Cochlear Implant

Bilateral Hearing Loss
Unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device may be considered medically necessary in patients with bilateral severe to profound pre-lingual or post-lingual sensorineural hearing loss (see Policy Guidelines) when the following criteria are met:

- The patient has a hearing threshold of pure-tone average (PTA) of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1,000 Hz, and 2,000 Hz, AND
- The patient has tried standard hearing aids but had limited or no benefit from their use.

Unilateral Hearing Loss
Cochlear implantation as a treatment for patients with unilateral hearing loss, with or without tinnitus, is considered investigational.

Upgrades
Upgrade of an existing internal and/or external cochlear system component is considered not medically necessary when the current device is working.

Replacements
Replacement of an external cochlear component (speech controller or speech processor) may be considered medically necessary only in a small subset of patients when:

- The processor is not working or broken and cannot be repaired or replaced under a manufacturer’s warranty.
- Replacement is needed because the patient’s condition has changed to the extent that the current processor is inadequate and no longer meets the functional needs for activities of daily living, and improvement is expected with a replacement device.

Hybrid Cochlear Implant/Hearing Aid
Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant (eg, the Nucleus® Hybrid™ L24 Cochlear Implant...
System) may be considered **medically necessary** for patients ages 18 years and older when ALL of the following criteria are met:

- Bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity; AND
- Receive limited benefit from appropriately fit bilateral hearing aids; AND
- Have the following hearing thresholds:
  - Low-frequency hearing thresholds no poorer than 60 dB hearing level up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation; AND
  - Severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥75 dB hearing level) 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 hearing level) in the contralateral ear; AND
  - Aided consonant-nucleus-consonant word recognition score from 10% to 60% 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.

### Related Policies

<table>
<thead>
<tr>
<th>Policy Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.01.528</td>
<td>Hearing Aids (Excludes Implantable Devices)</td>
</tr>
<tr>
<td>7.01.84</td>
<td>Semi-Implantable and Fully Implantable Middle Ear Hearing Aids</td>
</tr>
<tr>
<td>7.01.547</td>
<td>Implantable Bone Conduction and Bone-Anchored Hearing Aids</td>
</tr>
</tbody>
</table>

### Policy Guidelines

**Limited benefit from hearing aids**

Hearing loss is rated on a scale based on the threshold of hearing. Severe hearing loss is defined as a bilateral hearing threshold of 70 to 90 dB, and profound hearing loss is defined as a bilateral hearing threshold of 90 dB and above.

In adults, limited benefit from hearing aids is defined as scores of 50% or less correct on tape-recorded sets of open-set sentence recognition in the ear to be implanted.

In children, limited benefit is defined as failure to develop basic auditory skills, and in older children, scores of 30% or less correct on open-set tests.

**Bilateral cochlear implantation**

Bilateral cochlear implantation (CI) should be considered only when it has been determined that the use of a cochlear implantation in one ear plus a hearing aid in the opposite ear will not improve hearing in both ears (i.e., the hearing loss is considered severe to profound and a hearing aid will not deliver the required amplification of sound).

**Post-cochlear implantation rehabilitation**

A post cochlear implant rehabilitation program is necessary to learn the skills to achieve benefit from the cochlear implant. The rehabilitation program consists of 6 to 10 sessions that last approximately 2.5 hours each. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.
Contraindications to cochlear implantation

Contraindications to cochlear implantation may include:

- Absence of cochlear development as demonstrated on a computed tomography (CT) scan
- Cochlear ossification, may prevent electrode insertion
- Deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway or brain stem
- Infections, active or chronic, of the external or middle ear; or mastoid cavity
- Tympanic membrane perforation.

Children less than 12 months of age
The cochlear device is FDA labeled only for use in children 12 months of age and older. In certain situations, off-label use for CI may be considered before 12 months of age for severe bilateral hearing loss as defined in the policy statement. Each request for CI for children less than 12 months of age should be reviewed on an individual basis. One example situation is post-meningitis when cochlear ossification may prevent implantation. Another example is in children with a strong family history of profound hearing impairment/loss, when establishing a precise diagnosis is less certain. (See Rationale)

Reasonable Useful Life Expectancy for External Cochlear Implant Parts

<table>
<thead>
<tr>
<th>Parts</th>
<th>Life Expectancy</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batteries - Disposable</td>
<td>60 hours (1-3 days)</td>
<td>Replaced as needed</td>
</tr>
<tr>
<td>Batteries - Rechargeable</td>
<td>1 year or more</td>
<td>Many will last longer than 1 year</td>
</tr>
<tr>
<td>External speech processor</td>
<td>3 years or longer</td>
<td>Manufacturer’s warranty is usually 3 years. The component may last longer depending on care &amp; maintenance.</td>
</tr>
<tr>
<td>Headpieces/microphones</td>
<td>1-2 years</td>
<td>May last longer depending on care &amp; maintenance.</td>
</tr>
</tbody>
</table>


Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>HCPCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>69930 Cochlear device implantation, with or without mastoidectomy</td>
<td>L8614 Cochlear device, includes all internal and external components</td>
</tr>
<tr>
<td></td>
<td>L8615 Headset/headpiece for use with cochlear implant device, replacement</td>
</tr>
<tr>
<td></td>
<td>L8619 Cochlear implant external speech processor and controller, integrated system, replacement</td>
</tr>
</tbody>
</table>

Description

A cochlear implant is a device for treatment of severe-to-profound hearing loss in individuals who get only limited benefit from sound amplification with hearing aids. A cochlear implant provides direct electrical stimulation to the auditory nerve, bypassing the usual transducer cells that are absent or nonfunctional in the deaf cochlea.

Background

The basic structure of a cochlear implant includes both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are implanted surgically and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear. The parts outside the ear send sounds to the parts implanted inside the ear.

Sounds that are picked up by the microphone are carried to the external sound processor, which transforms sound into coded signals that are then transmitted transcutaneously to the implanted internal receiver. The receiver converts the incoming signals to electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve.
Regulatory Status

Several cochlear implants are commercially available in the United States and are manufactured by Cochlear Corp., Advanced Bionics, and the Med El Corp. Over the years, subsequent generations of the various components of the devices have been approved by FDA, focusing on improved electrode design and speech-processing capabilities. Furthermore, smaller devices and the accumulating experience in children have resulted in broadening of the selection criteria to include children as young as 12 months. The labeled indications from FDA for currently marketed implant devices are summarized in Table 1. FDA Product Code: MCM.

Table 1. Cochlear Implant Systemsa Approved by the Food and Drug Administration

<table>
<thead>
<tr>
<th>Variables</th>
<th>Manufacturer and Currently Marketed Cochlear Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predicate devices</td>
<td>HiResolution Bionic Ear System (HiRes 90K)</td>
</tr>
<tr>
<td>Adults</td>
<td>Clarion Multi-Strategy or HiFocus CII Bionic Ear (P940022)</td>
</tr>
<tr>
<td>≥18 y</td>
<td>≥18 y</td>
</tr>
<tr>
<td>Postlingual onset of severe to profound bilateral sensorineural HL (≥70 dB)</td>
<td>Pre-, peri-, or postlingual onset of bilateral sensorineural HL, usually characterized by:</td>
</tr>
<tr>
<td>Limited benefit from appropriately fitted hearing aids, defined as scoring ≤50% on a test of open-set HINT sentence recognition</td>
<td>Moderate-to-profound hearing loss in low frequencies; and</td>
</tr>
<tr>
<td>Children</td>
<td></td>
</tr>
<tr>
<td>12 mo to 17 y of age</td>
<td>25 mo to 17 y 11 mo</td>
</tr>
<tr>
<td>Profound bilateral sensorineural deafness (&gt;90 dB)</td>
<td>Severe to profound bilateral sensorineural HL</td>
</tr>
<tr>
<td>Use of appropriately fitted hearing aids for at least 6 mo in children 2-17 y or at least 3 mo in children 12-23 mo</td>
<td>MLNT scores ≤30% in best-aided condition in children 25 mo to 4 y 11 mo</td>
</tr>
<tr>
<td>Lack of benefit in children &lt;4 y defined as a failure to reach developmentally appropriate auditory milestones (eg, spontaneous response to name in quiet or to environmental sounds) measured using IT-MAIS or MAIS or &lt;20% correct on a simple open-set word recognition test (MLNT) administered using monitored live voice (70 dB SPL)</td>
<td>LNT scores ≤30% in best-aided condition in children 5 y to 17 y and 11 mo</td>
</tr>
<tr>
<td>Lack of hearing aid benefit in children &gt;4 y defined as scoring &lt;12% on a difficult open-set word recognition test (PBK test) or &lt;30% on an open-set sentence test (HINT for Children) administered using recorded materials in the soundfield (70 dB SPL)</td>
<td>12-24 mo</td>
</tr>
<tr>
<td>Profound sensorineural HL bilaterally</td>
<td>Profound sensorineural HL</td>
</tr>
<tr>
<td>Limited benefit from appropriate binaural hearing aids</td>
<td>Limited benefit from binaural hearing aids</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HINT: Hearing in Noise Test; HL: hearing loss; IT-MAIS: Infant-Toddler Meaningful Auditory Integration Scale; LNT: Lexical Neighborhood Test; MAIS: Meaningful Auditory Integration Scale; MLNT: Multisyllabic Lexical Neighborhood Test; PBK: Phonetically Balanced-Kindergarten; SPL: sound pressure level.

a The external Nucleus 5 sound processor is not a part of the recall. Advanced Bionics HiRes90K was voluntarily recalled in November 2010 and given FDA-approval for reentry to market the device in September 2011. Cochlear Ltd. voluntarily recalled the Nucleus CI500 range in September 2011 for device malfunction in the CI512 implant.

Hybrid Cochlear Implant System

In March 2014, FDA approved the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Corporation, Centennial, CO) through the premarket approval process.(1) 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 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 aid. The electrode array inserted into the cochlea is shorter than conventional cochlear implants. According to the FDA’s premarket approval notification, labeled indications for the device include:

- Preoperative hearing in the range from normal to moderate hearing loss (HL) in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz).
- Preoperative hearing 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.
- Preoperative hearing with 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.
- Consonant-Nucleus-Consonant (CNC) word recognition score between 10% to 60% (inclusively) in the ear to be implanted in the preoperative aided condition and in the contralateral ear equal to or better than that of the ear to be implanted but not more than 80% correct.

Other hybrid hearing devices have been developed but do not have FDA approval, including the Med El® EAS Hearing Implant System.

**Bilateral Cochlear Implants**

Although cochlear implants have typically been used unilaterally, interest in bilateral cochlear implantation has arisen in recent years. The proposed benefits of bilateral cochlear implants are to improve understanding of speech occurring in noisy environments and localization of sounds. Improvements in speech intelligibility with bilateral cochlear implants may occur through binaural summation (ie, signal processing of sound input from 2 sides may provide a better representation of sound and allow the individual to separate noise from speech). Speech intelligibility and localization of sound or spatial hearing may also be improved with head shadow and squelch effects (ie, the ear that is closest to the noise will receive it at a different frequency and with different intensity, allowing the individual to sort out noise and identify the direction of sound). Bilateral cochlear implantation may be performed independently with separate implants and speech processors in each ear or a single processor may be used. However, no single processor for bilateral cochlear implantation has been approved by FDA for use in the United States. In addition, single processors do not provide binaural benefit and may impair sound localization and increase the signal-to-noise ratio received by the cochlear implant.

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Benefit Application**

Some facilities may negotiate a global fee for the implantation of the device and the associated auditory rehabilitation. However, charges for rehabilitation services may be subject to individual contractual limitations.

A cochlear implant is a surgically implanted hearing device. The implanted receiver and electrode system device and implantation surgery should be reimbursed under the medical benefit.

Hearing aids may be excluded by contract. See Scope.
This policy was originally created in 1995 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed through December 20, 2016. The following is a summary of the key literature to date.

Cochlear Implantation for Bilateral Sensorineural Hearing Loss

*Cochlear Implantation in Adults: Unilateral Stimulation*

Cochlear implants are recognized as an effective treatment of sensorineural deafness, as noted in a 1995 National Institutes of Health Consensus Development conference, which offered the following conclusions:

- Cochlear implantation has a profound impact on hearing and speech reception in postlingually deafened adults with positive impacts on psychological and social functioning.
- Pre-lingually deafened adults may also benefit, although to a lesser extent than post-lingually deafened adults. These individuals achieve minimal improvement in speech recognition skills. However, other basic benefits, such as improved sound awareness, may meet safety needs.
- Training and educational intervention are fundamental for optimal post implant benefit.

The effectiveness of cochlear implants has been evaluated in several systematic reviews and technology assessments, both from the United States and abroad. In 2009, Bond et al authored a technology assessment in the United Kingdom to investigate the clinical and cost-effectiveness of unilateral cochlear implants (using or not using hearing aids) and bilateral cochlear implants compared with a single cochlear implant (unilateral or unilateral plus hearing aids) for severely to profoundly deaf children and adults. The clinical effectiveness review included 33 articles, 2 of which were randomized controlled trials (RCTs) (deaf children, n=1513; adults, n=1379). They used 62 different outcome measures and overall evidence was of moderate to poor quality. (The authors’ summary of the effectiveness of bilateral cochlear implants and cochlear implants in children are summarized in the following appropriate sections.) The authors concluded, “Unilateral cochlear implantation is safe and effective for adults and children and likely to be cost-effective in profoundly deaf adults and profoundly and prelingually deaf children.”

Bond et al published 2 other systematic reviews on the clinical and cost-effectiveness of unilateral cochlear implants, first focusing on children in 2009 and then adults in 2010. Both were conducted with a literature review that identified 1580 titles and abstracts on cochlear implants. In the 2010 review, the authors identified 9 studies that met their inclusion criteria addressing implantation in adults; all were methodologically weak and too heterogeneous to perform a meta-analysis. However, the authors concluded that there is sufficient, consistent evidence demonstrating positive benefits with unilateral cochlear implants in severely to profoundly hearing impaired adults when compared with acoustic hearing aids or no hearing support.

In January 2009, the National Institute for Health and Care Excellence (NICE) released technology appraisal guidance 166, Cochlear Implants for Children and Adults With Severe to Profound Deafness. This guidance was based on this technology assessment report by Bond et al.

The NICE guidance includes the following recommendations:

1. “Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids…”
2. For purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL [hearing level] at frequencies of 2 and 4 kHz without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as: for adults, a score of 50% or greater on Bamford-Kowal-Bench (BKB) sentence testing at a sound intensity of 70 dB SPL [sound pressure level].
3. Cochlear implantation should be considered for adults only after an assessment by a multidisciplinary team. As part of the assessment [implant candidates] should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).”

In April 2011, a technology assessment was completed by the Tufts Evidence-based Practice Center for the Agency for Health Care Research and Quality (AHRQ) on the effectiveness of cochlear implants in adults. This assessment examined 22 studies with 30 or more patients 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 multisyllable tests and open-set sentence tests demonstrated significant gains in speech perception whether or not a contralateral hearing aid was used along with the cochlear implant. Additionally, the assessment found generic and disease-specific health-related quality of life (QOL) improved with unilateral cochlear implants. However, the available evidence was insufficient to draw conclusions on improvements in open-set sentence test scores (ie, >40% and ≤50% or >50% and ≤60%), and any relationship between preimplantation patient characteristics and outcomes (eg, age, duration of hearing impairment, Hearing in Noise Test [HINT] scores and pre- or post-linguistic deafness).

In 2013, Gaylor et al. published an update to the AHRQ technology assessment.(8) Sixteen (of 42) studies published through May 2012 were of unilateral cochlear implants. 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 of 4 studies revealed a significant improvement in cochlear-implant relevant QOL after unilateral implantation (standard mean difference, 1.71; 95% confidence interval [CI], 1.15 to 2.27). However, these studies varied in design, and there was considerable heterogeneity observed across studies.(8) Similarly, a 2012 systematic review of 11 studies by Bittencourt et al also concluded cochlear implants improved hearing outcomes over conventional hearing aids in patients with severe to profound postlingual deafness.(9)

In 2011, Berrettini et al. published results of a systematic review of cochlear implant effectiveness in adults.(10) Included in the review were 8 articles on unilateral cochlear implants in advanced age patients. All of the studies reported benefits with cochlear implantation, despite advanced age at time of implant (age 70 years or older). In 6 studies, results were not significantly different between younger and older patients. However, 2 studies reported statistically significant inferior perceptive results (eg, HINT and consonant nucleus consonant test) in older patients. This systematic review also examined 3 studies totaling 56 adults with prelingual deafness who received unilateral cochlear implants. The authors concluded unilateral cochlear implants provided hearing and QOL benefits in prelingually deaf patients, but results were variable.

**Cochlear Implantation in Adults: Bilateral Stimulation**

While use of unilateral cochlear implants in patients with severe to profound hearing loss has become a well-established intervention,(7) bilateral cochlear implantation is becoming more common. Many publications have reported slight to modest improvements in sound localization and speech intelligibility with bilateral cochlear implants, especially with noisy backgrounds but not necessarily in quiet environments. When reported, the combined use of binaural stimulation improved hearing by a few decibels or percentage points.

The 2009 Bond et al. technology assessment on the clinical and cost-effectiveness of cochlear implants made the following conclusions on the evidence related to bilateral cochlear implants in adults:(3) The strongest evidence for an advantage from bilateral over unilateral implantation was for understanding speech in noisy conditions. The comparison of bilateral with unilateral cochlear implants plus an acoustic hearing aid was limited by small sample sizes and poor reporting. The authors concluded, “There are likely to be overall additional benefits from bilateral implantation, enabling children and adults to hold conversations more easily in social situations.”

In 2009, the NICE technology appraisal guidance noted above(6) indicates:

1. “Simultaneous bilateral cochlear implantation in adults is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids … [and] … who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.
2. Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.
3. For purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids. Adequate benefit from acoustic hearing aids for adults is defined for this guidance as: for adults, a score of 50% or greater on Bamford-Kowal-Bench (BKB) sentence testing at a sound intensity of 70 dB SPL.
4. Cochlear implantation should be considered for … adults only after an assessment by a multidisciplinary team. As part of the assessment … [implant candidates] should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).”

Crathorne et al published an update of the NICE systematic review in 2012.(11) The objective was to evaluate the clinical and cost-effectiveness of bilateral multichannel cochlear implants compared with unilateral cochlear implantation alone or in conjunction with an acoustic hearing aid in adults with severe-to-profound hearing loss. A literature search was updated through January 2012. Nineteen studies conducted in the United States and
Europe were included in this update; 6 had been included in the original NICE review. Two studies were RCTs with waiting-list controls, 10 were prospective pre/post repeated-measure or cohort designs, 6 were cross-sectional in design, and 1 was an economic evaluation. All studies compared bilateral with unilateral implantation, and 2 compared bilateral implants with a unilateral implant plus acoustic hearing aid. The studies selected were of moderate-to-poor quality, including the 2 RCTs. Meta-analyses could not be performed due to heterogeneity between studies in outcome measures and study designs. However, all studies reported that bilateral cochlear implants improved hearing and speech perception. One RCT found a significant binaural benefit over the first ear alone for speech and noise from the front (12.6%, p<0.001) and when noise was ipsilateral to the first ear (21%, p<0.001); another RCT found a significant benefit for spatial hearing at 3 months postimplantation compared with preimplantation (mean difference, 1.46; p<0.01). QOL results varied, showing bilateral implantation might improve QOL in the absence of worsening tinnitus.

Van Schoonhoven et al. independently published a systematic review in 2013 as an update to the original NICE review. As with the Crathorne review, all studies (N=19, published through March 2011) showed a significant bilateral benefit in localization over unilateral cochlear implantation. Similarly, meta-analyses could not be performed due to the heterogeneity of the studies and the level of evidence of the included studies, which was of moderate-to-poor quality. The 2011 AHRQ technology assessment, noted earlier, completed by the Tufts Evidence-based Practice Center on the effectiveness of cochlear implants in adults examined 16 studies on bilateral cochlear implantation of fair-to-moderate quality published since 2004. The assessment concluded bilateral cochlear implants provide greater benefits in speech perception test scores, especially in noise, when compared with unilateral cochlear implants (with or without contralateral hearing aids). Significant binaural head shadow benefits were noted along with some benefit in binaural summation, binaural squelch effects, and sound localization with bilateral 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. Hearing-specific QOL could not be assessed because only 1 study evaluated this outcome. Additionally, the evidence available on simultaneous bilateral implantation was found to be insufficient, although gains were experienced in speech perception using open-set sentences or multisyllable tests compared with unilateral cochlear implants or unilateral listening conditions. The assessment noted longer term studies are needed to further understand the benefits with bilateral cochlear implantation and identify candidacy criteria given the risks of a second surgery and the destruction of the cochlea preventing future medical intervention.

The update by Gaylor et al. to the assessment previously reported showed improvement across 13 studies in communication-related outcomes with bilateral implantation compared with unilateral implantation and additional improvements in sound localization compared with unilateral device use or implantation only. The risk of bias varied from medium to high across studies. Based on results from at least 2 studies, QOL outcomes varied across tests after bilateral implantation; meta-analysis was not performed because of heterogeneity in design between the studies.

In the 2011 Berrettini et al. review of cochlear implant effectiveness in adults (noted earlier), 13 articles on bilateral cochlear implants were reviewed. Sound localization improved with bilateral cochlear implants compared with monaural hearing in 6 studies. Significant improvements in hearing in noise and in quiet environments with bilateral implants compared with unilateral implants were reported in 10 studies and 7 studies, respectively. Five of the studies reviewed addressed simultaneous implantation, 5 studies reviewed sequential implantation, and 3 studies included a mix of simultaneous and sequential implantation. However, no studies compared simultaneous with sequential bilateral implantation results, and no conclusions could be made on the timing of bilateral cochlear implantation. Smulders et al. also examined the timing of bilateral cochlear implantation in a systematic review of 11 studies; 5 studies addressed postlingually deafened adults and 7 studies addressed prelingually deafened children (discussed next). One study on adults showed a delay in the timing of the second implantation resulting in poorer outcomes in quiet environments. Nevertheless, all studies reported benefits with bilateral implants, but all studies were considered to be of poor quality and with a high risk of bias.

Since the publication of the systematic reviews described above, additional comparative studies (eg, Blamey et al [2015])(14) and case series (eg, Harkonen et al [2015])(15) have reported on outcomes after bilateral cochlear implantation. For example, in a 2016 prospective observational study including 113 patients with postlingual hearing loss, of whom 50 were treated with cochlear implants and 63 with hearing aids, cochlear implant recipients’ depression scores improved from preimplantation to 12 months posttreatment (Geriatric Depression Scale score improvement, 31%; 95% CI, 10% to 47%).
Cochlear Implantation in Pediatrics

Similar to the adult population, the evidence related to the use of cochlear implants in children has been evaluated in several systematic reviews and technology assessments.

The 2009 Bond technology assessment on cochlear implants made the following observations regarding cochlear implantation in children: All studies in children that compared 1 cochlear implant with nontechnologic support or an acoustic hearing aid reported gains on all outcome measures.(3) Weak evidence showed greater gain from earlier implantation (before starting school). The 2009 NICE guidance noted earlier,(6) included the following recommendations for children:

1. “Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids…
2. Simultaneous bilateral cochlear implantation is recommended as an option for … [children] with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids…
3. Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.
4. For purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids. [For children, adequate benefit from acoustic hearing aids is defined for this guidance as … speech, language and listening skills appropriate to age, developmental stage, and cognitive ability.
5. Cochlear implantation should be considered for children only after an assessment by a multidisciplinary team. As part of the assessment, children … should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).”

As also noted earlier, Bond et al. published 2 systematic reviews on the clinical and cost-effectiveness of unilateral cochlear implants, first focusing on children in 2009(4) and subsequently focusing on adults in 2010.(5) Both reviews were conducted with a literature search that identified 1580 titles and abstracts on cochlear implants. In the 2009 review, the authors identified 15 studies that met their inclusion criteria addressing cochlear implantation in children.(4) The authors found the studies available were methodologically weak and too heterogeneous to perform a meta-analysis. However, they concluded there is sufficient, consistent evidence demonstrating positive benefits with unilateral cochlear implants in severely to profoundly hearing impaired children when compared with acoustic hearing aids or no hearing support.

Cochlear Implant Timing in Pediatrics

The optimal timing of cochlear implantation in children is of particular interest given the strong associations between hearing and language development. While there is current research investigating the ability to restore hearing by stimulating cochlear hair cell regrowth, cochlear implantation damages the cochlea and eliminates this possibility. However, the potential to restore cochlear function is not foreseeable in the near future. If cochlear implantation is believed to be most beneficial at a younger age, when the nervous system is “plastic,” the potential for cochlear hair cell regrowth seems too far in the future to benefit young children and should not be a deterrent to current candidates for a cochlear implant. A number of studies have evaluated the effect of age of implantation on hearing outcomes after cochlear implantation in children.

As reported by Sharma and Dorman, central auditory pathways are “maximally plastic” for a period of about 3.5 years, making a case for earlier cochlear implantation of children with hearing impairment.(17) Stimulation delivered before about 3.5 years of age results in auditory evoked potentials that reach normal values in 3 to 6 months. However, when stimulation occurs after 7 years of age, changes occur within 1 month, but then have little to no subsequent change. Sharma et al. observed this result when they reported on auditory development in 23 children with unilateral or bilateral implants.(18) In 1 child who received a bilateral device with implantation of the second ear after age 7 years, the auditory responses in the second ear were similar to that seen in “late-implanted” children.

In 2011, Forli et al. conducted a systematic review of 49 studies on cochlear implant effectiveness in children that addressed the impact of age of implantation on outcomes.(19) Heterogeneity of studies precluded performance of a meta-analysis. Early implantation was examined in 22 studies, but few studies compared outcomes of implantations performed before 1 year of age to implantations performed after 1 year of age. Studies suggest improvements in hearing and communicative outcomes in children receiving implants before 1 year of age, although it is not certain whether these improvements are related to duration of cochlear implant usage rather than age of implantation. However, the reviewers noted hearing outcomes have been shown to be significantly
inferior in patients implanted after 24 to 36 months. Finally, 7 studies were reviewed that examined cochlear implant outcomes in children with associated disabilities. In this population, cochlear implant outcomes were inferior and occurred more slowly but were considered to be beneficial.

As previously noted, the 1995 National Institutes of Health Consensus Development conference concluded cochlear implants are recognized as an effective treatment of sensorineural deafness.(2) This conference offered the following conclusions regarding cochlear implantation in children:

- Cochlear implantation has variable results in children. Benefits are not realized immediately but rather are manifested over time, with some children continuing to show improvement over several years.
- Cochlear implants in children under 2 years old are complicated by the inability to perform detailed assessment of hearing and functional communication. However, a younger age of implantation may limit the negative consequences of auditory deprivation and may allow more efficient acquisition of speech and language. Some children with postmeningitis hearing loss under the age of 2 years have received an implant due to the risk of new bone formation associated with meningitis, which may preclude a cochlear implant at a later date.

Studies published since the above systematic reviews suggest that cochlear implant removal and reimplantation (due to device malfunction or medical/surgical complications) in children is not associated with worsened hearing outcomes.(20)

**Specific Indications for Cochlear Implantation in Pediatrics**

Several systematic reviews have evaluated outcomes after cochlear implantation for specific causes of deafness and in subgroups of pediatric patients. In a 2011 systematic review of 38 studies, Black et al. sought to identify prognostic factors for cochlear implantation in pediatric patients.(21) A quantitative meta-analysis was not able to be performed due to study heterogeneity. However, the following 4 prognostic factors consistently influenced hearing outcomes:

- age at implantation,
- inner ear malformations,
- meningitis,
- connexin 26 (a genetic cause of hearing loss).

Pakdaman et al conducted a systematic review of cochlear implants in children with cochleovestibular anomalies in 2012.(22) Anomalies included inner ear dysplasia such as large vestibular aqueduct and anomalous facial nerve anatomy. Twenty-two studies were reviewed (total N=311 patients). The authors found implantation surgery was more difficult and speech perception was lower in patients with severe inner ear dysplasia. However, heterogeneity in the studies limited interpretation of these findings.

In 2013, Eze et al published a systematic review comparing outcomes for cochlear implantation among children with and without developmental disability.(23) The authors noted that while approximately 30% to 40% of children who receive cochlear implants have developmental disability, evidence about outcomes in this group is limited. Their review included 13 studies that compared receptive or expressive language outcomes in children with cochlear implants with and without developmental disability. The included studies were heterogeneous in terms of comparator groups and outcome measures, precluding data pooling and meta-analysis. In a structured systematic review, the authors reported that 7 of the eligible studies demonstrated a significantly poor outcome with cochlear implantation in children with developmental disability, while the remaining studies reported no significant difference in outcomes between the 2 groups.

**Auditory Neuropathy Spectrum Disorder**

Humphriss et al. published a systematic review evaluating outcomes after cochlear implantation among pediatric patients with auditory neuropathy spectrum disorder (ANSD), a sensorineural hearing disorder characterized by abnormal auditory brainstem response with preserved cochlear hair cell function as measured by otoacoustic emissions testing.(24) The authors identified 27 studies that included an evaluation of cochlear implantation in patients with ANSD, including 15 noncomparative studies, 1 that compared children with ANSD who received a cochlear implant with children with ANSD with hearing aids, and 12 that compared children with ANSD who received a cochlear implant with children with severe sensorineural hearing loss who received a cochlear implant. Noncomparative studies were limited in that most (11/15) did not include a measure of speech recognition before cochlear implantation. Among the comparative studies, those comparing cochlear implantation to “usual care,” typically a hearing aid, provide the most information about effectiveness of cochlear implantation among patients
with ANSD; the 1 small study that used this design found no significant differences between the groups. Overall, the authors suggest that further RCT evidence is needed.

In a 2015 systematic review, Fernandes et al evaluated 18 published studies and 2 dissertations that reported hearing performance outcomes for children with ANSD and cochlear implants.(25) Studies included 4 nonrandomized controlled studies considered high quality, 5 RCT's considered low quality, and 10 clinical outcome studies. Most studies (n=14) compared the speech perception in children with ANSD and cochlear implants with the speech perception in children with sensorineural hearing loss and cochlear implants. Most of these studies concluded that children with ANSD and cochlear implants developed hearing skills similar to those with sensorineural hearing loss and cochlear implants; however, these types of studies do not allow comparisons of outcomes between ANSD patients treated with cochlear implants and those treated with usual care.

**Cochlear Implantation in Infants Younger than 12 Months**
While currently available cochlear implants have FDA labeling for only children older than 12 months, earlier diagnosis of congenital hearing loss with universal hearing screening has prompted interest in cochlear implantation in children younger than 12 months.

In 2010, Vlastarakos et al conducted a systematic review of studies on bilateral cochlear implantation in a total of 125 children implanted before age 1.(26) For this off-label indication, the authors noted follow-up times ranged from a median duration of 6 to 12 months. While results seemed to indicate accelerated rates of improvement in implanted infants, the evidence available is limited and of lower quality.

A number of small studies from outside the United States have reported results on cochlear implantation in infants younger than 12 months old. For example, in a study from Australia, Ching et al (2009) published an interim report on early language outcomes among 16 children implanted prior to 12 months of age, compared with 23 who were implanted after 12 months of age (specific timing implantation was not provided).(27) The results demonstrated that children who received an implant before 12 months of age developed normal language skills at a rate comparable with normal-hearing children, while those implanted later performed at 2 standard deviations below normal. Reviewers noted that these results were preliminary, because there is a need to examine the effect of multiple factors on language outcomes and the rate of language development. Similarly, in a study from Italy, Colletti (2009) reported on findings from 13 infants who had implants placed before 12 months of age.(28) The procedures were performed between 1998 and 2004. In this small study, the rate of receptive language growth for these early-implant infants overlapped with scores of normal-hearing children. This overlap was not detected for those implanted at 12 to 23 or 24 to 36 months of age. Subsequently, Colletti et al (2011) reported on 10-year results among 19 infants with cochlear implants received between the ages of 2 and11 months (early implantation group) compared with 21 children implanted between the ages of 12 and 23 months and 33 children implanted between the ages of 24 and 35 months. (29) Within the first 6 months postimplantation, there were no significant differences among groups in Category of Auditory Performance testing, but patients in the infant group had greater improvements than older children at the 12-month and 36-month testing.

A more recent (2016) prospective study of 28 children with profound sensorineural hearing loss who were implanted early with cochlear implants (mean age at device activation, 13.3 months) reported that these children had social and conversational skills in the range of normal-hearing peers 1 year after device activation.(30)

**Cochlear Implantation in Children: Bilateral Stimulation**
In a 2014 systematic review, Lammers et al. summarized the evidence on the effectiveness of bilateral cochlear implantation compared with unilateral implantation among children with sensorineural hearing loss.(31) The authors identified 21 studies that evaluated bilateral cochlear implantation in children, with no RCTs identified. Due to a limited number of studies, heterogeneity in outcomes and comparison groups and high risk for bias in the studies, the authors were unable to perform pooled statistical analyses, so a best-evidence synthesis was performed. The best-evidence synthesis demonstrated that there is consistent evidence indicating the benefit of bilateral implantation for sound localization. One study demonstrated improvements in language development, although other studies found no significant improvements. The authors noted that the currently available evidence consists solely of cohort studies that compare a bilaterally implanted group with a unilaterally implanted control group, with only 1 study providing a clear description of matching techniques to reduce bias.

In 2010, Sparreboom et al. conducted a systematic review of bilateral cochlear implants in children with severe-to-profound deafness.(32) Due to the heterogeneity of the studies identified, the authors were unable to perform a
meta-analysis. A qualitative review of the studies found binaural ability takes time to develop; bilateral cochlear implants seem to provide better speech perception over unilateral implants; and delays in implanting the second cochlear implant seem to decrease speech perception in quiet and decrease or eliminate the potential for binaural summation. The author concluded while bilateral cochlear implants provide benefits of bilateral hearing in children, further research is needed.

As noted, Smulders et al. examined the timing of sequential bilateral cochlear implantation in a systematic review of 11 studies; 5 studies addressed postlingually deafened adults (previously discussed), and 7 studies addressed prelingually deafened children. Sound localization was not affected by second implantation delay in any study of the studies on children, but delays in second implantation resulted in poorer outcomes in quiet environments in 1 study and poorer outcomes in noise in 2 studies. However, all studies were considered to be of poor quality and with a high risk of bias.

Several publications not included in the Lammers and Sparreboom systematic reviews have evaluated bilateral cochlear implants in children. These studies, ranging in size from 91 to 961 patients, generally report improved speech outcomes with bilateral implantation, compared with unilateral implantation. In another retrospective case series of 73 children and adolescents who underwent sequential bilateral cochlear implantation with a long (>5 year) interval between implants, performance on the second implanted side was worse than the primary implanted side, with outcomes significantly associated with the interimplant interval.

**Section Summary**

Multiple trials of cochlear implantation in patients with bilateral sensorineural hearing loss, although in varying patient populations, have consistently demonstrated improvements in speech recognition in noise and improved sound localization.

**Cochlear Implantation for Unilateral Hearing Loss**

As noted, a number of potential benefits to binaural hearing exist, including binaural summation, which allows improved signal detection threshold, and sound localization. The potential benefits from binaural hearing have prompted interest in cochlear implantation for patients with unilateral hearing loss.

**Systematic Reviews**

In 2014, Vlastarakos et al published a systematic review of the evidence related to cochlear implantation for single-sided deafness and/or unilateral tinnitus. The authors included 17 studies (total N=108 patients), including prospective and retrospective comparative studies, case series, and case reports. The authors reported that sound localization is improved after cochlear implantation, although statistical analysis was not included in some of the relevant studies. In most patients (95%), unilateral tinnitus improved. The authors note that most of the studies included had short follow-up times, and evaluation protocols and outcome measurements were heterogeneous.

In 2015, van Zon et al. published another systematic review of studies evaluating cochlear implantation for single-sided deafness or asymmetric hearing loss. The authors reviewed 15 studies, 9 of which (n=112 patients) were considered high enough quality to be included in data review. The authors identified no high-quality studies of cochlear implantation in this population. Data were not able to be pooled for meta-analysis due to high between-study heterogeneity, but the authors conclude that studies generally report improvements in sound localization, QOL scores, and tinnitus after cochlear implantation, with varying results for speech perception in noise.

In 2014, Blasco and Redleaf published a systematic review and meta-analysis of studies evaluating cochlear implantation for unilateral sudden deafness. The review included 9 studies with a total of 36 patients. In pooled analysis, subjective improvement in tinnitus occurred in 96% of patients (of 27 assessed), subjective improvement in speech understanding occurred in 100% of patients (of 16 assessed), and subjective improvement in sound localization occurred in 87% of patients (of 16 assessed). However, the small number of patients in which each outcome was assessed limits conclusions that may be drawn.

**Case Series**

Several individual studies have reported on outcomes for cochlear implantation for single-sided deafness since
The longest follow-up was reported by Mertens et al (2015), in a case series with structured interviews, including 23 individuals who received cochlear implants for single-sided deafness with tinnitus. (41) Eligible patients had either single-sided deafness or asymmetric hearing loss and ipsilateral tinnitus. Subjects had a mean 8 years of experience with their cochlear implant (range, 3-10 years). Tinnitus symptoms were assessed by structured interview, visual analog scale (VAS), and the Tinnitus Questionnaire (TQ; a validated scale). Patients demonstrated improvements in VAS score from baseline (mean score, 8) to 1 month (mean score: 4; p<0.01 vs baseline) and 3 months (mean score, 3; p<0.01 vs baseline) after the first fitting. TQ scores improved from baseline to 3 months post fitting (55 vs 31, p<0.05) and were stable for the remainder of follow-up.

In 2015, Arndt et al reported outcomes for 20 children who underwent cochlear implantation for single-sided deafness, which represented a portion of their center’s cohort of 32 pediatric patients with single-sided deafness who qualified for cochlear implants. (42) Repeated-measure analyses of hearing data sets were available for 13 implanted children, excluding 5 who had undergone surgery too recently to be evaluated and 2 children who were too young to be evaluated for binaural hearing benefit. There was variability in the change in localization ability across the tested children. Self- or child-reported hearing benefit was measured with the Speech, Spatial and Qualities of Hearing Scale. Significant improvements were reported on the child and parent evaluations for the scale’s total hearing score and 3 subcategories: speech hearing, spatial hearing, hearing quality.

In 2017, Sladen et al retrospectively reviewed prospectively collected data of short-term (6-month) follow-up for 23 adults and children with single-sided deafness from a variety of mechanisms who received a cochlear implant. (43) In the implanted ear, CNC word recognition improved significantly from preimplantation to 3 months postactivation (p=0.001). However, for AzBio sentence understanding in noise (+5 dB signal-to-noise), there was no significant improvement from preimplantation to 6 months postactivation.

In a prospective repeated-measures cohort study that included 20 subjects with single-sided deafness implanted with cochlear implants (15 of whom had reached 6-month follow-up), Sladen et al (2016) reported on speech recognition and QOL. (44) Pure-tone audiometry improved with air conduction in the implanted ear. CNC scores in quiet improved from 4.8% in the preoperative period to 42.3% at the 6-month postactivation check in patients who reached that follow-up.

Also in 2016, Rahne et al reported on a retrospective review of 4 children and 17 adults with single-sided deafness treated with cochlear implants and followed for 12 months. (45) Sound localization with aided hearing improved from preimplantation for all individuals. The speech recognition threshold in noise (signal-to-noise) ratio improved from -1.95 dB (CI off, SD=2.7 dB) to -4.0 dB after 3 months (SD=1.3 dB; p<0.05), with continued improvements through 6 months.

Earlier, smaller studies, such as those reported by Arndt et al (2011)(46) with 11 adult patients, and by Hansen et al (2013)(47) with 29 patients, reported improvements in hearing ability compared with baseline for implanted subjects.

**Cochlear Implant for Tinnitus Relief in Patients With Unilateral Deafness**

The application of cochlear implants for tinnitus relief in patients with unilateral deafness has also been described. Studies of cochlear implants in patients with bilateral hearing loss, which is often associated with tinnitus, have reported improvements in tinnitus. For example, van Zon et al (2016) reported on a prospective study focusing on tinnitus perception conducted as a part of a multicenter RCT comparing unilateral with bilateral cochlear implantation in patients with severe bilateral sensorineural hearing loss. (48) This analysis included 38 adults enrolled from 2010-2012 and randomized to simultaneous bilateral or unilateral cochlear implants. At 1 year postimplantation, both unilaterally and bilaterally implanted patients had significant decreases in score on the Tinnitus Handicap Inventory (THI; a validated scale): change in score of 8 to 2 (p=0.03) and from 22 to 12 (p=0.04) for unilaterally and bilaterally implanted patients, respectively. Bilaterally implanted patients had a significant decrease in TQ: change in score of 20 to 9 (p=0.04).

Based on observations about tinnitus improvement with cochlear implants, several studies have reported on improvements in tinnitus after cochlear implantation in individuals with unilateral hearing loss. In the meta-analysis by Vlastarakos et al (2014) described above, for example, unilateral tinnitus improved in most patients (95%). (38) Ramos Macias et al (2015) reported results of a prospective multicenter study with repeated measures related to
tinnitus, hearing, and QOL, among 16 individuals with unilateral hearing loss and severe tinnitus who underwent cochlear implantation. All patients had a severe tinnitus handicap (THI score ≥58%). Eight (62%) of the 13 patients who completed the 6-month follow-up visit reported a lower tinnitus handicap on the THI score. Perceived loudness/annoyingness of the tinnitus was evaluated with a 10-point VAS. When the cochlear implant was on, tinnitus loudness decreased from 8.4 preoperatively to 2.6 at the 6-month follow-up; 11 of 13 patients reported a change in score of 3 or more.

Van de Heyning et al published a study in 2008 of 21 patients with unilateral hearing loss accompanied by severe tinnitus for at least 2 years. Patients underwent cochlear implants at a university center in Belgium. Three (of 21) patients showed complete tinnitus relief, whereas most demonstrated a significant reduction in tinnitus loudness based on a VAS (2 years after implantation, 2.5; before implantation, 8.5).

Tavora-Vieira et al reported results of a prospective case series that included 9 postlingually deaf subjects with unilateral hearing loss, with or without tinnitus in the ipsilateral ear, with functional hearing in the contralateral ear, who underwent cochlear implantation. Speech perception was improved for all subjects in the “cochlear implant on” state compared with the “cochlear implant off” state, and subjects with tinnitus generally reported improvement.

**Section Summary**

The available evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, is limited by small sample sizes, short follow-up times and heterogeneity in evaluation protocols and outcome measurements.

**Hybrid Cochlear Implantation**

A concern about traditional cochlear implants is that the implantation process typically destroys any residual hearing, particularly for hearing in the low-frequency ranges. Newer devices have used a shorter cochlear electrode in combination with a hearing aid-like amplification device to attempt to mitigate the damage to the cochlea and permit residual hearing.

In March 2014, FDA approved Nucleus® Hybrid™ L24 Cochlear Implant System for use through the premarket approval process. According to FDA’s Summary of Safety and Effectiveness Data, the approval was based on 2 clinical studies conducted outside of the United States and 1 pivotal study of the Hybrid L24 device conducted under investigational device exemption.

The pivotal trial was a prospective, multicenter, 1-arm, nonrandomized, nonblinded, repeated-measures clinical study among 50 subjects at 10 U.S. sites. Results were reported in FDA documentation and in peer-reviewed form by Roland et al (2016). Eligible patients were selected based on having severe high-frequency sensorineural hearing loss (≥70 dB hearing level averaged over 2000, 3000, and 4000 Hz) with relatively good low-frequency hearing (≤60 dB hearing level averaged over 125, 250, and 500 Hz) in the ear selected for implantation.

Performance was compared pre- and postimplantation within each subject; outcomes were measured at 3, 6, and 12 months postoperatively. The study tested 2 coprimary efficacy hypotheses: (1) that outcomes on CNC, a measure of word recognition and (2) AzBio sentences in noise presented through the hybrid implant system would be better at 6 months postimplantation than preoperative performance using a hearing aid.

All 50 subjects enrolled underwent device implantation and activation. One subject had the device explanted and replaced with a standard cochlear implant between the 3- and 6-month follow-up visits due to profound loss of low-frequency hearing; an additional subject was explanted before the 12-month follow-up visit, and 2 additional subjects were explanted after 12 months. For the 2 primary effectiveness end points, CNC word-recognition score and AzBio sentence-in-noise score, there were significant within-subject improvements from baseline to 6-month follow-up. The mean improvement in CNC word score was 35.8% (95% CI, 27.8% to 43.6%); for AzBio score, the mean improvement was 32.0% (95% CI, 23.6% to 40.4%). For safety outcomes, 65 adverse events were reported, most commonly profound/total loss of hearing (occurring in 44% of subjects) with at least 1 adverse event occurring in 34 subjects (68%).

Lenarz et al. reported results of a prospective multicenter European study evaluating the Nucleus Hybrid™ L24 system. The study enrolled 66 adults with bilateral severe-to-profound high-frequency hearing loss. At 1 year
postoperatively, 65% of subjects had significant gains in speech recognition in quiet, and 73% had significant gains in noisy environments. Compared with the cochlear implant hearing alone, residual hearing significantly increased speech recognition scores.

**Hearing Benefit With Shorter Cochlear Array**
The Nucleus Hybrid L24 system was designed with a shorter cochlear implant with the intent of preserving low-frequency hearing. A potentially relevant question is whether a shorter implant is associated with differences in outcomes, although studies addressing this question do not directly provide evidence about hybrid implants themselves. Gifford et al compared hearing outcomes pre- and postimplantation for 44 adult cochlear implant recipients with preserved low-frequency hearing in 2 test conditions: cochlear implant plus low-frequency hearing in the contralateral plus low-frequency hearing in the contralateral ear (bimodal condition) and cochlear implant plus low-frequency hearing in both ears (best-aided condition).(54) They reported that there were small but statistically significant differences in improvements in adaptive sentence recognition and speech recognition in a noisy “restaurant” environment, suggesting that the presence of residual hearing is beneficial.

In 2014, Santa Maria et al published a meta-analysis of hearing outcomes after various types of hearing-preservation cochlear implantation, which included implantation of hybrid devices, cochlear implantation with surgical techniques designed to preserve hearing, and the use of postoperative systemic steroids.(55) The study included 24 studies, but only 2 focused specifically on a hybrid cochlear implant system, and no specific benefit from a hybrid system was reported.

Causon et al (2015) evaluated factors associated with cochlear implant outcomes in a meta-analysis of articles published from 2003 to 2013, which reported on pure tone audiometry measurements pre- and post-cochlear implantation.(56) Twelve studies with available audiometric data (total N=200 patients) were included. The authors applied a formula to attempt to standardize degree of hearing preservation after cochlear implant, described as the HEARRING consensus statement formula, which calculates a percentage of hearing preservation at a specific frequency band, which is scaled to the preoperative audiogram by dividing the change in hearing by the difference between the maximum measurable threshold and the preoperative hearing threshold. The association of a variety of patient- and surgery-related factors, including insertion depth, and improvement in low-frequency hearing were evaluated. In this analysis, insertion depth was not significantly associated with low-frequency residual hearing.

In a retrospective review that included 10 subjects implanted with a cochlear implant with either a standard electrode (n=12) or the Nucleus Hybrid L24 electrode (n=10), loss of acoustic hearing to the severe-profound level occurred in a higher proportion of patients who received a standard electrode (58% vs 30%).(57)

Since the publication of the Santa Maria and Causon studies, which evaluated factors associated with cochlear implant outcomes, additional studies have attempted to evaluate whether shorter cochlear arrays are more likely to preserve hearing.

**Section Summary**
Prospective and retrospective studies using a single-arm, within-subjects comparison pre- and postintervention suggest that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. For patients who have high-frequency hearing loss but preserved low-frequency hearing, the available evidence suggests that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation following a hybrid cochlear implantation if there is loss of residual hearing.

**Summary of Evidence**
For individuals who have bilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes randomized controlled trials (RCTs) and multiple systematic reviews and technology assessments. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available studies have reported improvements in speech reception and quality-of-life measures. And, although the available RCTs and other studies measured heterogeneous outcomes and included varying patient populations, the findings are consistent across multiple studies and settings. In addition to consistent improvement in speech reception (especially in noise), studies showed improvements in sound localization with bilateral devices. Studies
have also suggested that earlier implantation may be preferred. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes prospective and retrospective studies reporting within-subjects comparisons and systematic reviews of these studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Given the natural history of hearing loss, pre- and postimplantation comparisons may be appropriate for objectively measured outcomes. However, the available evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, is limited by small sample sizes, short follow-up times, and heterogeneity in evaluation protocols and outcome measurements. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have high-frequency sensorineural hearing loss with preserved low-frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound processor, the evidence includes prospective and retrospective studies using single-arm, within-subjects comparison pre- and postintervention and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available evidence has suggested that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. The available evidence has also suggested that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation after a hybrid cochlear implantation if there is loss of residual hearing. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 2.

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NCT: national clinical trial.

### Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### 2016 Input

In response to requests, input was received from 2 specialty societies, one of which provided 4 responses and one of which provided 3 responses, and 3 academic medical centers while this policy was under review in 2016. Clinical input focused on the use of hybrid cochlear implants. Input was consistent that the use of a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant improves outcomes for patients with high-frequency hearing loss but preserved low-frequency hearing.
2010 Input
In response to requests, input was received from 2 physician specialty societies and 4 academic medical centers while this policy was under review in 2010. In addition, unsolicited input was received from a specialty society. Most of those providing input supported the use of cochlear implants in infants younger than 12 months of age; many of those supporting this use noted that there are major issues determining hearing level in infants of this age group, and others commented that use could be considered in these young infants in certain situations only. Those providing input were divided in their comments regarding the medical necessity of upgrading functioning external systems; some agreed with this and others did not.

Practice Guidelines and Position Statements

The American Academy of Otolaryngology-Head and Neck Surgery
The American Academy of Otolaryngology-Head and Neck Surgery has a position statement on cochlear implants that was revised in 2014. The Academy "considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can significantly perform better with two cochlear implants rather than one, bilateral cochlear implantation is accepted medical practice."(58)

Agency for Health Care Research and Quality
In April 2011, a technology assessment for the Agency for Health Care Research and Quality (AHRQ) on the effectiveness of cochlear implants in adults.(7) The assessment conclusions are noted within the body of this policy.

National Institute for Health and Care Excellence
In January 2009, the National Institute for Health and Care Excellence (NICE) released technology appraisal guidance 166, Cochlear Implants for Children and Adults With Severe to Profound Deafness, which includes recommendations for use of unilateral and bilateral cochlear implants in children and adults as noted within the body of this policy.(6)

National Institutes of Health
Cochlear implants are recognized as an effective treatment of sensorineural deafness, as noted in a 1995 National Institutes of Health (NIH) Consensus Development conference, which offered the following conclusions (2):

- Cochlear implantation has a profound impact on hearing and speech reception in post-lingual deafened adults with positive impacts on psychological and social functioning.
- Pre-lingual deafened adults may also benefit, although to a lesser extent than post-lingual deafened adults. These individuals achieve minimal improvement in speech recognition skills. However, other basic benefits, such as improved sound awareness, may meet safety needs.
- Training and educational intervention are fundamental for optimal post-implant benefit.

The conference offered the following conclusions regarding cochlear implantation in children:
- Cochlear implantation has variable results in children. Benefits are not realized immediately but rather are manifested over time, with some children continuing to show improvement over several years.
- Cochlear implants in children under 2-years-old are complicated by the inability to perform detailed assessment of hearing and functional communication. However, a younger age of implantation may limit the negative consequences of auditory deprivation and may allow more efficient acquisition of speech and language. Some children with post meningitis hearing loss under the age of 2 years have received an implant due to the risk of new bone formation associated with meningitis, which may preclude a cochlear implant at a later date.

U.S. Preventive Services Task Force Recommendations
Not applicable.
Medicare National Coverage
Existing national coverage states:

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

Coverage for cochlear implants may also be provided when the patient has “hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.”

References

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<tr>
<td>06/09/06</td>
<td>Disclaimer and Scope update - No other changes.</td>
</tr>
<tr>
<td>08/08/06</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statement.</td>
</tr>
<tr>
<td>04/10/07</td>
<td>Replace Policy - Policy updated with literature review. Policy statement changed to indicate bilateral cochlear implants are medically necessary. Reference numbers added.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References and codes added.</td>
</tr>
<tr>
<td>04/13/10</td>
<td>Replace Policy - Policy updated with literature search. Policy statements modified for clarity, intent unchanged. References and codes added.</td>
</tr>
<tr>
<td>08/09/11</td>
<td>Replace Policy – Policy updated with literature review; Rationale section and references reorganized. No changes in policy statements. Reference numbers 3-4, 6, 12, 16-17 added; numerous references to early, small studies removed. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>08/24/11</td>
<td>Benefit Application updated.</td>
</tr>
<tr>
<td>02/09/12</td>
<td>The CPT codes 92605 and 92606 were removed from the policy.</td>
</tr>
<tr>
<td>06/26/12</td>
<td>Related Policies update; title for 7.01.84 has been changed.</td>
</tr>
<tr>
<td>08/20/12</td>
<td>Replace policy. Clarification statement added to the policy guidelines second paragraph: In addition, unique clinical circumstance may justify individual consideration for implantation before 12 months of age, based on review of applicable medical records to verify the other pediatric criteria noted in this policy are met. Rationale section revised based on literature review through April 2012. Reference numbers 7-9, 13 and 22-24 added. Other references renumbered. CPT codes 92605 and 92606 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>09/25/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>10/18/12</td>
<td>Update Related Policies – 7.01.03 renumbered to 7.01.547.</td>
</tr>
<tr>
<td>08/12/13</td>
<td>Replace policy. Policy statement added: cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered investigational. Rationale updated based on literature review through May 2013. References 7, 10, 11, 28-32 added; others renumbered/removed. Policy statement changed as noted.</td>
</tr>
<tr>
<td>03/11/14</td>
<td>Coding Update. Remove codes 20.96, 20.97, and 20.98 per ICD-10 mapping project; these codes are not utilized for adjudication of policy.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. Add 1.01.528</td>
</tr>
<tr>
<td>05/15/14</td>
<td>Coding update. CPT codes 92607 and 92608 removed from the policy; these codes address the evaluation portion; this policy is specific to the device and evaluation is not addressed herein.</td>
</tr>
<tr>
<td>07/14/14</td>
<td>Annual Review. Policy statement added that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered investigational. Rationale section reorganized and policy updated with literature review through April 4, 2014. References reorganized, numbers 1, 20, 21, 27, 29, 30-32, 36-40 added, others renumbered/removed. Policy statement changed as noted. Coding update: Remove CPT codes 92507-92606 &amp; 92626-92633 from policy. Remove ICD-9 and ICD-10 diagnosis codes and ICD-10-PCS codes.</td>
</tr>
<tr>
<td>07/14/15</td>
<td>Annual Review. Policy updated with literature review through April 19, 2015; references 17, 23-24, 36-37, and 45 added. Policy statements unchanged. CPT codes 92626, 92627, 92630 and 92633</td>
</tr>
</tbody>
</table>
removed; these are codes fall under the rehabilitation benefit. HCPCS codes L8616, L8617, L8618, L8621, L8622, L8623 and L8624 removed; these are for replacement and do not fall within the scope of the policy.

12/12/15  Policy statement formatted to differentiate between different types of hearing loss/implants.
10/01/16  Annual Review, changes approved September 13, 2016. Policy updated with results of clinical input. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria. CPT codes 92601-92606, 92609 removed; these are not supportive of policy intent.
10/07/16  Update coding section. Changed code L8328 to L8628. Removed paragraph regarding codes 92601-92606, and 92609 as they were removed from policy.
01/01/17  Interim review, changes approved December 13, 2016. Removed age limit for policy statement about cochlear implants for bilateral hearing loss; added statement about replacement of cochlear implant components. Policy guidelines about individual review consideration for implantation in children under 12 months of age added. RUL table for cochlear implant components added to Policy Guidelines.
05/01/17  Annual review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 16 and 43-45 added. Coding updated; removed HCPCS codes L8627, L8628, and L8629. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.
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Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at:
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Oromoo (Cushite):

Français (French):

Getting Help in Other Languages

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本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要資訊。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請接電話 800-722-1471 (TTY: 800-842-5357)。

Italiano (Italian):
Premera Blue Cross Customer Service 800-722-1471

This Notice contains important information. It may be necessary for you to take action prior to certain deadlines. You have the right to receive this information and assistance in a language of your choice without charge. Call 800-722-1471 (TTY: 800-842-5357).

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Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Thai (Thai):
ประกาศนี้มีข้อมูลสําคัญ ประกาศนี้มีข้อมูลสําคัญเกี่ยวกับการติดต่อหรือการรับรองสิทธิการบริการสุขภาพของคุณผ่าน Premera Blue Cross และคุณมีสิทธิ์ที่จะได้รับการช่วยเหลือภาษาที่คุณต้องการในกรณีที่คุณต้องการ คุณสามารถติดต่อได้ในกรณีที่คุณต้องการการช่วยเหลือภาษีสิทธิการบริการสุขภาพที่คุณต้องการที่มีที่คุณต้องการ คุณมีสิทธิที่จะได้รับการช่วยเหลือภาษีสิทธิการบริการสุขภาพในภาษีของคุณโดยไม่ถูกหักค่าใช้จ่ายใด ๆ 800-722-1471 (TTY: 800-842-5357).

Polskie (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie pracy przedsiębiorstwa Premera Blue Cross. Prosimy zwrócić uwagę na kłuczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utraty polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie prawo do bezpłatnej informacji we własnym języku. Zadzwonienie pod 800-722-1471 (TTY: 800-842-5357).

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Română (Romanian):

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