



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Cochlear and Auditory
Brainstem Implants**

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INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA covers unilateral or bilateral cochlear implants as medically necessary for individuals with bilateral sensorineural hearing loss when there is reasonable expectation that a significant benefit will be achieved from the device and when the following age-specific criteria are met:

- For an adult (age 18 or older) with **BOTH** of the following:
 - bilateral, severe-to-profound sensorineural hearing loss determined by a pure-tone average of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz
 - limited or no benefit from appropriately fitted hearing aids
- For a child (age 12 months to 17 years, 11 months) with **BOTH** of the following:
 - profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz
 - limited or no benefit from a three-month trial of appropriately fitted binaural hearing aids

CIGNA covers an upgrade to an existing cochlear implant system already in place (e.g., upgrading processor from body-worn to behind-the-ear, upgrading from single- to multi-channel electrodes) as medically necessary when EITHER of the following criteria is met:

- The currently used component is no longer functional, and the component cannot be repaired.

- The currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living.

CIGNA covers an auditory brainstem implant (ABI) as medically necessary when ALL of the following criteria are met:

- The individual is 12 years of age or older
- Diagnosis of neurofibromatosis type 2
- The individual is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the individual will become completely deaf as a result of the surgery, or the individual had bilateral auditory nerve tumors removed and is now bilaterally deaf

CIGNA does not cover the replacement of cochlear implant external components with upgraded components when done solely to improve appearance or to treat psychological symptomatology or complaints because it is considered not medically necessary.

CIGNA does not cover the use of cochlear implants for the treatment of tinnitus in individuals who do not also have profound or severe sensorineural deafness/hearing loss warranting the need for cochlear implantation because such use is considered experimental, investigational or unproven.

Note: For adults and children, a post-cochlear or auditory brainstem implant rehabilitation program (aural rehabilitation) is medically necessary to achieve benefit from the devices. The rehabilitation program usually consists of six to ten sessions. Coverage is subject to plan benefits and limitations (Please refer to the Aural Rehabilitation Coverage Policy).

General Background

Hearing impairment is the consequence of sensorineural and/or conductive malfunctions of the ear. Hearing loss may be congenital or secondary to trauma or disease. Complete or partial hearing impairment may begin prior to speech and language acquisition (i.e., prelingually) or after the acquisition of speech and language (i.e., postlingually). Sensorineural hearing loss occurs when the sensory receptors of the inner ear are dysfunctional and involves the lack of sound perception due to a defect in the cochlea, the auditory division of the vestibulocochlear nerve, or both. Many patients with sensorineural hearing loss can be habilitated or rehabilitated with the use of hearing aids. Patients with profound bilateral sensorineural hearing loss (i.e., greater than 70°–90 decibels [dB]) who derive no benefit from conventional hearing aids may be appropriate candidates for cochlear implantation.

Cochlear Implants

The cochlear implant (CI) is an electronic prosthesis that stimulates cells of the auditory spiral ganglion to provide a sense of sound to persons with hearing impairment. The patient selection criteria for cochlear implants described in the Coverage Policy section above were adapted from the cochlear implant indications set forth by the U.S. Food and Drug Administration (FDA).

In addition to the above, the FDA criteria elaborates to define "limited benefit" for adults as "test scores of 40% or less correct in best-aided listening condition on open-set sentence recognition Hearing in Noise Test sentences" (FDA, 2001).

For children, limited benefit from appropriately fitted binaural hearing aids is defined based upon age as follows:

- For children age five and younger, "limited benefit" is defined as lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three- to six-month period.
- For children over age five, "limited benefit" is defined as less than 20% correct on open-set sentence discrimination on the Multi-Syllabic Lexical Neighborhood Test or Lexical Neighborhood Test, depending on the child's cognitive ability and linguistic skills (FDA, 2001).

Adults and children who are a candidate for CI should have a preoperative evaluation by an audiologist and otolaryngologist with experience in cochlear implantation to determine that there is a reasonable expectation that the patient will receive a significant benefit from the device and that there are no medical or surgical contraindications (e.g., acute or chronic middle ear pathology, terminal disease). The patient and/or family should be willing and motivated to participate in a post-cochlear rehabilitation program. The patient should have no psychological or cognitive deficiencies that would prohibit rehabilitation (American Academy of Audiology, 2009; National Library of Medicine, 2007; Centers for Medicare and Medicaid, 2005; FDA, 2001).

Proponents of cochlear device implantation in children age less than 12 months suggest that earlier cochlear implantation allows the child to maximize this critical period of neural development, enhancing receptive and expressive language skills, speech perception, speech intelligibility, and language outcomes. It is reported that children who receive implants at an earlier age out perform those who are implanted later in life. Concerns that have been raised with implantation of cochlear devices in children less than age 12 months include: the presence of an underdeveloped mastoid tip, thin skull, thin skin, anesthetic risks (e.g., respiratory complications, aspiration, bradycardia, cardiac arrest) and lack of audiological certainty in diagnosing profound hearing loss at this age (Valencia, et al., 2008; Dettman, et al., 2007; Luxford, et al., 2004; James and Papsin, 2004). Johr et al. (2008) stated "maturation of the central pathways within the first few months of life may unexpectedly improve the patient's hearing performance" and stressed the importance of repeated testing. One of the challenges of studies evaluating cochlear implantation in children less than age one year is the lack of available, effective tools for measuring speech perception abilities (Ertmer, et al., 2007). There is also a concern regarding the reliability of audiometric results for this age group. There are no objective means for determining the degree of hearing loss and predicting if the child age less than one year will benefit more from CI compared to traditional amplification (Johr, et al., 2008; Valencia, et al., 2008; Papsin and Gordon, 2007; Luxford, et al., 2004).

Holt and Svirsky (2008) noted that behavioral audiometric testing, the gold standard for measuring hearing sensitivity, is performed in infants using visual reinforcement audiometry and is not appropriate for infants less than age 5.5 months because they do not respond to sound with directed head turns. Because of developmental delays, this age may even be as late as eight months. If this is the case, objective measures of auditory function by audiologists is the alternative. Evoked otoacoustic emissions testing, auditory brainstem response testing (ABR), and auditory steady-state response testing are utilized to assess various elements of the auditory system. The authors stated that "there are no perfect measures for evaluating auditory status in infants" and the lack of sensitivity and specificity of each of these measures may result in inaccurate assessments of hearing capabilities and mislabeling of the degree of hearing loss in the child.

Audiological Tests and Guidelines for Cochlear Implant Candidates: Standard pure-tone and speech audiometry tests are used to screen likely CI candidates. For children, the speech reception threshold and/or pure-tone average should equal or exceed 90 dB. For adults, the speech reception threshold and/or pure-tone average should equal or exceed 70 dB. If the patient can detect speech with best-fit hearing aids in place, a speech-recognition test in a sound field of 55 dB hearing level sound pressure level is performed.

In adults, limited benefit from amplification is defined as scores of $\leq 40\%$ correct in the ear to be implanted on tape-recorded tests of open-set sentence recognition (e.g., Hearing in Noise Test sentences). This definition is based on the FDA labeling of current devices. The actual value may vary, depending on specific FDA labeling. In older children, limited benefit from amplification is defined as $< 20\%$ correct on the Multi-Syllabic Lexical Neighborhood Test or Lexical Neighborhood Test, depending on the child's cognitive ability and linguistic skills. In younger children, it is generally defined as failure to develop basic auditory skills.

Upgrades of Existing Device Components: In general, upgrading existing external or internal components that are functional is considered not medically necessary. Patients may seek component upgrades to make the device more aesthetically pleasing (e.g., replacing body-worn processors with behind-the-ear processors) or when they desire newer component models (e.g., upgrading from single- to multi-channel electrodes), even though a device is functioning adequately. External component replacement with the same or upgraded model is generally considered medically necessary only when the existing component is no longer functional or when it renders the implant recipient unable to perform his/her age-appropriate activities of daily living adequately or safely and cannot be repaired.

Tinnitus: Some patients who have received cochlear implants for profound hearing loss who also have accompanying tinnitus have reported incidental tinnitus relief following implantation. There is insufficient

evidence in the published peer-reviewed literature to support the use of cochlear implants as a treatment for patients with tinnitus who do not also have a profound or severe sensorineural deafness/hearing loss warranting the need for cochlear implantation. (For additional information on the treatment of tinnitus, please refer to the CIGNA Coverage Policy: Tinnitus Instruments, Devices and Retraining Therapy.)

Aural Rehabilitation: Aural rehabilitation following device implantation is considered an integral part of the overall management of cochlear implant in both adults and children. An aural rehabilitation program for implant programming usually consists of six to ten sessions for both adults and children. Auditory and speech therapy may be considered rehabilitative therapy, and are typically independent of the aural rehabilitation. (Please refer to the Aural Rehabilitation Coverage Policy for detailed information regarding aural rehabilitation following cochlear device implantation.)

U.S. Food and Drug Administration (FDA): FDA premarket approved speech processors and implant devices include the Nucleus[®] 22 and 24 Channel Systems (Cochlear Americas, Englewood, CO); CLARION[®] Implants (Advanced Bionics Corp., Sylmar, CO); and the MED-EL COMBI 40+ Cochlear Implant System (Durham, NC). Approval of these systems was based upon unilateral placement of the device. While the FDA approval language does not specifically address unilateral or bilateral use, no evidence for the safety and efficacy of bilateral cochlear implants was presented to the FDA during the approval process for cochlear implant devices currently on the market.

On October 17, 2002, a Public Health Web Notification (updated July 31, 2003) was issued by the FDA alerting providers “that children with cochlear implants are at a greater risk of developing bacterial meningitis caused by *Streptococcus pneumoniae* than children in the general population.” The FDA also issued a 2006 notification to healthcare providers which included updated information on the risk of bacterial meningitis in children with cochlear implants with positioners. To decrease the risk of meningitis, the FDA recommended the following: a) adherence to the CDC vaccination guidelines; b) early recognition of the signs of meningitis; c) prompt diagnosis and treatment of middle ear infections; and d) consideration of the use of prophylactic antibiotics perioperatively (FDA, 2006; Biernath, et al., 2006).

In addition to the increased risk of meningitis and the risks associated with general anesthesia, and surgical intervention to the middle or inner ear, other risks that may be associated with implantation of a cochlear device include: loss of any residual hearing in the implanted ear; injury to the facial nerve; leakage of perilymph fluid (i.e., fluid in the cochlea canal); infection of the wound; blood or fluid collection at the surgical site; episodes of dizziness or vertigo; tinnitus; taste disturbances; numbness around the ear; and localized inflammation and granuloma. In the case of failure of the internal device, the implant would have to be surgically removed. There are also concerns regarding changes in technology. External technological upgrades may not be compatible with the internal part (FDA, 2004; FDA, 2001).

Literature Review—Unilateral Implantation: No single test can predict which patients will achieve success with cochlear implantation. Evidence supporting the efficacy of cochlear implants in sensorineural deafness exists primarily in the form of data from a number of uncontrolled prospective and retrospective case series, comparative case series, and matched-pair case series.

Adults (i.e., age 18 years and older) and Children (i.e., age 1–18 years): Unilateral cochlear implantation is a well-established treatment option for adults (i.e., age 18 years and older) and children (i.e., age 1–18 years) with sensorineural hearing loss. Case series and retrospective reviews reporting up to ten-years of data demonstrated improved outcomes following unilateral implantation (Uziel, et al., 2007; Arnoldner, et al., 2005; Beadle, et al., 2005).

Children (i.e., age less than one year): James and Papsin (2004) retrospectively reviewed the medical records of 25 infants (group 1) who had received unilateral cochlear implantation (i.e., Nucleus 24) between the ages of 6–12 months. Review of records included computed tomography scan (CT) comparisons of mastoid bone anatomy to children who had received cochlear implant at ages 13 months to 3.5 years (group 2; n=25). The ages of Group 1 at the time of the CT scan ranged from 2.7–12 months compared to 13–42 months in group 2. The differences in mastoid bone size between the two age groups were not statistically significant (mean 153 mm² vs. 166 mm²). In group 1, three subjects had virtually no pneumatization at 12 months. Overall the proportion of pneumatization, which allows safe identification of surgical landmarks, was equal to marrow content in group 1. Pneumatization increased to approximately 60% by age 2 years, leaving very little marrow

($p < 0.001$). With a maximum follow-up of 42 months, no surgical or anesthetic complications were reported. Mean duration of surgery was 169 minutes for group 1 compared to 179 minutes for group 2. One child, who had a history of meningitis, required a double array CI.

Lesinski-Schiedat et al. (2004) conducted a retrospective study to compare the outcomes of profound bilaterally deaf children who received unilateral CI (i.e., Nucleus, Clarion) at ages 0.4–12 months (mean 0.8 years) (group 1) ($n=27$) and ages 1–2 years (mean 1.6 years) (group 2) ($n=89$). Outcomes measures included recognition of speech rhythm, consonant and vowel understanding, Response to noise three months postoperatively was observed in 75% of group 1 and 69% in group 2. Group 1 response improved to 97% ($n=6$) at 18 months. Fifty-nine percent ($n=20$) of group 1 and 48% of group 2 ($n=56$) were able to identify different noises after three months which increased to 91% ($n=8$) in group 1 and 87% ($n=44$) in group 2 at the 24-month follow-up. Parental response to the Meaningful Use of Speech Scale questionnaire for group 1 reported 58% of the children performed vocalization well at three months compared to 51% in group 2. At 12 months following CI, group 1 was performing at the same level as group 2 at 24 months. At three months, spoken language was utilized more by group 2 (14.3%) than group 1 (4.2%). Following implantation group 2 demonstrated stronger oral competence up until month 18. In open-set testing, group 2 had better Test of Auditory Perception of Speech scores and monosyllable test scores at 12 months, then group 1 who then exceeded group 2 at 18 and 24 months. After 24 months, group 1 scored 50% in the Glendonald Auditory Screening test compared to 30% by group 2 and 66% on the Common Phrases test compared to 53% by group 2. The 0.4 year-old child required intensive care due to severe lack of blood volume. Limitations of the study include the retrospective study design, small patient population, subjective parental responses for Meaningful Use of Speech Scale scores, and number of patients lost to follow-up.

Schauwers et al. (2004) conducted a prospective study to analyze the onset of prelexical babbling and audiologic outcome in 10 congenitally deaf children who received a unilateral Nucleus 24 multichannel cochlear implant. Five children received implants between ages 5.5–10 months and five between ages 1.1–1.7 months. Ten normal hearing children, ages six to 11 months, functioned as the control group. Beginning the first month following activation of the implant, monthly video recordings were obtained, and 20 minutes of each video were analyzed. The two youngest implant children (ages 8–10 months) were considered within normal hearing range (ages 6–8 months) at age of onset of babbling with two additional early implant children babbling at 11 months of age. The median onset of babbling was one month following activation of the implant. Compared to the normal hearing children (ages 8.5–10.5 months), the youngest CI child fell within the normal range for babbling spurts ($p < 0.05$). Of the children implanted prior to 12 months of age, four reached normal Categories of Auditory Performance scores three months following activation of the CI compared to zero to 12 months for children implanted after 12 months of age. Prior to implantation none of the children discriminated a single speech contrast. At six and 12 months following CI, almost all phoneme pairs were discriminated by the children.

Colletti et al. (2005) reported on 10 children, ages 4–11 months, who were fitted with a cochlear implant for deafness. Auditory performance was measured based upon the Categories of Auditory Performance (CAP). Speech performance was measured by babbling (i.e., presence of multiple articulatory movements in one breath with continuous or interrupted phonation), onset of babbling (i.e., the first appearance of at least two babbled utterances in the same observation session) and babbling spurts (i.e., marked increase in frequency of babbled utterances). All children had zero CAP scores prior to implantation. At the 12-month follow-up, five infants had a 4–5 CAP score. At the 24-month follow-up, CAP scores were 6–7 for the three children left in the study. CAP scores were better in the study group compared to other ages ($p=0.4$) in different cohorts. In children age less than one year, the CAP median score of 7 compared to a CAP median score of 3.5 for children who received CI at ages 12–23 months was statistically significant ($p=0.01$). The three youngest implant infants, ages 5–6 months, started babbling two months after cochlear implant activation compared to children implanted at 10–11 months who had onset of babbling at 1–3 months post-implant. The difference between the study group and normal-hearing control group as it relates to babbling onset and babbling spurts was not statistically significant. No complications due to implantation surgery or related to CI activation or long-term use were reported. Recognizing the limitations of this study (i.e., small population and short follow-up), the authors stated that the increase in auditory and linguistic skills encouraged very early implantation to facilitate the developmental processes during this critical period of initial language acquisition. Long-term studies are needed, but preliminary findings are encouraging.

Miyamoto et al. (2005) compared the outcomes of unilateral cochlear implantation using Med-EL, Nucleus 24 and Clarion devices, in eight children (group 1) under age one year (range 6.38–10.85 months) to a group of 17

infants (group 2) age one year or older (range 12.39–23.24 months). The authors developed assessment tools to quantify outcomes of group 1. Following implantation testing was divided into three intervals. Interval 1 was evaluated at one day, one week, and one month following implantation; interval 2 was assessed at two months, three months, and six months; and interval 3 was tested at nine months, 12 months and 18 months. At least one testing session within at least two interval groups was completed by all infants. Approximately 20% of the testing sessions could not be completed due to crying, fussiness, or equipment malfunction. For visual habituation (VH), five group 1 infants completed at least one test in interval 2 and in interval 3, and the same was true for intervals 2 and 3 for the preferential looking paradigm (PLP) testing. VH analysis revealed longer looking times to the novel trial compared to the old trial for group 1 ($p=0.02$), as well as group 2 ($p=0.03$) suggesting that the infants could discriminate between a continuous and a discontinuous sound. No other statistically significant differences were noted in the VH outcomes. PLP testing yielded significantly longer looking times to the target, representing a video-sound association, versus the nontarget in group 1 ($p=0.04$), but not in group 2 ($p=0.7$). Infants in group 1 were able to learn association between speech sound and objects, while group 2 did not exhibit this ability. The authors also noted that the age of implantation affected the mothers' speech styles, and infants implanted at an earlier age would be exposed to more closely matched normal maternal speech. No surgical or anesthetic complications were reported. Limitations of the study include the small patient population, self developed assessment tools for group 1, the number of testing sessions that could not be completed, and all infants did not complete each testing interval.

Waltzman and Roland 2005 conducted a prospective study of 18 children who underwent unilateral cochlear implantation using Nucleus C124RCS, 124RCA, or C124K. Subjects, implantation age range 6-11 months, had severe to profound sensorineural hearing loss. The mean preoperative Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) was 0.7 (1.75%). At six months postoperative ($n=18$), the IT-MAIS score was 30.4 (76%). Of the nine subjects available for the one year follow-up, the mean IT-MAIS score was 34.8% (87%) at one year compared to a score of 30.6 (76.5%) at the six-month follow-up. These results were higher compared to another study. The authors speculated that the use of hearing aids prior to CI may have been the reason. Speech perception scores ($n=4$) at the last evaluation included: Multi-Syllabic Lexical Neighborhood Test word score range 83–100% and Multi-Syllabic Lexical Neighborhood Test phoneme score range 95–100%; Lexical Neighborhood Test word score range 84–97% and Lexical Neighborhood Test phoneme score range 93–98%. Common phrases scores ranged from 60%–100%. One year postoperatively, one patient developed a breakdown on the antenna edge and eventually underwent reimplantation.

Dettman et al. (2007) conducted a review of 106 infants, who received a unilateral multichannel Cochlear Ltd. implant for profound bilateral sensorineural hearing loss. The children were divided into group 1 (age range 0.61–1.07 months; $n=19$), and group 2 (age range 1.13–2.00 years; $n=87$), and a comparison was made between the receptive and expressive language growth of the two groups. Activation of the cochlear implant occurred two to three weeks following surgery. Follow-ups ranged from one to three years. There was a significant difference between the average rate of language comprehension growth scores for group 1 (1.12) ($n=11$), compared to group 2 (0.71) ($p<0.001$), as well as a significant difference in the language expression rate of growth over time in group 1 (1.01) compared to group 2 (0.68) ($p<0.002$). Complications included one case of mastoiditis and three explantations in group 2.

Tait et al. (Oct 2007) conducted a two-center prospective study comparing 10 normal-hearing children, age range 8–11 months to 10 profoundly deaf children who received unilateral cochlear implantation at ages 8–11 months. Analyses were made from two-minute samples of environmental recordings obtained prior to implantation, and at six and 12 months following implantation. Vocal turn-taking, vocal autonomy, and non-looking vocal turns were used to measure the development of vocal communication and auditory processing. The mean preoperative vocal turns for the study group was 13.5 compared to 35.5 for the hearing group ($p=0.01$). There were no significant differences in vocal turn scores six months postoperatively (37.5 vs. 57.5, respectively) between the two groups, but one year postoperatively the study group score was 59.5 compared to 84.5 for the control group ($p=0.003$). There was no significant difference in the mean gestural turns or mean gestural autonomy between the two groups preoperatively or at six months. However, at one year the study group had a mean gestural turn of 27.5 compared to 12.0 for the control group ($p=0.01$) and a mean gestural autonomy of 15.5 vs. 2.5 ($p=0.01$). There were no significant differences between the two groups in mean and median vocal autonomy or non-looking vocal turns at six and 12 months following implantation. The results indicated that prior to implantation deaf children most often communicated silently. Following implantation, the deaf children communicated more vocally than silently. The authors noted that a limitation of the study was the small patient population. A second limitation of the study is the short-term follow-up.

Holt and Svirsky (2008) conducted a review of 96 children who were a subgroup of children who received cochlear implantation for profound bilateral sensorineural hearing loss. The goals of the study were to determine if significant gains were made by CI at age less than 12 months compared to later ages and to determine if “there is behavioral evidence for sensitive periods in spoken language development.” The subjects were subdivided into four groups. Group 1 (n=6) underwent CI between ages six and 12 months, group 2 (n=32) between ages 13 and 24 months, group 3 (n=37) between ages 25 and 36 months, and group 4 (n=21) between ages 37 and 48 months. Children were tested preoperatively and every six months following activation of CI for up to 2.5 years. Various restraints prevented all children from being tested at each interval. The Average Developmental Difference values (i.e., word recognition, receptive language, expressive language) between groups 1 and 2 were not significantly different, but they were significantly different between groups 1 and 3, groups 2 and 3, and groups 3 and 4. The significant mean Average Developmental Difference values varied between 15 to 18 percentage points indicating that children who received CI at earlier ages scored higher than children who received CI at older ages. Comparisons within each group of the Average Developmental Difference values for receptive language were significant ($p<0.05$). Word recognition results and expressive language performance were not significantly different between groups 1 and 2, but were significantly different between groups 1 and 3, groups 2 and 3, and groups 3 and 4 ($p<0.05$ for each). Group 1 demonstrated no significant difference in two of three outcomes (i.e., word recognition and expressive language) compared to group 2, but did demonstrate scores significantly higher than groups 3 and 4 ($p<0.05$ for each). No significant gains in expressive language development and spoken word recognition were accomplished by implantation prior to age 2 years. There was an advantage for receptive language development for group 1 compared to group 2 ($p=0.034$) and group 3 ($p=0.023$). Limitations of the study include the small patient population and short-term follow-up.

Valencia et al. (2008) conducted a retrospective review to evaluate the risks of cochlear implantation in children (n=15), ages 6.67–11.6 months, with severe and profound hearing loss. Follow-ups ranged from two months to five years. After observations with the use of hearing aids, it was concluded that the infants would benefit from CI. There were no anesthetic complications. Due to multiple anatomic malformations, electrode insertion in one child was difficult and accompanied by a continued leakage of spinal fluid around the electrode and the development of otorrhea. Late complications included two device failures and one infection requiring removal of the CI and re-implantation. One device failure was due to new bone growth that broke the CI wire. At the 1–3 month follow-ups, the post-stimulation range of pure tone average was a mean 27dB compared to 25dB at the 5–8 months follow-up. These results are borderline normal to mild hearing loss. The results of a parental survey of the functional benefit of the CI ranged from 33%–100%.

In a retrospective review, Migirov et al. (2008) compared the complication rate of CI in infants to CI in older children. Group 1 included 15 infants, ages 10–12 months. Group 2 included 57 children, ages one to two years. Med-EI, Nucleus and Clarion devices were implanted. In Group 1, there was one device failure, one perforated eardrum, and one wound infection. In Group 2 there were six device failures, four seromas, three cases of disequilibrium, two perforated eardrums, and one each foreign body reaction, allergic reaction to silicone, protruded positioner, flap breakdown, hematoma, magnet displacement and mastoiditis. There were no statistically significant differences in major (requiring explantation or revision surgery) and minor complications between the two groups. Major complications occurred in 6.7% infants vs. 17.5% toddlers ($p=0.297$), and minor complications occurred in 13.3% infants and 21.1% toddlers ($p=0.502$).

Literature Review—Bilateral Implantation: Bilateral cochlear implantation has been proposed for use by patients who meet the criteria for unilateral cochlear implant to enhance hearing capability in areas not achieved by unilateral CI. Some studies suggested that the use of bilateral cochlear implants can improve speech perception in quiet and noisy environments, as well as the listener’s ability to discriminate from which side the sound is coming (i.e., sound direction), identify source position (i.e., localization) and differentiate different talkers (i.e., squelch effect). They may also benefit from the summation effect that arises from input from both ears (Brown and Blakany, 2007; Murphy and O’Donoghue, 2007; Neuman, et al., 2007; Scherf, et al., 2007; Connell and Balkany, 2006; Litovksy, et al., 2006; Das and Buchman, 2005; Tyler, et al., 2003; Wilson, et al., 2003).

Adults (i.e., age 18 years and older) and Children (i.e., age 1–18 years): Meta-analysis, randomized controlled trials, case series and retrospective reviews support the safety and efficacy of bilateral cochlear implantation in adults (i.e., age 18 years and older) and children (i.e., age 1–18 years) (Tyler, et al., 2002; Kuhn-

Inacker, et al., 2004; Laszig, et al., 2004; Litovsky, et al., 2004; Schleich, et al., 2004; Nopp, et al., 2004; Ramsden, et al., 2005; Schoen, et al., 2005; Verschuur, et al., 2005; Ricketts, et al., 2006; Litovsky, et al., 2006; Quentin Summerfield, et al., 2006; Schafer and Thibodeau, 2006; Neuman, et al., 2007; Schafer and Thibodeau, 2006; Schafer, et al., 2007).

Children (i.e., age less than one year): Manrique et al. (2004) conducted a prospective study of 130 children who received bilateral CI for profound congenital bilateral sensorineural hearing impairment. Group 1 included 36 children, age range 0–1 year (mean 0.94 months). Ten children had not used hearing aids prior to implantation. Group 2 included 94 children age range 2–6 years (mean 3.3 years). Prior to implantation hearing aids had not been used by 11 of the group 2 children. With the exception of one child who received a Med-El Combi 40+, all children received a Nucleus device. Follow-up occurred for up to five years. In comparison to preoperative values, a statistically significant difference in mean pure-tone average thresholds was seen in each group ($p < 0.05$) postoperatively. During the five-year follow-up, group 1 experienced an improvement in closed-set tests (i.e., vowels, series of daily words) and open-set logaudiometric tests. Following implantation, mean vowel testing results were significantly better at years one and three, and series of daily words testing at years 2 and 4. A significant difference was noted with Central Institute for the Deaf (CID) sentences ($p < 0.05$). Group 2 also experienced a significant improvement in the closed-set tests ($p < 0.001$), as well as in the open-set logaudiometric tests during the five years of follow-up. Following implantation, group 1 demonstrated a slightly lower pure-tone average than group 2 with significantly lower differences in group 1 at years two and three following implantation ($p < 0.05$). Group 1 demonstrated significant results in the vowel identification test the first and third years following implantation ($p < 0.05$). Group 1 performed better in the closed-set tests and CID test, being statistically significant in years three and five postoperatively ($p < 0.05$). Group 1 experienced a relatively normal development of language compared to group 2 who demonstrated a two-year lag. During the five-year follow-up period, no complications were experienced by Group 1 compared to four complications (i.e., ulceration of cutaneous flap [$n=1$], device failures requiring reimplantation [$n=3$]) in group 2. Limitations of the study include the small patient population and lack of a control group.

Litovsky et al. (2006) conducted a study to evaluate sound localization acuity of children who received sequential bilateral cochlear (BI) implants, and to investigate the usefulness of a hearing aid in children with unilateral implant (HA). The BI group included 13 children, age range 3–16 years, and the HA group included six children, age range 4–14 years. Hearing tests were conducted in a hearing booth using spondaic words at random stimulus levels, ranging from 56–64 dB sound pressure level. A listening game was used to measure the child's ability to discriminate sounds from each ear. Seventy percent of the BI children were able to discriminate left from right ear sources, and 77% of these children performed better with BI than with unilateral implant alone. Minimal audible angle thresholds were better with unilateral implant than with BI. "Robust improvement" was seen in two BI children over the course of two years. Average group performance was better in the BI group than in the HA group, and was worse in the HA group when a hearing aid was added. The authors concluded that many BI children performed better on localization acuity and were better than children with one implant using a hearing aid. However, they stated that the results must be "interpreted with caution" because the long-term benefits of BI are not fully understood. Larger studies with additional measure need to be conducted.

Technology Assessments: A 2007 New Zealand Health Technology Assessment evaluated the effectiveness of CI at an early age compared to at a later age. The assessment evaluated studies that included some children less than age two years at time of implantation, a mean or median implantation age less than 36 months, and a sample size of at least 20 children. Three cross sectional studies and 13 cohort studies with small heterogeneous sample sizes ($n=26-216$) including degree and etiology of hearing loss with a lack of detail on socio-economic and educational status of parents were included in the analysis. Outcomes included "audiological performance, communication outcomes, educational achievement and quality of life". The following conclusions were made:

- "In general, implantation at a younger age improves the effectiveness of cochlear implantation in terms of audiological performance and communication outcomes.
- This is particularly evident when cochlear implantation occurs before the age of 24 months, which is more effective than implantation after 24 months.
- It is not clear whether implantation prior to the age of 12 months improves effectiveness when compared to implantation after 12 months of age.

- Because of the short length of time that implantation has been used in large numbers of infants and young children less than 2 years of age, evidence of an increase in effectiveness is only available for immediate outcomes such as communication skills, and has only been observed up to about 5–8 years after implantation
- It is not clear what effect cochlear implantation at a younger age has on long-term outcomes such as educational achievement, and quality of life.
- It is possible that those implanted at an older age (above 24 months) develop at a slower rate but eventually reach equivalent developmental milestones.” (Ali and O’Connell, 2007).

A technology report published by the American Speech-Language-Hearing Association (2004) states that bilateral implant study outcomes “are encouraging but inconclusive due to the limited number of participants and the scope of the projects. There is a clear need for further exploration of the many variables that can affect the performance of people with binaural implants before widespread use is warranted.”

Professional Societies/Organizations: The American Academy of Audiology “ (2009) recognizes multichannel cochlear implants as sensory aid options for children with profound hearing impairments who demonstrate limited or no functional benefit from conventional hearing aid amplification. Multichannel cochlear implants are appropriate for children with prelingual or postlingual deafness.” They go on to state that the parents or legal guardians have the right to select the type of implant that they believe is best for their child.

The American Academy of Otolaryngology—Head and Neck Surgery (2007) “considers cochlear implantation an appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can perform significantly better with two cochlear implants than one, bilateral cochlear implantation is accepted medical practice”.

In a 2007 position paper, the American Academy of Pediatrics states that cochlear implantation should be given careful consideration for children who seems to receive limited benefit from a hearing aid and that additional studies are needed on the efficacy of cochlear implants in children less than age 2 years. They also note that children with cochlear implants may be at a higher risk of acquiring bacterial meningitis than the normal population.

The National Institute on Deafness and Other Communication Disorders (2007) states that cochlear implants can be beneficial for children and for adults who have lost all or most of their hearing in later life. When coupled with intensive postimplantation therapy, children may acquire speech, language, developmental and social skills that they would not develop without the implant.

Auditory Brainstem Implantation (ABI)

The auditory brainstem implant (ABI) is a modified cochlear implant in which the electrode array is placed directly into the brain. ABI is approved for use in patients suffering from neurofibromatosis type 2 (NF2) who have developed tumors on both auditory nerves. NF2 is a genetic condition that is characterized by the growth of bilateral acoustic neuromas on the right and left auditory nerves. When it becomes necessary to remove these benign tumors surgically, portions of the auditory nerves must be removed along with the tumors. A cochlear implant cannot be used by a patient whose auditory nerve has been damaged by surgical removal of an acoustic neuroma. Postoperatively, ABI patients require follow-up rehabilitation, which is generally initiated two months post-implant (American Speech-Language-Hearing Association, 2004; Colletti and Shannon, 2005).

U.S. Food and Drug Administration (FDA): Brainstem implants are granted a premarket approval by the FDA for use in patients with NF2 who have lost integrity of auditory nerves following vestibular schwannoma removal. The FDA approved the Nucleus 24 Auditory Brainstem Implant system (Cochlear Corp., Englewood, CO) for use in teenagers and adults who have been diagnosed with NF2. According to the labeling, implantation may occur during the first- or second-side tumor removal, or in patients with previously removed bilateral acoustic tumors.

Literature Review: Although there are a limited number of scientific peer-reviewed studies evaluating ABI for this rare disease, ABI is an established treatment option for this population (Kanowitz, et al., 2004; Otto, et al., 2004).

Other Indications: It has been proposed that ABI may be a treatment option for children with cochlear and cochlear nerve abnormalities and cognitive defects who are not candidates for CI or have failed CI. Colletti et al. (2005) conducted a study in which ABIs were used on patients who had other cochlear or cochlear nerve abnormalities (e.g., congenital malformation, aplasia, head trauma, cochlear ossification, and auditory neuropathy). The study also included subjects who had a lack of hearing improvement with the use of cochlear implants. The trial was conducted over a five-year period and included adults (n=20) and children (n=9), ranging in age from 14 months to 70 years. Depending on the date of the procedure, subjects received either the Nucleus 22 or Nucleus 24 implant. Subjects treated with ABI had NF2, vestibular schwannoma, cochlear nerve aplasia, auditory neuropathy, head trauma or cochlear ossification. The control group (n=21) was comprised of subjects with NF2 who received a Nucleus 21 channel and was treated during a different timeframe. The one-year, closed-set word recognition average results were 55.3% and 44.3% for the study group and the control group, respectively. The one-year auditory-alone mode for sentence recognition test result averages were 38% and 6.2% for the study group and the control group, respectively. In addition, at one year, the nontumor study group subjects scored from 3 to 42 words/minute (normal is 70–80 words/minute) on the speech tracking test. Results of the speech tracking test for the control group were not available. Even though the study represents small numbers and has limitations of study design, they suggest that the indications for ABI should be extended to include severe cochlear and cochlear nerve malfunctions and malformations, as well as situations in which cochlear implants have failed.

Colletti and Zocante (2008) conducted a prospective study of 17 children, ages 14 months to 16 years, with cochlear nerve aplasia (two had NF2) who received ABIs. Six children had previously failed CI. Follow-up ranged from six months to seven years. At the last follow-up, the average Categories of Auditory Performance score was four (range 1–7, with zero being unawareness of sound). The average Meaningful Auditory Integration Scale score was 38% (range 2% to 97.5%), the Meaningful Use of Speech Scale was 49% (range 5%–100%), and the Listening Progress Profile was 45% (range 5%–100%). In the first six to 12 months following implantation, the nine children who could participate in the cognitive developmental testing showed statistically significant improvements in form completion and repeated pattern ($p < 0.05$ each) when compared to four deaf non-ABI children who served as controls.

The National Institute for Clinical Excellence (NICE) (United Kingdom) issued an interventional procedure guidance supporting the evidence on the safety and efficacy of ABI to treat total, bilateral deafness caused by vestibulocochlear nerve damage as a result of surgery or tumors (NICE, 2005).

Professional Societies/Organizations: The American Speech-Language-Hearing Association states that an ABI is indicated in individuals whose auditory nerve has been damaged during acoustic tumor removal and cannot benefit from the use of a cochlear implant. Substantial improvement in the quality of life can be obtained in patients with ABI (ASHA, 2004).

Summary

Evidence in the peer-reviewed scientific literature supports the use of unilateral or bilateral cochlear implantation for a carefully selected subset of individuals age 12 months or older.

Evidence in the scientific peer-reviewed literature supports the use of ABI in neurofibromatosis type 2 in individuals age 12 years or older. The evidence does not support the use of ABI for deafness from any other conditions.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	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 under 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years of older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years of older; subsequent reprogramming
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS Codes	Description
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, replacement
S2235	Implantation of auditory brain stem implant

ICD-9-CM Diagnosis Codes	Description
237.72	Neurofibromatosis, Type 2 (acoustic neurofibromatosis)
389.18	Sensorineural hearing loss, bilateral

*Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	0190	Cochlear and Auditory Brainstem Implants
Great-West Healthcare	4/23/2007	99.205.06	Cochlear Implant

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