

Corporate Medical Policy

Cochlear Implant

File Name: cochlear_implant
Origination: 2/1996
Last Review: 8/2024

Description of Procedure or Service

A cochlear implant is a surgically implanted, electronic 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 inner ear (cochlea) outer and inner hair cells that are absent or nonfunctional in a hearing-impaired individual.

The basic structure of a cochlear implant includes both external and internal components. The external components include an external sound processor with directional microphones and an external transmitter. The external sound processor contains a magnet to align with the internal receiver, battery power supply, and electronics to process the incoming sound signal from the environment. The internal component, or internal receiver is implanted behind the ear into the temporal bone. The internal receiver contains an electrode array that extends from the receiver and is implanted through the mastoid and facial recess into the cochlea through a surgically created opening in the round window membrane of the middle ear or through a separate bony cochleostomy. The internal receiver contains a magnet, antenna, electronics, and grounding function.

Sounds picked up by the externally worn sound processor's microphone are electrically transformed 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. These signals stimulate remaining second order neurons within the cochlea's spiral modiolus, resulting in stimulation of the auditory nerve and ultimately the brain.

Regulatory Status

Several cochlear implants have been cleared by the U.S. Food and Drug Administration (FDA) and are commercially available in the United States. The approved cochlear implants are manufactured by Cochlear Americas, Advanced Bionics, and the MED EL Corporation. Over time, subsequent generations of the various components of the devices have been approved by the FDA, focusing on improved electrode design, updated speech-processing capabilities, and MRI compatible magnets. Furthermore, smaller devices and the accumulating experience in children have resulted in broadening the selection criteria to include children as young as 9 months.

Hybrid Cochlear Implants: In March 2014, the FDA approved the Nucleus® Hybrid™ L24 Cochlear Implant System (Cochlear Americas, Centennial, CO) through the premarket approval process. This hybrid system is a combination of a cochlear implant that provides electrical stimulation to the cochlea, and a hearing aid that provides acoustic stimulation to the cochlear. The hybrid external sound processor contains an integrated hearing aid in addition to the cochlear implant electronics.

Hybrid cochlear implants are 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:

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- Preoperative hearing in the range from normal to moderate hearing loss (HL) in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz).
- Preoperative hearing with severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL) in the ear to be implanted.
- Preoperative hearing with moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 60 dB HL) in the contralateral ear.
- Consonant-Nucleus-Consonant (CNC) word recognition score between 10% to 60% (inclusively) in the ear to be implanted in the preoperative aided condition and in the contralateral ear equal to or better than that of the ear to be implanted but not more than 80% correct.
- Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fit with appropriate hearing aids.

Additional Hybrid Cochlear Implant Systems: Other hybrid hearing devices have been developed, including the Med El® EAS Hearing Implant System, which received expanded premarket approval by FDA in 2016. In 2022, the Nucleus® Hybrid™ L24 Cochlear Implant System received expanded approval for single-sided deafness and unilateral hearing loss in adults and children age 5 or older (P970051/S205).

Binaural Cochlear Implants: Although 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 two 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

Tinnitus Treatment

*****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

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

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

- Age 9 months and older; and
- Bilateral severe-to-profound pre- or post-lingual (sensorineural) hearing loss, defined as a hearing threshold pure-tone average (PTA) of 70dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz; and
- Limited or no benefit from appropriately fit, conventional hearing aids.

Single-sided Deafness & Asymmetrical Sensorineural Hearing Loss: Unilateral cochlear implantation of a FDA approved, non-hybrid cochlear implant device may be considered **medically necessary** in individuals who meet these criteria:

- 5 years of age and older, and
- Limited or no benefit after a minimum one-month trial wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device, and
- Either of the following:
 - Profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear, or
 - Profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in PTAs between ears.

Hybrid Cochlear Implant: 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 individuals 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
 - 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

Cochlear implantation as a treatment for individuals with tinnitus is considered **investigational** when the criteria above are not met.

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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.

A cochlear implant should not be implanted in individuals with single-sided deafness or asymmetrical hearing loss with any of the following:

- Profound hearing loss for more than ten years, or
- Acoustic neuroma.

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

- 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 individuals 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 as follows:
 - Profound hearing loss is defined as a hearing threshold of 90 decibels (dB) and above.
 - Severe hearing loss is defined as a bilateral hearing threshold of 70-90 dB.
 - Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.
 - Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.
 - Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.
- 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.
- For individuals ages 18 years-old and above, limited benefit from unilateral amplification is defined by test scores of five (5) percent correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone.
- For individuals between 5 and 17 years-old, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of five (5) percent or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.
- 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.
- 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.

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Bilateral Sensorineural Deafness: 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 an improvement in the net health outcome.

Single-Sided Deafness: For individuals who have unilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes small open-label RCTs, a feasibility study, and 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 post-implantation comparisons may be appropriate for objectively measured outcomes. Previously, the available evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, was 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 were reported in two small RCTs.

Recently, several retrospective studies, a prospective study, and two meta-analyses assessing outcomes compared to best-aided hearing controls have now been published. Evidence of benefit from cochlear implantation to treat single-sided deafness indicate that cochlear implant use is associated with improved speech perception, tinnitus control, sound localization, and quality of life. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Hybrid Cochlear Implants: 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. Studies reporting on long-term outcomes and results of re-implantation are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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. They are listed in the Category Search on the Medical Policy search page.

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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.

Scientific Background and Reference Sources

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

Centers for Medicare & Medicaid (CMS). National Coverage Determination (NCD) Pub 100.3, section 310.1 Cochlear Implantation. Retrieved 4/29/10 from:

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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

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. 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

Specialty Matched Consultant Advisory Panel – 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 2/13/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 7/16/2020

Specialty Matched Consultant Advisory Panel – 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.05, 2/11/2021

Specialty Matched Consultant Advisory Panel – 8/2021

Specialty Matched Consultant Advisory Panel – 8/2022

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Petros V Vlastarakos, Kostas Nazos, Evangelia-Filothei Tavoulari, Thomas P Nikolopoulos. Cochlear implantation for single-sided deafness: the outcomes. An evidence-based approach. *Eur Arch Otorhinolaryngol*. 2014 Aug;271(8):2119-26.doi: 10.1007/s00405-013-2746-z. Epub 2013 Oct 6.

Daniel M Zeitler, Michael F Dorman 3. Cochlear Implantation for Single-Sided Deafness: A New Treatment Paradigm. *J Neurol Surg B Skull Base*. 2019 Apr;80(2):178-186.doi: 10.1055/s-0038-1677482. Epub 2019 Feb 4.

Thompson, NJ. et al. Long-Term Improvement in Localization for Cochlear Implant Users with Single-Sided Deafness. *Laryngoscope*. 2022 Dec;132(12):2453-2458.doi: 10.1002/lary.30065. Epub 2022 Feb 17.

Zeitler DM et al. Cochlear implantation for single-sided deafness in children and adolescents. *Int J Pediatr Otorhinolaryngol*. 2019 Mar;118:128-133.doi: 10.1016/j.ijporl.2018.12.037. Epub 2019 Jan 2.

Thompson NJ et al. Long-Term Binaural Hearing Improvements for Cochlear Implant Users with Asymmetric Hearing Loss. *Laryngoscope*. 2023 Jun;133(6):1480-1485. doi: 10.1002/lary.30368. Epub 2022 Aug 29.

Specialty Matched Consultant Advisory Panel – 8/2023

Medical Director Review- 8/2023

Oh SJ, Mavrommatis MA, Fan CJ, et al. Cochlear implantation in adults with single-sided deafness: a systematic review and meta-analysis. *Otolaryngol Head Neck Surg*. 2023; 168(2):131-142.

Daher GS, Kocharyan A, Dillon MT, Carlson ML. Cochlear implantation outcomes in adults with single-sided deafness: a systematic review and meta-analysis. *Otol Neurotol*. 2023; 44(4):297-309.

Marx M, Mosnier I, Venail F, et al. Cochlear Implantation and Other Treatments in Single-Sided Deafness and Asymmetric Hearing Loss: Results of a National Multicenter Study Including a Randomized Controlled Trial. *Audiol Neurotol*. 2021;26(6):414-424. doi:10.1159/000514085

Specialty Matched Consultant Advisory Panel – 8/2024

Medical Director Review- 8/2024

Policy Implementation/Update Information

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.

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- 11/99 Revised. Removed cochlear implant 1.0 from approved indications since this is no longer manufactured.
- 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", 5th 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)

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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 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)

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- 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)
- 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)
- 11/24/20 Specialty Matched Consultant Advisory Panel review 2/11/2020. Reference added. Policy Guidelines updated. Policy statements updated to reflect expanded indications in children aged 9-12 months with profound bilateral sensorineural hearing loss. Specialty Matched Consultant Advisory Panel review 10/2/2020. (sk)
- 12/14/21 Reference added. Specialty Matched Consultant Advisory Panel review 8/18/2021. (sk)
- 5/2/23 Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 8/24/2022. (sk)
- 10/10/23 Added Related Policy. Updated FDA approved device in Description section. Criteria in the When Covered section expanded as follows: Unilateral cochlear implantation of a FDA approved non-hybrid cochlear implant device may be considered medically necessary in individuals who meet these criteria: 5 years of age and older, and limited or no benefit after a minimum one-month trial wearing a Contra Lateral Routing of Signal (CROS) hearing aid or other relevant device, and one of the following: profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear, or profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear, with a difference of at least 15 dB in PTAs between ears. When Not Covered section updated as follows: Cochlear implantation as a treatment for individuals with tinnitus is considered investigational when the criteria above are not met. Additional criteria added to the When Not Covered section specific to SSD/ASHL as follows: A cochlear implant should not be implanted in individuals with single-sided deafness or asymmetrical hearing loss with any of the following: Profound hearing loss for more than ten years, or acoustic neuroma. Expanded on definition of hearing loss ratings and defined limited benefit from unilateral amplification in adults and children in Policy Guidelines section. References updated. Medical Director Review 8/2023. Specialty Matched Consultant Advisory Panel review 8/2023. (ldh)
- 9/18/24 Description and Regulatory Status sections updated. When Covered section updated for clarity by rearranging bullets contained in the second coverage indication, added subsection headers, and clarified hearing aids under Bilateral Sensorineural Deafness to read, “appropriately fit, conventional hearing aids”. Policy Guidelines updated. No change to policy intent. References updated. Specialty Matched Consultant Advisory Panel review 8/2024. Medical Director review 8/2024. (ldh)

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

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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.