Cochlear Implant

Policy # 00017
Original Effective Date: 08/25/2002
Current Effective Date: 05/16/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Implantable Bone Conduction and Bone-Anchored Hearing Aids is addressed separately in medical policy 00004.

Note: Treatment of Tinnitus is addressed separately in medical policy 00127.

Note: Semi-Implantable and Fully Implantable Middle Ear Hearing Aids is addressed separately in medical policy 00425.

Note: Auditory Brainstem Implant is addressed separately in medical policy 00475.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device in patients age 12 months and older with bilateral severe-to-profound pre-or postlingual (sensorineural) hearing loss (HL) defined as a hearing threshold of pure-tone average of 70 dB (decibels) HL or greater at 500 Hz (hertz), 1,000 Hz, and 2,000 Hz, and have shown limited or no benefit from hearing aids to be **eligible for coverage.**

Based on review of available data, the Company considers replacement of internal and/or external components to be **eligible for coverage** in a small subset of patients who have inadequate response to existing component(s) to the point of interfering with the individual's activities of daily living, or the component(s) is/are no longer functional and cannot be repaired. *Note: Copies of original medical records must be submitted to support medical necessity.*

Based on review on available data, the Company considers 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, (e.g. the Nucleus®‡ Hybrid™‡ L24 Cochlear Implant System), for patients ages 18 years and older to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant will be met in patients who meet all of the following:

- Bilateral severe-to-profound high-frequency sensorineural HL 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 HL (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 HL (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.

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear (BTE) model, to be **not medically necessary.****

Based on review on available data, the Company considers replacement of internal and/or external components solely for the purpose of upgrading to a system with advanced technology or to a next-generation device to be **not medically necessary.****

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review on available data, the Company considers the use of cochlear implantation as a treatment for patients with unilateral HL with or without tinnitus to be **investigational.***

The use of cochlear implant when patient selection criteria are not met is considered to be **investigational.***

Policy Guidelines

Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implantation plus hearing aid in the contralateral ear will not result in a binaural benefit (i.e., in those patients with HL of a magnitude where a hearing aid will not produce the required amplification).

In certain situations, implantation may be considered before 12 months of age. One scenario is post meningitis when cochlear ossification may preclude implantation. Another is in cases with a strong family history, because establishing a precise diagnosis is less uncertain.

HL is rated based on the threshold of hearing. Severe HL is defined as a bilateral hearing threshold of 70 to 90 dB, and profound HL 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% correct or less in the ear to be implanted on tape-recorded sets of open-set sentence recognition. In children, limited benefit is defined as failure to develop basic auditory skills, and in older children, 30% or less correct on open-set tests.

A post cochlear implant rehabilitation program is necessary 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 may include deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brainstem; active or chronic infections of the external or middle ear; and mastoid cavity or tympanic membrane perforation. Cochlear ossification may prevent electrode insertion, and the absence of cochlear development as demonstrated on computed tomography scans remains an absolute contraindication.

Background/Overview

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.

Sounds 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 into electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several cochlear implants are commercially available in the United States and are manufactured by Cochlear Americas, Advanced Bionics, and the MED-EL Corp. Over time, subsequent generations of the various components of the devices have been approved by the U.S. 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 Systems[a] Approved by the Food and Drug Administration

Variables	Manufacturer and Currently Marketed Cochlear Implants		
	Advanced Bionics®‡ HiResolution®‡ Bionic Ear System (HiRes 90K)	**Cochlear®‡ Nucleus 22 and 24**	**Med El®‡ Maestro Combi 40+**
PMA	P960058	P840024, P970051	P000025
Predicate devices	Clarion Multi-Strategy or HiFocus CII Bionic Ear (P940022)	Freedom with Contour	
Indications			
Adults ≥ 18 y	• Postlingual onset of severe-to-profound bilateral SNHL (≥70 dB) • Limited benefit from appropriately fitted hearing aids, defined as scoring ≤50% on a test of open-set HINT sentence recognition	• Pre-, peri-, or postlingual onset of bilateral SNHL, usually characterized by: o Moderate-to-profound HL in low frequencies; and o Profound (≥90 dB) HL in mid-to-high speech frequencies • Limited benefit from binaural hearing aids (≤50% sentence recognition in ear to be implanted)	• Severe-to-profound bilateral SNHL (≥70 dB) • ≤40% correct HINT sentences with best-sided listening condition
Children	**12 mo to 17 y of age** • Profound bilateral SNHL (>90 dB) • 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 • Lack of benefit in children <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 <20% correct on a simple open-set word recognition test (MLNT) administered using monitored live voice (70 dB SPL) • Lack of hearing aid benefit in children >4 y defined as scoring <12% on a difficult open-set word recognition test (PBK test) or <30% on an open-set sentence test (HINT for Children) administered using recorded materials in the sound field (70 dB SPL)	**25 mo to 17 y 11 mo** • Severe-to-profound bilateral SNHL • MLNT scores ≤30% in best-aided condition in children 25 mo to 4 y 11 mo • LNT scores ≤30% in best-aided condition in children 5 y to 17 y and 11 mo **12-24 mo** • Profound SNHL bilaterally • Limited benefit from appropriate binaural hearing aids	**12 mo to 18 y** • Profound sensorineural HL (≥90 dB) • In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills with hearing aids over 3 to 6 mo • In older children, lack of aided benefit is defined as <20% correct on the MLNT or LNT, depending on child's cognitive ability and linguistic skills • A 3- to 6-mo trial with hearing aids is required if not previously experienced

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; SNHL: sensorineural hearing loss; 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 2010 and given approval by the Food and Drug Administration for reentry to market the device in 2011. Cochlear voluntarily recalled the Nucleus CI500 range in 2011 for device malfunction in the CI512 implant.

In 2014, the Nucleus Hybrid L24 Cochlear Implant System (Cochlear Americas) was approved by FDA through the premarket approval process. 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 ages 18 years and older who have residual low-frequency hearing sensitivity and severe-to-profound high-frequency sensorineural HL, and who obtain limited benefit from an appropriately fit bilateral hearing aid. The electrode array inserted into the cochlea is shorter than conventional cochlear implants. According to FDA's premarket approval notification, labeled indications for the device include:

- Preoperative hearing in the range from "normal to moderate 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 HL (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 HL (threshold average of 2000, 3000, and 4000 Hz ≥60 dB HL) in the contralateral ear"
- "The CNC [Consonant-Nucleus-Consonant] word recognition score will be between 10% and 60%, inclusively, in the ear to be implanted in the preoperative aided condition and in the contralateral ear 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.

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 (i.e., 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 (i.e., 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 the 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. Also, single processors do not provide binaural benefit and may impair sound localization and increase the signal-to-noise ratio received by the cochlear implant.

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Centers for Medicare and Medicaid Services (CMS)
Existing national coverage states:

> "…cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound HL 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 …, or a prospective, controlled comparative trial approved by CMS…."

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms
.
To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate.RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Unless otherwise noted, this evidence review refers to traditional cochlear implants (i.e., not hybrid cochlear implant/hearing aid systems [e.g., the Nucleus Hybrid L24 Cochlear Implant System]).

COCHLEAR IMPLANTATION FOR BILATERAL SENSORINEURAL HEARING LOSS
Cochlear Implantation: 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 improves communication ability in most adults with severe to profound deafness and frequently leads to positive psychological and social benefits as well."
>
> "Prelingually deafened adults may also be suitable for implantation, although these candidates must be counseled regarding realistic expectations. Existing data indicate that these individuals achieve minimal improvement in speech recognition skills.
>
> However, other basic benefits, such as improved sound awareness, may provide psychological satisfaction meet safety needs."
>
> "…training and educational intervention are fundamental for optimal postimplant benefit."

The effectiveness of cochlear implants has been evaluated in several systematic reviews and technology assessments, both from the United States and abroad. Bond et al (2009) authored a technology assessment 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 (1513 deaf children; 1379 adults), 2 of which were RCTs. They defined 62 different outcome measures, and overall evidence was of moderate-to-poor quality. Reviewers 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."

Gaylor et al (2013) published an updated technology assessment for the Agency for Healthcare Research and Quality. Sixteen (of 42) studies published through May 2012 evaluated unilateral cochlear implants. Most unilateral implant studies showed statistically significant improvement in mean speech scores, as measured by open-set sentence or multisyllable word tests; meta-analysis of 4 studies revealed significant improvements 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 considerable heterogeneity was observed across studies.

Cochlear Implantation: Bilateral Stimulation

While the use of unilateral cochlear implants in patients with severe-to-profound HL has become a well-established intervention, 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 dBs or percentage points.

Crathorne et al (2012) published a systematic review. 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 HL. A literature search was updated through January 2012. Nineteen studies conducted in the United States and Europe were included. The review included 2 RCTs with waiting-list controls, 10 studies with prospective pre/post

repeated-measure or cohort designs, 6 cross-sectional studies, and 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 both RCTs. Meta-analyses could not be performed due to heterogeneity among 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.

The Gaylor Agency for Healthcare Research and Quality 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 designs across studies.

Since the publication of the systematic reviews described above, additional comparative studies and case series have reported on outcomes after bilateral cochlear implantation. For example, in a 2016 prospective observational study including 113 patients with postlingual HL, 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%).

The van Zon et al (2016) prospective study focused on tinnitus perception conducted as a part of a multicenter RCT comparing unilateral with bilateral cochlear implantation in patients who had severe bilateral sensorineural HL. This analysis included 38 adults enrolled from 2010 to 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 (a validated scale), with a change in score from 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 Tinnitus Questionnaire score (change in score, 20 to 9; $p=0.04$).

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 Bond technology assessment (2009) 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. Weak evidence showed greater gain from earlier implantation (before starting school).

In a review, Bond et al (2009) identified 15 studies that met their inclusion criteria addressing cochlear implantation in children; all were methodologically weak and too heterogeneous to perform a meta-analysis. However, reviewers concluded that there was sufficient, consistent evidence demonstrating positive benefits with unilateral cochlear implants in severely to profoundly hearing impaired children 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. As reported by Sharma and Dorman (2006), central auditory pathways are "maximally plastic" for about 3.5 years, making a case for earlier cochlear implantation of children with hearing impairment. Stimulation delivered before about 3.5 years of age results in auditory evoked potentials that reach normal values in 3 to 6 months.

Forli et al (2011) conducted a systematic review of 49 studies on cochlear implant effectiveness in children that addressed the impact of age of implantation on outcomes Heterogeneity of studies precluded meta-analysis. Early implantation was examined in 22 studies, but few studies compared outcomes of implantations performed before 1 year of age with implantations performed after 1 year of age. Studies suggested improvements in hearing and communicative outcomes in children receiving implants before 1 year of age, although it is uncertain whether these improvements were related to the duration of cochlear implant usage or age of implantation. However, 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 noted, the 1995 National Institutes of Health Consensus Development conference concluded cochlear implants are recognized as an effective treatment of sensorineural deafness. 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 manifest 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 HL 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 systematic reviews above have suggested that cochlear implant removal and reimplantation (due to device malfunction or medical/surgical complications) in children is not associated with worsened hearing outcomes.

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 systematic review of 38 studies, Black et al (2011) sought to identify prognostic factors for cochlear implantation in pediatric patients. A quantitative meta-analysis was not performed due to study heterogeneity. However, 4 prognostic factors—age at implantation, inner ear malformations, meningitis, and connexin 26 (a genetic cause of HL) —consistently influenced hearing outcomes.

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

Auditory Neuropathy Spectrum Disorder
In a systematic review, Fernandes et al (2015) evaluated 18 published studies and 2 dissertations that reported hearing performance outcomes for children with auditory neuropathy spectrum disorder (ANSD) and cochlear implants. Studies included 4 nonrandomized controlled studies considered high quality, 5 RCTs considered low quality, and 10 clinical outcome studies. Most studies (n=14) compared the speech perception in children who had ANSD and cochlear implants to the speech perception in children who had sensorineural HL and cochlear implants. Most of these studies concluded that children with ANSD and cochlear implants developed hearing skills similar to those with sensorineural HL and cochlear implants; however, these types of studies do not permit comparisons across 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 are labeled by the FDA for use in children older than 12 months of age, earlier diagnosis of congenital HL with universal hearing screening has prompted interest in cochlear implantation in children younger than 12 months old.

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

A number of small studies from outside the United States have reported on cochlear implants 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 before 12 months of age, compared with 23 who were implanted after 12 months of age (specific timing implantation was not provided). 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 of the need to examine the effect of multiple factors on language outcomes and the rate of language development.

Similarly, in a study from Italy, 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. 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- and 36-month testing.

A more recent (2016) prospective study of 28 children with profound sensorineural HL 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.

Cochlear Implantation in Children: Bilateral Stimulation

In a systematic review, Lammers et al (2014) compared the evidence on the effectiveness of bilateral cochlear implantation with that for unilateral implantation among children with sensorineural HL. Reviewers identified 21 studies that evaluated bilateral cochlear implantation in children, with no RCTs identified. Due to the limited number of studies, heterogeneity in outcomes and comparison groups, and high risk for bias in the studies, reviewers could not 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. Reviewers noted that the currently available evidence consisted solely of cohort studies that compared a bilaterally implanted group with a unilaterally implanted control group, with only 1 study providing a clear description of matching techniques to reduce bias.

Several publications not included in the Lammers systematic review have evaluated bilateral cochlear implants in children. These studies, ranging in size from 91 to 961 patients, have generally reported improved speech outcomes with bilateral implantation, compared with unilateral implantation. In another retrospective case series (2013) 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: Cochlear Implantation for Bilateral Sensorineural Hearing Loss

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

COCHLEAR IMPLANTATION FOR UNILATERAL SENSORINEURAL HEARING LOSS
As noted, a number of potential benefits to binaural hearing exist, including binaural summation, which permits improved signal detection threshold, and sound localization. The potential benefits from binaural hearing have prompted interest in cochlear implantation for patients with unilateral HL.

Systematic Reviews
Van Zon et al (2015) published a systematic review of studies evaluating cochlear implantation for single-sided deafness or asymmetric HL. Reviewers assessed 15 studies, 9 of which (n=112 patients) were considered of sufficient quality to be included in data review. Reviewers identified no high quality studies of cochlear implantation in this population. Data were not pooled for meta-analysis due to high between-study heterogeneity, but reviewers concluded that studies generally reported improvements in sound localization, QOL scores, and tinnitus after cochlear implantation, with varying results for speech perception in noise.

Case Series
Several individual studies have reported on longer-term outcomes for cochlear implantation for single-sided deafness since the publication of the van Zon systematic review.

The longest follow-up was reported by Mertens et al (2015) in a case series with structured interviews, which included 23 individuals who received cochlear implants for single-sided deafness with tinnitus. Eligible patients had either single-sided deafness or asymmetric HL 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, and the Tinnitus Questionnaire (a validated scale). Patients demonstrated improvements in visual analog scale scores from baseline (mean score, 8) to 1 month (mean score: 4; $p<0.01$ vs baseline) and to 3 months (mean score, 3; $p<0.01$ vs baseline) after the first fitting. Tinnitus Questionnaire scores improved from baseline to 3 months after fitting (55 vs 31, $p<0.05$) and were stable for the remainder of follow-up.

Rahne et al (2016) reported on a retrospective review of 4 children and 17 adults with single-sided deafness treated with cochlear implants and followed for 12 months. 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, standard deviation, 2.7 dB) to -4.0 dB after 3 months (standard deviation, 1.3 dB; $p<0.05$), with continued improvements through 6 months.

Cochlear Implant for Tinnitus Relief in Patients With Unilateral Deafness
Based on observations about tinnitus improvement with cochlear implants, several studies have reported on improvements in tinnitus after cochlear implantation in individuals with unilateral HL. For example, in the meta-analysis by Vlastarakos et al (2014), tinnitus improved in most patients (95%).

Ramos Macias et al (2015) reported on results of a prospective multicenter study with repeated measures related to tinnitus, hearing, and QOL, among 16 individuals with unilateral HL and severe tinnitus who underwent cochlear implantation. All patients had a severe tinnitus handicap (Tinnitus Handicap Inventory score ≥58%). Eight (62%) of the 13 patients who completed the 6-month follow-up visit reported a lower

tinnitus handicap on the Tinnitus Handicap Inventory score. Perceived loudness/annoyingness of the tinnitus was evaluated with a 10-point visual analog scale. Tinnitus loudness decreased from 8.4 preoperatively to 2.6 at the 6-month follow-up.

Tavora-Vieira et al (2013) reported on results of a prospective case series that included 9 postlingually deaf subjects with unilateral HL, 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: Cochlear Implantation for Unilateral Sensorineural Hearing Loss
The available evidence for the use of cochlear implants in improving outcomes for patients with unilateral HL, 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 mitigate the damage to the cochlea and preserve residual hearing.

In March 2014, the FDA approved the Nucleus Hybrid L24 Cochlear Implant System for use through the premarket approval process. According to the FDA's summary of safety and effectiveness data, approval was based on 2 clinical studies conducted outside of the United States and a pivotal study of the Hybrid L24 device conducted under investigational device exemption.

The pivotal trial was a prospective, multicenter, single-arm, nonrandomized, nonblinded, repeated measures clinical study among 50 subjects at 10 U.S. sites. Results were reported in FDA documentation and peer-reviewed form by Roland et al (2016). Eligible patients were selected on the basis of having severe high-frequency sensorineural HL (≥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. The performance was compared pre- and postimplant within each subject; outcomes were measured at 3, 6, and 12 months postoperatively. The trial tested 2 coprimary efficacy hypotheses: (1) that outcomes on consonant-nucleus-consonant, 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 visit due to profound loss of low-frequency hearing; an additional subject was explanted before the 12-month follow-up visit, and 2 other subjects were explanted after 12 months. For the 2 primary effectiveness end points (consonant-nucleus-consonant word recognition score, AzBio sentence-in-noise score), there were

significant within-subject improvements from baseline to 6-month follow-up. Mean improvement in consonant-nucleus-consonant word score was 35.8% (95% CI, 27.8% to 43.6%); for AzBio score, 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 (2013) reported on 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 HL. 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 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.

Santa Maria et al (2014) 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. Reviewers included 24 studies, but only two 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. Twelve studies with available audiometric data (total N=200 patients) were included. Reviewers standardized degree of hearing preservation after cochlear implant using the HEARRING consensus statement formula. This formula 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.

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: Hybrid Cochlear Implantation

Prospective and retrospective studies using a single-arm, within-subjects comparison pre- and postintervention have suggested that a hybrid cochlear implant system is associated with improvements in

hearing of speech in quiet and noise. For patients who have high-frequency HL but preserved low-frequency hearing, the available evidence has 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 following hybrid cochlear implantation if there is a loss of residual hearing.

SUMMARY OF EVIDENCE

For individuals who have bilateral sensorineural HL who receive the cochlear implant(s), the evidence includes 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 QOL measures. 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral sensorineural HL who receive the 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 HL, 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 HL, 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 a high-frequency sensorineural HL with preserved low-frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound processor of the cochlear implant, the evidence includes prospective and retrospective studies using single-arm, within-subject 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 hybrid cochlear implantation if there is a loss of residual hearing. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy History

Original Effective Date: 08/25/2002
Current Effective Date: 05/16/2018

08/15/2002	Medical Policy Committee review
08/26/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
08/10/2004	Medical Director review
09/21/2004	Medical Policy Committee review. Format revision. No substance change to policy.
09/27/2004	Managed Care Advisory Council approval
09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review. Format revision.
09/22/2005	Quality Care Advisory Council approval
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Bilateral Cochlear Implantation changed from investigational to medically necessary
03/12/2008	Medical Director review
03/19/2008	Medical Policy Committee approval. Definition of hearing loss added to patient selection criteria.
03/04/2009	Medical Director review
03/18/2009	Medical Policy Committee approval. No change to coverage.
03/05/2010	Medical Policy Committee review
03/19/2010	Medical Policy Implementation Committee approval. No change to coverage.
03/03/2011	Medical Policy Committee review

03/16/2011	Medical Policy Implementation Committee approval. "Upgrades of an existing, functioning external system to achieve aesthetic improvement, such as smaller profile components or a switch from a body-worn, external sound processor to a behind-the-ear (BTE) model, are considered not medically necessary" was added to policy coverage statement.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/04/2013	Coding revised
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Policy extensively revised to track BCBSA.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Policy statement added that cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered investigational.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. Policy statement added that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered investigational.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria.
11/01/2016	Coding update
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. Policy statement added that replacement of components solely for the purpose of upgrading is not medically necessary. Coverage statement added for replacement of components in patients with an inadequate response or with nonfunctioning components that cannot be repaired.
01/01/2018	Coding update
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2019

Coding

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Code Type	Code
CPT	69930, 92601, 92602, 92603, 92604, 92633
HCPCS	L8614, L8615, L8616, L8617, L8618, L8619, L8621, L8622, L8623, L8624, L8627, L8628, L8629, V5273 Code added eff 1/1/18: L8625
ICD-10 Diagnosis	H90.3, H90.41-H90.42, H90.5, H90.A11-H90.A12, H90.A21-H90.A22, H90.A31-H90.A32

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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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Cochlear Implant

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