjects included 64 with a postlingual onset of a profound hearing loss on the implanted side and six with a prelingual onset of that loss. Three binaural effects - redundancy, head shadow, and squelch - were evaluated. Significant differences between the ‘CI on’ and ‘CI off’ conditions were found for all three binaural effects for the study group as a whole and for the postlingual subgroup. However, results for the subjects in the prelingual subgroup did not demonstrate any of the binaural advantages. According to the authors, patients with a postlingual onset of a profound hearing loss in one ear and normal hearing or only a moderate loss in the other ear are able to make the effective use of a CI in the profound-loss ear in conjunction with acoustic stimulation of the other ear. The findings are limited by lack of comparison groups with other approaches to SSD and tinnitus treatment and lack of testing outside of the laboratory setting.

Prejban et al. (2018) examined the extent that CI can improve speech perception outcomes in various noisy listening environments. The ability to use interaural level differences for sound localization and subjective benefit with the CI were also assessed. Ten SSD patients with CI were tested in different loudspeaker configurations with and without the CI. A multi-source noise field (MSNF) with uncorrelated noise from four different directions was used in addition to a setup with the signal from the CI side and noise from the normal-hearing side (SCINNH, azimuth of ±45 degrees). Ten normal-hearing subjects were used as a control for the setup. Speech understanding was measured by an adaptive sentence test (Oldenburg Sentence Test, OLSA) in stationary speech shaped noise and temporally modulated noise to assess the benefit in each listening situation. Sensitivity to interaural level differences was measured in a lateralization experiment. Furthermore, patients completed the Bern Benefit in Single-Sided Deafness (BBSS) questionnaire to assess subjective benefit with the CI. An overall average benefit in speech reception threshold (SRT) of 1.6dB (±0.6dB standard error of the mean [SEM]) was observed in the binaural listening condition (with CI) in all conditions. In the MSNF setup thresholds improved by 0.4dB (±0.5dB SEM) and in the SCINNH configuration by 2.7dB (±0.7dB SEM). The choice of masking noise effect also had a significant effect on the SRT outcome. The lateralization performance of the SSD users was on a par with the normal hearing group. BBSS scores reflect the overall benefit with the CI apparent in the speech test results. The authors concluded that patients with SSD benefit from a CI in difficult listening

environments and are able to localize sound based on interaural level differences. Considering these outcomes CI represents a promising treatment option for patients SDD. However, the real-life implication of these laboratory-based findings are unclear.

Mertens (2017) investigated CI in individuals with unilateral profound sensorineural hearing loss in a 12- and 36-month prospective cohort outcome study. Long-term (LT) evaluation was derived from 12 (SSD) CI recipients and from 11 CI recipients with AHL. A structured interview was conducted with each subject. Speech perception in noise and sound localization were assessed in a CIOFF and in a CION condition. Four binaural effects were calculated: summation effect (S0N0), squelch effect (S0NCI), combined head shadow effect (SCIN0), and spatial release from masking (SRM). At the LT evaluation, the contribution of a CI or a bone conduction device on speech perception in noise was investigated in two challenging spatial configurations in the SSD group. All (23/23) subjects wore their CI 7 days a week at LT follow-up evaluation, which ranged from 3 to 10 years after implantation. In the SSD group, a significant combined head shadow effect of 3.17 dB and an SRM benefit of 4.33 dB were found. In the AHL group, on the other hand, the summation effect (2.00 dB), the squelch effect (2.67 dB), the combined head shadow effect (3.67 dB), and SRM benefit (2.00 dB) were significant at LT testing. In both the spatial challenging configurations, the speech in noise results was significantly worse in the condition with the bone conduction device compared with the unaided condition. No negative effect was found for the CION condition. A significant benefit in the CION condition was found for sound localization compared with the CIOFF condition in the SSD group and in the AHL group. The investigators indicated that all subjects wore their CI 7 days a week at LT follow-up evaluation. The presence of binaural effects has been demonstrated with speech in noise testing, sound localization, and subjective evaluation. In the AHL group, all investigated binaural effects were found to be significant. In the SSD group on the other hand, only SRM and the head shadow, the two most robust binaural effects, were significantly present. However, it took 12 months before the SSD and the AHL subjects significantly benefit from the head shadow effect. These reported results could guide counseling of future CI candidates with SSD and AHL in general. This study is limited by lack of comparison group and an heterogenous and small sample.

Kitterick et al. (2016) conducted a systematic review and meta-analysis to assess the nature and quality of the evidence for the use of hearing instruments in adults with unilateral severe to profound sensorineural hearing loss. The included studies were prospective controlled or observational studies that assessed the impact of any form of hearing instrument, including devices that reroute signals between the ears or restore aspects of hearing to a deaf ear, in adults with a sensorineural severe to profound loss in one ear and normal or near-normal hearing in the other ear. Studies that met prospectively defined criteria were subjected to random effects meta-analyses. Twenty-seven studies reported in 30 articles were included. The evidence was graded as low-to-moderate quality having been obtained primarily from observational before-after comparisons. The findings related to CI identified limited evidence for the effects of CI on speech perception in noise. Although significant benefits were reported by three studies when the signal to noise ratio (SNR) was more favorable, the evidence could not be synthesized and subjected to a meta-analysis in this and other configurations of speech and noise because assessment methodologies were not consistent across studies. Although the restoration of functional hearing in both ears through cochlear implantation could be expected to provide benefits to speech perception, the inability to synthesize evidence across existing studies means that such a conclusion cannot yet be made. For the same reason, it remains unclear whether cochlear implantation can improve the ability to localize sounds despite restoring bilateral input. The meta-analysis did identify effects relating to reductions in self-reported difficulties with listening to speech for CI that were medium in size and consistent across studies. Although this evidence may suggest that the impact of any benefits to speech perception after implantation may extend to situations in everyday life, further evidence for the effects of CI on speech perception under controlled conditions is required to establish the bases of these reductions in listening difficulties. According to the investigators, prospective controlled studies that measure outcomes consistently and control for selection and observation biases are required to improve the quality of the evidence for the use of CI in patients with unilateral deafness. The cochlear implant studies included in this review are limited by a lack of a comparison group.

Peters et al. (2016) systematically reviewed the literature on CI for children with unilateral hearing loss (UHL). Five articles satisfied the eligibility criteria for inclusion in the review. All of these articles were case series or case reports and had a low to moderate directness of evidence (DoE) and a high risk of bias (RoB). In these studies, heterogeneous findings were reported in small patient samples. Speech perception in noise and localization ability improved in most patients. Although only measured in one study each, quality of life and speech and language development improved. Most of these results were not statistically significant. The investigators concluded that no firm conclusions can be drawn on the effectiveness of CI in children with UHL, due to heterogeneous findings, small sample sizes, and the lack of high level of evidence studies.

Cabral Junior et al. (2016) conducted a systematic review of recent studies to evaluate the outcomes of CI in patients with SSD with regards to speech discrimination, sound localization and tinnitus suppression. After critical appraisal, eleven studies were

selected for data extraction and analysis of demographic, study design and outcome data. The investigators concluded that although some studies have shown encouraging results on cochlear implantation and SSD, all fail to provide a high level of evidence. Larger studies are necessary to define the tangible benefits of cochlear implantation in patients with SSD.

van Zon et al. (2015) conducted a systematic review of the literature to evaluate the clinical outcome of cochlear implantation for patients with SSD or AHL. Fifteen studies satisfied the eligibility criteria. Critical appraisal showed that six studies reported on less than five patients or that they carried a low directness of evidence or a high risk of bias. Therefore, the data was extracted from nine studies (n = 112). Patient numbers, age, duration of deafness, classification of deafness, pure tone audiometry, follow-up duration, and outcome measurements were extracted from all nine articles. Because of large heterogeneity between studies, the investigators were not able to pool data in a meta-analysis. The investigators summarized the results of the studies specified per outcome. The investigators concluded that there are no high-level-of-evidence studies concerning cochlear implantation in patients with SSD or AHL. Current literature suggests important benefits of cochlear implantation regarding sound localization, QoL, and tinnitus. Varying results were reported for speech perception in noise, possibly caused by the large clinical heterogeneity between studies. Larger and high-quality studies are warranted.

Vlastarakos et al. (2014) conducted a systematic review to the current evidence on the efficacy of cochlear implantation as a treatment modality for SSD, and/or unilateral tinnitus. Systematic literature review in Medline and other database sources was conducted along with critical analysis of pooled data. The study selection included prospective and retrospective comparative studies, case series and case reports. The total number of analyzed studies was 17. A total of 108 patients with SSD have been implanted; 66 patients due to problems associated with SSD, and 42 primarily because of debilitating tinnitus. Cochlear implantation in SSD leads to improved sound localization performance and speech perception in noise from the ipsilateral side with an angle of coverage up to (but not including) 90(°) to the front, when noise is present in the contralateral quartile (Strength of recommendation B). Speech and spatial hearing also subjectively improve following the insertion of a cochlear implant (Strength of recommendation B); this was not the case regarding the quality of hearing. Tinnitus improvement was also reported following implant placement (Strength of recommendation B); however, patients need to be advised that the suppression is mainly successful when the implant is activated. According to the authors, the overall quality of the available evidence supports a wider use of cochlear implantation in SSD following appropriate selection and counseling (overall strength of recommendation B). According to the authors, it remains to be seen if the long-term follow-up of large number of patients in well conducted high quality studies will confirm the above-mentioned results. The included studies were limited by lack of comparison groups with other approaches to SSD and tinnitus treatment.

Two Hayes evidence analysis research briefs for MED-EL Cochlear Implant System with Synchrony/Synchrony 2 (MED-EL Corp) for adults and children with unilateral sensorineural hearing loss concluded that there is insufficient published evidence for the use of the MED-EL Cochlear Implant System with Synchrony/Synchrony 2 to assess the safety and/or health outcomes impact in adults and children with unilateral sensorineural hearing loss. The Hayes briefs indicated that this conclusion reflects the lack of published human clinical trials for this device only, and should not be generalized to the use of cochlear implants for this indication (Hayes Evidence Analysis Research Brief for MED-EL Cochlear Implant System with Synchrony/Synchrony 2 (MED-EL Corp) for adults with unilateral sensorineural hearing loss, 2019; Hayes Evidence Analysis Research Brief for MED-EL Cochlear Implant System with Synchrony/Synchrony 2 (MED-EL Corp) for children with unilateral sensorineural hearing loss, 2019).

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. Cochlear 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) performed 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 nine 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.

Aural Rehabilitation

Brodie et al. (2018) conducted a systematic literature review to evaluate the impact of different types of hearing rehabilitation after hearing loss and their impact on quality of life. A systematic literature search was conducted on Pubmed which retrieved 549 articles. Of these, 29 articles regarding cochlear implants, bone anchored hearing devices and traditional amplification hearing aids were systematically reviewed. The main finding was that hearing rehabilitation is beneficial in all types of hearing loss and treatment regarding quality of life. However, bone-anchored hearing devices and cochlear implants were shown to produce greater improvements in terms of quality of life than conventional hearing aids. The authors concluded that hearing rehabilitation has a positive impact on quality of life after hearing loss.

Additional Search Terms

Cochlear prosthesis

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. 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®
• https://www.advancedbionics.com/content/advancedbionics/us/en/home.html (Accessed April 13, 2020)
• 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

FDA-Approved Cochlear Implants (Non-Hybrid)	FDA Labeled Indications
Advanced Bionics® • https://www.advancedbionics.com/content/advancedbionics/us/en/home.html (Accessed April 13, 2020) • HiResolution® Bionic Ear System (HiRes 90K) • Predecessors: ○ Clarion Multi-Strategy Clarion HiFocus	• 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 sound field (70 dB SPL).
Cochlear™ Nucleus® • http://www.cochlear.com (Accessed April 13, 2020) • Nucleus® 5 and 6 series of CI devices • Predecessors: ○ Nucleus 22 Channel Cochlear Implant System ○ Nucleus 24 Contour Systems ○ 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 9 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. On March 17, 2020, the FDA updated the age for which implantation is appropriate for the Cochlear™ Nucleus® System to include children who are 9 months of age and older. Refer to the following for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S172. (Accessed July 13, 2020)
Med El® • http://www.medel.com/us/ (Accessed April 13, 2020) • Maestro® (Sonata or Pulsar) • SYNCHRONY Cochlear Implant • Predecessor: ○ Combi 40+	Bilateral Sensorineural Hearing Loss *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

FDA-Approved Cochlear Implants (Non-Hybrid)	FDA Labeled Indications
Med El® • http://www.medel.com/us/ (Accessed April 13, 2020) • Maestro® (Sonata or Pulsar) • SYNCHRONY Cochlear Implant • Predecessor: Combi 40+	*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 3–6-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. Refer to the following websites for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/P000025b.pdf. (Accessed April 13, 2020) Unilateral Sensorineural Hearing Loss On July 19, 2019, the FDA expanded the approval for the Med-El Cochlear Implant System (Med El Corp.) indications to include patients 5 years and above with single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. Refer to the following for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000025S104. (Accessed March 15, 2020)

For a current list of indications for each device, refer to the following FDA websites [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 April 2, 2020)

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 2, 2020)

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 2, 2020)

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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Policy History/Revision Information

Date	Summary of Changes
05/01/2022	Related Policies • Updated reference link to reflect title change for the Coverage Determination Guideline titled *Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for New Jersey Only)* [previously titled *Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements (for New Jersey Only)*]
05/01/2021	Template Update • Replaced content sub-heading titled “Professional Societies” with “Clinical Practice Guidelines” in *Clinical Evidence* section • Removed *CMS* section • Replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria” in *Instructions for Use*
03/01/2021	Template Update • Reformatted policy; transferred content to new template Coverage Rationale

Date	Summary of Changes

	• Added language to indicate hybrid and non-hybrid cochlear implantation are unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:
	  ○ Single sided deafness or unilateral Sensorineural Hearing Loss
	  ○ All other conditions that do not meet the [proven and medically necessary] criteria [listed in the policy]
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version CS019NJ.L

Instructions for Use

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

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical 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.