

MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|-------------------------|--|
| Medical Policy Title | Cochlear Implants and Auditory Brainstem Implants |
| Policy Number | 7.01.26 |
| Category | Technology Assessment |
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| Current Effective Date | 05/19/22 |
| Archived Date | N/A |
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| Product Disclaimer | <ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. • If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. |

This policy addresses cochlear implants and auditory brainstem implants only. Bone conduction, semi-implantable, and fully implantable hearing aids (e.g., Branemark Bone-Anchored Hearing Aid or BAHA System, Esteem Implanted Hearing System, Vibrant Soundbridge System, and RetroX Hearing System) and the associated surgery are alternatives to conventional acoustic hearing aids and are not addressed in this policy.

POLICY STATEMENT

Cochlear Implant

- I. Based upon our criteria and assessment of the peer-reviewed literature, unilateral and bilateral* cochlear implants have been medically proven to be effective and, therefore, are considered **medically appropriate** as a prosthetic for hearing loss when approved by the U.S. Food and Drug Administration (FDA) for the patient's age, and the patient meets **BOTH** of the following criteria:
 - A. Severe to profound bilateral sensorineural hearing loss (defined as a hearing threshold of 70 decibels or above) that cannot benefit from hearing aids; and
 - B. Cognitive ability to use auditory clues and a willingness to undergo an extended program of auditory rehabilitation.

*Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit (e.g., in those patients with hearing loss of a magnitude where a hearing aid will not produce the required amplification).
- II. Contraindications: Based upon our criteria and assessment of the peer-reviewed literature, cochlear implants are contraindicated for the following conditions and, therefore, are considered **not medically necessary** for the treatment of:
 - A. deafness due to lesions of the acoustic nerve or central auditory pathway;

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- B. otitis media or other active, aural disease processes; or
- C. complete cochlear aplasia.

III. Based upon our criteria and assessment of the peer-reviewed literature, cochlear implantation with a hybrid cochlear implant/hearing aid device, in which the hearing aid is integrated into the external sound processor of the cochlear implant (e.g., Nucleus Hybrid L24 Cochlear Implant System) is considered **investigational**.

Auditory Brainstem Implants

IV. Based upon our criteria and assessment of the peer-reviewed literature, FDA-approved auditory brainstem implants have been medically proven to be effective and, therefore, are considered **medically appropriate** for individuals 12 years of age or older with neurofibromatosis type II who are rendered deaf due to bilateral resection or treatment of neurofibromas of the auditory nerve.

Repair and Replacement

- V. Repair and/or replacement of a medically necessary cochlear implant, auditory brainstem implant and/or external components not under warranty will be considered **medically appropriate** when the following criteria are met:
- A. Physician documentation to include:
 - 1. Date of device implantation; and
 - 2. Manufacturer warranty information; and
 - 3. Attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; AND
 - B. Repair of the currently used device when it is no longer functioning adequately, inadequate function interferes with activities of daily living, and repair is expected to make the equipment fully functional (as defined by manufacturer); OR
 - C. Replacement of the currently used device when it is no longer functioning adequately and has been determined to be non-repairable: OR
 - D. Replacement of the currently used device when there is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.
- VI. The replacement of properly functioning cochlear implants, auditory brainstem implants, and/or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

Refer to Corporate Medical Policy # 1.01.18 External Prosthetic Devices.

Refer to Corporate Medical Policy # 7.01.77 Implantable Bone Conduction Hearing Aids.

Refer to Corporate Medical Policy # 11.01.03 Experimental and Investigational Services.

POLICY GUIDELINES

- I. Cochlear implants and auditory brainstem implants are prosthetic devices. Coverage for prosthetic devices is contract-dependent.

DESCRIPTION

Profound deafness in childhood affects the development of auditory speech perception, speech production, and language skills. Failure to develop adequate oral communication skills can have a significant negative impact on these individuals.

A cochlear implant is intended to restore a level of auditory sensation to individuals with severe to profound sensorineural hearing loss by electrical stimulation of the acoustic nerve. The basic system consists of:

- I. A microphone, which picks up sound from the environment;
- II. An external signal/speech processor, which selects and arranges sounds picked up by the microphone;

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- III. An external transmitter and an internal receiver, implanted in the temporal bone, which receives signals from the speech processor and converts them into electrical impulses; and
- IV. An electrode array implanted in the cochlea, which collects the impulses from the stimulator and sends them to the brain. Electrical stimulation of the cochlea by the electrode enables many profoundly deaf people to experience the sensation of sound.

A cochlear implant does not restore or create normal hearing, but can give deaf persons a useful auditory understanding of the environment and help them understand speech. For profoundly postlingual deaf adults who cannot significantly benefit from a hearing aid, the cochlear implant provides awareness of environmental sounds and facilitates lip reading.

Cochlear implant devices are available in single- and multi-channel models. However, current therapy warrants a multi-channel device if one is implanted. (The multi-channel devices appear to facilitate some speech discrimination without lip-reading.) Some examples of cochlear implants that have been approved by the FDA and are currently marketed include the Advanced Bionics HiResolution Bionic Ear System (HiRes 90k), the Cochlear Nucleus 5, and the Med El Maestro (Sonata or Pulsar).

Bilateral cochlear implants have been proposed for use in patients who meet the criteria for unilateral cochlear implant, when it has been determined that a unilateral cochlear implant plus a hearing aid in the contralateral ear will not result in a binaural benefit (e.g., patients with hearing loss of such magnitude that a hearing aid will not produce the required amplification). The proposed benefits of bilateral cochlear implants are to improve understanding of speech in noise, localization of sounds, and speech intelligibility. Bilateral implantation may be performed independently with separate implants and speech processors in each ear, or with a single processor. However, no single processor for bilateral implantation has been approved by the FDA. Bilateral cochlear implantation may be done sequentially or simultaneously.

On March 20, 2014, the FDA approved a hybrid cochlear implant, the Nucleus Hybrid L24 cochlear implant. The implant is intended for patients aged 18 years and older who have severe or profound sensorineural hearing loss of high-frequency sounds in both ears, but who can still hear low-frequency sounds with or without a hearing aid. The device combines the function of a cochlear implant and a conventional hearing aid.

A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program consists of six to 10 sessions that last approximately two and a half hours each. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

Auditory brainstem implants are devices designed to restore some hearing in patients with neurofibromatosis type II who are rendered deaf by bilateral removal of the characteristic neurofibromas involving the auditory nerve. The device consists of an externally worn speech processor that provides auditory information to an electrical signal, which is transferred to a receiver/stimulator that is implanted in the temporal bone. The receiver stimulator is attached to an electrode array that is implanted on the surface of the cochlear nerve in the brainstem, thus bypassing the inner ear and auditory nerve. The electrode stimulates multiple sites on the cochlear nucleus, which is then processed normally by the brain. The Nucleus 24 Auditory Brainstem Implant System (Cochlear Corporation) is the only device that has received approval by the FDA for auditory brainstem implantation. The device is indicated for individuals 12 years of age and older who have been diagnosed with neurofibromatosis type II.

RATIONALE

Pre- and post-implantation testing demonstrate that in appropriately selected individuals with severe to profound sensorineural hearing loss, an FDA-approved cochlear implant, along with auditory rehabilitation therapy, can restore a level of auditory sensation to individuals.

In 2017, Sladen *et al.* retrospectively reviewed prospectively collected data of short-term (six-month) follow-up for 23 adults and children with single-sided deafness from a variety of mechanisms who received a cochlear implant. In the implanted ear, consonant-nucleus-consonant (CNC) word recognition improved significantly from preimplantation to three months postactivation ($p=0.001$). However, for AzBio sentence understanding in noise (+5 dB signal-to-noise), there

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was no significant improvement from preimplantation to six months postactivation. (Level of Evidence 4, Case series; case control study (diagnostic studies); poor reference standard; analyses with no sensitivity analyses.)

In 2016, Sladen *et al.*, in a prospective repeated-measures cohort study that included 20 subjects with single-sided deafness implanted with cochlear implants (15 of whom had reached six-month follow-up), reported on speech recognition and quality of life. Pure-tone audiometry improved with air conduction in the implanted ear. CNC scores in quiet improved from 4.8% in the preoperative period to 42.3% at the six-month postactivation check in patients who reached that follow-up. (Level of Evidence 4, Case series; case control study (diagnostic studies); poor reference standard; analyses with no sensitivity analyses.)

Also in 2016, Rahne *et al.* reported on a retrospective review of four children and 17 adults with single-sided deafness treated with cochlear implants and followed for 12 months. Sound localization with aided hearing improved from preimplantation for all individuals. The speech recognition threshold in noise (signal-to-noise) ratio improved from -1.95 dB (CI off, SD=2.7 dB) to -4.0 dB after 3 months (SD=1.3 dB; $p<0.05$), with continued improvements through six months.

In 2002, the FDA issued an alert stating that children with cochlear implants were at greater risk of developing bacterial meningitis caused by streptococcus pneumoniae than children in the general population. Their investigation showed that cochlear implants with electrode positioners were associated with greater risk of developing meningitis than implants without positioners. The only model with a positioner was withdrawn from the market in July 2002. In 2006, an alert was issued discussing results of a two-year follow-up of the children identified in the earlier investigation. To decrease the risk of meningitis, the FDA recommends: adherence to the CDC vaccination guidelines, early recognition of the signs of meningitis, prompt diagnosis and treatment of middle ear infections, and consideration of the use of prophylactic antibiotics perioperatively. In October 2007, the FDA issued a Public Health Notification: Importance of Vaccination in Cochlear Implant Recipients, and Advice for Patients with Cochlear Implants: New Information on Meningitis Risk. Both reminded of the increased, life-threatening risk of bacterial meningitis in cochlear implant recipients, especially those with a positioner, and the importance of full vaccination of those recipients, as two patients had recently died from infection, and neither one was fully vaccinated.

On March 17, 2020, the FDA expanded the approval for the Nucleus 24 Cochlear Implant System (Cochlear Americas) to include patient populations aged nine to 12 months (previously approved for use in patients aged 12 months and older) who have profound sensorineural hearing loss (SNHL) in both ears. The decision was based on data collected from prospectively-designed, retrospective, clinical analysis, and data reported in the literature, which demonstrated the safety, and the associated risks, of cochlear implantation in pediatric patients between nine and 12 months of age were comparable to patients aged 12 months and older. Published case reports and cohort studies (Karlton et al., 2020) support the efficacy of the cochlear implant in children under the age of one year.

Published studies addressing bilateral cochlear implantation show consistent improvement in speech reception, especially in noise, and in sound localization with bilateral devices.

In July 2019, the FDA expanded the indication for the MED-EL Cochlear Implant System to include individuals aged five years and older with single-sided deafness (SSD) or asymmetric hearing loss (AHL). For individuals with unilateral sensorineural hearing loss who receive cochlear implant(s), the evidence includes prospective and retrospective studies and systematic reviews of these studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. Given the natural history of hearing loss, pre- and postimplantation comparisons may be appropriate for objectively measured outcomes. However, the available evidence for the use of cochlear implants in improving outcomes for patients with unilateral hearing loss, with or without tinnitus, is limited by small sample sizes, short follow-up times, and heterogeneity in evaluation protocols and outcome measurements. The evidence is insufficient to determine the effects of the technology on health outcomes.

Hybrid cochlear implant devices are considered investigational, as peer-reviewed, published literature has not demonstrated improved outcomes with these devices over standard cochlear implant devices. Additional published studies regarding the hybrid device are generally non-randomized, uncontrolled studies with small patient populations and short-term follow-up.

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For individuals who have high-frequency sensorineural hearing loss with preserved low-frequency hearing who receive a hybrid cochlear implant that includes a hearing aid integrated into the external sound processor, the evidence includes prospective and retrospective studies using single-arm, pre- and postintervention comparisons and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related mortality and morbidity. The available evidence has suggested that a hybrid cochlear implant system is associated with improvements in hearing of speech in quiet and noise. The available evidence has also suggested that a hybrid cochlear implant improves speech recognition better than a hearing aid alone. Some studies have suggested that a shorter cochlear implant insertion depth may be associated with preserved residual low-frequency hearing, although there is uncertainty about the potential need for reoperation after a hybrid cochlear implantation if there is loss of residual hearing. The evidence is insufficient to determine the effects of the technology on health outcomes.

A prospective, multicenter study of 66 adult hearing-impaired subjects with bilateral severe-to-profound high frequency hearing loss was undertaken to investigate the preservation of residual hearing in subjects who received the Nucleus Hybrid L24 Cochlear Implant System and to investigate the performance benefits up to one year post-implantation in terms of speech recognition, sound quality, and quality of life. The group median increase in air-conduction thresholds in the implanted ear for test frequencies 125-1000 Hz was less than 15 dB across the population, both immediately and one year post-operatively. Eighty-eight percent of the patients used the Hybrid processor at one year postimplantation; 65% of the patients had significant gain in speech recognition in quiet, and 73% in noise (greater than or equal to 20% points/2 dB signal to noise ratio). Mean Speech, Spatial and Other Qualities (SSQ) subscale scores were significantly improved (+ 1.2, + 1.3, + 1.8 points, p less than 0.001), as was mean Health Utilities Index Mark 3 (HUI3) score (+ 0.117, p less than 0.01). Combining residual hearing with CI gave 22-26 percentage points mean benefit in speech recognition scores over CI alone (p less than 0.01). The authors concluded that useful residual hearing was conserved in 88% of subjects, and speech perception was significantly improved over pre-operative hearing aids, as was sound quality and quality of life. (Lenarz, *et al.*, 2013).

A small, retrospective, single-center study investigating the Nucleus Hybrid L24 Cochlear Implant System was undertaken to evaluate the hearing preservation rate in 21 patients with high-frequency hearing loss who had the Nucleus Hybrid device implanted. Pure tone thresholds were recorded prior to the surgery and at the time of speech processor switch-on. Patients were subdivided into two groups with respect to their pure tone audiometry (PTA) thresholds: group A - classic indications and group B - extended indications. Average PTA for three frequencies (250, 500, and 1,000 Hz) were calculated for each patient pre- and post-operatively. In 17 of the 21 implanted patients, preservation of hearing (12 patients from group A, five patients from group B) with a mean value of 13.1 dB was observed. In four out of 21 patients, deafness on the implanted ear was noted. The authors concluded that the results indicate standard procedure hearing preservation can be obtained in a majority of patients. Hearing preservation was not achieved in 19%, but because the design of the electrode of the Cochlear Nucleus Hybrid-L enables it to work as a cochlear implant platform alone, re-implantation was not required in patients who lost their hearing after surgery. The authors stated that the device is a safe and reliable method to help patients with a specific type of hearing loss. (Szyfter, *et al.*, 2013).

In January 2016, Roland, *et al.* reported a prospective, single-arm, repeated measures, single-subject design study undertaken to evaluate the safety and efficacy of acoustic and electric sound processing for individuals with significant residual low-frequency hearing and severe-to-profound high-frequency sensorineural hearing loss. Fifty individuals, aged 18 years and older, with low-frequency hearing and severe high-frequency loss were implanted with the Cochlear Nucleus Hybrid L24 implant at 10 investigational sites. Preoperatively, subjects demonstrated CNC word scores of 10% through 60% in the ear to be implanted. Subjects were assessed prospectively, preoperatively, and postoperatively on co-primary endpoints of consonant-nucleus-consonant words, AzBio sentences in noise, and self-assessment measures. Significant mean improvements were observed for co-primary endpoints: consonant-nucleus-consonant words (35.8 percentage points) and AzBio sentences in noise (32.0 percentage points), both at $P < 0.001$. 96% of subjects performed equal or better on speech in quiet and 90% in noise. 82% of subjects showed improved performance on speech in quiet and 74% in noise. Self-assessments were positive, corroborating speech perception results. 65 adverse events involving 34 of the 50 subjects were reported. The type and frequency of events were consistent with those reported in cochlear implantation (e.g., electrode open or short circuits, postoperative dizziness, changes in tinnitus) or other mastoid operations; no unanticipated adverse events were reported. The authors concluded the Nucleus Hybrid System provides significant improvements in

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speech intelligibility in quiet and noise for individuals with severe high-frequency loss and some low-frequency hearing and expands indications to hearing-impaired individuals who perform poorly with amplification due to bilateral high-frequency hearing loss and who previously were not implant candidates. However, they also noted additional longer term follow-up for safety and study of the device in larger and diverse subgroups is important.

The 2018 results by Roland, *et al.*, of three related clinical studies compiled to provide outcome data after one, three and five years of implant use in a group of subjects who presented with preoperative high-frequency hearing loss and were implanted with a Nucleus Hybrid L24 (Cochlear Ltd., Sydney, Australia) cochlear implant concluded the results demonstrate long-term success and benefits significantly better than those in the preoperative best-aided condition. The level of evidence given to these studies is 2b.

A final outcomes study by the same authors was reported by Gantz, *et al.* in April 2016. A total of 87 subjects received a Nucleus Hybrid S8 CI in their poorer ear. Speech perception in quiet (CNC words) and in noise (Bamford-Kowal-Bench Sentences-In-Noise [BKB-SIN]) were collected pre- and postoperatively at three, six, and 12 months. Subjective questionnaire data using the Abbreviated Profile for Hearing Aid Benefit (APHAB) were also collected. Some level of hearing preservation was accomplished in 98% subjects, with 90% maintaining a functional low-frequency pure-tone average (LFPTA) at initial activation. By 12 months, five subjects had total hearing loss, and 80% of the subjects maintained functional hearing. CNC words demonstrated that 82.5% and 87.5% of subjects had significant improvements in the hybrid and combined conditions, respectively. The majority had improvements with BKB-SIN. Results also indicated that, as long as subjects maintained at least a severe LFPTA, there was significant improvement in speech understanding. Furthermore, all subjects reported positive improvements in hearing in three of the four subscales of the APHAB. Fourteen subjects requested that the Hybrid S8 implant be removed for various reasons of dissatisfaction with the device and had a standard length Nucleus Freedom CI placed. Most experienced a progressive loss of acoustic hearing in the implant ear. Two subjects who opted to have the Hybrid S8 device removed did not experience a significant ipsilateral threshold shift, but did not have good speech perception outcomes with the hybrid device. The authors concluded that the concept of hybrid speech processing has significant advantages for subjects with residual low-frequency hearing: the Nucleus Hybrid S8 provided improved word understanding in quiet and noise, and there appeared to be stability of the residual hearing after initial activation of the device. They also stated that the reasons for loss of hearing after activation of the implant and acoustic amplification required more research.

The American Academy of Otolaryngology–Head and Neck Surgery position statement on cochlear implants was revised in 2014 and “considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children with severe to profound hearing loss. Based on extensive literature demonstrating that clinically selected adults and children can significantly perform better with two cochlear implants rather than one, bilateral cochlear implantation is accepted medical practice.”

The Nucleus 24 Auditory Brainstem Implant System (Cochlear Corporation) received FDA premarket approval in 2000 for neurofibromatosis type II patients, aged 12 years and older, who are rendered deaf due to bilateral resection of neurofibromas of the auditory nerve. Studies have shown that, while the use of an auditory brainstem implant is associated with a very modest improvement in hearing, this level of improvement is considered significant in this group of patients who have no other treatment options. Its use for other cochlear and cochlear nerve abnormalities has been investigated; however, FDA approval has not been granted for other indications.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

| Code | Description |
|-------|---|
| 69930 | Cochlear device implantation, with or without mastoidectomy |

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| Code | Description |
|-------|---|
| 92601 | Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming |
| 92602 | subsequent reprogramming |
| 92603 | Diagnostic analysis of cochlear implant, age 7 years or older; with programming |
| 92604 | subsequent reprogramming |
| 92605 | Evaluation for prescription of non-speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour |
| 92618 | each additional 30 minutes (List separately in addition to code for primary procedure) |
| 92640 | Diagnostic analysis with programming of auditory brain stem implant, per hour |

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HCPCS Codes

| Code | Description |
|-------------|---|
| L8614 | Cochlear device, includes all internal and external components |
| L8615-L8619 | Replacement components of cochlear implant device/system (code range) |
| L8621-L8624 | Replacement batteries used with cochlear implant device/system (code range) |
| L8625 | External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each |
| 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 |
| S2235 | Implantation of auditory brainstem implant |

ICD10 Codes

| Code | Description |
|-------------|--|
| H90.3-H90.8 | Conductive and sensorineural hearing loss (code range) |
| H91.3 | Deaf nonspeaking, not elsewhere classified |
| Q85.02 | Neurofibromatosis, type 2 |

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- *Key Article

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KEY WORDS

Hearing implant, Advanced Bionics HiResolution Bionic Ear System (HiRes 90k), Cochlear Nucleus 5, Med El Maestro (Sonata or Pulsar), Nucleus 24 Auditory Brainstem Implant System, Nucleus Hybrid L24 Cochlear Implant System.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Cochlear Implantation. Please refer to the following website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&Keyword=cochlear+implant&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAA](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&Keyword=cochlear+implant&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAA&) &.

Neither a National Coverage Determination nor a Local Coverage Determination has been identified for auditory brainstem implants. However, the Medicare Benefit Policy Manual addresses auditory brainstem implants under Chapter 16, Section 100 of the manual and states auditory brainstem implants can be considered as prosthetic devices when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery. Please refer to the following website for Medicare Members: <http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf>.