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Developed By: Medical Criteria Committee	

Robert Mills, MD, MBA

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Description:

A cochlear implant is an electronic prosthesis that stimulates cells of the auditory spiral ganglion to provide a sense of sound to persons with hearing impairment. The device is made up of external and internal components. The external components include a microphone that picks up sounds from the environment, an external speech processor that arranges the sound transmitted by the microphone and an external transmitter. The internal components are surgically implanted. They include an internal receiver that is implanted in the temporal bone and receives signals from the external transmitter. The receiver converts the signals into electrical impulses. The impulses are collected by an electrode array that extends from the receiver into the cochlea. Cochlear implant devices are available in single-channel and multi-channel models. The cochlea is the part of the internal ear that is responsible for hearing. Audiologic criteria for children follow guidelines similar to those for adults. For adults and children able to respond reliably, standard pure-tone and speech audiometry tests are used to screen potential candidates.

Auditory brainstem implants (ABI) are another electronic prosthesis used in patients who have had surgical removal of auditory nerve tumors and as a result have total hearing loss. Like a cochlear implant, ABI's have several components including a microphone, a speech processor, a transmitter coil worn behind the ear, and an implant which is embedded in the skull. The implant relays signals to an electrode placed on the brainstem near the severed auditory nerve. After implantation, the ABI is programmed and tested and the individual must undergo training to recognize sounds and facilitate communication with the device.

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.

Summary of the FDA-labeled indications for currently marketed electrode arrays.

FDA Approval Status of Currently Marketed Cochlear Electrodes			
Clarion® HiFocus*	Nucleus® 24	Nucleus® 24 Contour	Med El Combi 40
Children: 12 mo.- 18 yr.; Profound hearing loss	Children: 18-24 mo.; Profound hearing loss	Children: 12 mo.- 18 yr.; Profound hearing loss	Children: 18 mo. - 18 yr.; Profound hearing loss
Adults: Postlingual profound hearing loss	Older children: 2-17 yr.; Severe to profound loss	Older children: Severe to profound loss	Adults: Bilateral severe to profound hearing loss
	Adults: Severe to profound loss pre- and postlingually	Adults: Severe to profound loss pre- and postlingually	

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Criteria:

Note: ODS does not consider a cochlear implant to be an implantable hearing aid. It is the position of ODS that bone-anchored hearing aids (BAHA) and temporal conduction implants are considered hearing aids. Plan benefits for hearing aids would apply.

- I. ODS will provide coverage of an auditory brainstem implant when **all** of the following criteria are met:
 - A. The member is 12 years of age or older; and
 - B. The member has been diagnosed with neurofibromatosis type 2; and
 - C. The member is completely deaf as a result of bilateral resection of neurofibromas of the auditory nerve, or the member is undergoing bilateral resection of neurofibromas of the auditory nerves and it is anticipated that the member will become completely deaf as a result of the surgery.

- II. ODS will provide coverage for unilateral or bilateral cochlear implantation for children (age 12 months to 17 years) when it is determined to be medically necessary and **all** of the following criteria are met:
 - A. Children 12 months to 17 years of age with profound, bilateral sensorineural hearing loss established by a pure tone average of 90 dB or greater at 500, 1000, and 2000 Hz; and
 - B. Child has limited benefit from a three month trial of appropriately fitted binaural hearing aids (This requirement may be waived if radiological evidence of cochlear ossification is present)
 - i. For children 4 years of age or younger, limited benefit is defined as lack of progress in the development of simple auditory skills as measured by Infant Toddler Speech Perception Test, Early Speech Perception Test, or a score of less than 20% correct on the Lexical Neighborhood Test in conjunction with appropriate amplifications and participation in intensive aural habilitation over a 3-6 month period.
 - ii. For children older than 4 years of age, limited benefit is defined as less than 20 percent correct on open-set sentence discrimination (e.g., Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive ability and linguistic skills).
 - C. A 3-6 month hearing aid trial is required for children without previous experience with hearing aids. Children need to be receptive to wearing a hearing aid before implantation because all current implants require an external processor; and
 - D. Child meets the FDA age indication for the specific device; and
 - E. Child has no contraindications to cochlear implantation surgery (listed below); and
 - F. Child has had an assessment by an audiologist and otolaryngologist experienced with cochlear implants
 - G. The member must be enrolled in an educational program supportive of listening and speaking with aided hearing

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- III. ODS will provide coverage for unilateral or bilateral cochlear implantation for adults (age 18 and older) when it is determined to be medically necessary when **all** of the following criteria are met:
- A. Adults age 18 and older with severe to profound bilateral sensorineural hearing impairment; and
 - B. Member is unable to benefit from appropriately fitted binaural hearing aids; and
 - C. Member has no contraindications to cochlear implantation surgery (listed below); and
 - D. Member has had an assessment by an audiologist and otolaryngologist experienced with cochlear implants
 - E. The member must be enrolled in an educational program supportive of listening and speaking with aided hearing.

For adults and children, a post-cochlear implant rehabilitation program is necessary to achieve benefits from the cochlear implant. The rehabilitation program consists of six to ten sessions that last approximately two and a half hours each, and may include long term speech therapy. (Note: ODS does not provide coverage for therapy that exceeds the limits of the plan benefit)

Contraindications for the Cochlear Implant:

1. Deafness due to lesions of the acoustic nerve or central auditory pathway
2. Otitis media or other active, unresolved ear problems
3. Radiographic evidence of absent cochlear development
4. Inability or lack of willingness to participate in post-implantation aural rehabilitation

Upgrades for the Cochlear Implant:

1. If an original implant is working, a replacement or upgrade to another device would not be a covered benefit.
2. 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.

Replacement Parts for the Cochlear Implant:

1. ODS will cover replacement parts, such as batteries and microphones, when:
2. The part is no longer functional and not repairable; and
3. The member has a benefit for a cochlear implant
4. Member is no longer able to adequately and /or safely perform his or her age-appropriate activities of daily living with component currently in use.
5. Usual medically necessary frequency of replacement of cochlear implant parts:

Replacement Parts	Life Expectancy
Battery charger kit	1 per 3 years
Cochlear auxiliary cable adapter	1 per 3 years

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Cochlear belt clip	1 per 3 years
Cochlear harness extension adapter	1 per 3 years
Cochlear signal checker	1 per 3 years
Disposable batteries for ear-level processors	72 per 6 months
Headset (3-piece component)	1 per 3 years
Headset cochlear coil (individual component)	1 per year
Headset cochlear magnet (individual component)	1 per year
Headset microphone (individual component)	1 per year
Headset cable or cord	4 per 6 months
Microphone cover	1 per year
Pouch	1 per year
Rechargeable batteries (per set of 2)	1 per year
Transmitter cable or cord	4 per 6 months

Adapted from Wisconsin Department of Health and Family Services, 2005

Information to be Submitted with Pre-Authorization Request:

1. Medical records from the requesting specialist
2. Assessment by an audiologist and otolaryngologist
3. Appropriate hearing and speech test results

CPT/HCPC Codes

This list of codes may not be all inclusive

Code	Description
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69930	Cochlear device implantation, with or without mastoidectomy
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming

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92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement

References:

- 74th Oregon Legislative Assembly – 2007. Enrolled Senate Bill 491.
- Ali, W. O’Connell, R. The effectiveness of early cochlear implantation for infants and young children with hearing loss. NZHTA Technical Brief 2007; 6(5). Accessed Apr 4, 2011. Available at URL address: <http://nzhta.chmeds.ac.nz/#tech>
- American Academy of Audiology (AAA). Cochlear implants in children. 2011. Accessed Apr 4, 2011. Available at URL address: <http://www.audiology.org/resources/documentlibrary/Pages/CochlearChildren.aspx>
- American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS). Policy statement: cochlear implants. Dec 27, 2007. Accessed Apr 4, 2011. Available at URL address: <http://www.entnet.org/Practice/policystatements.cfm>
- Bond M, Mealing S, Anderson R, et al. The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: A systematic review and economic model. Health Technol Assess. 2009;13(44):1-330.
- Center for Devices and Radiological Health (CDRH) Consumer Information, New Device Approval,
- Centers for Medicare & Medicaid Services (CMS). Hearing aids and auditory implants. Medicare Benefit Policy Manual, Ch. 16 - General Exclusions from Coverage, Sec. 100 (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05). Baltimore, MD: CMS; 2005. Accessed July 23, 2011 at: <http://www.cms.hhs.gov/manuals/downloads/bp102c16.pdf>.
- Ching TY, van Wanrooy E, Dillon H. Binaural-bimodal fitting or bilateral implantation for managing severe to profound deafness: a review. Trends Amplif. 2007 Sep;11(3):161-92.
- Colletti V, Carner M, Miorelli V, et al. Auditory brainstem implant (ABI): new frontiers in adults and children. Otolaryngol Head Neck Surg. 2005 Jul;133(1):126-38.
- Colletti V, Shannon R, Carner M, Veronese S, Colletti L. Outcomes in nontumor adults fitted with the auditory brainstem implant: 10 years' experience. Otol Neurotol. 2009 Aug;30(5):614-8.
- Dunn CC, Noble W, Tyler RS, Kordus M, Gantz BJ, Ji H. Bilateral and unilateral cochlear implant users compared on speech perception in noise. Ear Hear. 2010 Apr;31(2):296-8.
- Elvsåshagen T, Solyga V, Bakke SJ, et al. Neurofibromatosis type 2 and auditory brainstem implantation. Tidsskr Nor Laegeforen. 2009;129(15):1469-1473.
- FDA Approval Letter, August 2001 Accessed on July 1, 2010 at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm089750.htm> and <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm085394.htm>

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- Laszig R, Aschendorff A, Stecker M, et al. Benefits of bilateral electrical stimulation with the nucleus cochlear implant in adults: 6-month postoperative results. *Otol Neurotol*. 2004 Nov;25(6):958-68.
- Litovsky R, Parkinson A, Arcaroli J, Sammeth C. Simultaneous bilateral cochlear implantation in adults: a multicenter study. *Ear Hear*. 2006 Dec;27(6):714-31.
- Moller AR. History of cochlear implants and auditory brainstem implants. *Adv Otorhinolaryngol*. 2006;64:1-10.
- Moller AR. Physiological basis for cochlear and auditory brainstem implants. *Adv*
- National Institute for Health and Clinical Excellence (NICE). Cochlear implants for children and adults with severe to profound deafness. NICE Technology Appraisal Guidance 166. London, UK: NICE; January 2009.
- Papsin BC, Gordon KA. Bilateral cochlear implants should be the standard for children with bilateral sensorineural deafness. *Curr Opin Otolaryngol Head Neck Surg*. 2008;16(1):69-74.
- Rotteveel LJ, Snik AF, Cooper H, Mawman DJ, van Olphen AF, Mylanus EA. Speech perception after cochlear implantation in 53 patients with otosclerosis: multicentre results. *Audiol Neurootol*. 2010;15(2):128-36.
- Schafer EC, Amlani AM, Seibold A, Shattuck PL. A meta-analytic comparison of binaural benefits between bilateral cochlear implants and bimodal stimulation. *Journal of the American Academy of Audiology* 2007;18(9):760-76. [Context Link [1](#), [2](#), [3](#)
- Schwartz MS, Otto SR, Shannon RV, et al. Auditory brainstem implants. *Neurotherapeutics*. 2008;5(1):128-136
- Shepherd RK, McCreery DB. Basis of electrical stimulation of the cochlea and the cochlear nucleus. *Adv Otorhinolaryngol*. 2006;64:186-205.
- Tait M, Nikolopoulos TP, De Raeve L, Johnson S, Datta G, Karltorp E, Ostlund E, Johansson U, van Kneysel E, Mylanus EA, Gulpen PM, Beers M, Frijns JH. Bilateral versus unilateral cochlear implantation in young children. *Int J Pediatr Otorhinolaryngol*. 2010 Feb;74(2):206-11.
- Tyler RS, Dunn CC, Witt SA, Noble WG. Speech perception and localization with adults with bilateral sequential cochlear implants. *Ear Hear*. 2007 Apr;28(2 Suppl):86S-90S.
- U.S. Food and Drug Administration (FDA). FDA public health notification: Importance of vaccination in cochlear implant recipients. Rockville, MD: FDA; October 10, 2007. Accessed on July 22, 2011 at: <http://www.fda.gov/cdrh/safety/101007-cochlear.html>. Updated August 2002.
- Waltzman SB. Cochlear implants: current status. *Expert Review of Medical Devices* 2006;3(5):647-55. DOI: 10.1586/17434440.3.5.647.
- Physician Advisors