Cochlear Implants and Auditory Brainstem Implants

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Cochlear Implants and Auditory Brainstem Implants: Guideline Note 31, Line 323

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: This policy does not apply to osseointegrated implants (aka bone-anchored hearing aids (BAHA)), which are addressed in a separate medical policy (see Policy Cross References below).

Cochlear Implants: Children

I. The use of FDA-approved unilateral or bilateral cochlear implants (Table. 1) in children (up to 17 years of age) may be considered **medically necessary** when **all** of the following criteria (A.-D.) are met:

   A. Patient has been diagnosed with unilateral or bilateral profound sensorineural hearing loss with thresholds of 90 dB (decibels) or greater at 1000 Hz (Hertz); **and**
   B. Patient has limited or no benefit from properly fitted bilateral hearing aids defined by **at least one** of the following criteria (1.-2.):
      1. In younger children (up to 4 years of age) **both** criteria (a. and b.) are met:
         a. Quantifiable lack of progress in the development of simple auditory skills (e.g., Meaningful Auditory Integration Scale or Early Speech Perception Test) in conjunction with appropriate amplification; **and**
         b. Participation in intensive aural habilitation over a three-to-six-month period; **or**
      2. In older children (5-17 years of age) a ≤30% correct on open-set tests (e.g., Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills); **and**
   C. Patient and/or caregiver is able to participate in a post-cochlear implant rehabilitation program in order to achieve maximum benefit from the cochlear implant device; **and**
   D. Patient is an appropriate candidate for cochlear implantation and has **none** of the following contraindications (1.-4.):

1. Absent cochlear nerve or cochlear development as evidenced by imaging; **or**
2. Deafness resulting from damage to the acoustic nerve or central auditory pathway; **or**
3. Active or chronic infections of the middle ear or mastoid cavity; **or**
4. Tympanic membrane perforation at the time of procedure.

II. The use of a unilateral or bilateral cochlear implant in children (up to 17 years of age) is considered **not medically necessary** when criterion I. above is not met.

Cochlear Implants: Adults

III. The use of FDA-approved unilateral or bilateral cochlear implants (Table. 1) in adults (18 years of age or older) may be considered **medically necessary** when **all** of the following criteria (A.-D.) are met:

A. Patient has been diagnosed with unilateral or bilateral severe-to-profound sensorineural hearing loss determined by a pure tone average of 70 dB (decibels) or greater at 500, 1000, and 2000 Hz (Hertz); **and**
B. Patient has limited or no benefit from properly fitted bilateral hearing aids, as defined by scoring ≤50% correct on tape-recorded tests of open-set sentence recognition; **and**
C. Patient and/or caregiver is able to participate in a post-cochlear implant rehabilitation program in order to achieve maximum benefit from the cochlear implant device; **and**
D. Patient is an appropriate candidate for cochlear implantation and has **none** of the following contraindications (1.-4.):
    1. Absent cochlear nerve or cochlear development as evidenced by imaging; **or**
    2. Deafness resulting from damage to the acoustic nerve or central auditory pathway; **or**
    3. Active or chronic infections of the middle ear or mastoid cavity; **or**
    4. Tympanic membrane perforation at time of procedure.

IV. The use of a unilateral or bilateral cochlear implant in adults is considered **not medically necessary** when criterion III. above is not met.

Upgrade/Replacement of Cochlear Implants

V. Upgrade or replacement of an existing implant and/or external system (e.g., external receiver, external speech processor) may be considered **medically necessary** when **at least one** of the following criteria (A.-B.) is met:

A. There is clinical documentation of quantifiable testing (e.g., pure-tone testing) indicating the patient's auditory response with the existing components is inadequate; **or**
B. One or more of the device components is no longer functional and is no longer under warranty and cannot be repaired.

VI. Upgrade or replacement of an existing implant and/or external system (e.g., external receiver, external speech processor) is considered **not medically necessary** when criterion V. above is not met.

VII. Upgrade or replacement of an existing functional implant and/or external system (e.g., external receiver, external speech processor) for convenience or aesthetic purposes (e.g., smaller profile components or switching from a body-worn to a behind-the-ear external sound processor) is considered **cosmetic**.

Auditory Brainstem Implants

VIII. The use of FDA-approved auditory brainstem implants (Table. 2) may be considered **medically necessary** when **all** of the following criteria (A.-C.) are met:

A. Patient is 12 years of age or older; **and**
B. Patient has been diagnosed with Neurofibromatosis Type 2 (NF2); **and**
C. The patient meets **at least one** of the following criteria (1.-2.):
    1. The patient is completely deaf due to bilateral surgical resection of neurofibromas of the auditory nerve; **or**
    2. Bilateral surgical resection of neurofibromas of the auditory nerve is planned and is expected to result in complete bilateral deafness.

IX. The use of an auditory brainstem implant is **considered not medically necessary** when criterion VIII. above is not met.

Hybrid Cochlear Implants

X. The use of FDA-approved hybrid cochlear implant (cochlear implant with external hearing aid) (Table. 3) may be considered **medically necessary** when **all** of the following criteria (A.-H.) are met:
    A. Patient is 18 years of age or older; **and**
    B. Patient has bilateral severe to profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; **and**
    C. Patient obtains limited benefit from appropriately fit bilateral hearing aids; **and**
    D. Patient has normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz) in the ear selected for implantation; **and**
    E. Patient has 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**
    F. Patient has moderately severe to profound mid to high-frequency hearing loss (threshold average of 2000, 3000, and 4,000 Hz ≥ 60 dB HL) in the contralateral ear; **and**
    G. Patient's preoperative speech perception is as follows (1.-2.):
        1. Consonant-Nucleus-Consonant word recognition score between 10% and 60%, inclusively, in the ear to be implanted; **and**
        2. Consonant-Nucleus-Consonant word recognition score in the contralateral ear equal to, or better than that of the ear to be implanted, but not more than 80% in the best-aided condition; **and**
    H. Patient has none of the following contraindications (1.-4.):
        1. Deafness due to lesions of the acoustic nerve or central auditory pathway; **or**
        2. Active middle ear disease, with or without tympanic membrane perforation; **or**

3. Absence of cochlear development; **or**
4. Duration of severe to profound hearing loss of 30 years or greater.

XI. The use of a hybrid cochlear implant is considered **not medically necessary** when criterion X. above is not met.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Hearing Aids, MP261
- Bone-Anchored Hearing Aids, MP398

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Sensorineural Hearing Loss (SNHL) and Cochlear Implants

"SNHL occurs when there is damage to the inner ear (cochlea), or to the nerve pathways from the inner ear to the brain."[1] SNHL is due to a loss of cilia (specialized cells) lining the cochlear; thus sound waves entering the cochlea cannot be transformed into nerve impulses. The most common causes of cochlear damage includes, prolonged noise exposure, head trauma, congenital abnormalities, and viruses or infection (e.g., mumps, meningitis, otitis media). Typically, hearing loss will be characterized as prelingual (before speech) versus postlingual (after speech) and unilateral (normal hearing in one ear and impaired hearing in the other ear) versus bilateral (impaired hearing in both ears).

In the United States, the prevalence of hearing loss in children is 5 per 1000, and about 16% of adults have hearing impairment.[2,3] Hearing loss can cause significant impacts on speech and language, cognition, education, social skills, and employment. Cochlear implants have been developed for children and adults with severe-to-profound bilateral sensorineural hearing loss, with the goal of improving hearing and subsequently reducing these life-long functional impacts.

Cochlear Implants

The cochlear implant device is composed of external parts (microphone, speech processor, and transmitter) and surgically implanted internal parts (receiver and electrodes) that function together to allow the use to perceive sound.[4] The microphone picks up sounds and transfers them to the speech processor, the speech processor analyzes the sounds and directs them to the transmitter, the transmitter sends the signals to the implanted receiver, the receiver delivers the coded electrical signals to the array of electrodes implanted in the cochlea, and the electrodes stimulate the auditory nerve; thus producing sound sensations.

Placement of the cochlear implant requires a surgical procedure and 4-6 weeks of healing. After implantation and recovery, the patient is fit with the external parts and the device electrodes are activated, adjusted, and programmed. Typically, the fitting and adjustment process takes place over the course of several weeks to months. Also, both children and adults require extensive auditory rehabilitation to learn how to use the implant, interpret sounds, and develop communication skills.

Hybrid Cochlear Implants

Hybrid cochlear implants have also been developed for adults with severe-to-profound sensorineural hearing loss limited to high frequencies.[5] The device consists of a unilateral (one-side) cochlear implant electrode array with external acoustic amplification (i.e. hearing aid). Since these individuals can still perceive low frequency sounds, the hybrid cochlear implant is shorter and narrower and is only implanted partway into the cochlea; therefore, avoiding damage to areas of the cochlea that remain intact.[6] As with traditional cochlear implants, the hybrid devices require surgical implantation and extensive auditory rehabilitation.

Neurofibromatosis Type 2 (NF2) and Auditory Brainstem Implants (ABI)

NF2 is a rare (1 in 200,000) genetic disorder which causes the growth of benign tumors on the auditory nerves (pathway of information from the inner ear to the brain).[7-9] Symptoms of NF2 typically appear around puberty or early adulthood and include balance issues, tinnitus (ringing in the ears), and/or progressive hearing loss. Although the tumors are noncancerous, surgical treatment of NF2 is sometimes indicated when there is brainstem compression, deterioration of hearing, and/or facial nerve dysfunction. The surgery requires severing or cutting the auditory nerves in order to remove the tumors; thus causing total hearing loss. Due to the damage of the auditory nerves, these patients are not candidates for hearing aids or cochlear implants.

An auditory brainstem implant (ABI) is used to improve hearing in NF2 patients who have total hearing loss or are expected to have total hearing loss after surgical excision of the auditory nerve tumors.[9] Typically, the ABI is placed at the same time as the first-side surgical removal of the auditory nerve tumors; thus allowing the patient time to adjust before total loss of hearing in the second ear.[10] The ABI electrodes are implanted in the cochlear nucleus complex of the brain, the last step in the auditory pathway, in order to bypass the cochlea and damaged auditory nerves. The ABI is also composed of external parts, a sound processor and microphone. The microphone picks up the sound and turns it into an electrical signal, the processor transmits the electrical signal to the receiver, and the receiver sends the signal to the electrode array implanted in the brainstem.

Table. 1 FDA-Approved Cochlear Implants

The U.S. Food and Drug Administration (FDA) has approved cochlear implants from 3 manufacturers under the premarket approval (PMA) process.[11]

Device & Manufacturer	FDA Labeled Indications: Adults	FDA Labeled Indications: Children
HiResolution™ Bionic Ear System[12] by	• 18 years of age or older	• 12 months through 17 years of age • Profound, bilateral sensorineural deafness (>90 dB)

Advanced Bionics *Example Devices Include:* • Naida CI M30 • Naida CI M90 • Sky CI M90	• Severe-to-profound, bilateral sensorineural hearing loss (>70 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)	• 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, which is defined as: ○ In younger children (<4 years of age): ▪ A failure to reach a developmentally appropriate auditory milestones (such as spontaneous response to name in quiet or to environmental sounds) measured using: • the Infant-Toddler Meaningful Auditory Integration Scale; or • Meaningful Auditory Integration Scale; or • <20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice (70 dB SPL)
The Cochlear™ Nucleus® Cochlear Implant System[13] by Cochlear Americas®	• Individuals 18 years of age or older who have bilateral, pre, peri or post linguistic sensorineural hearing impairment • Limited benefit from appropriate binaural hearing aids, as 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 • Moderate to profound hearing loss in the low frequencies and profound (≥ 90 dB HL) hearing loss in the mid to high speech frequencies	• Children 9 to 24 months of age who have bilateral profound sensorineural deafness • Children two years of age or older may demonstrate severe to profound hearing loss bilaterally • Limited benefit from appropriate binaural hearing aids, which is defined as: ○ In younger children: ▪ 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. ○ In older children: ▪ ≤ 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.
Med-EL® Cochlear Implant System[14,15] by Med-EL®	• 18 years of age or older who have bilateral, sensorineural hearing impairment • Limited benefit from appropriately fitted binaural hearing aids, defined by test scores of 40% correct or less in best aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences) • Bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz	• 12 months to 17 years 11 months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. • Lack of hearing aid benefit is defined as: ○ In younger children: ▪ 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 ○ In older children: ▪ < 20% correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills • A three to six month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.
	Individuals ages 5 years and above with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where: • SSD is defined as profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear. • AHL is defined as a profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in pure tone averages (PTAs) between ears. • Profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild	

	hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Table. 2 FDA-Approved Auditory Brainstem Implant

The U.S. Food and Drug Administration (FDA) has approved one auditory brainstem implant under the premarket approval (PMA) process.[16]

Device & Manufacturer	FDA Labeled Indications
Nucleus® 24 ABI by Cochlear Americas®[13]	• Individuals 12 years of age or older • Diagnosed with Neurofibromatosis Type 2 (NF2) • Implantation may occur during first- or second-side tumor removal or in patients with previously removed acoustic tumors bilaterally • Because the surgical tumor excision and electrode placement eliminates residual hearing, preoperative audiological criteria are not relevant • Prospective implant recipients and their families should have appropriate expectations, regarding the potential benefits of an auditory brainstem implant, and should be highly motivated to participate in the rehabilitation process

Table. 3 FDA-Approved Hybrid Cochlear Implants

The U.S. Food and Drug Administration (FDA) has approved hybrid cochlear implants from 2 manufacturers under the premarket approval (PMA) process.[17,18]

Device & Manufacturer	FDA Labeled Indications
Nucleus® Hybrid™ L24 Cochlear Implant System[19] by Cochlear Americas®	• Individuals 18 years of age or older • Patient has bilateral severe to profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity • Patient obtains limited benefit from appropriately fit bilateral hearing aids • Patient has normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz) in the ear selected for implantation • Patient has 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 • Patient has moderately severe to profound mid to high-frequency hearing loss (threshold average of 2000, 3000, and 4,000 Hz ≥ 60 dB HL) in the contralateral ear • Patient's preoperative speech perception is as follows: ○ Consonant-Nucleus-Consonant (CNC) word recognition score between 10% and 60%, inclusively, in the ear to be implanted

	○ CNC word recognition score in the contralateral ear equal to, or better than that of the ear to be implanted, but not more than 80% in the best-aided condition • Patient has none of the following contraindications: ○ Deafness due to lesions of the acoustic nerve or central auditory pathway ○ Active middle ear disease, with or without tympanic membrane perforation ○ Absence of cochlear development ○ A duration of severe to profound hearing loss of 30 years or greater
Med EL EAS™ by Med-EL®[20]	• Individuals 18 years of age or older • Patient has residual low-frequency hearing sensitivity • Patient has severe to profound high-frequency sensorineural hearing loss • Candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids • Patient obtains minimal benefit from conventional acoustic amplification • Patient has normal to moderate hearing loss in the low frequencies (thresholds no poorer than 65 dB HL up to and including 500 Hz) in the ear selected for implantation • Patient has severe to profound mid- to high-frequency hearing loss (threshold 2000 Hz and above ≥ 70 dB HL) 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 • 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 • Patient has none of the following contraindications: ○ Intolerance of the materials used in the implant (medical grade silicone, platinum, platinum iridium) ○ Absence of cochlear development ○ Cause of deafness is non-functionality of the auditory nerve and/or the auditory pathways ○ External or middle ear infections ○ Perforated tympanic membrane in the ear to be implanted ○ Medical contraindications present against surgery of the middle and inner ear and anesthesia as required ○ Anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull, or prevent placement of the chosen electrode array into the cochlea. In such cases, using the cochlear implant must be carefully considered prior to surgery ○ Unstable psychological status of the patient ○ Unrealistic expectations ○ Partial deafness with unstable progressive hearing loss ○ Inability to use amplification devices, and /or presence of cochlear malformations

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of cochlear implants as a treatment for severe-to-profound bilateral sensorineural hearing loss in adults and children. Below is a summary of the available evidence identified through April 2025.

Cochlear Implants in Children and Adults

- In 2009, Bond and colleagues conducted a technology assessment to evaluate the efficacy and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults.[21] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The outcomes of interest were sensitivity to sound, speech perception, speech production, psychological outcomes, educational outcomes, adverse events, and health-related quality of life.

  The authors identified 33 publications eligible for inclusion giving a sample size of n=848. All studies indicated cochlear implants significantly improved sound and speech outcomes. Unilateral cochlear implants, when compared to hearing aids, produced significantly better results on all outcomes. Bilateral cochlear implants were statistically significantly better in the ability to understand speech in noisy conditions versus unilateral implants. Results also indicated bilateral cochlear implants significantly improved the ability to detect direction of sound and speech perception when compared to a unilateral implant with external hearing aid.

  In regard to safety, major complications occurred in 6.8% of pediatric procedures and 1.4% to 1.7% of adult procedures. The incidence of meningitis was reported to be 29 per 100,000 cochlear implanted adults and children. Minor complications occurred in 34.7% of children and 35.3% of adults. Commonly, device removal was due to device failure and occurred at rates of 0.9% in adults and children throughout 2 years. This rate increased to 5.1% to 10% over 11 or more years of follow-up. Also, 92% of implanted devices in adults and children lasted 11 years.

  This technology assessment was of good quality and had several strengths, including:

1. the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers following a pre-defined protocol
2. contacting authors of selected studies for additional information or data
3. assessment of heterogeneity and publication bias

The authors did indicate some included studies had limitations in design and internal validity and rated the overall evidence to be of moderate to poor quality. Another limitation noted by the authors was the large degree of heterogeneity between studies; therefore, meta-analyses were not possible. Also, there is a lack of randomized controlled trials evaluating cochlear implants and only two were identified for inclusion in the systematic review. Ultimately, the authors concluded "unilateral and bilateral cochlear implants are safe and effective for children and adults."[21]

Cochlear Implants in Adults

Systematic Reviews

Unilateral and Bilateral Cochlear Implants

- In 2013, Gaylor and colleagues conducted a systematic review and meta-analysis evaluating cochlear implantation in adults.[22] Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. Authors aimed to answer the following:

    1. What communication and health-related quality of life (QOL) outcomes are achieved in adults who undergo unilateral cochlear implantation?
    2. What communication and health-related quality of life (QOL) outcomes are gained from the use of bilateral compared with unilateral cochlear implants.

  The authors identified 45 publications eligible for inclusion, of which 23 articles were found to have a medium risk of bias and 22 articles were found to have a high risk of bias. Due to the heterogeneity between testing methods, meta-analysis was not able to be performed for speech-related outcomes.

  In regards to communication-related outcomes in unilateral implantation, 16 studies were identified that measured this outcome by open-set sentence tests or syllable word tests. All studies reported improvement in mean speech scores after implantation; however, 5 studies found no statistically significant difference. The higher-quality studies all indicated significant improvement in speech outcomes after implantation compared with before. For the evaluation of QOL outcomes with unilateral cochlear implants, 13 studies were identified that indicated significant improvement in QOL after unilateral implantation. In addressing communication-related outcomes in bilateral implantation, the authors identified 15 studies which all showed statistically significant improvement in communication scores when compared with unilateral implantation. Also, bilateral cochlear implants showed increased efficacy in sound localization compared to unilateral implants.

Only 3 studies were identified for the evaluation of QOL before and after bilateral cochlear implants, and the results varied across studies.

Strengths of this systematic review included the selection of studies by independent reviewers following a pre-defined protocol, including a large number of studies, assessment of quality, and evaluation of heterogeneity prior to conducting meta-analyses. Limitations were seen in the poor quality of selected studies, the inability to conduct a meta-analysis for speech-related outcomes due to heterogeneity, short follow-up periods, and a lack of randomization of included studies. Ultimately, the authors concluded both unilateral and bilateral cochlear implants in adults provide improved hearing. Bilateral cochlear implants enhance sound localization and unilateral implants were shown to significantly improve quality of life. The authors also stated, "future studies of longer duration, higher quality reporting, and large databases or registries of patients with long-term follow-up data are needed to yield stronger evidence."[22]

- In 2011, Berrettini et al. conducted a systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in adult patients.[23] Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The authors aimed to evaluate (1) unilateral cochlear implants in advanced-age adult patients (2) bilateral cochlear implants versus unilateral cochlear implants versus bimodal stimulation (unilateral cochlear implant with external hearing aid on the contralateral side) and (3) benefits from a unilateral cochlear implant procedure in adult patients with prelingual deafness. A total of 24 publications were identified as eligible for inclusion. Due to heterogeneity between the selected studies, meta-analysis was determined to be inappropriate.

  Of the selected publications, 8 evaluated unilateral cochlear implants in advanced age adult patients. All studies indicated improved perceptive abilities post-cochlear implant. Also, 6 of the 8 studies reported no statistically significant difference between elderly and younger patients in audiological, language, and communication outcomes. Elderly cochlear implant patients also showed statistically significant improvements in quality of life. For the evaluation of bilateral cochlear implants versus unilateral cochlear implants, versus bimodal stimulation, 13 articles were identified. Ten of the 13 studies indicated bilateral cochlear implants statistically significantly improved hearing ability in noisy environments. Bilateral cochlear implants also significantly improved sound localization and hearing ability in a silent environment when compared to a unilateral implant. Only three studies were identified that evaluated the benefits of a unilateral cochlear implant in adult patients with prelingual deafness. The selected studies reported hearing and quality of life benefits following unilateral cochlear implantation; however, the study sample was limited and inter-study variability was present.

  Strengths of this systematic review included the selection of studies by independent reviewers following a pre-defined protocol, assessment of quality, and evaluation of heterogeneity prior to conducting meta-analyses. Limitations were seen in the poor quality of selected studies, the inability to conduct a meta-analysis due to significant heterogeneity between studies, short follow-up periods, and a lack of randomization of included studies. The authors concluded unilateral cochlear implants are efficacious in older adult patients, bilateral cochlear implants offer advantages in

hearing ability in louder environments and sound localization, and the use of unilateral cochlear implants in prelingually deafened adults should be analyzed on a case-by-case basis.

Bilateral Cochlear Implants

- In 2013 (updated in 2017, archived in 2018), Hayes published an evidence review evaluating bilateral cochlear implantation in adults with bilateral sensorineural hearing loss.[3] The review included 17 studies, with sample sizes ranging from 20 to 182 patients and follow-up periods ranging from 6 months to 5 years. Outcomes of interest included speech perception, speech comprehension, speech production, sound detection, sound localization, and quality of life.

  The Hayes evidence review found that bilateral cochlear implantation in adults with postlingual sensorineural hearing loss improves speech perception and localization, especially in noisy conditions. Studies also showed an improvement in functional hearing and quality of life in postlingually deafened adults after bilateral cochlear implants. There were very few adverse events associated with bilateral cochlear implants, and these complications were no greater than those seen with a unilateral implant. The Hayes review also indicated there was not enough evidence to confirm efficacy of bilateral cochlear implants in prelingually deafened adults. Also, there is no evidence supporting bilateral cochlear implants in adults with disabilities other than hearing loss.

  Ultimately, Hayes gave a, "B rating for bilateral cochlear implants in adults with severe to profound postlingual bilateral sensorineural deafness who will be able to undergo auditory rehabilitation after the procedure, have no disabilities that might interfere with auditory training, and have no structural abnormalities that might interfere with the success of the implantation."[3] Hayes reported a D2 rating for bilateral cochlear implants in prelingually deafened adults, adults with only moderate deafness, or adults with significant disabilities other than hearing loss due to an insufficient amount of published evidence to assess safety and efficacy.

- In 2013, van Schoonhoven and colleagues conducted a systematic review to evaluate the effectiveness of bilateral cochlear implants for severe-to-profound deafness in adults.[24] Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The authors aimed to assess the clinical effectiveness of bilateral cochlear implantation (BiCI) compared with unilateral cochlear implantation (UCI) alone or with a contralateral hearing aid (CIHA). A total of 14 publications were identified as eligible for inclusion, and most studies had a low level of evidence with a low, medium, or high risk of bias. Due to heterogeneity between the selected studies, meta-analysis was determined to be inappropriate.

  BiCI showed statistically significant improvements in sound localization when compared to UCI. The results also indicated BiCI were significantly better than UCI at helping patients perceive speech in noise. Speech perception in quiet outcomes showed no significant difference between BiCI, UCI, or CIHA. When compared to UCI, BiCI also showed significant improvements in hearing-related quality of life outcomes. Strengths of this study included the systematic selection and review of evidence following a pre-defined protocol, quality assessment following the Cochrane collaboration, and

assessment of the level of evidence. Limitations were identified in the heterogeneity between studies resulting in the inability to conduct a meta-analysis, inclusion of only one randomized controlled trial, and a poor level and quality of evidence. The authors concluded, "the current review provides additional evidence in favor of bilateral cochlear implantation, even in complex listening situations."[24]

- In 2012, Crathorne et al. conducted a systematic review to evaluate the effectiveness and cost-effectiveness of bilateral multichannel cochlear implants in adults with severe-to-profound hearing loss.[25] Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The systematic review of evidence produced 19 studies eligible for inclusion (n=843); of these, 18 measured clinical effectiveness, one was an economic evaluation, and one study measured both clinical and cost effectiveness. Due to heterogeneity in methodology and outcome measures between studies, meta-analysis was not possible.

  A total of 18 studies evaluated the effectiveness of bilateral versus unilateral cochlear implants, and all indicated bilateral cochlear implants improved hearing and speech perception. In regards to understanding speech, all studies (n=13) found significant improvement with bilateral cochlear implants and speech perception in noisy environments. All studies that evaluated hearing and/or sound localization identified a trend towards hearing improvement with bilateral cochlear implants, and five of these studies reported statistically significant differences between bilateral and unilateral cochlear implant groups. A total of 3 studies also incorporated quality of life outcomes, and all indicated improvements in quality of life after bilateral cochlear implants; however, one study found a statistically significant reduction at 3-months post-implant due to tinnitus (ringing in the ears). There was limited evidence evaluating cost-effectiveness (n=2), and the studies concluded "more quality of life was likely to be gained per unity of expenditure for unilateral than bilateral implants."[26,27]
  Strengths of this review included the systematic selection and review of evidence by independent reviewers following a pre-defined protocol, critical appraisal of selected studies, and the evaluation of heterogeneity between selected studies. Limitations were identified in the exclusion of studies not in the English language (potential publication bias), poor methodological quality of selected studies, inclusion of only 2 randomized controlled trials, and inability to perform meta-analyses. Ultimately, the authors concluded, "despite inconsistency in the quality of available evidence, the robustness of systematic review methods gives weight to the positive findings of included studies demonstrating that bilateral implantation is clinically effective in adults but unlikely to be cost-effective."[25]

Unilateral Cochlear Implants

- In 2010, Bond and colleagues conducted a systematic review of the literature to evaluate the effectiveness and cost-effectiveness of multi-channel unilateral cochlear implants in adults.[28] The authors aimed to identify if unilateral implants were more effective than non-technological hearing support or acoustic hearing aids and the economic evidence of unilateral cochlear implants in adults. Independent reviewers systematically searched research databases, identified relevant

studies, assessed quality, and extracted data. A total of 9 studies were determined to be eligible for inclusion, and the quality of selected studies ranged from poor to good quality. Due to methodological differences between studies, meta-analysis was not possible.

All but one study reported a significant benefit or a non-significant trend towards benefit from unilateral cochlear implants. The authors also evaluated duration of deafness and its potential impact on the effectiveness of unilateral cochlear implants. Duration of deafness was found to have an impact on speech perception and quality of life. Studies also showed that as the duration of deafness increased the effectiveness of the implant decreased. Also, increased effectiveness was demonstrated when the implant was placed in the ear with a shorter duration of deafness. A total of 3 studies evaluated unilateral cochlear implants versus acoustic hearing aids, and all studies indicated a greater benefit from cochlear implants. Adverse events were infrequent, and did not typically require removal of the implant. In regards to the cost-effectiveness evaluation, 4 studies were identified and all indicated unilateral cochlear implants to be cost-effective in adults; however, these economic evaluations occurred in the U.K. and may not be applicable to the U.S. population.

Strengths of this review include the systematic review of evidence by independent reviewers following a pre-defined protocol. Limitations were identified in the poor methodological quality of some included studies, inability to perform a meta-analysis due to the heterogeneity between studies, and a lack of randomized controlled trials included in the review. The authors concluded, "the methodologically weak but universally positive body of effectiveness evidence supports the use of unilateral cochlear implants in adults."[47] Based on the economic evaluations, the authors also indicate unilateral cochlear implants appear to be cost-effective in bilaterally deafened adults.

Randomized Controlled Trials (RCTs)

Bilateral versus Unilateral Cochlear Implants

- In 2016, Smulders et al. conducted a randomized controlled trial in order to compare bilateral cochlear implants (BCI) versus unilateral cochlear implants (UCI) in adults.[29] Eligible patients with bilateral sensorineural hearing loss were randomized 1:1 to undergo BCI or UCI (n=19 BCI and n=10 UCI) and were post-operatively followed through 1-year. Blinding was not possible due to the external components of the device (i.e., someone could see if a patient had one or two implants). Outcomes of interest were quality-of-hearing, speech intelligibility in noise, and sound localization.

  No losses to follow-up occurred, and all patients were available for 1-year follow-up. The results indicated improved hearing in both the BCI and UCI groups when compared with pre-operative hearing abilities. Statistically significant hearing improvements were seen in the BCI group for sound localization and hearing abilities when noise came from various directions. All participants reported significant improvements at 1-year follow-up in their quality-of-hearing and no statistically significant differences between the two groups were identified.

Methodological strengths of this study include the randomized, controlled design, recruitment of patients from 5 different health centers, no losses to follow-up, and *a priori* power calculations to detect clinically relevant differences between groups. Limitations were identified in the small sample sizes, short follow-up period, and a statistically significant difference between groups at baseline regarding pre-implantation hearing aid usage. Although blinding was not possible due to the nature of the device, potential bias cannot be excluded. The authors concluded the, "randomized clinical trial demonstrates a significant benefit of simultaneous BCI above UCI in daily listening situations for adults with postlingual deafness."[29]

- In 2017, van Zon and colleagues reported the 2-year follow-up results of the aforementioned randomized controlled trial.[30] Of the originally randomized patients, one withdrew from the study for personal reasons; therefore, 37 participants were available for 2-year follow-up. The results indicated no statistically significant differences between BCI and UCI for hearing abilities when sound and noise was present from straight ahead. Statistically significant differences were detected in favor of the BCI group when noise came from different directions and when speech was presented to the worst ear. The BCI group also had statistically significant improvements in sound localization when compared to the UCI group. At the 2-year follow-up, statistically significant differences were seen in favor of the BCI group for the patient-reported outcomes of speech intelligibility in silence, background noise, resonating environments, on the telephone, and on quality of hearing. No significant differences between groups were identified for the quality-of-life outcomes. When compared with the 1-year follow-up data, no significant differences at 2 years were found for any of the outcome measures. The authors concluded bilaterally implanted patients have significantly better every day hearing abilities (e.g. hearing in noisy environments and when noise comes from different directions) and sound localization throughout two years.

Cochlear Implants in Children

Systematic Reviews

Unilateral and Bilateral Cochlear Implants

- In 2011, Forli et al. conducted a systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in pediatric patients.[31] Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The authors aimed to evaluate (1) post-CI outcomes linked to precocity of CI (2) bilateral CI (simultaneous and sequential) versus unilateral CI and (3) benefits derived from the CI procedure in deaf children with associated disabilities. A total of 49 publications were identified as eligible for inclusion; including, 22 articles on aim 1, 20 articles on aim 2, and 7 articles on aim 3. Due to heterogeneity in methodological design and outcome measures between studies, meta-analysis was not able to be performed.

There were few studies identified in the literature regarding post-CI outcomes in children receiving cochlear implants with the first year of life. The few studies that were identified suggested children implanted at <12 months old have better communicative outcomes compared with children implanted

at >12 months old; however, studies did not report statistical significance and long-term outcomes remain unknown. In regards to cochlear implants in children after 1 year of age, all studies confirmed an advantage with respect to implant precocity, and, "many documented an advantage in children who received cochlear implants before 18 months of age compared to those implanted at a later stage."[31] In regards to bilateral CI versus unilateral CI, the selected studies indicate that bilateral CI offers advantages in the outcomes of sound localization and hearing in noise. Some studies also reported benefits in patients implanted with sequential bilateral CI with a short interval between implants. The evidence identified for aim 3, CI in deaf children with associated disabilities, indicated the CI procedure is suitable for children with other disabilities.

Strengths of this systematic review included the selection of studies by independent reviewers following a pre-defined protocol, assessment of quality, and evaluation of heterogeneity prior to conducting meta-analyses. Limitations were seen in the poor quality of selected studies, the inability to conduct a meta-analysis due to significant heterogeneity between studies, short follow-up periods, and a lack of randomization of included studies. Overall, the systematic review concluded that bilateral cochlear implantation provides significant benefits in sound localization and hearing in noise for bilaterally deafened children.

Bilateral Cochlear Implants

- In 2014, Lammers and colleagues conducted a systematic review of the literature to evaluate the effectiveness of bilateral cochlear implants over unilateral implants in children with sensorineural hearing loss.[32]Two independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. Outcomes of interest included preverbal communication, language development, sound localization, speech perception in quiet and in noise, speech production, and quality of life (generic and disease specific). Due to heterogeneity between studies, meta-analysis was not able to be performed; therefore, a best-evidence synthesis was conducted.

The systematic search of literature identified 21 articles eligible for inclusion that compared a bilateral cochlear implant group with a separate unilateral cochlear implant group. The authors identified consistent evidence demonstrating a benefit of bilateral implantation and sound localization. Bilaterally implanted children were found to be more responsive to vocal cues in the absence of visual reinforcement. Results varied regarding improved speech perception in noise with bilateral cochlear implants. The evidence also indicted a potential benefit for preverbal communication in children with bilateral cochlear implants. Regarding disease specific quality of life, bilaterally implant children demonstrated significantly higher scores for spatial and speech domains. No significant differences were identified between bilateral and unilateral implanted children for language development, speech perception in quiet, speech production, and generic quality of life.

Strengths of this study included the systematic review of evidence following a pre-defined protocol, assessment of quality, and evaluation of heterogeneity before pooling the data. Limitations were identified in the lack of randomization or blinding of included studies (deemed to be unethical or not feasible), the poor methodological quality of some selected studies, and the inability to perform a meta-

analysis due to significant heterogeneity between studies. The authors also noted limitations in data extraction due to several studies only reporting results in figures and graphs. Ultimately, the authors concluded that, "although randomized controlled trials are lacking, the results of our best-evidence synthesis indicate that the second cochlear implant might be especially useful in sound localization and possibly also in language development."[32]

- In 2013 (updated in 2017, archived in 2018), Hayes published an evidence review evaluating bilateral cochlear implantation in children with bilateral sensorineural hearing loss.[2] The review included 18 studies, with sample sizes ranging from 20 to 73 children and follow-up periods ranging from 3 months to 4 years. Outcomes of interest included speech perception, speech comprehension, speech production, sound detection, sound localization, and quality of life.

The Hayes evidence review found that, compared with unilateral cochlear implants, bilateral cochlear implants in children improves performance on speech perception and sound localization. Children using bilateral cochlear implants also showed significant hearing improvements in noisy conditions. Some studies indicated bilateral cochlear implants improve hearing-related quality of life; however, there was insufficient evidence to determine if these were meaningful functional quality of life benefits. There were very few adverse events associated with bilateral cochlear implants, and these complications are no greater than those seen with a unilateral implant. The Hayes review also indicated there was not enough evidence to confirm efficacy of bilateral cochlear implants in postlingually deafened children.

Ultimately, Hayes gave a "C rating for bilateral CI in children and adolescents with severe to profound prelingual bilateral deafness who will be able to undergo auditory rehabilitation after the procedure, have no significant disabilities other than hearing loss, and have no structural abnormalities that might interfere with the success of the implantation."[2] Hayes reported a D2 rating for bilateral cochlear implants in postlingually deafened children, children with only moderate deafness, or children with significant disabilities other than hearing loss due to an insufficient amount of published evidence to assess safety and efficacy.

Randomized Controlled Trials (RCTs)

No RCTs were identified for the evaluation of unilateral and/or bilateral cochlear implants in a pediatric population. Although the methodological design of an RCT is ideal for evaluating clinical effectiveness, this design could be unethical in a pediatric population. Studies evaluating cochlear implants in children utilized the cohort, cross-sectional, and case-control study designs.

Nonrandomized Studies

Unilateral Cochlear Implants

- In 2007, Uziel and colleagues conducted a 10-year follow-up of a consecutive series of children implanted with multichannel cochlear implants.[33] A total of 82 children with bilateral, profound sensorineural hearing loss who received cochlear implants through January 1989 and December

1995 were recruited from a pediatric cochlear implant program. The children were periodically monitored for more than 10 years, and only one child was lost to follow-up.

A total of 11 children experienced device failure or complications requiring re-implantation. These were commonly due to a defective device or an internal electrode array failure. All children who experienced device failure successfully received another cochlear implant on the opposite side. At 10 years follow-up, 96% of children reported they were still using the cochlear implant device and it continued to improve their hearing a speech capabilities. On average, 72% of words were correctly identified on speech discrimination tests, and word recognition increased by 7% between 5 and 10 years. Also, 66% of implanted children showed improved speech and were able to produce speech intelligible to the average listener. The authors also evaluated the children's academic and/or occupational status at the 10-year follow-up. All of the children attending high school were in mainstream classes and required no additional support. Of the children in junior high schools, 81% were in mainstream classes and half of them require additional speech therapy and/or educational support. Six children were attending a school for the deaf.

A significant strength of this study is the extended follow-up time of 10 years; thus allowing for long-term outcome and device durability assessments. Also, recruiting children over a 6-year time-period allows for inclusion of a wider range of children more generalizable to a larger population. Limitations are seen in the nonrandomized design and the recruitment of children from only one auditory rehabilitation program. The authors concluded their long-term study showed that cochlear implants in profoundly deaf children can help them develop functional levels of speech perception and production and perform satisfactory in academic environments.

Bilateral Cochlear Implants

- In 2015, Killan et al. conducted a retrospective data review to evaluate the effect of early auditory experience on the spatial listening skills of children with bilateral cochlear implants.[34] The authors pooled data collected during research and routine clinical testing of children aged 4-17 years who had received bilateral cochlear implants. The children were pooled into four groups: congenital early bilateral group (n=28), congenital late bilateral group (n=38), acquired/progressive group (n=16), and normal hearing (n=32). The outcomes of interest were sound-source localization and spatial release from masking (SRM) (a measure of the ability to use both ears to understand speech in noise).

In regards to sound-source localization, there was no significant difference in performance between congenital early and congenital late groups. A statistically significant difference in sound-source localization was reported in favor of the acquired/progressive group when compared with the congenital early and congenital late groups. A trend towards increased accuracy in sound-source localization was identified from the congenital late group (least accurate) to the congenital early group (moderate accuracy) to the acquired progressive group (most accurate). All three groups of bilaterally cochlear implanted children performed similarly on SRM testing.

Strengths of this study include the larger sample size, data acquisition from multiple health centers, and categorizing by the onset of deafness to evaluate implant efficacy. Limitations are present in the retrospective, nonrandomized design and the lack of patient and outcome data. Ultimately, the authors concluded "children with bilateral cochlear implants and early experience of acoustic hearing showed more accurate localization skills, on average, than children born profoundly deaf."[34]

- In 2019, Hoff and colleagues published a retrospective review of the safety and effectiveness of cochlear implantation of children under the age 37 months.[35] There were 219 children implanted, 55 (25.1%) of which had unilateral implantation, 53 (24.2%) with simultaneous bilateral implantation, and 111 (50.7%) with sequential bilateral implantation. There were few surgical complications, with 7 patients experiencing cerebrospinal fluid leak and one wound infection. Children implanted under 12 months developed open-set earlier (3.3 years vs 4.3 years, p≤0.001) and were more likely to develop oral-only communication (88.2% vs 48.8%, p≤0.001). Limitations of the study include its retrospective design and using data from a single center. The authors concluded that cochlear implantation can safely be done in children under 37 months or age, and that implantation below 12 months is positively associated with earlier open-set ability and oral-only communication.

Unilateral Versus Bilateral Cochlear Implants

- In 2010, Tait and colleagues conducted a prospective, observational study to compare the preverbal communication skills of two groups of very young children: those with unilateral cochlear implants and those with bilateral cochlear implants.[36] The study enrolled 69 children (n=42 unilaterally implanted and n=27 bilaterally implanted) and measured their preverbal skills at baseline and 1-year post-implantation using TAIT video analysis (an analysis method found to predict later speech outcomes in early implanted children). The TAIT video analysis evaluated "turns", which is when a child has the opportunity to communicate. Within these turns, preverbal skills are measured as either vocal or gestural.

At 12-months post-implantation there was no statistically significant difference between groups for vocal autonomy; however, a strongly significant difference was reported for vocal turn-taking and non-looking vocal turns in favor of the bilaterally implanted group. There was also a statistically significant difference between the two groups for gestural turn-taking and gestural autonomy. Strengths of this study include the prospective design and enrollment of children from multiple health centers. Limitations were identified in the small sample size, lack of randomization, and short follow-up period. Also, it is uncertain if the TAIT video analysis is a verified and reliable measure of speech outcomes in cochlear implanted children. The authors concluded, "profoundly deaf bilaterally implanted children are significantly more likely to use vocalization to communicate, and to use audition when interacting vocally with an adult, compared with unilaterally implanted children."[36]

Cochlear Implants for Unilateral Hearing Loss/Single-Sided Deafness

Systematic Reviews

- In 2024, ECRI published a systematic review assessing the efficacy of cochlear implants for treating single-sided deafness with and without tinnitus.[37] Authors assessed 5 systematic reviews (SRs) and 2 RCTs reporting on speech perception, sound localization, tinnitus suppression, quality of life, and surgery-related trauma. The SRs noted several limitations to the evidence base on CIs: 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. Only one RCT was noted. Despite the lack of high-quality evidence, all SRs consistently reported clinically significant improvement after CI. High-quality RCTs are needed to confirm these findings and determine the actual degree of hearing improvement possible with CI and differences in improvement depending on age and comorbidities. Authors concluded that evidence supporting cochlear implants for treating single-sided deafness with and without tinnitus is "favorable." They state: "CIs improve speech perception, sound localization, tinnitus, and quality of life (QOL), according to evidence from five systematic reviews (SRs) and two randomized controlled trials (RCTs). One SR indirectly compared CIs with bone conduction devices (BCDs), and two RCTs compared CIs with BCD, contralateral routing of sound (CROS), or no treatment and reported better audiologic outcomes and QOL with CIs; however, studies assessed too few patients per treatment arm and are at too high a risk of bias to be conclusive."

- In 2021, Benchetrit and colleagues conducted a systematic review and meta-analysis assessing the safety and efficacy of cochlear implantation in children with single-sided deafness.[38] Investigators systematically searched the literature through February 2020, identified eligible studies, assessed study quality, extracted data and pooled data using fixed-effect and random-effect models. Outcomes of interest included (1) postoperative changes in speech perception (in quiet was measured as a proportion of correct responses, and in noise was measured as decibel signal to noise ratio for speech reception threshold) and sound localization (measured in degree of localization error), (2) patient-reported audiological outcomes (measured by the speech, spatial, and qualities of hearing scale), and (3) device use rates among children who received cochlear implantation for single-sided deafness (SSD). In total, 12 observational studies evaluating 119 children were included for review.

Sounds localization as measured by degrees of error from true location improved significantly after cochlear implantations. Patients with acquired SSD and shorter duration of deafness compared with those with congenital SSD reported greater improvements in speech and spatial hearing qualities. The duration of deafness among device nonusers was also statistically significantly longer than the duration of deafness among regular device users. Investigators concluded that cochlear implantation for children with SSD was associated with clinically meaningful improvements in audiological and patient-reported outcomes; and that shorter duration of deafness may lead to better outcomes. Limitations included the reviewed studies' small sample sizes and significant patient and treatment heterogeneity. Additional research efforts, refined cochlear implantation, and candidacy criteria were also recommended.

- A 2020 systematic review by Levy and colleagues analyzed the benefit of cochlear implants for tinnitus relief among individuals with single-sided deafness (SSD).[39] A total of 17 studies met

inclusion criteria, totalling 247 patients with SSD. Tinnitus Handicap Inventory (THI) and Visual Analog Scale (VAS) for loudness measures were analyzed. Sample sizes ranged from5 to 26 participants, with 11 prospective and 6 retrospective studies. Among the 6 studies that provided data on THI, a mean difference between post- and pre-treatment of -35.4 points (95% CI, -55.8 to -15.0; $p < 0.001$) was found. The mean follow up period was 8.6 (range, 3-13) months post implantation. Among the 7 studies that documented VAS loudness, a post-implantation mean difference of -4.6 (CI, -6.0 to -3.3; $p< 0.001$) was found. Mean follow up duration was 14.8 (6-26) months, with 4 studies not documenting follow-up time. A weighted proportion of 14.9% (CI, 6.4–26.1) of patients experienced complete resolution of tinnitus, while 74.5% (CI 63.1–84.5) experienced partial improvement; 7.6% (CI, 4.1–12.6) of patients had no change in severity, and 3.0% [CI 1.0–6.7] experienced worsening of their tinnitus.

This systematic review has a number of limitations. There were no comparator studies reviewed, and a number of the studies were retrospective. Each study had a small sample size, and even the meta-analysis sample size was fairly small. There is potential for high risk of selection bias within the studies and there was substantial heterogeneity across study methods and outcome measures. The authors concluded that patients with SSD reported significant reduction in THI and VAS loudness scores, representing an overall improvement in tinnitus severity.

- In 2019, Peters and colleagues published a systematic review on cochlear implantation in children with unilateral hearing loss.[40] Five studies met inclusion criteria, 2 prospective case series, 2 retrospective case series, and one case report, with sample sizes ranging from 1-13 participants. The authors found that all studies had a high risk of bias and that there were high levels of heterogeneity in patient groups, methodology, and outcome measures. The authors noted that speech perception in noise and localization ability improved in most patients, but no conclusions could be made on the effectiveness of cochlear implants in children with UHL due to the lack of high level evidence available.

- A 2015 systematic review published by Cabral junior and colleagues evaluated the outcomes of cochlear implantation in patients with SSD with regards to speech discrimination, sound localization, and tinnitus suppression.[41] Eleven studies were included in the analysis, 9 of which were prospective comparator studies and 2 case series. Sample sizes ranged from 4-28 participants, totalling 137 participants. Data were not pooled due to clinical heterogeneity among the studies. Three studies were analyzed for sound localization outcomes, all of which showed improvement with cochlear implants versus nothing or bone anchored hearing aids or contralateral routing of sound in postlingual participants. One study evaluated outcomes of cochlear implants in patients with prelingual onset of deafness and implants showed no benefit. Four studies found significant improvement in speech understanding with cochlear implantation. Five out of 7 studies that evaluated tinnitus relief or suppression found statistically significant reductions of symptoms. The authors conclude that because of the high heterogeneity among the studies and the lack of high level-of –evidence studies, no conclusions can be made on the benefit of cochlear implants for patients with UHL.

<u>Observational Studies</u>

Several recent prospective and retrospective studies and case series evaluated the safety and efficacy of unilateral cochlear implants for unilateral hearing loss, yet the studies were limited by their small sample sizes, observational, non-randomized study design, and mixed results. [42-48]

Auditory Brainstem Implants

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of auditory brainstem implants as a treatment for total hearing loss in neurofibromatosis type 2 patients. Below is a summary of the available evidence identified through February 2023.

Systematic Reviews

- In 2017, Lloyd et al. conducted a systematic review of the literature to evaluate hearing optimization in neurofibromatosis type 2 (NF2) patients.[49] Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The authors aimed to identify the best way to preserve hearing in NF2 patients; therefore, the authors identified research relevant to conservative management, radiotherapy, chemotherapy, hearing preservation surgery, cochlear implants, and auditory brainstem implants (ABI).

  A total of 40 publications evaluating ABI in NF2 patients were identified as eligible for inclusion. The mean average word perception in ABI patients was 72.9% when combined with lip reading and 35.3% without lip reading. The mean average sentence perception in ABI patients was 57.7% when combined with lip reading and 12.3% without lip reading. The authors also indicated ABI hearing efficacy showed a trend towards improvement over several years; whereas, cochlear implant hearing efficacy decreases with increased time since implantation. Three publications were also reviewed that reported subjective benefits of ABI in NF2 patients. About 95% to 100% of ABI patients reported an ability to differentiate between speech and environmental sounds. The patients also reported the ABI was most useful for conversation in a quiet place and improved lip reading abilities.

  Strengths of this study included the systematic review of evidence following a pre-defined protocol, assessment of quality, and evaluation of heterogeneity before pooling the data. Limitations were identified in the lack of randomization or blinding of included studies (deemed to be unethical or not feasible), the poor methodological quality of some selected studies, and the inability to perform a meta-analysis due to significant heterogeneity between studies. The authors concluded, “auditory brainstem implantation offers limited hearing rehabilitation in those who do not have a functional cochlear nerve.”[49]

Nonrandomized Studies

- Six additional nonrandomized studies were identified regarding auditory brainstem implants (ABI) in neurofibromatosis type 2 (NF2) patients.[50-55] Study designs included retrospective case studies, retrospective cohort studies, and retrospective chart reviews. Due to the rarity of NF2, sample sizes

were very small and ranged from 12 to 31 patients. Follow-up times varied by patient with some having outcome data through 2 months while data was available for other participants through 10 years. Although all studies have significant methodological limitations, the reported results indicate ABIs are safe and allow NF2 patients to experience improved hearing, communication, and quality of life.

Hybrid Cochlear Implants

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of hybrid cochlear implants as a treatment for severe-to-profound high frequency sensorineural hearing loss. Below is a summary of the available evidence identified through March 2022.

Systematic Reviews

- In 2015 (archived in 2018), Hayes published an evidence review evaluating the Nucleus Hybrid L24 Cochlear Implant System (Cochlear Limited) for hearing loss.[6] The review included 6 studies, with sample sizes ranging from 21 to 196 patients and follow-up periods ranging from 3 months to 2 years. Outcomes of interest included hearing loss, preservation of residual hearing, speech recognition in noisy and quiet conditions, and sentence recognition testing. All studies were deemed to be of poor quality due to lack of randomization, lack of comparison groups, retrospective design, short follow-up periods, and lack of statistical analyses.

The Hayes evidence review found that the hybrid cochlear implant may improve mid-to-high frequency hearing and residual hearing preservation for patients suffering from severe to profound mid- and high-frequency sensorineural hearing loss. The review indicated no major safety issues were found to be associated with the device; however, the hybrid cochlear implant device carries a high risk for loss of residual hearing.

Ultimately, Hayes gave a "C" rating for the use of the hybrid cochlear implant device in patients who meet the U.S. FDA indications for use. This rating is due to the overall low quality of evidence from a very small number of studies. The Hayes review recommended, "additional studies, especially those that incorporate a control group or parallel comparison group, and are conducted independently of the manufacturer, need to be performed to verify the long-term safety, efficacy, and impact on quality of life of the Nucleus Hybrid L24 cochlear implant system."[6]

- A 2014 ECRI Institute custom product brief guidance evaluated the Nucleus Hybrid L24 Cochlear Implant System (Cochlear Americas) for Treating Residual Low-frequency Hearing Sensitivity and Severe to Profound High-frequency Sensorineural Hearing Loss.[56] The ECRI guidance reviewed selected 4 cohort studies for review; thus providing a sample size of 167 adult patients with severe and profound sensorineural hearing loss with residual low-frequency hearing sensitivity. The results of the review suggested the device is efficacious for restoring sensorineural hearing while preserving low-frequency hearing; however, the ECRI guidance stated, "the evidence base is relatively small and the quality of studies reviewed is low because they lack control groups and follow-up periods are short-term only."[56]

Randomized Controlled Trials

No randomized controlled trials were identified for hybrid cochlear implants. A search of clinicaltrials.gov identified current and future clinical trials, including a prospective cohort study which will report 60-month follow-up data; however, none of these studies are randomized.

Nonrandomized Studies

- In 2018, Pillsbury and colleagues conducted a prospective, repeated measures study evaluating the safety and efficacy of the MED-EL Electric-Acoustic Stimulation (EAS) System for the treatment of severe-to-profound hearing loss in mid- to high frequencies.[57] In total, 67 of 73 subjects with residual low-frequency hearing completed audiometric testing at 3-, 6-, and 12-months post-activation. Primary outcomes of interest were speech perception and subjective benefit. Among 67 patients (mean age = 53.7 years), 79% experienced less than a 30dB HL low-frequency pure-tone average shift, with 97% of subject able to use the acoustic unit at 12-months follow-up. Among those fitted with the EAS system, 94% of subjects' speech perception was at least as good as their baseline performance, with 85% demonstrating improvement. Limitations include inadequate the study's small sample size, inadequate follow-up, the potential for ceiling effects on speech perception measures, authors' conflicts of interest with the device manufacturer.

- In 2018, Roland and colleagues published results at 5-year follow-up for 32 patients treated with the Cochlear™ Nucleus® Hybrid™ L24 Implant System.[58] Outcomes of interest included audiometric, speech perception and subjective satisfaction measures. Both mean unilateral speech perception, and subjective satisfaction scores improved significantly at all postoperative intervals (i.e. 12 months, 3 years, and 5 years). Ninety-four percent of subjects (n=30) demonstrated measurable hearing and 72% (n=23) continued to use electric-acoustic stimulation 5 years on from implantation. Despite reporting positive results at long-term follow-up, the study's small sample size, high attrition rate (36%) from the initial patient cohort,[59] lack of reported *p*-values and authors' conflicts of interest with the device manufacturer may limit results' generalizability.

- In 2017, Kelsall and colleagues conducted a prospective, non-randomized study[60] evaluating patient-reported outcomes (PROs) among 50 subjects who participated in the trial of discussed below.[59] Investigators reported that up to 77% of patients (n=38) experienced "benefit/high benefit" (i.e. improvements) in patients' device use, music perception and scores on the speech, spatial and qualities of hearing scale (SSQ) at both 6- and 12-month follow-up intervals. Limitations include the study's lack of objective measures, small sample size, inadequate follow-up, the potential for enthusiasm bias, and author conflicts of interest with the device's manufacturer.

- In 2016, Roland and colleagues conducted a prospective, multicenter clinical trial to evaluate the safety and efficacy of the cochlear Nucleus Hybrid Implant System.[59] The study recruited 50 adult patients who had severe high-frequency sensorineural hearing loss and relative good low-frequency hearing. The patients were given the hybrid cochlear implant and followed-up at 3, 6, and 12 months. The outcomes of interest were word and sentence perception in difficult noise, speech in quiet and in noise, and safety.

In regards to word and sentence perception in difficult hearing situations, patients experienced a significant mean improvement of 35.8% and 32.0%, respectively. When compared to the preoperative hearing aid testing, 75% of patients experienced improved word and sentence perception. The study also reported significant improvements at 6-month follow-up with bilateral hearing. Of the 50 subjects, 34 had adverse events including profound or total loss of low frequency hearing (n=22), electrode open/short circuits (n=11), increased tinnitus (n=6), and onset of tinnitus (n=6).

Study limitations include small sample size, lack of randomization or blinding, and the short follow-up period.

- Six additional nonrandomized, observational studies evaluating hybrid cochlear implants for adults with severe high-frequency sensorineural hearing loss and relatively preserved low-frequency hearing loss were identified.[61-66] Studies were generally of low-quality and were included in the Hayes and ECRI evidence reviews described above.[6,56]

CLINICAL PRACTICE GUIDELINES

Cochlear Implants

American Academy of Audiology (AAA)

- In 2018, the American Academy of Audiology endorsed multichannel cochlear implants as sensory aid options children with profound hearing impairments who demonstrate limited or no functional benefit from conventional hearing aid amplification. The AAA stated that multichannel cochlear implants were appropriate for children with pre-lingual or post-lingual deafness, with a pure tone average (500, 1000, 2000 Hz) of 90dB HL or greater in both ears generally indicated.[67]

- In 2019, the AAA published clinical practice guidelines on cochlear implants, stating that cochlear implants are being successfully used with individuals with unilateral deafness or asymmetric hearing loss where only the ear to be implanted meets cochlear implant criteria. No sources were cited.[68]

American Academy of Otolaryngology

The 2020 American Academy of Otolaryngology – Head and Neck Surgery position statement supports the use of unilateral and bilateral cochlear implantation as an appropriate treatment for adults and children with moderate to profound hearing loss who have failed a trial with appropriately fit hearing aids. This stance is based on the committee's systematic review of evidence demonstrating, "clinically selected adults and children can perform significantly better with two cochlear implants than one."[69]

National Institute for Health and Care Excellence (NICE)

The 2019 NICE evidence-based clinical practice guideline on cochlear implants for children and adults with severe to profound deafness recommended unilateral cochlear implants, "as a possible option for

everyone with severe to profound deafness if they do not get enough benefit from hearing aids."[70] The guideline also recommended bilateral cochlear implants for adults with other disabilities (e.g., blindness) and children who have severe to profound deafness and do not get enough benefits from a 3 month trial of hearing aids.

American Academy of Pediatrics Joint Committee on Infant Hearing

The 2019 American Academy of Pediatrics Joint Committee on Infant Hearing position statement on the principles and guidelines for early hearing detection stated, "Cochlear implants are indicated for children (> 12 months of age) with bilateral severe-to-profound sensorineural hearing loss (including auditory neuropathy) who fail to make expected progress with appropriately fitted amplification."[71]

Auditory Brainstem Implants

National Institute for Health and Care Excellence (NICE)

The 2005 NICE evidence-based interventional procedures guidance stated, "current evidence of the safety and efficacy of auditory brain stem implants appears adequate to support the use of this procedure by surgical teams experienced in this technique, provided that normal arrangements are in place for consent, audit and clinical governance."[72]

Hybrid Cochlear Implants

No clinical practice guidelines were identified regarding the use of hybrid cochlear implants.

EVIDENCE SUMMARY

The evidence confirms the efficacy and safety of both unilateral and bilateral cochlear implants in children and adults with severe to profound bilateral sensorineural hearing loss who meet the U.S. FDA approved indications for use. When compared to unilateral implants, bilateral cochlear implants are superior in terms of improved sound localization and hearing perception in noisy environments.

Low-quality but consistent evidence indicates that children and adults with profound unilateral hearing loss may also benefit from cochlear implants.

Although the evidence does not indicate auditory brainstem implants are superior to cochlear implants, neurofibromatosis Type 2 patients with auditory nerve damage are contraindicated for cochlear implants; therefore, an auditory brainstem implant is the only treatment option to help restore hearing in this small subset of patients.

Although the evidence base comprises largely low-quality studies, investigators consistently report positive clinical outcomes among patients with hybrid cochlear implants.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

- HCPCS code L9900 is never allowed separate reimbursement because it is considered a bundled item or service, even if billed alone.

- HCPCS code S2235 is not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy (HCPCS S-Codes and H-Codes, 22.0). Providers need to use alternate available CPT or HCPCS codes to report for this service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

CODES*		
Cochlear Implants		
CPT	69930	Cochlear device implantation, with or without mastoidectomy
	69949	Unlisted procedure, inner ear
HCPCS	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

	L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement
	L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "I" code
Auditory Brainstem Implant		
CPT	92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
HCPCS	S2235	Implantation of auditory brainstem implant

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
7/2023	Annual update. No change to criteria. Updated billing guidelines and coding table.
11/2023	Interim update. Updated billing guidelines and coding table.
8/2024	Annual update. Changed denials from investigational to not medically necessary.
6/2025	Annual update. No changes to criteria.