



CIGNA MEDICAL COVERAGE POLICY

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

**Subject Cochlear and Auditory
Brainstem Implants**

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Coverage Policy

COCHLEAR IMPLANT

CIGNA covers a unilateral or bilateral cochlear implant as medically necessary for an individual 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 years 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 a second cochlear implant in the contralateral (opposite) ear as medically necessary in an individual with an existing unilateral cochlear implant when the hearing aid in the contralateral ear produces limited or no benefit.

CIGNA covers the replacement of an existing cochlear implant as medically necessary when EITHER of the following criteria is met:

- currently used component is no longer functional and cannot be repaired
- currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living

CIGNA does not cover upgrading of a cochlear implant system or component (e.g., upgrading processor from body-worn to behind-the-ear, upgrading from single- to multi-channel electrodes) of an existing, properly functioning cochlear implant because it is considered not medically necessary.

CIGNA does not cover a cochlear implant for the treatment of tinnitus in an individual who does 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.

AUDITORY BRAINSTEM IMPLANT

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

- diagnosis of neurofibromatosis type 2
- age 12 years or older
- 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 individual had bilateral auditory nerve tumors removed and is now bilaterally deaf.

Note: For an adult or child, a post-cochlear or auditory brainstem implant rehabilitation program (aural rehabilitation) is medically necessary to achieve benefit from the device. Coverage is subject to plan benefits and limitations (Refer to the Aural Rehabilitation Coverage Policy).

General Background

Hearing impairment is the consequence of sensorineural and/or conductive malfunctions of the ear and may be congenital or secondary to trauma or disease (e.g., autoimmune disorders, auditory neuropathy, meningitis, otosclerosis). 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 there is a 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 little or 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 individuals with hearing impairment. Depending on the etiology and severity of the condition, a CI may be worn unilaterally, or may be worn unilaterally with a hearing aid in the contralateral (opposite) ear, or when a hearing aid in the contralateral ear produces limited or no benefit, a bilateral CI may be indicated. Typically, if a contralateral hearing aid used with a CI produces beneficial hearing, a bilateral CI is not indicated.

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). The FDA criteria also elaborate 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 on 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, 2011; 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 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. If the replacement of an existing component is medically necessary and the patient has bilateral implants, replacement of the contralateral (opposite) implant is not medically necessary unless the contralateral implant is also malfunctioning or 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 cochlear implantation as 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, refer to the Tinnitus Treatment Services and Devices Coverage Policy.)

Aural Rehabilitation: Aural rehabilitation following device implantation is considered an integral part of the overall management of cochlear implant in both adults and children. Auditory and speech therapy may be considered rehabilitative therapy, and are typically independent of the aural rehabilitation. (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 on 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.

In 2002, a Public Health Web Notification 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).

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, 2009; FDA, 2001).

Literature Review—Unilateral Implantation: No single test can predict which patients will achieve success with cochlear implantation. Evidence supporting the efficacy of unilateral 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 (Niparko, et al., 2010; Uziel, et al., 2007; Arnoldner, et al., 2005; Beadle, et al., 2005).

Children (i.e., age less than one year): There insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of CI in children age less than one year. Studies are primarily in the form of case series and retrospective reviews with small patient populations of various age groups, and short-term follow-ups. The studies are also limited by author-developed assessment tools, subjective parental responses on questionnaires, number of infants unable to complete testing, and the number of infants lost to follow-up.

Vlastarakos et al. (2010a) conducted a systematic review and meta-analysis to evaluate cochlear implantation in infants less than age one year. Fifty-one publications met inclusion criteria and 125 children receiving cochlear implant prior to age one year were identified. Follow-up ranged from 6–12 months with 17 children followed for at least two years. No randomized controlled trials were found and only ten children receiving implants before the first year of life were compared to children implanted between the first and second year of life. “Reliable outcomes” were available on 42 infants (i.e., open- and/or closed-set testing [n=15], developmental rating scales [n=14], prelexical speech discrimination tools [n=13]). A meta-analysis of the 42 infants revealed that only four infants had shown statistically better performance. The authors concluded that “robust and reliable outcome measures of monitoring implanted infants are lacking” and “evidence that supports infant implantation, with regard to speech perception and production outcomes, is still limited and of lower quality.”

Roland et al. (2009) conducted a retrospective review on 50 children, age less than one year, who underwent either a Nucleus or Advanced Bionics cochlear implantation. Age at implant ranged from 5–11 months (mean 9.9). Upon diagnosis, all infants wore hearing aids. Three patients had simultaneous bilateral implants. There were no perioperative anesthetic complications. Minor complications (10%) included hematoma, cellulites, and skin flap erythema (n=1 each) and two wound problems. Major complications (6%) included cerebral spinal fluid leak, device failure, and infection/exposed implant (n=1 each). Forty-two patients were available for postoperative speech perception testing. Various testing tools were used including Multisyllable Lexical Neighborhood Test (MLNT), Phonetically Balanced Kindergarten Test (PBK), Lexical Neighborhood Test (LNT), and the Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS). Eighteen patients scored a mean 93% on LNT/PBK, and similar scores were seen on five MLNT patients. Eight patients had postoperative GASP scores of 57% and IT-MAIS scores of 32 (out of a possible 40). Prospective long-term monitoring of outcomes is needed to validate the outcomes of this study.

Retrospective reviews have evaluated the risks and complication rates of CI. Migirov et al. (2008) compared the complication rate of unilateral CI in infants to CI in older children with a minimal follow-up of 12 months. Group 1 included 15 infants, ages 10–12 months. Group 2 included 57 children, ages one to two years. There were no statistically significant differences in major (requiring explantation or revision surgery) ($p=0.297$) or minor complications ($p=0.502$) between the two groups. 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. There were no anesthetic complications. One child developed a leakage of spinal fluid around the electrode otorrhea. Late complications included two device failures and one infection requiring removal of the CI and re-implantation. 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 were borderline normal to mild hearing loss.

Holt and Svirsky (2008) conducted a case series of 96 children who were a subgroup of children who received cochlear implantation for profound bilateral sensorineural hearing loss to determine if significant gains were made by CI at age less than 12 months. 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. The Average Developmental Difference values 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 ($p = 0.023$).

Dettman et al. (2007) conducted a retrospective 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. 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 ($n = 11$), compared to group 2 ($p < 0.001$), as well as a significant difference in the language expression rate of growth over time in group 1 compared to group 2 ($p < 0.002$). 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. There were no significant differences in vocal turn scores six months postoperatively between the two groups, but one year postoperatively the study group score was 59.5 compared to 84.5 for the control group ($p = 0.003$). 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. Following implantation, the deaf children communicated more vocally than silently.

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). 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. 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 were reported.

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. Approximately 20% of the testing sessions could not be completed due to crying, fussiness, or equipment malfunction. Video 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. Preferential Looking Paradigm (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. No surgical or anesthetic complications were reported.

Waltzman and Roland 2005 conducted a prospective study of 18 children who underwent unilateral Nucleus cochlear implantation. 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 out of a possible 40 (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. 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.

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. 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. 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). 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. 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 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.

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. 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.

Literature Review—Bilateral Implantation: To enhance hearing capability in areas not achieved by unilateral CI, bilateral cochlear implantation has been proposed. Some studies reported that a subsequent cochlear implantation typically improved hearing when a unilateral cochlear implant had been worn with a hearing aid in the contralateral ear and the hearing aid provided little or no benefit. The outcomes suggested that the use of bilateral cochlear implants, implanted sequentially or simultaneously, 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; Schafer, et al., 2007; Scherf, et al., 2007; Connell and Balkany, 2006; Litovksy, et al., 2006; Das and Buchman, 2005; Tyler, 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; Buss, et al., 2008; Tait, et al., 2010; Dunn et al., 2010).

Children (i.e., age less than one year): Evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of bilateral CI in children age less than 12 months. 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.

Technology Assessments: The National Institute for Health and Clinical Excellence (NICE) (United Kingdom) (2009) technology appraisal on cochlear implants recommended unilateral cochlear implantation for individuals with “severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.” Simultaneous bilateral implantation is indicated for individuals with “severe to profound deafness who do not receive adequate benefit from acoustic hearing aids” and “adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.” NICE also noted that some children and adults may be considered for a simultaneous implant when they meet the criteria for implantation and the second implant would provide sufficient benefit.

A National Institute for Health Research Technology Assessment (Bond, et al., 2009) included 33 randomized and nonrandomized studies ($n = 848$) that met inclusion criteria for the evaluation of the clinical and cost effectiveness of CI for children and adults. All studies reported gains on all outcomes. Greater gains in outcomes were seen with unilateral cochlear implants compared to acoustic hearing aids. The strongest advantage for bilateral implants compared to unilateral implants was the ability to understand speech in noisy conditions. Studies with small sample sizes ($n = 10–30$) compared bilateral implants to unilateral CI plus an acoustic hearing aid and reported improvement in the ability to detect the direction of sound and speech perception with bilateral implants. Overall, the studies were of moderate to poor quality, and a total of 62 different outcome measures were used. The authors concluded that unilateral and bilateral cochlear implants were safe and effective for children and adults.

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: In a policy statement, 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 Joint Committee on Infant Hearing stated that cochlear implantation should be given careful consideration for children who seems to receive limited benefit from a hearing aid. Additional studies are needed on the efficacy of cochlear implants in children less than age 2 years. The Committee also noted that children with cochlear implants may be at a higher risk of acquiring bacterial meningitis than the normal population.

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 following implantation (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 (FDA, 2000).

Literature Review: Although there are a limited number of published scientific peer-reviewed studies primarily in the form of retrospective reviews, ABI is an established treatment option for this patient population (Grayeli, et al., 2008; Kanowitz, et al., 2004; Otto, et al., 2004).

Other Indications: It has been proposed that ABI may be a treatment option for patients with non-tumor conditions including cochlear and cochlear nerve abnormalities and for patients who have failed CI. Studies have primarily been in the form of case series and retrospective reviews with small patient populations. Colletti et al. (2009) retrospectively compared the outcomes of ABI in NF2 tumor patients (n=32) to outcomes in non-tumor (NT) patients (n=49) by reviewing open-set sentence recognition scores. The NT group included patients with cochlear malformations, auditory neuropathy, bilaterally altered cochlear patency, bilateral cochlear ossification, cochlear derangement of the turns, and cochlear fracture from head trauma. The duration of deafness ranged from 3.2–8.5 years. Sentence recognition was significantly better (p=0.0007) in the NT group (10–100%) compared to the tumor group (5–31%). The NT group was subdivided into four subgroups: trauma, neuropathy, cochlear malformations, and altered cochlear patency. With the exception of the neuropathy

subgroup, the subgroups showed significantly better performance following ABI compared to the tumor group ($p < 0.01$).

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. Comparative studies with larger patient populations are indicated to validate the results of this trial.

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.

Professional Societies/Organizations: The National Institute for Clinical Excellence (NICE) (2005) issued an interventional procedure guidance supporting the evidence on the safety and efficacy of ABI for the treatment of bilateral deafness caused by vestibulocochlear nerve damage as a result of surgery or tumors.

The American Speech-Language-Hearing Association (2004) stated 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.

Summary

Professional societies and evidence in the peer-reviewed scientific literature support unilateral or bilateral cochlear implantation for a carefully selected subset of individuals age 12 months or older. The safety and efficacy of unilateral and bilateral cochlear implantation in children less than age 12 months has not been established.

Auditory brainstem implant (ABI) is an established treatment modality for individuals age 12 years or older with neurofibromatosis type 2. The evidence does not support ABI for deafness from any other conditions.

Coding/Billing Information

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

Cochlear Implant

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 younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour

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 and controller, integrated system, replacement
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement

ICD-9-CM Diagnosis Codes	Description
389.18	Sensorineural hearing loss, bilateral
389.22	Mixed conductive and sensorineural hearing loss, bilateral

Experimental/Investigational/Unproven/Not Covered in the absence of profound or severe sensorineural deafness/hearing loss warranting the need for cochlear implantation:

ICD-9-CM Diagnosis Codes	Description
388.30- 388.32	Tinnitus

Auditory Brainstem Implant

Covered when medically necessary:

CPT^{®*} Codes	Description
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour

HCPCS Codes	Description
S2235	Implantation of auditory brain stem implant

ICD-9-CM Diagnosis Codes	Description
237.72	Neurofibromatosis, Type 2 (acoustic neurofibromatosis)

***Current Procedural Terminology (CPT[®]) © 2010 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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