



Louisiana

Cochlear Implant

Policy # 00017

Original Effective Date: 08/25/2002

Current Effective Date: 10/12/2020

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 9 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 may consider 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.*

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When Services May Be 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 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 for patients ages 18 years and older who meet ALL of the following:

- 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 HL (threshold average of 2000, 3000, and 4000 Hz \geq 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 \geq 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.

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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 of available data, the Company considers the use of cochlear implantation as a treatment for patients with unilateral hearing loss (HL) with or without tinnitus to be **investigational**.*

The use of cochlear implantation 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 (ie, in those patients with hearing loss 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.

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Hearing loss is rated 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% 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.

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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. Food and Drug Administration (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 the FDA for currently marketed implant devices are summarized in Table 1. FDA product code: MCM.

Table 1. Cochlear Implant Systems 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	<ul style="list-style-type: none"> • Postlingual onset of severe-to-profound bilateral SNHL (≥70 dB) • Limited benefit from appropriately 	<ul style="list-style-type: none"> • Pre-, peri-, or postlingual onset of bilateral SNHL, usually characterized by: <ul style="list-style-type: none"> ○ Moderate-to-profound HL in low 	<ul style="list-style-type: none"> • Severe-to-profound bilateral SNHL (≥70 dB) • ≤40% correct HINT sentences with best-sided listening condition

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Variables	Manufacturer and Currently Marketed Cochlear Implants		
	<p>fitted hearing aids, defined as scoring $\leq 50\%$ on a test of open-set HINT sentence recognition</p>	<p>frequencies; and</p> <ul style="list-style-type: none"> ○ Profound (≥ 90 dB) HL in mid-to-high speech frequencies <ul style="list-style-type: none"> ● Limited benefit from binaural hearing aids ($\leq 50\%$ sentence recognition in ear to be implanted) 	<ul style="list-style-type: none"> ● SSD (≥ 90 dB) or AHL ($\Delta 15$ dB PTA) <ul style="list-style-type: none"> ○ Limited benefit from unilateral amplification, defined by test scores of 5% or less on monosyllabic CNC words in quiet when tested in the ear to be implanted alone ○ Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit
Children	<p>12 mo to 17 y of age</p> <ul style="list-style-type: none"> ● Profound bilateral SNHL (> 90 dB) 	<p>25 mo to 17 y 11 mo</p> <ul style="list-style-type: none"> ● Severe-to-profound bilateral SNHL ● MLNT scores $\leq 30\%$ in best-aided condition in 	<p>12 mo to 18 y</p> <ul style="list-style-type: none"> ● Profound sensorineural HL (≥ 90 dB) <ul style="list-style-type: none"> ○ In younger children, little or no benefit is

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	<ul style="list-style-type: none"> • 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) 	<p>children 25 mo to 4 y 11 mo</p> <ul style="list-style-type: none"> • LNT scores $\leq 30\%$ in best-aided condition in children 5 y to 17 y and 11 mo <p>9 - 24 mo</p> <ul style="list-style-type: none"> • Profound SNHL bilaterally with limited benefit from appropriate binaural hearing aids 	<p>defined by lack of progress in the development of simple auditory skills with hearing aids over 3 to 6 mo</p> <ul style="list-style-type: none"> ○ 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 <p>5 y to 18 y</p> <ul style="list-style-type: none"> • SSD (≥ 90 dB) or AHL ($\Delta 15$ dB PTA) <ul style="list-style-type: none"> ○ Insufficient functional access to sound in the ear to be

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Variables	Manufacturer and Currently Marketed Cochlear Implants	
	<p>administered using monitored live voice (70 dB SPL)</p> <ul style="list-style-type: none"> 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) 	<p>implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted</p> <ul style="list-style-type: none"> Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit

AHL: asymmetric hearing loss; CNC: consonant-nucleus-consonant; CROS: contralateral routing of signal; 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; PTA: pure tone average; SNHL: sensorineural hearing loss; SPL: sound pressure level; SSD: single-sided deafness.

^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 U.S. Food and Drug Administration for

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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 the 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 hearing loss, 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 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 \geq 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 \geq 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. The Med-EI EAS System received expanded premarket approval by the FDA in 2016 (PMA P00025/S084). FDA product code: PGQ.

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 the noise and identify the direction of sound). Bilateral cochlear

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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 the 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.

In March 2020, the FDA approved to expand the indication for the Nucleus 24 Cochlear Implant System to include children aged 9 to 24 months of age who have bilateral profound sensorineural deafness and have demonstrated limited benefit from appropriate trials of binaural hearing aids. Children 2 years of age and old may demonstrate severe to profound bilateral hearing loss.

The approval was based on a retrospective analysis of prospective data from 5 centers in the United States in children aged between 9 and 12 months who were implanted between 2012 and 2017. Data were collected through March 2019 and included a total of 84 subjects (50% female). Average patient age was 10 months 15 days and 61 subjects received bilateral implants. Post-operative follow up duration was 6 months. The most common adverse events observed were minor post-operative complications (7.1%) and difficulties with temperature regulation during implantation (7.1%). 24 patients experienced 28 medical/surgical complications and 26 of those complications were resolved without major surgical or medical intervention. Two reimplantation surgeries were reported.

The benefits of the device for the age expansion from 12 to 9 months were based on a systematic review of the literature to support premarket approval. A literature search yielded 49 peer-reviewed studies that reported data on safety and/or effectiveness of implantation in children prior to 12 months of age reflecting data on 750 subjects. Significant benefits in terms of improved speech and language development are expected through expansion of the indication in children from 12 to 9 months as reflected by significant improvements in speech intelligibility rating and categorical auditory performance scores. Older implanted children (12-29 months) demonstrated more delayed and atypical language abilities over time. The study was limited by lack of effectiveness measures, failure to reach a minimum sample size of 100 patients, lack of a prespecified primary safety endpoint, and insufficient follow-up duration to capture long-term adverse events.

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Rationale/Source

A cochlear implant is a device for treatment of severe-to-profound hearing loss in individuals who only receive limited benefit from 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 deaf cochlea.

For individuals who have bilateral sensorineural hearing loss who receive the 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. 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 hearing loss who receive the cochlear implant(s), the evidence includes a feasibility study, prospective and retrospective studies reporting within-subjects comparisons, and systematic reviews of observational 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 and heterogeneity in evaluation protocols and outcome measurements. A small feasibility study in adults with single-sided deafness or asymmetric hearing loss demonstrated improvements in sound perception, sound localization, and subjective measures of quality of life compared to baseline conditions. However, studies assessing outcomes compared to best-aided hearing controls across multiple time points are lacking. An ongoing post-marketing study in adults and children may further elucidate outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

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For individuals who have a 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 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. Studies reporting on long-term outcomes and results of re-implantation are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From 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, 1 of which provided 4 responses and 1 of which provided 3 responses, and 3 academic medical centers while this policy was under review in 2016. 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. Also, unsolicited input was received from a specialty society. Most providing input supported the use of cochlear implants in infants

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younger than 12 months of age; many supporting this use noted that there are major issues when determining the hearing level in infants of this age group, and others commented that use could be considered in these young infants only in certain situations. Those providing input were divided on the medical necessity of upgrading functioning external systems—some agreed, and others did not.

Practice Guidelines and Position Statements

American Academy of Otolaryngology - Head and Neck Surgery Foundation

In 2014, the American Academy of Otolaryngology – Head and Neck Surgery Foundation has a position statement on cochlear implants that was revised. The Foundation “...considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can perform significantly better with 2 cochlear implants [rather] than one, bilateral cochlear implantation is accepted medical practice.”

Agency for Health Care Research and Quality

In 2011, a technology assessment for the Agency for Health Care Research and Quality assessed the effectiveness of cochlear implants in adults. The assessment conclusions are noted within the body of this evidence review.

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence (NICE) released a technology appraisal guidance on cochlear implants for children and adults with severe-to-profound deafness. The guidance included the following updated recommendations:

- 1.1 “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, as defined in 1.5.
- 1.2 Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.
 - a. Children

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b. Adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

1.3 Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.

1.5 For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL [hearing level] at 2 or more frequencies bilaterally (500 Hz, 1 kHz, 2 kHz, 3 kHz, 4 kHz) without acoustic hearing aids. Adequate benefit from acoustic hearing aids is defined for this guidance as:

a. for adults, a phoneme score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA

b. for children, speech, language and listening skills appropriate to age, developmental stage, and cognitive ability.

1.6 Cochlear implantation should be considered for children and adults only after an assessment by a multidisciplinary team. As part of the assessment, children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate)."

1.7 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)."

National Institutes of Health

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 perception in postlingually deafened adults."

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- “Prelingually deafened adults generally show little improvement in speech perception scores after cochlear implantation, but many of these individuals derive satisfaction from hearing environmental sounds and continue to use their implants.” However, improvements in other basic benefits, such as sound awareness, may meet safety needs.
- “...training and educational intervention are fundamental for optimal postimplant benefit.” The conference offered the following conclusions regarding cochlear implantation in children:
- “Cochlear implantation outcomes are more variable in children. Nonetheless, gradual, steady improvement in speech perception, speech production, and language does occur.”

Cochlear implants in children under 2 years old are complicated by the inability to perform a 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 a 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 might preclude implantation 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 ..., or a prospective, controlled comparative trial approved by CMS...”

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Ongoing and Unpublished Clinical Trials

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

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02941627 ^a	The Neuro Zti Cochlear Implant System Efficacy and Safety in Adults	55	Jul 2018 (unknown)
NCT03007472 ^a	Clinical Evaluation of the Cochlear Nucleus(R) CI532 Cochlear Implant in Adults	100	Jul 2019 (ongoing)
NCT02532972	Cochlear Implantation for Treatment of Single-sided Deafness	11	Nov 2019 (ongoing)
NCT02075229	A Proposal to Evaluate Revised Indications for Cochlear Implant Candidacy for the Adult CMS Population	90	Jun 2020 (recruiting)
NCT02203305 ^a	Cochlear Implantation in Cases of Single-Sided Deafness	50	Dec 2020 (ongoing)
NCT03929809	Iowa Cochlear Implant Clinical Research Center Study of SSD Using Med-El Cochlear Implants	10	May 2021 (recruiting)
Unpublished			
NCT02105441	Cochlear Implantation Among Adults and Older Children With Unilateral or Asymmetric Hearing Loss	40	Mar 2018 (completed)

NCT: national clinical trial.

^a Industry-sponsored or partially sponsored.

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Policy History

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- 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

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- 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

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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.
05/02/2019	Medical Policy Committee review
05/15/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2020	Medical Policy Committee review
05/13/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Eligible for coverage statement for unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device revised to reflect expanded indications in children aged 9 months and older with profound bilateral sensorineural hearing loss. Added a bullet to the eligible for coverage criteria for cochlear implantation with a hybrid cochlear implant/hearing aid device as follows: <ul style="list-style-type: none">• Bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity.

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Next Scheduled Review Date: 09/2021

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	69930, 92601, 92602, 92603, 92604, 92633
HCPCS	L8614, L8615, L8616, L8617, L8618, L8619, L8621, L8622, L8623, L8624, L8625, L8627, L8628, L8629, V5273
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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***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- 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.

****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- 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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