

## Corporate Medical Policy

### Cochlear Implant

<b>File Name:</b>	cochlear_implant
<b>Origination:</b>	2/1996
<b>Last CAP Review:</b>	2/2019
<b>Next CAP Review:</b>	2/2020
<b>Last Review:</b>	2/2019

#### Description of Procedure or Service

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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.

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

Several cochlear implants are commercially available in the United States, and are manufactured by Cochlear Americas, Advanced Bionics, and the MED EL Corporation. Over the years, 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 the selection criteria to include children as young as 12 months.

In March 2014, FDA approved the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Americas, Centennial, CO) 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 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 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.
- Consonant-Nucleus-Consonant (CNC) word recognition score between 10% to 60% (inclusively) in the ear to be implanted in the preoperative aided condition and in the contralateral ear equal to or better than that of the ear to be implanted but not more than 80% correct.

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

While cochlear implants have typically been used unilaterally, in recent years, interest in bilateral cochlear implantation has arisen. 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 may occur with bilateral cochlear implants through binaural summation; i.e., signal processing of sound input from 2 sides may provide a better representation of sound and allow one to separate out 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 one to sort out noise and identify the direction of sound. Bilateral cochlear implantation may be performed independently with separate implants and speech processors in each ear or with a single processor. However, no single processor for bilateral cochlear implantation has been approved by the FDA for use in the United States. In addition, single processors do not provide binaural benefit and may impair sound localization and increase the signal to noise ratio received by the cochlear implant.

## **Related Policies:**

Implantable Bone Conduction Hearing Aids

Semi-Implantable and Fully Implantable Middle Ear Hearing Aid

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## **Policy**

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**BCBSNC will provide coverage for Cochlear Implants when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## **When Cochlear Implant is covered**

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Unilateral or bilateral cochlear implantation of an FDA approved cochlear implant device may be considered **medically necessary** in patients who meet these criteria:

- Age 12 months and older; and
- Bilateral severe-to-profound pre- or post-lingual (sensorineural) hearing loss, defined as a hearing threshold of pure-tone average of 70dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz; and
- Limited or no benefit from hearing aids.

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) may be considered **medically necessary** for patients ages 18 years and older who meet all of the following criteria:

- 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

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- Severe to profound mid- to high-frequency hearing loss (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 hearing loss (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.

Replacement of internal and/or external components is considered **medically necessary** only in a small subset of individuals 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. Copies of original medical records must be submitted either hard copy or electronically to support medical necessity.

## When Cochlear Implant is not covered

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Cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered **investigational**.

A cochlear implant is **contraindicated** for the following conditions:

- Deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway, or brain stem,
- Active or chronic infections of the external or middle ear; and mastoid cavity or tympanic membrane perforation,
- Cochlear ossification that prevents electrode insertion, or
- Absence of cochlear development as demonstrated on CT scans.

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 model (BTE), are considered **not medically necessary**.

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 is considered **not medically necessary**.

## Policy Guidelines

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- Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit; i.e., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification.
- Hearing loss is rated on a scale based on the threshold of hearing. Severe hearing loss is defined as a bilateral hearing threshold of 70-90 decibels (dB) and profound hearing loss is defined as a hearing threshold of 90 dB and above.
- In adults, limited benefit from hearing aids is defined as scores 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,  $\leq 30\%$  correct on open-set tests.
- A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program typically consists of 6 to 10 sessions that last approximately 2 1/2 hours each. The rehabilitation program should include development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

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- A multi-channel model should be used, if possible. An upgrade from single to multi-channel electrodes or the newer processor is considered not medically necessary. If an existing implant is functioning, an upgrade or replacement of electrodes to another processor should not be made.

## Summary

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

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

Clinical input strongly supported the use of a hybrid cochlear implant for patients with high-frequency hearing loss but preserved low-frequency hearing.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 69930, 92507, 92601, 92602, 92603, 92604, 92605, 92606, 92607, 92608, 92609, 92626, 92627, 92630, 92633, L8614, L8615, L8616, L8617, L8618, L8619, L8621, L8622, L8623, L8624, L8625, L8627, L8628, L8629, V5273*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual

FDA approval letter

TEC Evaluations, 1990

FDA Letter of Approval - Clarion Multi-Strategy Cochlear Implant - 2/14/96

BCBSA Medical Policy Reference Manual, 9/23/98

Consultant Review 3/99

Medical Policy Advisory Group - 5/99

Specialty Matched Consultant Advisory Panel - 7/00

Medical Policy Advisory Group - 9/14/00

FDA Approval letter stamped Nov. 1 2000

Specialty Matched Consultant Advisory Panel 6/2002

BCBSA Medical Policy Reference Manual, 7.01.05, 8/15/01

FDA Approval letter stamped August 20, 2001

ECRI, Target Fact Sheet. August, 2001

BCBSA Medical Policy Reference Manual, 12/18/02; 7.01.05

BCBSA Medical Policy Reference Manual, 12/17/03; 7.01.05

Specialty Matched Consultant Advisory Panel 6/2004

BCBSA Medical Policy Reference Manual, 6/27/05; 7.01.05

Specialty Matched Consultant Advisory Panel - 6/1/2006

BCBSA Medical Policy Reference Manual, 4/25/06; 7.01.05

BCBSA Medical Policy Reference Manual, 2/15/07; 7.01.05

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 4/17/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 4/9/08.

Specialty Matched Consultant Advisory Panel - 6/1/2008

National Institute for Health and Clinical Excellence (NICE). Technology Appraisal Guidance 166. Cochlear Implants for children and adults with severe to profound deafness. Retrieved 4/29/10 from [www.nice.org.uk/TA166](http://www.nice.org.uk/TA166)

Centers for Medicare & Medicaid (CMS). National Coverage Determination (NCD) Pub 100.3, section 310.1 Cochlear Implantation. Retrieved 4/29/10 from: [http://www.cms.gov/mcd/viewncd.asp?ncd\\_id=50.3&ncd\\_version=2&basket=ncd%3A50%2E3%3A2%3ACochlear+Implantation](http://www.cms.gov/mcd/viewncd.asp?ncd_id=50.3&ncd_version=2&basket=ncd%3A50%2E3%3A2%3ACochlear+Implantation)

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 3/11/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 10/04/2011

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Specialty Matched Consultant Advisory Panel – 2/29/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 6/14/2012

Specialty Matched Consultant Advisory Panel –2/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 6/13/2013

Specialty Matched Consultant Advisory Panel –2/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 5/22/2014

FDA. Approval Letter: Nucleus Hybrid L24 Cochlear Implant System -- P130016. 2014. Available online at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf13/P130016a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130016a.pdf). Last accessed November 14, 2014.

American Academy of Otolaryngology-Head and Neck Surgery Foundation. Position Statement on Bilateral Cochlear Implants. 2014 revision. Available online at: <http://www.entnet.org/content/position-statement-cochlear-implants> . Last accessed November 14, 2014.

Specialty Matched Consultant Advisory Panel – 2/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 5/21/2015

Specialty Matched Consultant Advisory Panel – 2/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 7/14/2016

Specialty Matched Consultant Advisory Panel – 2/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 2/9/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 2/8/2018

Specialty Matched Consultant Advisory Panel – 2/2018

Specialty Matched Consultant Advisory Panel – 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 2/14/2019

## Policy Implementation/Update Information

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2/96	Original policy issued.
4/96	Revised: Clarion Multi-Strategy Implant added with indications for use, FDA approval 2/14/96
2/97	Reaffirmed
3/99	Consultant review. Consultant states that they agree with the addition of the Nucleus 24 for children. Criteria for diagnosis of profound hearing loss is correct. Rehabilitation is necessary. Agrees with policy.
4/99	Reaffirm
5/99	Revised: Removed the criteria for the Clarion device- risk of ossification of the cochlea is no longer an FDA requirement. Changes approved by the Medical Policy Advisory Group.
6/99	Reformatted, Medical Term Definitions added.
11/99	Revised. Removed cochlear implant 1.0 from approved indications since this is no longer manufactured.

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- 7/00 Sent to Specialty Matched Consultant Advisory Panel. No change to criteria.
- 9/00 Medical Policy Advisory Group. Approved. Typographical errors corrected. Corrected outline of criteria. No change to content of criteria.
- 6/01 Changed indication for Nucleus 24 Cochlear Implant to state, "Use in severe-to-profoundly deaf adults and profoundly deaf children age 12 months and older. The pediatric indication includes both prelingually and post-lingually deafened children." Coding format changes.
- 7/02 Specialty Matched Consultant Advisory Panel review. Added Med El Combi 40 + as an approved device. Indications and criteria listed in policy. "Description" section updated to include new devices. Separated Nucleus 24 Channel into two models-Nucleus 24 Channel and Nucleus 24 Contour. "When Cochlear Implant is Covered" section reformatted for clarity. Added code V5273 to the policy.
- 6/03 Added codes 92601, 92602, 92603, 92604 to Billing/Coding section.
- 7/03 Disclaimer added. Benefits Application section revised.
- 3/04 Billing/Coding sections updated for consistency.
- 10/14/04 Specialty Matched Consultant Advisory Panel review 6/21/04. Added HiResolution™ Bionic Ear System to "Description" and "When Covered" sections. "Description" section updated. Added statement to "Policy" and "When not Covered" sections that bilateral cochlear implants are not covered because they are considered investigational. Defined "limited benefit from hearing aids" for adults and children in "Policy Guidelines" section. Added CPT code 92507 to "Billing/Coding" section. Sources added.
- 7/7/05 Added new HCPCS codes K0731 and K0732 to "Billing/Coding" section. Codes will be effective 7/1/05.
- 1/5/06 Removed codes 92507, 92510, K0731 & K0732 from "Billing/Coding" section. Added codes 92626, 92627, 92630, 92633, L8615, L8616, L8617, L8618, L8621, L8622, L8623 & L8624.
- 7/10/06 Description section updated. Medical term definitions and reference sources added. Specialty Matched Consultant Advisory Panel review 6/1/06. No changes to criteria.
- 2/20/07 Added statement to "When Covered" section to indicate that bilateral cochlear implants are considered medically necessary. Removed statement from "Policy" and "When not Covered" sections re: bilateral cochlear implantation being investigational. (pmo)
- 7/16/07 Information added to "Description" section. Added information to "When Covered" section re: verifying FDA approval if the specific device is not mentioned in the policy. Reference sources added. (pmo)
- 7/14/08 Under "Policy Guidelines", 5<sup>th</sup> bullet, changed "An upgrade from single to multi-channel electrodes or the newer processor may not be medically necessary." to "...is not medically necessary". Specialty Matched Consultant Advisory Panel review 6/2008. No changes to criteria. (pmo)
- 1/5/2010 Policy reformatted. HCPCS codes L8627, L8628 and L8629 effective January 1, 2010 added to Billing/Coding Section. System Application Guidelines not updated due to conversion to the QMP real time database. (pmo)
- 6/22/10 Policy Number(s) removed. (amw)
- 7/6/2010 Description section revised. Criteria in the When Covered section was deleted and replaced with the following: "Unilateral or bilateral cochlear implantation of an FDA approved cochlear implant device may be considered medically necessary in patients age 12 months and older with bilateral severe-to-profound pre- or post-lingual (sensorineural) hearing loss defined as a hearing threshold of pure-tone average of 70dB (decibels) hearing loss or greater at 500 Hz (hertz), 100 Hz and 2000 Hz, and have shown limited or no benefit from hearing aids." The following statement was added to the When Not

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Covered section: “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 model, are considered not medically necessary.” The other information in the When Not Covered section (contraindications) was revised to state “contraindications to cochlear implantation may include deafness due to lesions of the eighth cranial nerve or brain stem, chronic infections of the middle ear and mastoid cavity or tympanic membrane perforation. The absence of cochlear development as demonstrated in CT scans remains an absolute contraindication.” The following was added to the Policy Guidelines section: “Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit; i.e., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification.” References updated. Specialty Matched Consultant Advisory Panel review 5/24/10. No change to policy statement. (adn)

- 3/15/11 Specialty Matched Consultant Advisory Panel review 2/23/11. No change to policy statement or coverage criteria. (adn)
- 3/20/12 Specialty Matched Consultant Advisory Panel review 2/29/12. Description section revised and FDA approval Status table removed. Semi-Implantable and Fully Implantable Middle Ear Hearing Aid added to Related Policies. Additional information added to contraindications section “A cochlear implant is contraindicated for the following conditions: Deafness due to lesions of the eighth cranial (acoustic) nerve, central auditory pathway or brain stem, 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 CT scans is an absolute contraindication”. No change to policy intent. Reference added. (sk)
- 3/12/13 Reference added. Specialty Matched Consultant Advisory Panel Review 2/20/13. No change to policy statement. (sk)
- 8/13/13 Reference added. Medical Director review. Policy statement added that cochlear implantation as a treatment for patients with unilateral hearing loss with or without tinnitus is considered investigational. Summary statement added. Notification given 8/13/13 for policy effective date 10/15/13. (sk)
- 4/15/14 Specialty Matched Consultant Advisory Panel review 2/25/14. No change to policy statement. (sk)
- 11/25/14 References added. Information on hybrid cochlear implant/hearing aid system added to Description section. Policy statement added that cochlear implantation with a hybrid cochlear implant/ hearing aid system is considered investigational. Notification given 11/25/2014 for policy effective date 1/27/2015. (sk)
- 3/10/15 Specialty Matched Consultant Advisory Panel review 2/25/15. (sk)
- 7/1/15 Reference added. Related Guideline removed. (sk)
- 4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/16. (sk)
- 8/30/16 Reference added. Policy Guidelines updated. Policy statement changed to indicate that cochlear implantation with a hybrid cochlear implant/hearing aid system is considered medically necessary for patients meeting criteria. (sk)



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- 6/30/17 Specialty Matched Consultant Advisory Panel review 2/22/17. Reference added. Statement added to indicate that replacement of cochlear implant components only to upgrade to a system with advanced technology or to a next-generation device is considered not medically necessary and that replacement of components when individuals have inadequate response to existing components or components are no longer functional is medically necessary. (sk)
- 12/29/17 Code L8625 added to Billing/Coding section for effective date 1/1/2018. (sk)
- 3/9/18 Reference added. Specialty Matched Consultant Advisory Panel review 2/28/2018. (sk)
- 3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)
- 4/16/19 Reference added. (sk)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.