

Cochlear Implants (for Ohio Only)

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[➔ Instructions for Use](#)

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Related Policies

- [Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements \(for Ohio Only\)](#)
- [Hearing Aids and Devices Including Wearable, Bone-Anchored and Semi-Implantable \(for Ohio Only\)](#)

Application

This Medical Policy only applies to the state of Ohio.

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); 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 or moderate sloping 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

Note: The external components and the implantable of the cochlear implant are covered under different benefits. The Cochlear implant’s external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME

benefit, and the implantable components are considered under the medical-surgical benefit. Check the federal, state or contractual requirements for benefit plan coverage. Refer to the Coverage Determination Guideline titled [Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements \(for Ohio Only\)](#).

Definitions

Degree of Hearing Loss:

Degree of Hearing Loss	Range (dbHL = Decibels Hearing Level)
Normal Hearing	-10 to 15 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, 2015, 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-Samuels, 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 over 9 months of age with moderate to profound hearing loss who have failed a trial with appropriately fit hearing aids. 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 4 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 clarity 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 χ^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 clarity 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, aetiology and site of lesion.

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 postimplantation, 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 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 30dB HL low-frequency pure-tone average (250-1000Hz) 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.

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 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.

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)

Cochlear implants (CI) were approved by FDA for SSI in 2019. The benefit of CI for SSD is supported by a large number of usually small case series (aka before-after, within-subject, or participant as their own control design) but very limited data comparing this approach to a parallel comparison group receiving a different intervention. Case series are generally considered one of the lowest level of evidence quality due to their inherent high risk for bias and the potential impact of other concurrent treatments that could impact outcomes. A recent comparative study, with its own significant limitations, provides mixed findings across outcome. Therefore, and despite its volume, the evidence remains of insufficient quality to consider CI for SSI proven.

A 2021 ECRI clinical evidence assessment report reviewed the use of cochlear implants (CI) for treating single-sided deafness with and without tinnitus. The assessment included six systematic reviews and one prospective pre-post study from January 2016 through March 18, 2021. A review was performed on the full text of 4 SRs and 1 clinical study and abstracts of 2 SRs reporting on 2,849 patients (included studies in the SRs may have some overlap). Results indicated that CIs improve speech perception, sound localization, tinnitus, and quality of life, based on evidence from 6 systematic reviews (SRs) and 1 prospective pre-post study. Clinically significant improvements are seen in children and adults with SSD who receive a CI. There has been some surgery-related cochlear trauma reported which may improve with better surgical techniques. Limitations include, small sample sizes, pediatric SSD population heterogeneity, variation in how audiologic outcomes are assessed, inconsistent reporting of comorbidities, lack of a control group in most studies, patient selection bias, and retrospective designs in many studies. According to the authors, while there is only 1 RCT and lack of high quality evidence, all SRs consistently reported clinically significant improvement after CI placement. The authors conclude that high-quality RCTs would be useful to reaffirm these findings and determine the actual degree of hearing improvement possible with CIs and any differences in improvement related to age and comorbidities. (Benchetrit et al, 2021, Poncet-Wallet et al 2020 and Donato et al., 2021 are included in this report)

Donato et al. (2021) conducted a systematic review with meta-analysis of the studies published on the efficacy of bone conduction devices and cochlear implantation in single-sided deafness, through the evaluation of speech discrimination in noise, sound localization and tinnitus suppression. As a secondary outcome, patient satisfaction is also assessed. Systematic search in PubMed, Embase and CENTRAL was conducted, including all articles written in English and published in the last 10 years. The outcomes selected were speech perception in noise, sound localization, tinnitus intensity and, secondarily, quality of life assessment. Nineteen articles reporting a total of 210 patients (95 patients with bone conduction devices and 115 in the cochlear implantation group) were included. The meta-analysis recognizes statistically significant benefits in cochlear implantation for sound localization, tinnitus suppression, in global quality of life assessment and in 2 of the 3 subscales of quality of life assessment (ease of communication and reverberation). Bone conduction devices are better regarding speech discrimination in noise and background noise quality of life assessment. Cochlear implants were found to offer better results in stereophony and decreased tinnitus intensity, 2 of the 3 evaluated parameters that were evaluated. Bone conduction devices should continue to be considered in the treatment of these patients because, in addition to allowing better discrimination in noise, patient satisfaction is greater in environments with background noise. The rehabilitation process was faster and more comfortable with the bone conduction devices. The findings of this systematic review on CI are however limited by the design of the reviewed studies that lacked comparison group undergoing different therapeutic approaches. (The review includes the findings of Arndt et al., 2011)

Marx et al. (2021) assessed the outcomes of cochlear implantation and other treatment options in single-sided deafness (SSD) and asymmetric hearing loss (AHL) on quality of life from a National Multicenter Study including a randomized controlled trial (Marx 2019). This prospective multicenter study was conducted in 7 tertiary university hospitals and included an observational cohort study of SSD/AHL adult patients treated using contralateral routing of the signal (CROS) hearing aids or bone-anchored hearing systems (BAHSs) or who declined all treatments, and a randomized controlled trial in subjects treated by cochlear implantation, after failure of CROS and BAHS trials. In total, 155 subjects with SSD or AHL, with or without associated tinnitus, were enrolled. After 2 consecutive trials with CROS hearing aids and BAHSs on headband, all subjects chose any of the 4 treatment options (abstention of other treatments, CROS, BAHS, or CI). The subjects who opted for a CI were randomized between 2 arms (CI vs. initial observation). Six months after the treatment choice, quality of life was assessed using both generic (EuroQoL-5D, EQ-5D) and auditory-specific quality-of-life indices (Nijmegen Cochlear Implant Questionnaire [NCIQ] and Visual Analogue Scale [VAS] for tinnitus severity). Performances for speech-in-noise recognition and localization were measured as secondary outcomes. CROS was chosen by 75 subjects, while 51 opted for CI (25 randomized to CI and 26 to observation for 6 months), 18 for BAHSs, and 11 for abstention. Six months after treatment, EQ-5D VAS, auditory-specific quality-of-life, and tinnitus severity were significantly better in the "CI" arm versus "observation" arm, but the study failed to

demonstrate any impact of CI on the hearing outcomes, including speech recognition in noise or horizontal localization, even after baseline adjustment. While some of the outcomes were better with CI than abstinence or CROS, none of the quality of life or hearing outcomes were statistically significantly superior to BAHS. The authors concluded that cochlear implantation leads to significant improvements in quality of life in SSD and AHL patients, particularly in subjects with associated severe tinnitus, who are thereby the best candidates to an extension of CI indications. Larger prospective RCT's are needed to confirm the effectiveness of cochlear implants on SSD/ADL. The authors also note that much robust evidence may emerge from an ongoing RCT (Peters et al. 2015) where a CI arm is compared to both CROS and BAHS. The findings of the current study are limited by the small sample size and lack of blinding of the RCT portion of the study and the lack of randomization for the other comparisons. Furthermore, four out of the 25 participants (16%) randomized to CI were excluded from the analysis after randomization, which could have introduced biases in the findings.

Benchetrit et al. (2021) conducted a systematic review and meta-analysis to evaluate the audiological and patient-reported outcomes in children who underwent cochlear implantation for SSD and to assess the association between time of implantation, subjective outcomes, and cochlear implant use rates. Twelve small case series with sample size ranging from 3 to 23 that evaluated a total of 119 children (average age 6.6yrs) with SSD who received a cochlear implant were included. Six studies were included in the meta-analysis. Most children showed clinically meaningful improvement in speech perception in noise (39 of 49 children [79.6%]) and in quiet (34 of 42 children [81.0%]). Long duration of deafness (> 4 years in congenital SSD and > 7 years in perilingual SSD) was the most proposed reason for lack of improvement. Sound localization as measured by degrees of error from true location (mean difference [MD], -24.78°; 95% CI, -34.16° to -15.40°; I² = 10%) improved statistically significantly after cochlear implantation. Patients with acquired SSD and shorter duration of deafness compared with those with congenital SSD reported greater improvements in speech (MD, 2.27; 95% CI, 1.89-2.65 vs 1.58; 95% CI, 1.00-2.16) and spatial (MD, 2.95; 95% CI, 2.66-3.24 vs 1.68; 95% CI, 0.96-2.39) hearing qualities. The duration of deafness among device nonusers was statistically significantly longer than the duration of deafness among regular device users (median difference, 6.84; 95% CI, 4.02-9.58). This systematic review and meta-analysis found that cochlear implantation for children with SSD was associated with improved objective and subjective auditory outcomes. Children with acquired SSD and shorter duration of deafness reported greater advantages and were more likely to use the implant devices. Limitations included lack of comparison group undergoing different therapeutic approaches, small sample size, the inability to control for the differences in the pediatric SSD population for things such as cause of deafness, onset and duration, age at implantation, device manufacturer and the extent and availability of social and rehabilitative support. Quantitative limitations included the use of study level data when patient specific data was not available. The use of different tests and configurations to evaluate audiological outcomes. The meta-analysis did use comparable outcomes and design although there were still some drawbacks. They were unable to perform a comorbidity analysis due to inconsistent reporting. Further research is needed with a larger sample size and less differences in the study population.

Nicolas et al. (2021) in a systematic review and meta-analysis evaluated the benefits or harms on quality of life in treating children with moderate to profound unilateral hearing loss (UNL) using cochlear implants or other devices. The systematic review and meta-analysis searched databases between September 2018 and May 2019. In the studies with the lowest risk of bias, a meta-analysis was conducted. Study population included children 6-15 years old with moderate to profound unilateral hearing loss. 731 unique articles were identified from the primary search. Of these, 18 articles met the Population, Intervention, Control, Outcomes and Study design selection criteria. Most studies used a case series design without comparison groups, and two studies had a control group. All the studies of cochlear implant were case series without a control group undergoing different therapeutic approaches. In the eight studies with the lowest risk of bias, two meta-analysis were conducted. There was not enough data on academic results to conduct a meta-analysis. The 6 before-and-after studies comprised 61 children, with severe to profound (72%) sensorineural (67%) UHL. Half of the children (50%) received a bone conduction device, the other half received a cochlear implant, at the mean age of 9.66 years (SD = 2.60). In 73 children included in a fixed effect meta-analysis (two studies), no effect of treatment could be shown ($g = -0.20$, $p = 0.39$). In 61 children included in a random-effect meta-analysis (six studies), a strong positive effect of hearing treatment on quality of life was demonstrated ($g = 1.32$, $p < 0.05$). The treatment of unilateral hearing loss seems to improve children's quality of life. Further research is needed to identify the most effective treatment and its equivalent indications. This systematic review and meta-analysis identified no randomized controlled trials on UHL rehabilitation in children. The findings are limited by lack of comparison groups undergoing different therapeutic approaches in the studies of cochlear implant. Further research is needed to build robust conclusions on the effects of hearing devices on quality of life and academic results in children with UHL.

The Ontario Health quality (2020) conducted a technology assessment on implantable devices for single-sided deafness and conductive or mixed hearing loss. A systematic literature search for systematic reviews and cost-effectiveness studies of cochlear implants and bone-conduction implants, compared to no interventions, for these conditions in adults and children. Twenty systematic reviews were included in the clinical evidence review. For adults and children with single-sided deafness, cochlear implantation when compared with no treatment improves speech perception in noise (% correct responses: 43% vs. 15%, $P < .01$; GRADE: Moderate), sound localization (localization error: 14° vs. 41° , $P < .01$; GRADE: Moderate), tinnitus (Visual Analog Scale, loudness: 3.5 vs. 8.5, $P < .01$; GRADE: Moderate), and hearing-specific quality of life (Speech Spatial and Qualities of Hearing Scale, speech: 5.8 vs. 2.6, $P = .01$; spatial: 5.7 vs. 2.3, $P < .01$; GRADE: Moderate); for children, speech and language development also improve (GRADE: Moderate). For those with single-sided deafness in whom cochlear implantation is contraindicated, bone-conduction implants when compared with no intervention provide clinically important functional gains in hearing thresholds (36-41 dB improvement in pure tone audiometry and 38-56 dB improvement in speech reception threshold, $P < .05$; GRADE: Moderate) and improve speech perception in noise (signal-to-noise ratio -2.0 vs. 0.6, $P < .05$ for active percutaneous devices; signal-to-noise ratio improved by 1.3-2.5 dB, $P < .05$ for active transcutaneous devices; GRADE: Moderate) and hearing-specific quality of life (Abbreviated Profile for Hearing Aid Benefit, ease of communication: 12%-53% vs. 24%-59%; background noise: 18%-48% vs. 33%-79%; listening in reverberant condition: 26%-55% vs. 41%-65%, $P < .05$ [active percutaneous devices]; ease of communication: 7% vs. 20%; background noise: 46% vs. 69%; listening in reverberant condition: 27% vs. 43%; $P < .05$ [active transcutaneous devices]; Children's Home Inventory for Listening Difficulties score 7.3 vs. 3.4; $P < .05$ [passive transcutaneous devices]; GRADE: Moderate). For those with conductive or mixed hearing loss, bone-conduction implants when compared with no intervention improve hearing thresholds (improved 19-45 dB [active percutaneous devices], improved 24-37 dB [active transcutaneous devices], improved 31 dB [passive transcutaneous devices], and improved 21-49 dB [active transcutaneous middle-ear implants]; GRADE: Moderate), speech perception (% correct: 77%-93% vs. $< 25\%$; $P < .05$ [active transcutaneous devices], % speech recognition: 55%-98% vs. 0-72%; $P < .05$ [active transcutaneous middle-ear implants]; GRADE: Moderate), and hearing-specific quality of life and subjective benefits of hearing (GRADE: Moderate). In interviews, people with single-sided deafness and conductive or mixed hearing loss reported that standard hearing aids did not meet their expectations; therefore, they chose to undergo surgery for an implantable device. Most participants with experience of a cochlear implant or bone-conduction implant spoke positively about being able to hear better and enjoy a better quality of life. People with a cochlear implant reported additional benefits: binaural hearing, better sound localization, and better hearing in noisy areas. Based on evidence of moderate quality, cochlear implantation and bone-conduction helped people with single-sided deafness or conductive or mixed hearing loss hear better and improved their hearing-specific quality of life. Qualitative results of interviews with patients are consistent with the findings of the systematic reviews we examined.

Hayes 2020 evidence analysis research brief on cochlear implantation for children with single-sided deafness and tinnitus indicated that there is an insufficient quantity of published, peer-reviewed, human clinical data to evaluate CIs for SSD with tinnitus in children in a health technology assessment. A search of the peer-reviewed, published literature in PubMed and Embase generated a large body of literature pertaining to CIs for the treatment of SSD in children. Due to the volume of literature, the search was limited to studies with > 10 patients published in the last 10 years. However, no eligible abstracts for CIs for the treatment of SSD with tinnitus in children were found.

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 $82\text{dB} \pm 17$; that of the nonimplanted ear was $32\text{dB} \pm 17$. SSNHL and MD demonstrated the highest speech perception score at 3 months (93 and 95%), and "Other" demonstrated the lowest scores at 88%. All 3 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 3 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 undergoing different therapeutic approaches.

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 1 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 undergoing different therapeutic approaches 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 uncertainty, 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. (This systematic review includes the findings of Arndt et al., 2011 and Van de Heyning et al., 2008).

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).

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 postimplantation 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. (This systematic review includes the findings of: Arndt et al., 2011; Dillon et al., 2017 and Van de Heyning et al., 2008).

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 6 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.

Tavora-Vieria et al. (2019) in a case series evaluated the long-term benefits and hearing outcomes of thirty-four SSD cochlear implant users at two different locations in terms of speech perception, subjective hearing performance, and sound localization. The long-term hearing outcomes (between 4 and 10 years of CI use) were evaluated using speech in noise tests, a subjective hearing performance questionnaire (Speech, Spatial and Qualities Questionnaire [SSQ12]), and sound localization tests. Statistically significant improvements were observed in speech perception in noise and sound localization results postoperatively with the use of a CI in comparison to the preoperative measurements in the same CI group. Subjective hearing abilities also significantly improved after long-term CI use. Study limitations include inconsistency in testing materials related to spatial setup and lack of a comparison group undergoing a different treatment.

Buss et al. (2018) evaluated a population of twenty adult cochlear implant recipients with moderate-to-profound sensorineural UHL and normal or near-normal hearing in the other ear, using methods designed to maximize the likelihood of observing a spatial hearing benefit. A MED-EL standard electrode was implanted in the diminished ear. Outcome measures included: (a) sound localization on the horizontal plane (11 positions, -90° to 90°), (b) word recognition in quiet with the CI alone, and (c) masked sentence recognition with the target at 0° and the masker at -90°, 0°, or 90°. The recipients of the cochlear implant provided baseline data in perception and localization protocols prior to implantation and then at 1, 3, 6, 9, and 12 months after CI activation. The normal-hearing control group was composed of 20 adults with pure-tone thresholds of 35 dB HL or less at 125 to 8000 Hz in both ears, and all were native English speakers. When comparing the study subjects before and after the implantation, the CI improved localization accuracy and reduced side bias. Word recognition with the CI alone was like performance of traditional CI recipients. The CI improved masked sentence recognition when the masker was presented from the front or from the side of normal or near-normal hearing. The binaural benefits observed with the CI increased between the 1- and 3-months mark but appeared stable after that. The authors noted that in contrast to previous reports on localization and speech perception in patients with unilateral sensorineural hearing loss, CI benefits were consistently observed across individual subjects, and performance was stable by the 3-month test interval. These results are very similar to the preliminary localization outcome data reported by (Dillon 2017 and Thompson 2020). Study limitations included lack of a comparison group receiving a different intervention for unilateral sensorineural hearing loss, and small sample size.

Firszt et al. (2018) in a prospective case series reviewed the behavioral outcomes in adults with asymmetric hearing who received a CI in the poor ear. The degree of hearing asymmetry varied based on better ear hearing, which ranged from normal hearing to moderately severe impairment. This study included 47 adults from two different clinic sites with post-lingual onset of asymmetric hearing loss, i.e., one poor-hearing ear that met clinical CI candidacy criteria (moderate to profound hearing loss, $\leq 50\%$ on open set sentences) and one better-hearing ear. By 6-months post-implant, bimodal performance was improved from the pre-implant performance of everyday listening condition, which for most was listening with the better ear alone (with or without a hearing aid). Improvements were recognized for speech recognition in noise and at soft levels in quiet, for sound localization, and for everyday communication function. The authors concluded that this study indicated that cochlear implantation was an effective treatment for this study group, post linguually deafened adults with asymmetric hearing (one ear with SPHL and better hearing in the other ear). The also noted that: more appropriate tests to measure outcomes are needed to refine consistency in reporting outcomes; a CI is rarely used all day in asymmetric hearing loss and the evaluation of the better ear is also critical in the population; and aural rehabilitation in this population is extremely important and warrants additional research to determine the need for continued programming and/or aural rehabilitation to optimize bimodal hearing outcomes. The findings are limited by lack of comparison to a group of participants undergoing a different treatment for asymmetric hearing.

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 (± 0.6 dB 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 (± 0.5 dB SEM) and in the SCINNH configuration by 2.7dB (± 0.7 dB 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 (S0NCl), 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 undergoing different therapeutic approaches. (This systematic review includes the findings of: Arndt et al., 2011 and Van de Heyning et al., 2008).

Clinical Practice Guidelines

American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS)

The AAO-HNS (2019) issued an updated clinical practice guideline for sudden hearing loss in 2019 that addresses unilateral sudden sensorineural hearing loss (SSNHL). The guideline gives a strong recommendation for the use of cochlear implantation in the rehabilitation of patients with unrecovered severe to profound SSNHL. The Academy states that literature supports cochlear implantation for unilateral sensorineural hearing loss leading to significant improvement in hearing and quality of life.

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 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.

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.

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
<p>Advanced Bionics®</p> <ul style="list-style-type: none"> ● https://www.advancedbionics.com/content/advancedbionics/us/en/home.html (Accessed April 22, 2021) ● HiResolution® Bionic Ear System (HiRes 90K) ● Predecessors: <ul style="list-style-type: none"> ○ Clarion Multi-Strategy ○ Clarion HiFocus 	<p>Adults</p> <ul style="list-style-type: none"> ● 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) <p>Children</p> <ul style="list-style-type: none"> ● 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: <ul style="list-style-type: none"> ○ 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 $\leq 20\%$ 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 $\leq 12\%$ on a difficult open-set word recognition test (Phonetically Balanced-Kindergarten Test) or $\leq 30\%$ on an open-set sentence test (Hearing in Noise Test for Children) administered using recorded materials in the sound field (70 dB SPL).
<p>Cochlear™ Nucleus®</p> <ul style="list-style-type: none"> ● http://www.cochlear.com (Accessed April 22, 2021) ● Nucleus® 5 and 6 series of CI devices ● Predecessors: <ul style="list-style-type: none"> ○ Nucleus 22 Channel Cochlear Implant System ○ Nucleus 24 Contour Systems ○ Nucleus Freedom 	<p>Adults</p> <ul style="list-style-type: none"> ● 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. <p>Children 9 to 24 Months of Age</p> <ul style="list-style-type: none"> ● 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. <p>Children 25 Months Through 17 years of Age</p> <ul style="list-style-type: none"> ● Bilateral severe-to-profound sensorineural hearing loss. ● Limited benefit from appropriate binaural hearing aids. In older children, limited benefit is defined as $\leq 30\%$ correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the

FDA-Approved Cochlear Implants (Non-Hybrid)	FDA Labeled Indications
	<p>child’s cognitive and linguistic skills. A 3-to-6-month hearing aid trial is recommended for children without previous aided experience.</p> <p>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. See the following for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S172. (Accessed April 22, 2021)</p>
<p>Med EI®</p> <ul style="list-style-type: none"> ● http://www.medel.com/us/ (Accessed April 22, 2021) ● Maestro® (Sonata or Pulsar) ● SYNCHRONY Cochlear Implant ● Predecessor: <ul style="list-style-type: none"> ○ Combi 40+ 	<p>Bilateral Sensorineural Hearing Loss</p> <p><i>Adults</i></p> <ul style="list-style-type: none"> ● 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 <p><i>Children</i></p> <ul style="list-style-type: none"> ● 12 months through 17 years of age with profound bilateral sensorineural hearing loss (≥ 90dB) ● Limited benefit from appropriate binaural hearing aids <ul style="list-style-type: none"> ○ 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. <p>See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/P000025b.pdf. (Accessed April 22, 2021)</p> <p>Unilateral Sensorineural Hearing Loss</p> <p>On July 19, 2019, the FDA expanded the approval for the Med-EI Cochlear Implant System (Med EI 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.</p> <p>See the following for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000025S104. (Accessed April 22, 2021)</p>

For a current list of indications for each device, refer to the following FDA websites:

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> [use product code MCM (implant, cochlear)]
- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

(Accessed April 22, 2021)

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 21, 2021)

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 21, 2021)

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).

References

- American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS). Cochlear Implants. Position Statement. 2014. Available at: <http://www.entnet.org/content/position-statement-cochlear-implants>. Accessed April 21, 2021.
- American Academy of Pediatrics (AAP), Joint Committee on Infant Hearing. Year 2007 position statement: Principles and guidelines for early hearing detection and intervention programs. Pediatrics. 2007 Oct;120(4):898-921. Available at: https://www.infanthearing.org/resources/2007_JCIH.pdf. Accessed April 21, 2021.
- American Speech-Language-Hearing Association (ASHA). Public information. Hearing & balance. Disorders and Disease. Type, Degree, and Configuration of Hearing loss. 2015. Available at: <https://www.asha.org/uploadedFiles/AIS-Hearing-Loss-Types-Degree-Configuration.pdf>. Accessed April 21, 2021.
- American Speech-Language-Hearing Association (ASHA). Public information. Sensorineural Hearing Loss. Available at: <https://www.asha.org/public/hearing/sensorineural-hearing-loss/>. Accessed April 21, 2021.
- American Speech-Language-Hearing Association. Technical Report: Cochlear Implants. 2004. Available at: <https://www.asha.org/policy/TR2004-00041/>. Accessed April 21, 2021.
- Arndt S, Aschendorff A, Laszig R, Beck R, et al. Comparison of pseudobinaural hearing to real binaural hearing rehabilitation after cochlear implantation in patients with unilateral deafness and tinnitus. Otol Neurotol. 2011 Jan;32(1):39-47.
- Benchetrit L, Ronner EA, Anne Set al. MS. Cochlear implantation in children with single-sided deafness: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2021 Jan 1;147(1):58-69.
- Brodie A, Smith B, Ray J. The impact of rehabilitation on quality of life after hearing loss: a systematic review. Eur Arch Otorhinolaryngol. 2018 Oct;275(10):2435-2440.
- Bruijnzeel H, Ziyilan F, Stegeman I, et al. A Systematic review to define the speech and language benefit of early (< 12 months) pediatric cochlear implantation. Audiol Neurootol. 2016;21(2):113-26.

Buss E, Dillon MT, Rooth MA, et al. Effects of cochlear implantation on binaural hearing in adults with unilateral hearing loss. *trends hear.* 2018 Jan-Dec; 22.

Clark, J. G. (1981). Uses and abuses of hearing loss classification. *Asha*, 23, 493–500.

Cohen SM, Svirsky MA. Duration of unilateral auditory deprivation is associated with reduced speech perception after cochlear implantation: A single-sided deafness study. *Cochlear Implants Int.* 2019 Mar;20(2):51-56.

Dettman SJ, Dowell RC, Choo D, et al. Long-term communication outcomes for children receiving cochlear implants younger than 12 months: A multicenter study. *Otol Neurotol.* (2016 Feb); 37(2):e82–e95.

Dillon MT, Buss E, Anderson ML, et al. Cochlear implantation in cases of unilateral hearing loss: initial localization abilities. *Ear Hear.* 2017 Sep/Oct;38(5):611-619.

Dillon MT, Buss E, Rooth MA, et al. Effect of cochlear implantation on quality of life in adults with unilateral hearing loss. *Audiol Neurootol.* 2017;22(4-5):259-271.

Donato M, Santos R, Correia F, et al. Single-sided deafness: Bone conduction devices or cochlear implantation? A systematic review with meta-analysis. *Acta Otorrinolaringol Esp.* 2021 Mar-Apr;72(2):101-108.

Durisin M, Büchner A, Lesinski-Schiedat A, et al. Cochlear implantation in children with bacterial meningitic deafness: The influence of the degree of ossification and obliteration on impedance and charge of the implant. *Cochlear Implants Int.* 2015 May;16(3):147-58.

ECRI. Cochlear implants for treating single-sided deafness with and without tinnitus. Plymouth Meeting (PA): ECRI; 2021 Apr 1. (Clinical Evidence Assessment).

Firszt JB, Reeder RM, Holden LK, et al. Asymmetric Hearing Study Team. Results in adult cochlear implant recipients with varied asymmetric hearing: a prospective longitudinal study of speech recognition, localization, and participant report. *Ear Hear.* 2018 Sep/Oct;39(5):845-862.

Forli F, Arslan E, Bellelli S, et al. Systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in paediatric patients. *Acta Otorhinolaryngol Ital.* 2011 Oct;31(5):281-98.

Francis HW, Yeagle JD, Brightwell T, et al. Central effects of residual hearing: implications for choice of ear for cochlear implantation. *Laryngoscope.* 2004;114(10 I):1747-1752.

Friedland DR, Runge-Samuelson C. Soft cochlear implantation: rationale for the surgical approach. *Trends Amplif.* 2009 Jun;13(2):124-38.

Friedland DR, Runge-Samuelson C. Soft cochlear implantation: rationale for the surgical approach. *Trends Amplif.* 2009 Jun;13(2):124-38.

Galvin KL, Hughes KC, Mok M. Can adolescents and young adults with prelingual hearing loss benefit from a second, sequential cochlear implant? *Int J Audiol.* 2010 May;49(5):368-77.

Gantz BJ, Dunn C, Oleson J, et al. Multicenter clinical trial of the Nucleus Hybrid S8 cochlear implant: Final outcomes. *Laryngoscope.* 2016 Apr;126(4):962-73.

Gantz BJ, Dunn CC, Oleson J, et al. Acoustic plus electric speech processing: Long-term results. *Laryngoscope.* 2018 Feb;128(2):473-481.

Gaylor, JM, Raman, G, Chung, M, et al. Cochlear implantation in adults: a systematic review and meta-analysis. *JAMA otolaryngology– head & neck surgery.* 2013 Mar;139(3):265-72.

Härkönen K, Kivekäs I, Kotti V, et al. Hybrid cochlear implantation: quality of life, quality of hearing, and working performance compared to patients with conventional unilateral or bilateral cochlear implantation. *Eur Arch Otorhinolaryngol.* 2017 Oct;274(10):3599-3604.

Hayes Inc. Hayes Evidence Analysis Research Brief. MED-EL Cochlear Implant System with Synchrony/Synchrony 2 (MED-EL Corp) for adults with unilateral sensorineural hearing loss. Lansdale, PA: Hayes Inc.; November 2019. Archived December 20, 2020.

Hayes Inc. Hayes Evidence Analysis Research Brief. Cochlear implantation for adults with single-sided deafness and tinnitus. Lansdale, PA: Hayes Inc.; October 2020..

Hoff S, Ryan M, Thomas D, et al. Safety and effectiveness of cochlear implantation of young children, including those with complicating conditions. *Otol Neurotol.* 2019;40(4):454–463.

Hwa TP, Sturm JJ, Losenegger T, et al. Impact of underlying diagnosis on speech and quality of life outcomes after cochlear implantation for single-sided deafness. *Otol Neurotol*. 2020 Apr;41(4):e432-e440.

Kelsall DC, Arnold RJG, Lionnet L. Patient-reported outcomes from the United States clinical trial for a hybrid cochlear implant. *Otol Neurotol*. 2017 Oct;38(9):1251-1261.

Kim Y, Patel VA, Isildak H, et al. An analysis of safety and adverse events following cochlear implantation in children under 12 months of age. *Otol Neurotol*. 2017 Dec;38(10):1426-1432.

Kitterick PT, Smith SN, Lucas L. Hearing instruments for unilateral severe-to-profound sensorineural hearing loss in adults: a systematic review and meta-analysis. *Ear Hear*. 2016 Sep-Oct;37(5):495-507.

Labadie RF, Carrasco VN, Gilmer CH, et al. Cochlear implant performance in senior citizens. *Otolaryngol Head Neck Surg*. 2000;123(4):419-424.

Lammers MJ, van der Heijden GJ, Pourier VE, Grolman W. Bilateral cochlear implantation in children: a systematic review and best-evidence synthesis. *Laryngoscope*. 2014 Jul;124(7):1694-9.

Lorens A, Kruszyńska M, Obrycka A, et al. Binaural advantages in using a cochlear implant for adults with profound unilateral hearing loss. *Acta Otolaryngol*. 2019 Feb;139(2):153-161.

Majdani O, Leinung M, Rau T, et al. Demagnetization of cochlear implants and temperature changes in 3.0T MRI environment. *Otolaryngol Head Neck Surg*. 2008;139(6):833-839.

McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of cochlear implantation outcomes evaluated with general health-related patient-reported outcome measures. *Otol Neurotol*. 2018 Jan;39(1):29-36.

McRackan TR, Bauschard M, Hatch JL, et al. Meta-analysis of quality-of-life improvement after cochlear implantation and associations with speech recognition abilities. *Laryngoscope*. 2018 Apr;128(4):982-990.

Mertens G, De Bodt M, Van de Heyning P. Evaluation of long-term cochlear implant use in subjects with acquired unilateral profound hearing loss: focus on binaural auditory outcomes. *Ear Hear*. 2017;38(1):117-25.

Neben N, Buechner A, Schuessler M, et al. Outcome evaluation on cochlear implant users with residual hearing. *Cochlear Implants Int*. 2018 Mar;19(2):88-99.

Nicolas S, Gallois Y, Calmels MN, et al. Quality of life of children treated for unilateral hearing loss: a systematic review and meta-analysis. *Arch Dis Child*. 2021 Feb 26;archdischild-2020-320389.

Noble W, Tyler R, Dunn C, et al. Unilateral and bilateral cochlear implants and the implant-plus-hearing-aid profile: comparing self-assessed and measured abilities. *Int J Audiol*. 2008 Aug;47(8):505-14.

Ontario Health (Quality). Implantable devices for single-sided deafness and conductive or mixed hearing loss: A Health Technology Assessment. *Ont Health Technol Assess Ser*. 2020 Mar 6;20(1):1-165.

Peter N, Liyanage N, Pfiffner F, et al. The influence of cochlear implantation on tinnitus in patients with single-sided deafness: a systematic review. *Otolaryngol Head Neck Surg*. 2019 Oct;161(4):576-588.

Peters JP, van Zon A, Smit AL, et al. CINGLE-trial: cochlear implantation for siNGLE-sided deafness, a randomised controlled trial and economic evaluation. *BMC Ear Nose Throat Disord*. 2015 May 23;15:3.

Philippon D, Bergeron F, Ferron P, et al. Cochlear implantation in postmeningitic deafness. *Otol Neurotol*. 2010 Jan;31(1):83-7.

Pillsbury HC 3rd, Dillon MT, Buchman CA, et al. Multicenter US clinical trial with an Electric-Acoustic Stimulation (EAS) System in adults: Final outcomes. *Otol Neurotol*. 2018 Mar;39(3):299-305.

Poncet-Wallet C, Mamelle E, Godey B, et al. Prospective multicentric follow-up study of cochlear implantation in adults with single-sided deafness: tinnitus and audiological outcomes. *Otol Neurotol*. 2020 Apr;41(4):458-466.

Prejban DA, Hamzavi JS, Arnoldner C, et al. Single sided deaf cochlear implant users in the difficult listening situation: speech perception and subjective benefit. *Otol Neurotol*. 2018 Oct;39(9):e803-e809.

Raman, G, Lee, J, Chung, M. et al. Effectiveness of Cochlear Implants in Adults with Sensorineural Hearing Loss. *Technology Assessment Report*. April 2011.

Roland JT Jr, Gantz BJ, Waltzman SB, et al. Long-term outcomes of cochlear implantation in patients with high-frequency hearing loss. *Laryngoscope*. 2018 Aug;128(8):1939-1945.

Roland JT Jr, Gantz BJ, Waltzman SB, et al.; Multicenter Clinical Trial Group. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. *Laryngoscope*. 2016 Jan;126(1):175-81.

Rubin LG, Papsin B; American Academy of Pediatrics Committee on Infectious Diseases and Section on Otolaryngology-Head and Neck Surgery. Cochlear implants in children: surgical site infections and prevention and treatment of acute otitis media and meningitis. *Pediatrics*. 2010 Aug;126(2):381-91.

Smulders, YE, van Zon, A, Stegeman, I, et al. Comparison of bilateral and unilateral cochlear implantation in adults: A randomized clinical trial. *JAMA Otolaryngology– Head & Neck Surgery*. 2016;142:249-56.

Távora-Vieira D, Rajan GP, Van de Heyning P, et al. Evaluating the long-term hearing outcomes of cochlear implant users with single-sided deafness. *Otol Neurotol*. 2019 Jul;40(6):e575-e580.

Thompson NJ, Dillon MT, Buss E, et al. Subjective benefits of bimodal listening in cochlear implant recipients with asymmetric hearing loss. *Otolaryngol Head Neck Surg*. 2020 Jun;162(6):933-941.

Van de Heyning P, Vermeire K, Diebl M, et al. Incapacitating unilateral tinnitus in single-sided deafness treated by cochlear implantation. *Ann Otol Rhinol Laryngol*. 2008 Sep;117(9):645-52

van Zon A, Smulders YE, Stegeman I, et al. Stable benefits of bilateral over unilateral cochlear implantation after two years: A randomized controlled trial. *Laryngoscope*. 2017 May;127(5):1161-1168.

Policy History/Revision Information

Date	Summary of Changes
02/01/2023	<ul style="list-style-type: none"> Created state-specific policy version
08/01/2021	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised coverage criteria for hybrid cochlear implantation; replaced criterion requiring “diagnosis of bilateral severe to profound Sensorineural Hearing Loss in the mid to high frequencies with residual low-frequency hearing sensitivity” with “diagnosis of bilateral severe to profound <i>or moderate sloping to profound</i> Sensorineural Hearing Loss in the mid to high frequencies with residual low-frequency hearing sensitivity” Added language to indicate the cochlear implant’s external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and the implantable components are considered under the medical-surgical benefit <ul style="list-style-type: none"> Check the federal, state or contractual requirements for benefit plan coverage Refer to the Coverage Determination Guideline titled <i>Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements</i> <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information Archived previous policy version CS019.M

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.

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