

Cochlear Implant

Policy # 00017

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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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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.

Note: Copies of original medical records must be submitted to support medical necessity.

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 unilateral or bilateral cochlear implantation to be **eligible for coverage**** for individuals who meet **ALL** of the following criteria:

- Request is for a U.S. Food and Drug Administration (FDA)-approved cochlear implant device; **AND**
- Age 7 months and older; **AND**
- Bilateral severe-to-profound pre- or postlingual sensorineural hearing loss (HL); **AND**
- A hearing threshold pure-tone average of 70 dB hearing loss or greater at 500, 1000, and 2000 Hz, in both ears; **AND**
- Have shown limited or no benefit from hearing aids; **AND**

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.

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- None of the contraindications to cochlear implantation are present:
 - Deafness due to lesions of **ANY** of the following:
 - Eighth cranial (acoustic) nerve; **OR**
 - Central auditory pathway; **OR**
 - Brainstem; **OR**
 - Active or chronic infections of the external or middle ear; **OR**
 - Mastoid cavity; **OR**
 - Tympanic membrane perforation; **OR**
 - Cochlear ossification (may prevent electrode insertion); **OR**
 - The absence of cochlear development as demonstrated on computed tomography scans.

***Note:** 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 individuals with hearing loss of a magnitude where a hearing aid will not produce the required amplification).*

Based on review of available data, the Company may consider replacement of internal and/or external components to be **eligible for coverage**** when the following criteria are met:

- In a small subset of individuals who have inadequate response to existing component(s); **AND**
- In **ONE** of the following situations:
 - Documented interference 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 of available data, the Company may consider cochlear implantation with a hybrid cochlear implant and hearing aid device to be **eligible for coverage**** for individuals who meet **ALL** of the following criteria:

- For individuals ages 18 years and older; **AND**
- Includes the hearing aid integrated into the external sound processor of the cochlear implant, (e.g. the Nucleus[®] Hybrid[™] L24 Cochlear Implant System); **AND**
- 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 **ALL** of the following hearing thresholds:
 - Low-frequency hearing thresholds no poorer than 60 dB hearing level up to and including 500 Hz (averaged over 125, 250, and 500 Hz) in the ear selected for implantation; **AND**
 - Severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 75 dB hearing level) in the ear to be implanted; **AND**

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- Moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 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; **AND**
- None of the contraindications to cochlear implantation are present:
 - Deafness due to lesions of **ANY** of the following:
 - Eighth cranial (acoustic) nerve; **OR**
 - Central auditory pathway; **OR**
 - Brainstem; **OR**
 - Active or chronic infections of the external or middle ear; **OR**
 - Mastoid cavity; **OR**
 - Tympanic membrane perforation; **OR**
 - Cochlear ossification (may prevent electrode insertion); **OR**
 - The absence of cochlear development as demonstrated on computed tomography scans.

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**.**

The use of cochlear implantation when coverage criteria are not met is considered 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 individuals with unilateral hearing loss (HL) with or without tinnitus to be **investigational**.*

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Policy Guidelines

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

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.

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.

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)

Table 1. Cochlear Implant Systems Approved by the U.S. Food and Drug Administration

Variables	Manufacturer and Currently Marketed Cochlear Implants			
Device	Advanced Bionics ^{®†} HiResolution ^{®†} Bionic Ear System (HiRes Ultra3D)	Cochlear ^{®†} Nucleus Nexa System	MED-EL ^{®†} Maestro/SYNCHRONY2	Neuro Cochlear Implant System (Oticon Medical)
PMA	P960058	P840024, P970051	P000025	P200021
Indications				
Adults ≥18 y	• Postlingual onset of severe-to-profound	• Pre-, peri-, or postlingual onset of bilateral	• Moderate -to-profound bilateral SNHL defined as PTA at 250 Hz, 500	• Severe-to-profound bilateral SNHL (≥70

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	bilateral SNHL (≥ 70 dB) Limited benefit from appropriately fitted hearing aids, defined as scoring $\leq 50\%$ on a test of open-set HINT sentence recognition	SNHL, usually characterized by: - Moderate-to-profound HL in low frequencies; and - Profound (≥ 90 dB) HL in mid-to-high speech frequencies - Severe to profound unilateral SNHL (SSD or AHL) - PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of > 80 dB HL - Normal or near normal hearing in the contralateral ear defined as PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of ≤ 30 dB HL - Limited benefit from an appropriately fitted unilateral hearing device	Hz, and 1000 Hz of > 40 dB HL and ≤ 65 HL at 3000-8000 Hz - SSD (≥ 90 dB) or AHL ($\Delta 15$ dB PTA) - Limited benefit from unilateral amplification, defined by test scores of 50% or less on monosyllabic CNC words in quiet when tested in the ear to be implanted alone and 60% or less in the non-implant ear - Patients must have at least 1 month experience wearing a CROS hearing aid or other relevant device and not show any subjective benefit, but radiological evidence of cochlear ossification may preclude a hearing aid trial	dB at 500, 1000, and 2000 Hz) Limited benefit from appropriately fit hearing aids, defined as scoring $\leq 50\%$ correct HINT sentences in quiet or noise with best-sided listening condition
Children	12 mo to 17 y of age Profound bilateral SNHL (> 90 dB)	25 mo to 17 y, 11 mo of age	MED-EL strongly recommends a hearing aid trial of 1-3 months; lack of aidable hearing may	Not applicable

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	Use of appropriately fitted hearing aids for at least 6 mo in children 2 to 17 y or at least 3 mo in children 12 to 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	- Severe-to-profound bilateral SNHL - MLNT scores ≤30% in best-aided condition in children - LNT scores ≤30% in best-aided condition in children 9 to 24 mo of age - Profound SNHL bilaterally - Limited benefit from appropriate binaural hearing aids 5 y to 18 y of age - Severe to profound unilateral SNHL (SSD or AHL) - PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of > 80 dB HL - Normal or near normal hearing in the contralateral ear defined as PTA at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz of ≤ 30 dB HL - Limited benefit from an appropriately	preclude a hearing aid trial 7 to <12 mo - Profound SNHL (≥90 dB) at 500, 1000, and 2000 Hz 1 to <6 y - Moderately-severe to profound SNHL (≥55 dB) at 500, 1000, and 2000 Hz 6 y to 18 y of age - Moderate to profound SNHL with a low-frequency PTA >40 dB HL at 250, 500, and 1000 Hz and unaided thresholds ≥65 dB HL at 3-8kHz	
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	Children) administered using recorded materials in the sound field (70 dB SPL)	fitted unilateral hearing device		
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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; PMA: premarket approval; PTA: pure tone average; SNHL: sensorineural hearing loss; SPL: sound pressure level; SSD: single-sided deafness.

In 2025, the Nucleus[®]† Nexa[™]† System was approved as the first smart cochlear implant system that allows recipients to receive firmware updates without replacing the implant.

In 2014, the Nucleus[®]† Hybrid[™]† L24 Cochlear Implant System (Cochlear Americas) was approved by the FDA through the premarket approval (PMA) 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 aged 18 years and older who have residual low-frequency hearing sensitivity and severe-to-profound high-frequency sensorineural hearing loss, and who obtain limited benefit from an appropriately fit bilateral hearing aid. The electrode array inserted into the cochlea is shorter than conventional cochlear implants. According to the FDA's PMA 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.”

In 2022, the Nucleus[®]† Hybrid[™]† L24 Cochlear Implant System received expanded approval for single-sided deafness or unilateral hearing loss in adults and children age 5 or older (P970051/S205).

Other hybrid hearing devices have been developed. The MED-EL EAS System received expanded PMA by the FDA in 2016 (PMA P000025/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

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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 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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

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.

Summary of Evidence

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 an improvement in the net health outcome.

For individuals who have unilateral sensorineural hearing loss who receive the cochlear implant(s), the evidence includes small open-label RCTs, 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

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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. Inconsistent sound localization and binaural hearing outcomes have been reported in 2 small RCTs. Prospective studies assessing outcomes compared to best-aided hearing controls beyond 6 months are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Clinical input obtained in 2016 supports the use of hybrid cochlear implants in patients with high-frequency hearing loss but preserved low frequency hearing.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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

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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 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

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology - Head and Neck Surgery

In 2020, the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) released an updated position statement on cochlear implants. The AAO-HNS "...considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children over 9 months of age with moderate to profound hearing loss who have failed a trial with appropriately fit hearing aids."

In 2023, the AAO-HNS published position statements on the use of cochlear implants in patients with unilateral hearing loss. For adults the AAO-HNS recommended: "A cochlear implant restores binaural hearing in these patients and markedly improves sound localization, speech perception in noise, reduces or eliminates tinnitus, and improves quality of life and hearing. The AAO-HNS endorses cochlear implantation for cases of asymmetric or unilateral sensory hearing loss in adult patients." Recommendations were similar for children: "It is the position of the AAO-HNS that cochlear implantation is an appropriate management option for rehabilitation of unilateral sensorineural hearing loss in appropriately selected children."

In 2024, the AAO-HNSF published clinical practice guidance for age-related hearing loss. The authors give a strong recommendation that "Clinicians should refer patients for an evaluation of cochlear implantation candidacy when patients have appropriately fit amplification and persistent hearing difficulty with poor speech understanding" based on evidence from multiple systematic reviews and meta-analyses of prospective clinical trials which observed a more significant benefit than harm.

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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 medical policy.

National Institute for Health and Care Excellence

In 2019, the 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
- 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:

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- “Cochlear implantation has a profound impact on hearing and speech perception in postlingually deafened adults.”
- “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 effective for services performed on or after April 4, 2005 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...”

Coverage was updated on September 26, 2022 to state the following:

"... 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. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition. Patients must meet all of the following criteria.

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- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

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
<i>Ongoing</i>			
NCT07139327	A Pre-market, Prospective, Interventional, Multicenter, Pivotal Study to Evaluate Efficacy and Safety of a Totally Implantable Cochlear Implant System in an Adult Population With Sensorineural Hearing Loss	36	Oct 2027 (recruiting)
NCT07287124	A Pivotal, Pre-market, Prospective, Interventional, Multi-centre Study to Evaluate Clinical Benefit, Performance, and Safety of the TI1132 Implant in an Adult Population With Sensorineural Hearing Loss	56	Aug 2028
NCT04793412	Cochlear Implantation in Children With Asymmetric Hearing Loss or Single-Sided Deafness Clinical Trial	80	Aug 2026 (recruiting)
NCT04506853 ^a	Single-Sided Deafness and Asymmetric Hearing Loss Post-Approval Study	65	Dec 2026 (recruiting)
NCT04738968	Cochlear Implant for Young Children and One Deaf Ear	70	Dec 2026 (active)
NCT05318417 ^a	A Post-approval, Prospective, Nonrandomized, Single-arm Multicenter Investigation to Evaluate the Safety and Effectiveness of Cochlear Implantation in Children and Adults With Unilateral Hearing Loss/Single-sided Deafness	60	Jun 2027 (recruiting)

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NCT05154188 ^a	Post Approval Study to Assure the Continued saFety and effectIveness of Neuro Cochlear Implant System in Adult Users (PACIFIC)	60	Feb 2029 (not yet recruiting)
NCT05775367	Cochlear Implantation in Infants and Toddlers With Single-Sided Deafness	60	May 2030 (recruiting)
<i>Unpublished</i>			
NCT03900897 ^a	Expanded Indications in the MED-EL Pediatric Cochlear Implant Population	247	Nov 2023 (completed)
NCT03236909 ^a	Expanded Indications in the Adult Cochlear Implant Population	44	Mar 2023 (completed)
NCT03052920	Cochlear Implantation in Adults With Asymmetric Hearing Loss Clinical Trial	40	Mar 2021 (completed)
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 co-sponsored trial.

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08/15/2002 Medical Policy Committee review

08/26/2002 Managed Care Advisory Council approval

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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.
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

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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: • Bilateral severe-to-profound high-frequency sensorineural hearing loss with residual low-frequency hearing sensitivity.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/04/2025	Medical Policy Committee review

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09/10/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/03/2026 Medical Policy Committee review

09/09/2026 Medical Policy Implementation Committee review

09/17/2026 Medical Quality Management Committee approval. Updated the eligible for coverage criteria age requirement to 7 months and older for unilateral or bilateral cochlear implantation of a U.S. Food and Drug Administration (FDA)-approved cochlear implant device. The use of cochlear implantation when criteria are not met was changed from investigational to not medically necessary. Three paragraphs from the Policy Guidelines were moved to the eligible for coverage with criteria section: definitions of limited benefits from hearing aids for adults and children, bilateral cochlear implantation considerations, and criteria for cochlear implantation contraindications.

Next Scheduled Review Date: 09/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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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	All related Diagnoses

*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 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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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.