

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.

*'Ohana Health Plan a plan offered by,
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

HealthEase of Florida, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.



Cochlear Implantation

Guideline Number: HS-039

Original Effective Date: 8/21/2008

Revision Date: 9/3/2009

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline HS-039

Cochlear Implantation

Original Effective Date: 8/21/2008

Revised Date(s): 9/3/2009

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Unilateral or bilateral cochlear implantation in adults aged 18 years and older is considered medically necessary if ALL of the following criteria are met:

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment (as defined by a pure tone average of 70 dB or greater at 500, 1000 and 2000 Hz) with limited benefit from appropriate hearing aids (defined as scores less than 40% correct in the best-aided condition on tape recorded tests of open-set sentence recognition); **AND,**
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation; **AND,**
- Absence of middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; **AND,**
- No contraindications to surgery; **AND,**
- The device must be used in accordance with FDA-approved labeling.

Unilateral or bilateral cochlear implantation in children aged 12 months to 17 years is considered medically necessary if ALL of the following criteria are met:

- Child has profound, bilateral sensorineural hearing loss determined by a pure tone average of 90 dB or greater at 500, 1000, and 2000 Hz; **AND,**
- Child has limited benefit from appropriately fitted binaural hearing aids (Limited benefit is defined as failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale, the Meaningful Auditory Integration Scale or the Early Speech Perception test in children 4 and younger; for children older than 4 years, limited benefit is defined as less than 12% correct on the Phonetically Balanced-Kindergarten Test, or less than 30% correct on the Hearing in Noise Test or Lexical Neighborhood Test); **AND,**
- A 3 to 6 month hearing aid trial has been undertaken by a child without previous experience with hearing aids.

Note: Cochlear implantation may be covered if the member has hearing test scores greater than 40% and less than or equal to 60% only when the provider and the member are participating in either a(n):

- a) FDA-approved category B investigational device exemption clinical trial; **OR**,
- b) A trial under the CMS Clinical Trial Policy; **OR**,
- c) A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

BACKGROUND

In the United States, approximately 28 million persons suffer from hearing loss. Significant hearing loss affects 33% of adults over the age of 60 years, 50% of adults over the age of 75 years, and one in every 1000 newborns. If severe enough, hearing loss occurring before the development of speech skills, or prelingual hearing loss, leads to poor speech perception and speech production, which adversely influences the development of language and social skills. Hearing depends on a series of mechanical and neural processes. Sound waves captured by the outer ear produce vibrations, which the middle ear amplifies and transmits to the cochlea of the inner ear, causing sensitive cochlear hair cells to vibrate. Cochlear hair cell vibration stimulates the auditory nerve, thereby converting sound vibrations into nerve impulses, which travel along the auditory nerve pathway to the auditory cortex of the brain, where they are interpreted as sound. While hearing loss may relate to abnormalities in the sound conduction system of the outer and middle ear, most hearing deficits in newborns and the elderly result from sensorineural abnormalities, particularly cochlear hair cell loss, which limits cochlear ability to convert sound vibrations into nerve impulses, may be caused by a variety of disorders and mechanisms, and cannot be remedied by any known means. This type of hearing loss typically has been treated with rehabilitation strategies involving hearing aids, vibrotactile aids, lip reading, and/or sign language, as well as speech and language therapy. Of these techniques, all assist communication ability, but only hearing aids can improve hearing. This is achieved by amplifying incoming sounds, which amplifies vibrations received by remaining cochlear hair cells. However, amplification does not replace the function of lost cochlear hair cells and often cannot provide adequate hearing in the case of severe cochlear hair cell loss. If neural elements that transmit information from the cochlea to the auditory cortex remain intact and functional, it is possible to stimulate auditory nerve impulses with a prosthetic cochlear implantation (CI) device. With CI, externally worn components, including a microphone, a speech processor, and a transmitter, capture sounds from the environment, transform sounds into electronic impulses, and send electronic impulses to an implanted receiver/stimulator, which conveys electronic impulses to the auditory nerve via electrodes implanted in the cochlea. By electrically stimulating the auditory nerve, CI performs the function normally performed by cochlear hair cells, thereby restoring some degree of hearing.

CI is undertaken only in patients with bilateral sensorineural hearing loss (SNHL) whose hearing loss relates to cochlear hair cell loss and who obtain minimal benefit from conventional hearing aids, which typically is determined by administering speech perception tests while the patient wears appropriately fitted hearing aids, often described as the best-aided condition. On speech perception tests, words or sentences are presented without visual cues and the patient identifies what he or she has heard/perceived by repeating it orally and/or by sign language when using open-set test format or by selecting the appropriate choice from multiple selections or following presented instructions when using closed-set test format. CI devices are programmed on an individual basis, and recipients must undergo training and (re)habilitation to learn to use auditory cues obtained from the device. Typically, patients undergo unilateral CI. However, bilateral CI is also being performed, with two devices implanted at the same time or sequentially (Hayes, 2007).

CODING

Covered CPT®* Codes

69930 Cochlear device implantation, with or without mastoidectomy

Covered ICD-9-CM Procedure Codes

20.96 Implantation or replacement of cochlear prosthetic device, not otherwise specified

20.97 Implantation or replacement of cochlear prosthetic device, single channel

20.98 Implantation or replacement of cochlear prosthetic device, multiple channel

Covered HCPCS Codes

L8614 Cochlear device, includes all internal and external components

Covered ICD-9-CM Diagnosis Codes

389.10 Sensorineural hearing loss, unspecified
389.15 Sensorineural hearing loss, unilateral
389.16 Sensorineural hearing loss, asymmetrical
389.18 Sensorineural hearing loss of combined types, bilateral

***Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©**

REFERENCES

1. Centers for Medicare and Medicaid Services National Coverage Determination. Cochlear Implantation (50.3). July 25, 2005.
2. Hayes Directory. Cochlear Implantation. December 9, 2007.
3. American Academy of Audiology, Cochlear Implants in Children. 2008.
4. American Academy of Otolaryngology-Head and Neck Surgery. Policy Statement. Cochlear Implants. December 27, 2007.
5. National Institutes of Health Consensus Development Program. Cochlear Implants in Adults and Children. Conference Statement, May 1995.