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Medical Policy Manual

Topic: Cochlear Implant

Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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 signal 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.

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.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

Regulatory Status

Note: Full FDA approval includes only Premarket Approval (PMA) and 510k approval. Devices with Investigational Device Exemption (IDE) or Humanitarian Device Exemption (HDE) are not considered fully FDA approved. An example of a cochlear implant that is not fully FDA approved but is approved for use in the clinical trial setting is the Nucleus Hybrid S12 (Cochlear Americas).

Several cochlear implants are commercially available in the United States. The FDA-labeled indications for currently marketed electrode arrays are summarized in the table below. . Over the years, subsequent generations of the various components of the devices have been FDA approved, focusing on improved electrode design and speech-processing capabilities. Furthermore, smaller devices and the accumulating experience in children have resulted in broadening of the selection criteria to include children as young as 12 months.

Manufacturer and FDA approved Cochlear Implants	Indications
Advanced Bionics® • HiResolution Bionic Ear System (HiRes 90K*) • Clarion Multi-Strategy • HiFocus CII Bionic Ear	<u>Adults</u>: • ≥ 18 years of age • Post-lingual onset of severe to profound bilateral sensorineural hearing loss [≥70 decibels (dBs)] • Limited benefit from appropriately fitted hearing aids, defined as scoring ≤ 50% on a test of open-set Hearing in Noise Test (HINT) sentence recognition <u>Children:</u> • 12 months to 17 years of age • Profound bilateral sensorineural deafness (>90dB) • Use of appropriately fitted hearing aids for at least 6 months in children 2 to 17 years of age or at least 3 months in children 12 to 23 months of age. • Lack of benefit in children <4 years of age is defined as a failure to reach developmentally-appropriate auditory milestones (e.g., spontaneous response to name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or < 20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice [70 dB SPL (sound pressure level)] • Lack of hearing aid benefit in children >4 years of age is defined as scoring < 12% on a difficult open-set word recognition test

	(Phonetically Balanced-Kindergarten Test) or < 30% on an open-set sentence test (HINT for Children) administered using recorded materials in the soundfield (70 dB SPL)
Cochlear® • Nucleus® 5* • Nucleus 22, Freedom with Contour	<u>Adults</u>: • ≥ 18 years old • Pre- or post-lingual onset of moderate to profound bilateral sensorineural hearing loss • ≤50% sentence recognition in the ear to be implanted • ≤60% sentence recognition in the opposite ear or binaurally <u>Children 12 months to 24 months:</u> • Profound sensorineural hearing loss bilaterally • Limited benefit from appropriate binaural hearing aids • Lack of progress in the development of auditory skills <u>Children 25 months to 17 years 11 months</u>: • Severe to profound bilateral sensorineural hearing loss • Multi-syllabic Lexical Neighborhood Test (MLNT) scores of ≤30% in best-aided condition in children 25 months to 4 years 11 months • Lexical Neighborhood Test (LNT) scores of ≤30% in best-aided condition in children 5 years to 17 years and 11 months • Lack of progress in the development of auditory skills
Med El® • Maestro (Sonata or Pulsar) • Combi 40+	<u>Adults</u>: • ≥ 18 years old • Severe to profound bilateral sensorineural hearing loss (≥70dB) • ≤40% correct Hearing in Noise test (HINT) sentences with best-sided listening condition <u>Children:</u> • 12 months to 18 years with profound sensorineural hearing loss (≥90dB) • In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills with hearing aids over a 3-6 month period • In older children, lack of aided benefit is defined as <20% correct on the MLNT or LNT depending upon the child's cognitive ability and linguistic skills • A 3-6 month trial with hearing aids is required if not previously experienced

*Note: Cochlear, Ltd. voluntarily recalled the Nucleus CI500 range in September 2011 for device malfunction in the CI512 implant. The external Nucleus 5 sound processor is not a part of the recall. Advanced Bionics HiRes90K was voluntarily recalled in November 2010 and given FDA-approval for re-entry to market the device in September 2011.

While cochlear implants have typically been used mono laterally, in recent years, interest in bilateral cochlear implantation has arisen. 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 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 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 FDA approved for use in the United States. In addition, single processors do not provide binaural benefit and may impair localization and increase the signal to noise ratio received by the cochlear implant.

Notes:

- This policy does not apply to surgically anchored bone conduction hearing aids or externally worn air conduction hearing aids. Cochlear implants are not hearing aids. While hearing aids function by amplifying sound, cochlear implants replace the functions of an absent or nonfunctioning cochlea.
- This policy does not address the use of the Nucleus® 24 Auditory Brain Stem Implant, which is designed to restore hearing in patients with neurofibromatosis who are deaf secondary to removal of bilateral acoustic neuromas.

MEDICAL POLICY CRITERIA

I. Unilateral or bilateral implantation of fully FDA approved cochlear implants (i.e., PMA or 510k only) and associated aural rehabilitation may be considered **medically necessary** when **all** of the following criteria are met:

A. Age 12 months or older

B. Bilateral severe to profound pre- or postlingual (sensorineural) hearing loss, defined as a hearing threshold of pure-tone average of 70 decibels (dB) or greater hearing loss at 500 Hz (hertz), 1000 Hz and 2000 Hz

C. Limited or no benefit from hearing aids unless hearing aids are unreasonable

1. Adults: Scores $\leq$ 50 percent correct on tape recorded sets of open-set sentence recognition in the ear to be implanted

2. Children: Failure to develop basic auditory skills, and in older children, $\leq$ 30 percent correct on open-set tests

Note: Repeat hearing tests or trials of hearing aids are not necessary for patients who have

previously met criteria I.B and I.C as it is unlikely that natural hearing or the benefit from hearing aids will improve significantly over time.

II. Contraindications for cochlear implantation include:

A. Deafness due to lesions of the acoustic nerve (eighth cranial nerve), central auditory pathways, or brain stem in the implanted ear

B. Active or chronic infections of the external or middle ear and mastoid cavity in the implanted ear, including but not limited to otitis media.

C. Tympanic membrane perforation

D. Radiographic evidence of absent cochlear development in the implanted ear

E. Inability or lack of willingness to participate in post-implantation aural rehabilitation.

III. Replacements and Upgrades

A. Implant replacement with a next-generation device may be considered **medically necessary** only in the small subset of patients whose response to existing components is inadequate to the point of interfering with activities of daily living, which would include school and work.

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

SCIENTIFIC EVIDENCE

Background

Cochlear implants (CI) are recognized effective treatment of sensorineural deafness in select patient, as noted in a 1995 National Institutes of Health Consensus Development conference, which offered the following conclusions[1]

- Cochlear implantation has a profound impact on hearing and speech reception in postlingually deafened adults with positive impacts on psychological and social functioning.
- The results are more variable in children. Benefits are not realized immediately but rather are manifested over time, with some children continuing to show improvement over several years.
- Prelingually deafened adults may also benefit, although to a lesser extent than postlingually deafened adults. These individuals achieve minimal improvement in speech recognition skills. However, other basic benefits, such as improved sound awareness, may meet safety needs.
- Training and educational intervention are fundamental for optimal post implant benefit.

- Cochlear implants in children under two years old are complicated by the inability to perform detailed assessment of hearing and functional communication. However, a younger age of implantation may limit the negative consequences of auditory deprivation and may allow more efficient acquisition of speech and language. Some children with post-meningitis hearing loss have been implanted under the age of 2 years due to the risk of new bone formation associated with meningitis, which may preclude a cochlear implant at a later date.

Literature Appraisal

Infants under Age 12 Months

FDA approval of cochlear implants (CI) includes patients over 12 months of age; therefore, implantation in infants who are under the age of 12 months is an off-label use of these devices.

The literature review focused on studies comparing the impact on hearing, speech development and recognition, and complication rates of implantation in infants younger than 12 months with those of older age groups. This includes the question of whether any early benefits that may occur in these very young patients later converge with those in older patients.

Systematic Reviews

Two systematic reviews were identified that addressed CI in children under 12 months of age. The reviews, summarized below, reported few studies of CI in this age group compared with CI in children over one year of age. Both systematic reviews ranked the available studies as poor to fair due to heterogeneity in study participants and study designs, and high risk for potential bias. In addition, differences in outcomes between the age groups did not reach statistical significance. Therefore, it remains unclear whether the benefits of early cochlear implantation outweigh the risk of surgery and anesthesia in these very young patients.

- In 2010, Vlastarakos, et al, conducted a systematic review of studies on bilateral cochlear implants in a total of 125 children implanted before one year of age.[2] The authors noted that follow-up times ranged from a median duration of 6 to 12 months and, while results seemed to indicate accelerated rates of improvement in implanted infants, the evidence available was limited and of lower quality. Additionally, the lack of reliable outcome measures for infants demonstrated the need for further research before cochlear implantation prior to one year of age becomes widespread.
- In 2011 Forli and colleagues reported similar findings in seven studies comparing CI implanted prior to one year of age with implantations performed after one year of age.[3] The studies were heterogeneous for age ranges analyzed and outcomes evaluated. While studies suggested improvements in hearing and communicative outcomes in children receiving implants prior to one year of age, between-group differences did not reach statistical significance. In addition, it is not certain whether any improvements were related to duration of cochlear implant usage rather than age of implantation. Nor is it clear whether any advantages of early implantation are retained over time.

Non-randomized Clinical Trials

Johr et al. highlighted the surgical and anesthesiological considerations when performing cochlear implant surgery in very young infants.[4] This was an observational study and literature review by pediatricians at a tertiary children's hospital in Switzerland. Surgical techniques and anesthesiological aspects of elective surgeries in small infants were analyzed in patients younger than 1 year of age undergoing cochlear implant surgeries. The results demonstrated that the age of the patient and the

pediatric experience of the anesthesiologist, but not the duration of the surgery, are relevant risk factors. The authors concluded, "Further research is needed to provide more conclusive evidence that the performance outcome for children implanted before 12 months of age does not converge with the results of children implanted between 12 and 18 months."

A number of small studies from outside the U.S. have reported results on cochlear implantation in infants younger than 12 months:

- In a study from Australia, Ching and colleagues published an interim report on early language outcomes of children with cochlear implants.[5] This study evaluated 16 children who had implants before 12 months of age compared to 23 who had implants after 12 months (specific time of implantation was not provided). The preliminary results demonstrated that children who received an implant before 12 months of age developed normal language skills at a rate comparable to normal-hearing children, while those with later implants performed at 2 standard deviations below normal. The authors noted that these results are preliminary, as there is a need to examine the effect of multiple factors on language outcomes and the rate of language development.
- Similarly, in a study from Italy, Colletti reported on findings from 13 infants who had implants placed before 12 months.[6] The procedures were performed between 1998 and 2004. In this small study, the rate of receptive language growth for these early implant infants overlapped scores of normal-hearing children. This overlap was not detected for those implanted at 12–23 or 24–36 months.
- Subsequently, Colletti et al. reported on the 10-year results comparing 19 children with cochlear implants received between the ages of 2 to 11 months to 21 children implanted between 12-23 months and 33 children implanted between 24-35 months.[7] Within the first 6 months post-implantation, there was no significant difference among groups in Category of Auditory Performance testing but differences became significantly better in the infant group (early implantation) at the 12 and 36 month testing.

<u>Adults and Children over Age 12 Months</u>

Technology Assessments

- In June 2011 the most recent technology assessment, by the Tufts Evidence-based Practice Center for the Agency for Health Care Research and Quality (AHRQ), reported the following findings on the effectiveness of unilateral and bilateral cochlear implants (CIs) in adults:[8]
  - For unilateral CIs, the assessment examined 22 studies with 30 or more patients and concluded that, while the studies reviewed were rated as poor to fair quality, unilateral cochlear implants are effective in adults with sensorineural hearing loss. Pre- and post-cochlear implant scores on multi-syllable tests and open-set sentence tests demonstrated significant gains in speech perception regardless of whether a contralateral hearing aid was used along with the cochlear implant. Additionally, the assessment found generic and disease-specific health-related quality of life improved with unilateral cochlear implants. However, the available evidence was insufficient to draw conclusions on improvements in open-set sentence test scores (i.e., >40% and ≤50% or >50% and ≤60%), and any relationship between pre-implantation patient characteristics and outcomes [e.g., age, duration of hearing impairment, Hearing in Noise Test (HINT) scores and pre- or post-linguistic deafness.]
  - For bilateral CIs, the technology assessment examined 16 studies published since 2004 which were determined to be of fair to moderate quality. The assessment concluded that bilateral

cochlear implants provided greater benefits in speech perception test scores, especially in noise, when compared with unilateral cochlear implants with or without contralateral hearing aids. Significant binaural head shadow benefits were noted along with some benefit in binaural summation, binaural squelch effects, and sound localization with bilateral cochlear implants. However, it was unclear if these benefits were experienced under quiet conditions, although benefits increased with longer bilateral cochlear implant usage indicating a need for longer term studies. Hearing-specific quality of life could not be assessed because only one study evaluated this outcome. Additionally, although gains were experienced in speech perception using open-set sentences or multi-syllable tests compared with unilateral cochlear implants or unilateral listening conditions, the evidence available on simultaneous bilateral implantation was found to be insufficient. The assessment noted longer term studies are needed to further understand the benefits with bilateral cochlear implantation and identify candidacy criteria given the risks of a second surgery and the destruction of the cochlea preventing future medical intervention.

Systematic Reviews

The following is a summary of the most recent systematic reviews related to CI. These reviews included a critical analysis of the quality of the included studies. While noting the heterogeneity of the studies, and the potential for bias, these reviews found that the studies consistently reported beneficial outcomes for both bilateral and unilateral CI in select children and adults compared with no hearing devices or with conventional hearing aids.

Adults

- In 2013, the authors of the 2011 AHRQ technology assessment reported the following findings of an updated systematic review of studies published through May 2012[9]:

  - Unilateral cochlear implants
    Sixteen (of 42) studies were of unilateral cochlear implants. Most unilateral implant studies showed a statistically significant improvement in mean speech scores as measured by open-set sentence or multi-syllable word tests. A meta-analysis of 4 studies revealed a significant improvement in cochlear-implant relevant quality of life (QOL) after unilateral implantation. However, these studies varied in design and there was considerable heterogeneity observed across studies, making it difficult to compare outcomes across studies.
  - Bilateral cochlear implants
    Thirteen studies reported improvement in communication-related outcomes with bilateral implantation compared with unilateral implantation and additional improvements in sound localization compared with unilateral device use or implantation only. The risk of bias varied from medium to high across studies. Based on results from at least 2 studies, the QOL outcomes varied across tests after bilateral implantation. A meta-analysis was not performed because of heterogeneity in design between the studies.

- Bittencourt et al. published a 2012 systematic review of 11 studies. [10] The strength of evidence was rated 2b in 4 studies and 2c in 7 studies, defined as cohort studies and low quality randomized controlled trials (RCTs), and "outcomes" research, respectively. There were no high-quality RCTs. Based on this evidence, the authors concluded that cochlear implants improved hearing outcomes over conventional hearing aids in patients with severe to profound postlingual

deafness.

- In 2012 and 2013 Crathorne et al. and van Schoonhoven et al., respectively, published updated systematic reviews for the National Institute for Health and Care Excellence (NICE). Included studies were from the U.S. and Europe and compared bilateral with unilateral cochlear implants. In two studies the unilateral implant group also had an acoustic hearing aid for the contralateral ear. Neither systematic review was able to conduct a meta-analysis due to the heterogeneity of the studies and the level of evidence of the studies which was rated as moderate-to-poor.

- In October 2011, Berrettini and colleagues published results of a systematic review of unilateral and bilateral cochlear implant effectiveness in adults.[11]

    - Unilateral cochlear implants
      Eight articles on unilateral cochlear implants in advanced age patients were included. All of the studies reported benefits with cochlear implantation despite advanced age at time of implant (age 70 years or older). In six studies, results were not significantly different between younger and older patients. However, two studies reported statistically significant inferior perceptive results (e.g., hearing in noise test and consonant nucleus consonant test) in older patients. This systematic review also examined three studies totaling 56 adults with pre-lingual deafness who received unilateral cochlear implants. The authors concluded unilateral cochlear implants provided hearing and quality-of-life benefits in prelingually deaf patients, but results were variable.
    - Bilateral cochlear implants
      Thirteen articles on bilateral cochlear implants were reviewed. Sound localization improved with bilateral cochlear implants compared with monaural hearing in six studies. Significant improvements in hearing in noise and in quiet environments with bilateral implants compared with unilateral implants were reported in ten studies and seven studies, respectively. Five of the studies reviewed addressed simultaneous implantation, five studies reviewed sequential implantation, and three studies included a mix of simultaneous and sequential implantation. However, no studies compared simultaneous to sequential bilateral implantation results, and no conclusions could be made on the timing of bilateral cochlear implantation.

Children

- The 2011 Forli et al systematic review noted above also addressed the effect of bilateral versus unilateral cochlear implants on verbal perception in children. Bilateral CI improved verbal perception in noise, and sound localization compared with unilateral implants in 19 of 20 studies reviewed. [3] However, none of the studies compared learning development and language in bilateral versus unilateral cochlear implant recipients. Simultaneous versus sequential bilateral cochlear implantation results were not examined in any of the studies reviewed. Seven studies were reviewed that examined cochlear implant outcomes in children with associated disabilities. In this population, cochlear implant outcomes were inferior and occurred more slowly but were considered to be beneficial.
- In a 2011 systematic review of 38 studies, Black and colleagues sought to identify prognostic factors for cochlear implantation in pediatric patients.[12] A quantitative meta-analysis was not able to be performed due to study heterogeneity. However, four prognostic factors: age at implantation, inner ear malformations, meningitis, and Connexin 26 (a genetic cause of hearing loss), consistently influenced hearing outcomes.

- Pakdaman et al. conducted a systematic review of cochlear implants in children with cochleovestibular anomalies in 2011.[13] Anomalies included inner ear dysplasia such as large vestibular aqueduct and anomalous facial nerve anatomy. Twenty-two studies were reviewed totaling 311 patients. The authors found implantation surgery was more difficult and speech perception was lower in patients with severe inner ear dysplasia. However, heterogeneity in the studies limited interpretation of these findings.
- In another 2011 systematic review, Roush and colleagues examined the audiologic management of children with auditory neuropathy spectrum disorder.[14] The review included 15 studies that addressed cochlear implantation in these patients. All of the studies reported auditory benefit with cochlear implantation in children with auditory neuropathy spectrum disorder. However, the studies were noted to be limited methodologically and further research is needed in this population.

Adults and Children

- Smulders et al examined the timing of cochlear implantation in a systematic review of 11 studies; 5 studies addressed postlingually deafened adults and 7 studies addressed prelingually deafened children (discussed below).[15] One study on adults showed a delay in the timing of the second implantation resulted in poorer outcomes in quiet environments. Nevertheless, all studies reported benefits with bilateral implants, but all studies were considered to be of poor quality and with a high risk of bias.

Non-randomized Clinical Trials

Numerous case reports have been published on patients with bilateral cochlear implants.[16-26] Most but not all patients reported slight to modest improvements in sound localization and speech intelligibility with bilateral cochlear implants especially with noisy backgrounds but not necessarily in quiet environments.

When reported, the combined use of binaural stimulation improved hearing in the range of 1–4 decibels or 1%–2%. While this improvement seems slight, any improvement in hearing can be considered beneficial in the deaf. However, this improvement may not outweigh the significant risks of a second implantation. In addition, similar binaural results can be achieved with a contralateral hearing aid, assuming the contralateral ear has speech recognition ability. A number of studies have reported benefits for patients with a unilateral cochlear implant with hearing aid (HA) in the opposite ear.

Adults

- Ricketts and colleagues reported on 16 similar adults with post-lingual bilateral hearing loss.[24] They found a small but significant advantage for bilateral implants for speech recognition in noise. While a training effect was noted over time for a subset of patients followed up to 17 months, a consistent bilateral advantage was noted.
- Ramenden and colleagues reported on 30 adults in England who had bilateral cochlear implants and received their second implant a mean of three years after the first.[25] At nine months a significant (12.6%, p=less than 0.001) binaural advantage was seen for speech and noise from the front. They were not able to predict when the second ear would be the better performer. Sequential implantation with long delays between ears resulted in poor second ear performance for some of their subjects.

- Ching reported on twenty-one adults who used unilateral cochlear implants and hearing aid in the opposite ear.[18] Measures included speech recognition, sound localization, and functional performance. Binaural benefits were seen for at least one measure for their patients

Children

- Sharma and colleagues reported that central auditory pathways are maximally plastic for a period of about 3.5 years.[16] Stimulation delivered within this period resulted in auditory evoked potentials that reached normal values in three to six months. However, when stimulation occurred after seven years, changes occurred within one month, but then had little to no subsequent change.
- Sharma and Dorman also reported on auditory development in 23 children with unilateral or bilateral implants.[17] In one child who received a bilateral device with later (after age seven) implantation of the second ear, the auditory responses in the second device were similar to that seen in "late-implanted" children.
- Kuhn-Inacker reported that bilateral implants improved the children's communicative behavior, especially in complex listening situations.[26]
- Holt concluded that children who used cochlear implant and hearing aid benefited from combining the acoustic input, particularly in background noise.[20]
- Litovsky reported that nine of 13 (70%) children with bilateral cochlear implants discriminated source separations of equal to or less than 20 degrees and seven out of nine performed better when using bilateral (versus unilateral) devices.[21]

Adults and Children

- Ching and colleagues subsequently reported on 29 children and 21 adults with unilateral cochlear implant and a contralateral hearing aid.[19] They noted that both children and adults localized sound better with bilateral inputs.

Other Considerations

Unilateral Hearing Loss with or without Tinnitus

The use of cochlear implants in patients with unilateral hearing loss is an off-label use of these devices. As noted in the 2011 AHRQ technology assessment, a number of narrative literature reviews[27-29] and small ($n \leq 30$) observational studies[30,31] conducted primarily in adult patients have been published. However, these studies have included small numbers of patients ($n \leq 30$) and had risk of reporting bias. For example, Arndt and colleagues, for example, published a pilot study in 2010 of 11 adult patients with unilateral hearing loss of various causes. [30] The aim was to evaluate the use of unilateral electrical stimulation with normal hearing on the contralateral side and after a period of 6 months compared with the preoperative unaided situation, conventional contralateral routing of signal or bone-anchored hearing aid hearing aids. Ten patients also suffered from tinnitus. Two tests were used to assess speech comprehension, localization was assessed using an array of multiple speakers, and QOL was evaluated using 3 questionnaires. The study results were presented as p-values without adjustment for multiple testing. The authors reported that cochlear implantation improved hearing abilities in these study patients and was superior to the above alternative treatment options. The use of the cochlear implant did not interfere with speech understanding in the normal-hearing ear.

The application of cochlear implants for tinnitus relief in patients with unilateral deafness has also been described in previous studies. For example, van de Heyning and colleagues published a study in 2008 of 21 patients with unilateral hearing loss accompanied by severe tinnitus for at least 2 years who underwent cochlear implants at a university center in Belgium. [31] The majority of patients demonstrated a significant reduction in tinnitus loudness based on a visual analogue scale (2 years after implantation, 2.5 +/- 1.9; before implantation, 8.5 +/- 1.3). Three patients showed complete tinnitus relief.

Cochlear Restoration

While there is current research investigating the ability to restore hearing by stimulating cochlear hair cell regrowth, cochlear implantation damages the cochlea and eliminates the possibility of cochlear restoration. However, the potential to restore cochlear function is not foreseeable in the near future; therefore, if implantation of cochlear implants is felt to be most beneficial at a younger age when the nervous system is "plastic", this potential development seems too far in the future to benefit young children who are current candidates for a cochlear implant.

Practice Guidelines and Position Statements

American Academy of Otolaryngology- Head and Neck Surgery Foundation (AAO-HNS)

A 2007 position statement from the AAO-HNS considers cochlear implantation an appropriate treatment for adults and children with severe to profound hearing loss; bilateral cochlear implantation is accepted medical practice in selected adults and children.[32]

In 2006, the AAO-HNS released the following criteria for cochlear implants for adults and pediatric patients:[33]

Adult Criteria

1. 18 years or older, with bilateral, severe to profound sensorineural hearing loss, i.e., 70dB or greater PTA (pure-tone air-conduction average) at 500, 1000, and 2000 Hz;
2. Have tried but have limited benefit from adequately fitted binaural hearing aid; or
3. Have sentence recognition score of 50 percent or less in the ear to be implanted and 60 percent or less in the contralateral ear in best aided conditions using Hearing in Noise Test (HINT) or City University of New York (CUNY) tests.

Pediatric Criteria

1. 12 months to 17 years of age.
2. Infants age 12-24 months should have bilateral, profound hearing loss with thresholds of 90dB or greater at 1000 Hz.
3. Children 24 months to 17 years should have bilateral severe to profound (greater than 70dB) hearing loss.
4. Infants and older children should demonstrate lack of progress in simple auditory skills in conjunction with appropriate auditory amplification and participation in intensive aural habilitation for three to six months. Less than 0.14520 percent correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive and linguistic abilities.

5. A three-to six-month trial of appropriate hearing aids is required. If meningitis is the cause of hearing loss or if there is radiologic evidence of cochlear ossification a shorter hearing aid trial and earlier implantation may be reasonable."

Summary

Cochlear implants have been recognized as effective treatment of *bilateral* severe to profound sensorineural hearing loss in patients aged 12 months or older. Numerous published studies and systematic reviews have reported consistent improvement in health outcomes with bilateral devices, specifically, speech reception (especially in noise) and sound localization. Therefore, cochlear implants may be considered medically necessary in specific patients with bilateral hearing loss who meet the policy criteria. Cochlear implants are considered not medically necessary when the medical necessity criteria are not met, including but not limited to unilateral hearing loss.
There are currently no cochlear implants that have approval from the U.S. Food and Drug Administration (FDA) for use in patients who are younger than 12 months of age. The published evidence for cochlear implantation in patients younger than 12 months of age is currently limited to lower quality studies that do not permit conclusions on whether the benefits of early cochlear implantation outweigh the risk of surgery and anesthesia in these very young patients. In addition, there are no clinical practice guidelines from U.S. professional societies that recommend cochlear implantation in these very young patients. Therefore, cochlear implantation in patients younger than 12 months of age is considered not medically necessary.

Replacement of an existing cochlear implant with a next-generation device may be considered medically necessary only in those patients whose response to the existing device is inadequate to the point of interfering with activities of daily living, including school or work.

An upgrade of a functioning external system to improve appearance is considered not medically necessary. Examples include components with a smaller profile, or to switch from a body-worn external sound processor to a behind-the-ear model.

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CROSS REFERENCES

Implantable Bone Conduction and Bone-Anchored Hearing Aids, Surgery, Policy No. 121

CODES	NUMBER	DESCRIPTION
CPT	69930	Cochlear device implantation, with or without mastoidectomy

CODES	NUMBER	DESCRIPTION
	92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
	92602	;subsequent reprogramming
	92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
	92604	;subsequent reprogramming
	92630	Auditory rehabilitation; pre-lingual hearing loss
	92633	Auditory rehabilitation; post-lingual hearing loss
HCPCS	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
	L8621	Zinc air battery for use with cochlear implant device, replacement, each
	L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
	L8623	Lithium ion battery for use with cochlear implant device speech processor
	L8624	Lithium ion battery for use with cochlear implant device speech processor, ear
	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