

VHA & DoD PROSTHETIC CLINICAL MANAGEMENT PROGRAM (PCMP) CLINICAL PRACTICE RECOMMENDATIONS FOR PRESCRIPTION OF COCHLEAR IMPLANTS

I. BACKGROUND

VHA's Prosthetic and Sensory Aids Service Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program (PCMP). The objectives are to coordinate the development of clinical practice recommendations for prosthetic prescription practices and contracting opportunities to assure technology uniformity and ease of access to prosthetic prescriptions and patient care that will lead to valid outcome measures and analysis for research purposes.

A work group with input from Veterans Health Administration and Department of Defense audiologists, otolaryngologists, and prosthetics specialists convened to recommend clinical practice recommendations regarding issuance criteria of cochlear implants. Contributors to this document were: Nancy Cambron, Chair; Willie Anthony, Lucille Beck, Patty Benson, Terry Bowen, David Chandler, Mike Crabtree, Kyle Dennis, Bryanne Patail, Kathy Pessagno, Julie Rickert, Jay Rubinstein, Brandon M. Tourtillot, Ben Sierra, and Jennifer Tay. The draft was submitted to the VHA Audiology and Speech Pathology Field Advisory Council, VHA VISN managers, and VHA and DoD cochlear implant managers for review.

A cochlear implant provides an option for managing patients with severe to profound hearing loss who derive little or no benefit from other treatment options. Implantation involves the inter-disciplinary collaboration of audiologists, otolaryngologists, psychologists, speech-language pathologists, social workers, and others. The cochlear implant is the first step in a comprehensive, long-term rehabilitation of the patient. Surgical implantation is followed by a prescribed course of training and rehabilitation aimed at achieving maximum patient benefit. There are three FDA-approved manufacturers used by VA implant centers: Cochlear Corporation, Advanced Bionics, and MedEl.

II. POLICY

The purpose of the clinical practice recommendations is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care and safety, and to promote cost-effective prescribing.

III. CANDIDACY GUIDELINES FOR ADULTS (AGE 18 YEARS AND OLDER)

It is highly recommended that the following guidelines be met for an adult to be considered a candidate for a cochlear implant:

A. General Criteria

1. The cochlear implant must be medically necessary. The Cochlear Implant Team determines medical necessity using current FDA guidelines, IRB-approved protocol,
2. Veteran has the cognitive and emotional capacity to adapt to and benefit from implantation.
3. Veteran displays reasonable and appropriate expectations of potential benefit.
4. Veteran agrees to participate in the treatment and rehabilitative protocol.

B. Medical Criteria

1. No medical contraindications for anesthesia or surgery
2. No active middle-ear infection
3. No evidence of VIII nerve disease.
4. CT scan or MRI demonstrating feasibility of implantation.
5. Physicians should consider prophylactic perioperative antibiotic treatment.
6. Cochlear implant candidates, as well as those already implanted, may benefit from vaccinations against organisms that commonly cause bacterial meningitis, particularly *Streptococcus pneumoniae* and *Hemophilus influenza*. Immunization status should be ascertained for all candidates before surgery. Vaccines are available against influenza and pneumococcal organisms in children and adults, but the effectiveness of such vaccines is not fully known.

C. Audiologic Criteria

1. Derives marginal benefits from conventional amplification
2. Bilateral primarily sensori-neural severe to profound hearing loss
3. Speech recognition ability for open-set speech meets FDA guidelines or IRB-approved protocol when veteran is fit with optimal amplification.

IV. CLINICAL PRACTICE RECOMMENDATIONS FOR EVALUATION/IMPLANTATION/TRAINING

A. Service Delivery

All eligible veterans who meet selection criteria and demonstrate medical necessity will receive a cochlear implant. For the purposes of this Clinical Management Program, an eligible veteran is one who is enrolled for VA health care or is exempt from such enrollment (as defined in 38 CFR 17.36) and otherwise meets selection criteria.

1. Selection criteria will conform to current FDA guidelines or IRB-approved protocol. Prior approvals by the CI Advisory Board and IRB locally are required for devices with an Investigational Device Exemption (IDE). Bilateral cochlear implants will be considered by the CI Advisory Board on a case-by-case basis. Devices or protocols without IDE or FDA approval will not be considered.
2. Medical necessity will exist when the selection criteria are met and the implant team certifies that the patient is a candidate for a cochlear implant.
3. VHA will establish Cochlear Implant Centers (CIC) according to site criteria. New sites must apply to the CI Advisory Board for approval.
4. Facility Directors may elect to provide cochlear implant services through non-VA health care facilities provided they meet the site criteria.
5. No veteran will be denied cochlear implant services because he/she resides outside of the VISN of a designated Cochlear Implant Center or other healthcare entity contracted to provide cochlear implant services.
6. The cochlear implant team, with input from the veteran, will determine which multi-channel device is most appropriate for each cochlear implant candidate. It is recommended that two speech processors be provided for each cochlear implant candidate.
7. Cochlear implant recipients will return to the host site after the surgical site is well healed for activation of the cochlear implant and training. Initial activation and training will require multiple visits. Follow-up appointments will be scheduled at regular intervals throughout the first year post-activation to address programming changes and rehabilitation needs. Thereafter, cochlear implant recipients will be followed annually, or on an as-needed basis, by either the host site or an approved contract facility. Audiologic rehabilitation will be provided as necessary through clinic appointments and/or take-home materials.
8. Batteries and repairs will be provided to cochlear implant users.

Replacement of speech processors will be provided if veteran demonstrates need.

B. Cochlear Implant Site Criteria

1. Equipment

- a. Sites must possess all standard audiometric equipment to perform comprehensive audiometric evaluations as well as acoustic immittance, auditory evoked potentials, and otoacoustic emissions (Transient Otoacoustic Emissions or Distortion-Product Otoacoustic Emissions).
- b. Sites will calibrate audiometric equipment bi-annually and perform listening checks daily.
- c. Sites will maintain calibration records. Sites will conform to applicable ANSI standards.
- d. Sites must have equipment to perform speech identification tasks in sound field.
- e. Sites must have at least one suitable sound-treated room that meets applicable ANSI and VHA specifications.
- f. Sites must have all specialized equipment for selecting, evaluating, programming, and activating implant devices and hearing aids.
- g. Sites must have test materials for evaluating implant candidates and outcomes.

2. Personnel

- a. Each site must have at least one qualified audiologist on staff who is specifically trained in cochlear implant management. An audiologist trained in cochlear implant fittings is responsible for performing audiologic assessments, counseling the patient, programming the device after implantation, and providing extensive training and rehabilitation to the patient. This rehabilitation program is designed to produce maximum benefit from the implant by integrating the auditory-electrical code with environmental, visual, and contextual cues.
- b. Cochlear implant audiologists will meet training requirements set forth by the American Speech Language-Hearing Association or the American Academy of Audiology.
- c. Each site must have at least one qualified otolaryngologist on staff

or on contract who is experienced in the medical and surgical management of cochlear implants. The cochlear implant otolaryngologist, a physician who specializes in diseases of the ear, is responsible for the management of medical and surgical aspects of evaluation and treatment.

d. The cochlear implant team is an inter-disciplinary group of otolaryngologists, audiologists, and can include psychologists, speech-language pathologists, social workers, and others.

Each site must demonstrate interdisciplinary collaboration of services such as Surgery, Medicine, Otolaryngology, Neurology, Psychology, Social Work, Speech-language Pathology, Radiology, and ancillary services.

3. Training and Experience

a. The implant audiologist will have specialized training from the manufacturer in the evaluation, activation, and programming of the speech processor.

b. The implant otolaryngologist will have specialized training from the manufacturer, or equivalent training during a neurotology fellowship, in the evaluation and implantation of the device.

c. The audiologist will demonstrate not less than 1 CEU (10 contact hours) per year in cochlear implant management or related areas.

d. Each implant audiologist and otolaryngologist will demonstrate involvement in at least ten (10) cochlear implants to be certified as an implant audiologist and implant otolaryngologist respectively.

4. Documentation

a. Each site will maintain thorough medical documentation.

b. Documentation includes but is not limited to: audiologic records, pertinent medical, social and family histories, evaluations, communication scales and inventories, programming, training, progress notes, and outcomes.

c. At minimum, each site will collect the following speech recognition measures in quiet on each veteran:

Preoperatively, the following sentence tests will be presented in sound field at 0° azimuth at a level of 70 dB SPL while the veteran is fit with optimal amplification:

- City University of New York sentences - 1 list per ear and binaurally

- Hearing in Noise Test sentences - 2 lists per ear and binaurally

Postoperatively, the following sentence tests will be presented in sound field at 0° azimuth at a level of 70 dB SPL while veteran is fit with best map in speech processor:

- City University of New York sentences - 1 list
- Hearing in Noise Test sentences - 2 lists

The postoperative testing will be conducted at six months post-activation & at annual evaluations.

These measures are the minimum testing required for VHA reporting purposes. Clinicians are encouraged to also test patients preoperatively and postoperatively with monosyllabic words and sentences in noise.

- d. Each site will administer the Performance Inventory for Profound and Severe Loss (PIPSL) both preoperatively and at one year postoperatively as well as other outcome measures as appropriate.
- e. Each site will enter speech recognition and outcomes data in the Cochlear Implant Registry in ROES.
- f. Each site will order cochlear implants and replacement parts electronically.

C. Cochlear Implant Advisory Board

1. The Audiology and Speech Pathology Program Office will establish and oversee a Cochlear Implant Advisory Board.
2. The purpose of the Cochlear Implant Advisory Board is to:
 - a. Provide guidance to the National Director, Audiology and Speech Pathology Service, on current cochlear implant practices, selection criteria, and device standards.
 - b. Monitor clinical practices and outcomes at implant sites. Determine approval for new implant centers.
 - c. Establish and maintain a cochlear implant registry
 - d. Report periodically to the National Director on the status of the implant program

3. The membership of the Cochlear Implant Advisory Board will be:

- a. Two audiologists with experience in cochlear implants
- b. Two otolaryngologists with experience in cochlear implants
- c. Director, Surgical Service
- d. Director, Audiology and Speech Pathology Service
- e. Representation from the Department of Defense
- f. Representation from Prosthetics and Sensory Aids Service
- g. Ad hoc, representatives from each cochlear implant site

D. Cost and Logistics

1. For the purposes of this Clinical Practice Recommendation, the facility referring the implant candidate is the *referring facility*. The facility providing the implant services is the *host facility*.

2. The host facility is responsible for paying the cost of evaluation, implantation surgery, anesthesia, inpatient costs, ancillary services, other services that may be medically necessary for the management of the patient, follow-up evaluations, and other visits as may be required to ensure that the patient obtains maximum benefit from the implant.

3. Veterans will receive care from the VHA cochlear implant center or approved contracted center nearest their home. For VHA patients, the referring facility will pay for travel to the host facility and the host facility will pay for lodging and return travel in accordance with VHA Policy on "travel and lodging for patients, spouses and significant others". Travel funding for DoD patients will follow Joint Travel Regulation guidelines.

4. The host facility is responsible for paying the cost of the implant device, accessories, repairs, and replacements. VHA cochlear implant centers will receive funding for the implant devices from PSAS centralized funds.

5. The cochlear implant manufacturer will provide two implants at time of surgery, the primary implant and one back-up implant. The back-up implant will be provided at no extra charge if it is returned to the manufacturer following surgery.

6. The host facility is responsible for coordinating all evaluations, tests,

surgical and radiological services, ancillary services, training sessions, and other services that are medically necessary. Where appropriate, the referring facility may provide initial evaluations, medical tests, audiologic tests, and radiology exams as necessary to determine candidacy. However, the host facility is responsible for evaluating the completeness or adequacy of clinical data provided by the referring facility.

V. REFERENCES

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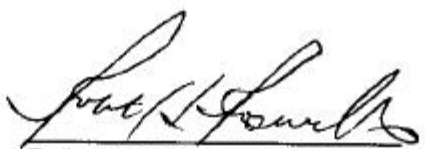
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Date

Addendum

PEDIATRIC CANDIDACY GUIDELINES FOR DEPARTMENT OF DEFENSE CENTERS

It is highly recommended that the criterion described below be met for all pediatric patients being considered for cochlear implant candidacy.

A. General Criteria

1. The cochlear implant must be medically necessary. The Cochlear Implant Team determines medical necessity using current FDA guidelines, IRB-approved protocol,
2. Candidate has the cognitive and emotional capacity to adapt to and benefit from implantation.
3. Family and patient display reasonable and appropriate expectations of potential benefit.
4. Family agrees to participate in the treatment and rehabilitative protocol.
5. Candidates between the age of 12 months and 17 years.

B. Medical Criteria

1. No medical contraindications for anesthesia or surgery.
2. No active middle-ear infection.
3. No evidence of VIII nerve disease.
4. CT scan or MRI demonstrating feasibility of implantation.
5. Physicians should consider prophylactic preoperative antibiotic treatment.
6. Cochlear implant candidates, as well as those already implanted, may benefit from vaccinations against organisms that commonly cause bacterial meningitis, particularly *Streptococcus pneumoniae* and *Hemophilus influenza*. Immunization status should be ascertained for all candidates before surgery. Vaccines are available against influenza and pneumococcal organisms in children and adults, but the effectiveness of such vaccines is not fully known.

C. Audiological Measures

1. Audiometric testing under headphones if possible, Visually Reinforced Audiometry (VRA), Acoustic Immittance.
2. Auditory Brainstem Response (ABR) (Sedated if necessary to confirm hearing loss).
3. Otoacoustic Emissions (OAEs).
4. Soundfield testing unaided and in best aided condition.
5. Speech perception testing when possible. The following tests are recommended. However, other developmentally appropriate measures may be necessary, especially with multiply handicapped children.

0-24 months

- Parental questionnaires
 - i. Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)
 - ii. Ling Schedule of Development

2-4 years

- Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS), Early Speech Perception (ESP), LING Six Sound Test
- Multisyllabic Lexical Neighborhood Test (MLNT), Lexical Neighborhood Test (LNT), Phonetically Balanced Kindergarten (PBK) Word List, Glen Donald Auditory Screening Procedure (GASP), Hearing in Noise Test for Children (HINT-C)

5+ years

- Meaningful Auditory Integration Scale (MAIS), Early Speech Perception (ESP), Test of Auditory Comprehension (TAC), LING Six Sound Test, Pediatric Speech Intelligibility Test (PSI)
- Multisyllabic Lexical Neighborhood Test (MLNT), Lexical Neighborhood Test (LNT), Phonetically Balanced Kindergarten (PBK) Word List, Hearing in Noise Test for Children (HINT-C), Glen Donald Auditory Screening Procedure (GASP)

D. Audiological Criteria

1. Bilateral sensori-neural hearing loss (SNHL), primarily of severe to profound severity.
2. 3-6 month Hearing Aid trial with no significant benefit (hearing aid trial can be waived in cochlear ossification pathologies).

- Upon conclusion of trial a re-assessment of speech/language milestones is obtained
- If no improvement is noticed in the speech/language development milestones, patient is considered a CI candidate.

4. Age Based Criteria

≤ 4 years

- Multisyllabic Lexical Neighborhood Test word scores $\leq 20\%$
- Infant-Toddler Meaningful Auditory Integration Scale scores ≤ 2 on questions 3,5,6

> 4 years

- Phonetically Balanced Kindergarten word list 0-12%
- Hearing in Noise Test for Children score $\leq 30\%$

E. Cochlear Implant Team

As a minimum the team should consist of the following:

1. Audiologist
2. Speech-Pathologist
3. Otolaryngologist/Neurotologist
4. Developmental Pediatrician
5. Educational Specialist