COCHLEAR IMPLANTS

SCOPE: To provide guidelines for a multidisciplinary approach for patient selection and treatment with cochlear implants.

PURPOSE: To establish guidelines for utilization decisions for the Prior Authorization and Quality Review.

DEFINITIONS: Standard operating procedures – an operating instruction used to instruct staff on the process for completing a task or associated tasks.
Regulatory – refers to any applicable state rules in contracts, law, audit criteria or any other official state document or communication (i.e. email).

POLICY: Cochlear implantation may be undertaken as a treatment option in patients with severe to profound bilateral sensorineural hearing loss (pure tone average of 70 decibels or greater). It is technically not a hearing aid as it does not amplify sound. It consists of internal and external components (speech processor) which allow electrical transmission to auditory (internal ear) nerve fibers. The cochlear implant requires extensive audiometric/speech therapy services to allow it to be effective in the post operative period. There may be up to a 15-20% failure rate. The following describes patient selection criteria and documentation requirements that are thought to be acceptable for medical necessity for Children’s Rehabilitative Service.

PATIENT SELECTION:

1. PRE-IMPLANT EVALUATION: Member must undergo a pre-implant evaluation as follows within 6 months of the potential implant date.

   A. Exam and Diagnostic Imaging. Otologic examination and CT scan.

   B. Comprehensive audiologic evaluation. The test battery may include behavioral, Auditory Brainstem Response (ABR) and/or Oto-Acoustic Emissions (OAE) threshold assessments as needed, as well as speech perception tests appropriate to child’s age, and assessment of middle ear function.

   C. Hearing Aid Testing. Aided testing with child’s conventional amplification, including age-appropriate speech and sound perception tests, as well as hearing aid function checks.

   D. Communication Assessment. Communication assessment, which may consist of comprehensive speech-language evaluation and/or assessment of augmentative/alternative or sign language skills.

   E. Psychological Evaluation: Assessment of developmental, emotional, social, and behavioral functioning, as well as overall adjustment to the medical condition. Assessment of patient readiness and family expectations, as well as motivation for adherence to treatment regimen.

   F. Academic Performance. Review of preschool or school records for academic performance, special education service and any communication therapy progress.
G. Assessment by audiologist and social worker or psychologist. Assessment of family understanding of implant process and outcome expectations, as well as their previous record of compliance with child’s medical, audiologic, and therapy plans.

H. Team conference or review of summation of evaluations. Findings are reviewed and documented regarding implantation. For Multi Specialty Interdisciplinary Clinics (MSICs) opting for Team Conference, participants should include, minimally, the otologist, audiologist, speech-language pathologist, and psychologist. Educational professionals, early interventionists, social worker and parents may also participate.

2. Criteria for Qualification:

A. Completed Pre-Implant Evaluation: as above.

B. Diagnosis: Sensorineural Hearing Loss. Diagnosis of congenital or acquired profound sensorineural hearing loss with full audiologic evaluation and/or Auditory Brain Stem evaluation (with pure tone average 70DBHL in better ear or worse).

C. Age. Be at least 12 months of age, consistent with FDA guidelines. Exceptions may be made for post meningitis patients.

D. Bilateral Cochlear Implants. Bilateral cochlear implants may be done simultaneously or sequentially, according to the clinical circumstances.

E. Previous Amplification Trial. An appropriate hearing aid trial relative to the patient’s age and hearing thresholds should be done prior to cochlear implant placement. This requirement may be waived in post-meningitis patients.

When considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team should be mindful of the need to ensure equality of access. Tests should take into account a person’s disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, and may need to be adapted. If it is not possible to administer tests in a language in which a person is sufficiently fluent for the test to be appropriate, other methods of assessment should be considered.

F. Anatomic Structural Compatibility. Have an accessible cochlear lumen structurally suited to the implant in the auditory nerve and acoustic areas of the cochlear nerve fibers demonstrated by CT scan or other appropriate radiological test and electrical promontory stimulation when auditory nerve integrity is in doubt.

G. Vaccination. Age appropriate vaccination for meningitis as per CDC guidelines.

H. Medical Contraindications. Be free of the following medical contraindications:

1. Chronic or active middle ear disease
2. Tympanic membrane disruption
3. Conditions which create risk for general anesthesia
4. Acoustic nerve or central auditory pathway lesions

I. Family Understanding. Have demonstrated parent/family understanding of implant process, benefits, and limitations, and outcome expectations which are realistic in context of child’s age, hearing impairment, and apparent learning capabilities.
Family Support. Have record of strong family support, including:
1. Good compliance with past medical and habilitative interventions
2. Clear, strong commitment to the post-implant speech-language therapy and audiology interventions necessary to make the implant a success.
3. Child’s ability to benefit from CI from an emotional, behavioral, social, and developmental perspective.

K. Children older than five years with congenital or early-onset severe to profound hearing loss may meet most of the above criteria and still not be good candidates for cochlear implant if they have had little or no auditory/oral training, speech-language therapy, or background. Children of elementary school age and above should be considered as viable implant candidates only if they meet the above criteria, AND:

1. The sensorineural hearing loss is post-lingual in onset, such as
   a. Relatively recent or sudden-onset loss, such as meningitis or injury
   b. Gradual progressive loss which was initially mild enough that early oral language developed, but has progressed to a severe to profound degree

OR

2. The youngster, regardless of age at onset of hearing loss, is judged by the speech language pathologist to demonstrate good auditory/oral skills and a strong desire to communicate orally. They must have access to intensive speech-language therapy/auditory training.

3. Clinical Precautions:
   Cochlear implantation is associated with a variety of potential complications and parents or guardians should have documentation of being counseled.

   A. Possible Meningitis. The complication of greatest concern is the possible development of meningitis which may result in death. Children with cochlear implants with electrode positioners appear to be at greater risk of developing meningitis than children with cochlear implants with no positioners. This data emphasizes the importance of ensuring that all pediatric cochlear implant users are appropriately vaccinated against S. pneumoniae and are monitored and promptly treated for bacterial infections.

   B. Possible Worse Hearing. Improper placement of the internal cochlear implant components, requiring second surgery; device failure; destruction of residual hearing in the implanted ear, which renders native hearing worse than before cochlear implantation; facial nerve injury; and leakage of perilymphatic fluid which may result in meningitis.

   C. Diagnostic Contraindication. Refer to current FDA guidelines.

4. Post-Implant Process:

   A. Otologic.
   1. Approximately one week post-op, initial post-op exam to assess incision site healing, general recovery and decide approximate time for Initial Stimulation.
2. During the first year post-implant, physician visits are typically scheduled at three to six-month intervals, at the physician’s discretion. Audiology and otology visits to be coordinated as necessary.

3. Children with cochlear implants should be seen at least annually by the managing otologist. At the otologist’s discretion, an older child or teen may be seen every two years rather than annually.

B. Audiologic.
1. Approximately three to five weeks post-op (timeframe at physician’s recommendation based on age of child and other factors), Initial Stimulation occurs. Audiologist attaches the external speech processor, transmitting coil, and microphone, and performs initial mapping.

2. At one week and at three to four weeks following Initial Stimulation, child returns to audiologist for mapping, evaluation and programming adjustments. Mapping includes establishing behavioral threshold levels for each active electrode, neural response measures, and/or electrically-evoked stapedius reflex thresholds. These first audiology visits are typically two hours in length. Note: age of the child impacts frequency of follow-up—infants may require more frequent follow-up and adjustments.

3. Audiology visits with adjustments occur at intervals throughout the first year, depending on need and patient progress.

4. Child returns to audiologist for assessment, programming, equipment “trouble-shooting,” and adjustments at three month intervals, or more often if needed, during first year post-implant. At three, six and twelve months post-implant, the audiologist performs appropriate tests of speech perception, depending on child’s age and abilities.

5. During second and subsequent years post-implant, child returns as needed, usually one or two times per year.

C. Therapy.
Intensive auditory training and speech-language therapy are required over an extended period of time in order for most children to learn to use the auditory input they receive with the implant device.

1. Approximately one month post-implant, the child begins communication therapy with either rehabilitation audiologist and/or speech-language pathologist. Child, accompanied by parents, should be seen at least once a week. Optimally, therapy/training should occur twice a week during first three months.

2. At the discretion of the team speech-language pathologist, part of child’s post-implant therapy may take place in the educational setting or in the community, if it is clear that therapy is being provided by a professional who has understanding of the unique therapy needs of children with severe hearing loss and those with cochlear implants.

3. Weekly therapy is required for at least one year. To achieve good aural/oral language, most children will require therapy throughout childhood. Factors such as educational setting, the child’s age at onset of hearing loss, the child’s age at implant, parental involvement and support influence the progress of the child.
4. At the end of one year, the speech-language pathologist completes a speech-language evaluation which includes measures of receptive and expressive vocabulary, word- and sentence-level articulation, and normed tests of auditory processing skills.

D. Evaluation of Function.
At six and twelve months post-implant for the first year and then, at a minimum, annual evaluations of the child's progress, family satisfaction, any concerns, etc. should be addressed by the Cochlear Implant specialist and/or audiologist. When the core team has been established, they may meet with the child's parents/family and educational professionals to address these functions more formally as a team.

A child with a nonfunctioning implant should be seen as soon as possible for evaluation and repair.

References:

1. Treatment of hearing impairment in children, Author Betsy Sanford, MCD; CCC-A Peter C Weber, MD; FACS ; Section Editor Ellen M Friedman, MD; Deputy Editor, Mary M Torchia, MD; UpToDate; Last literature review for version 16.3: October 1, 2008 This topic last updated: October 6, 2008


5. AHCCCS ESPDT 430 C.8 Cochlear Implant 1994


