Corporate Medical Policy

Cochlear Implant

File Name: cochlear_implant
Origination: 2/1996
Last CAP Review: 2/2012
Next CAP Review: 2/2013
Last Review: 2/2012

Description of Procedure or Service

A cochlear implant is a device for individuals with severe to profound hearing loss 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 Corporation, 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.

While cochlear implants have typically been used unilaterally, in recent years, there is now interest in bilateral cochlear implantation. The proposed benefits of bilateral cochlear implants are to improve understanding of speech in noise 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 be received 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 and Bone Anchored Hearing Aids
Semi-Implantable and Fully Implantable Middle Ear Hearing Aid

Related Guideline:
Auditory Brain Stem Implant

******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

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.

When Cochlear Implant is not covered

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
- Absence of cochlear development as demonstrated on CT scans is an absolute contraindication.

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.

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 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.
- 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.

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.

Applicable codes: 69930, 92601, 92602, 92603, 92604, 92626, 92627, 92630, 92633, L8614, L8615, L8616, L8617, L8618, L8619, L8621, L8622, L8623, L8624, 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: 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

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.
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)

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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 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)

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.