VHA AND DOD PROSTHETIC CLINICAL MANAGEMENT PROGRAM
CLINICAL PRACTICE RECOMMENDATIONS
FOR PRESCRIPTION OF COCHLEAR IMPLANTS

I. BACKGROUND

Veterans Health Administration (VHA) 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 were to coordinate the development of clinical practice recommendations (CPRs) 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 VHA and Department of Defense audiologists, otolaryngologists, and prosthetic specialists convened in 2004 to recommend clinical practice recommendations (CPRs) regarding issuance criteria of cochlear implants (CIs). Revision of the CI CPRs was completed in 2017 by the VHA Cochlear Implant Advisory Board:

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The draft was submitted to the VHA Audiology and Speech Pathology Field Advisory Council, and VHA and DoD cochlear implant coordinators for review.

Cochlear implants provide an option for managing patients with hearing loss who derive limited 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 part of a comprehensive, long-term rehabilitation program for patients with hearing loss. Surgical implantation is followed by a prescribed course of programming, training and rehabilitation aimed at achieving maximum patient benefit. The VHA uses only cochlear implants approved by the US Food and Drug Administration (FDA) or an Institutional Review Board (IRB).

II. PURPOSE

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 recommended that potential cochlear implant candidates meet the following criteria:

A. General Criteria

1. The cochlear implant must be medically necessary. The Cochlear Implant Team determines medical necessity using the guidelines specified in this document or an IRB-approved protocol.

2. Veteran demonstrates the cognitive and emotional capacity to adapt to and benefit from implantation. Referral for neurocognitive assessment by a trained psychologist is recommended if cognitive or emotional capacity for implantation is in question.

3. Veteran displays reasonable and appropriate expectations of potential benefits and limitations.

4. Veteran agrees to participate in the treatment and rehabilitative protocol.

B. Medical Criteria

1. No absolute medical contraindications for anesthesia or surgery. Local anesthesia can be an option in selected patients.

2. Active middle ear disease should be managed prior to CI surgery.

3. Consideration of VIII nerve disease. Rare individuals with conditions affecting the VIII nerve may still be candidates for cochlear implantation with appropriate preoperative management and counseling (e.g. post-radiation, neurofibromatosis, superficial siderosis). CT scan or MRI should demonstrate feasibility of implantation.

4. Physicians should consider prophylactic perioperative antibiotic and steroid treatment.

5. Physicians should comply with the Centers for Disease Control and Prevention (CDC) recommendations for pneumococcal vaccinations for cochlear implant candidates and recipients.

C. Audiologic Criteria

1. Standard cochlear implants:

    a. Moderate to profound hearing loss bilaterally.

    b. Limited benefit from appropriate binaural hearing aids, as defined by aided test scores of 50% or less in the ear to be implanted and 60% or less in the opposite ear or binaurally on recorded tests of AzBio sentence recognition presented in quiet at 60 dBA.

2. Electro-acoustic cochlear implants:

    a. Pure tone average of 2,000, 3,000, and 4000 Hz ≥ 60 dB HL in both ears.

    b. Aided CNC word recognition score from 10% to 60% in the ear to be implanted.

c. Contralateral ear aided CNC word recognition score equal to or better than that of the ear to be implanted but not better than 80% correct.

d. Unilateral use only.

3. Exceptions to the above criteria must have approval by

   a. The VHA Cochlear Implant Advisory Board or

   b. An Institutional Review Board.

IV. CLINICAL PRACTICE RECOMMENDATIONS FOR EVALUATION / IMPLANT ACTIVATION / 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 & 17.37) and otherwise meets selection criteria.

1. Selection criteria will conform to the Candidacy Guidelines in section III or Institutional Review Board (IRB)-approved protocol. Prior approvals by the VHA CI Advisory Board and local IRB are required for devices with an Investigational Device Exemption (IDE). Cochlear Implant Centers who identify a Veteran who might benefit from a cochlear implant but does not meet VA or IRB guidelines will submit the case to the VHA Cochlear Implant Advisory Board for review.

2. Bilateral cochlear implants will be considered by the local cochlear implant team on a case-by-case basis after the Veteran has been evaluated using the VA bilateral candidacy protocol (See ASPS SharePoint site). Unless simultaneous implantation is medically indicated (as in the case of meningitis), bilateral cochlear implantation will be completed sequentially.

3. Cochlear Implant Centers will provide full surgical and audiologic services for cochlear implant patients. Prospective Cochlear Implant Centers must apply for approval by submitting a Business Plan to their management per Directive 2009-001 and an application to the VHA CI Advisory Board (See ASPS SharePoint site).

4. Cochlear Implant Programming Centers will provide audiologic services for cochlear implant patients in support of the nearest VHA-approved Cochlear Implant Center(s). The Cochlear Implant Programming Center and Cochlear Implant Center(s) will develop a service agreement that defines which services will be provided by each facility. Close communication is necessary between the centers to facilitate patient care. Prospective Cochlear Implant Programming Centers must apply for approval by submitting an application to the CI Advisory Board (See ASPS SharePoint site).

5. Cochlear Implant Centers and Cochlear Implant Programming Centers will serve any Veteran for whom they are the nearest center. No Veteran will be denied cochlear implant services because he/she resides outside the VISN of a designated Cochlear Implant Center.

6. Facility Directors may elect to provide cochlear implant services through non-VA health care facilities provided they meet the site criteria.

7. The cochlear implant team, with input from the Veteran, will determine which device is most appropriate for each cochlear implant candidate. Two sound processors will be provided for each internal cochlear implant.

8. Cochlear implant recipients will return to the Cochlear Implant Center or Cochlear Implant Programming Center 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. Audiologic rehabilitation will be provided as necessary through clinic appointments and/or take-home materials.

9. Batteries and repairs will be provided to cochlear implant recipients. Sound processor upgrades may be considered when the device proves to be irreparable or if significant improvement in communication function is expected with new technology. Devices will not be replaced simply because of age or a new model is available.

B. <u>Cochlear Implant Site Criteria</u>

1. Equipment

   Cochlear Implant Centers and Cochlear Implant Programming Centers will:

   a. Possess all standard audiometric equipment to perform comprehensive audiometric evaluations, as well as acoustic immittance, auditory evoked potentials, and otoacoustic emissions. Sites must also have access to videonystagmography testing.

   b. Calibrate audiometric equipment semi-annually and perform listening checks daily.

   c. Maintain equipment and conform to applicable ANSI standards.

   d. Have equipment to perform speech recognition tasks in sound field and calibrate appropriately.

   e. Have at least one suitable sound-treated room that meets applicable ANSI specifications.

f. Have all specialized equipment for selecting, evaluating, and programming cochlear implants and hearing aids, including probe microphone measures.

g. Have test materials for evaluating implant candidates and measuring outcomes.

2. Personnel

a. Each site must have at least one qualified audiologist on staff or on contract who is specifically trained in cochlear implant management. An audiologist trained in cochlear implant technology is responsible for performing audiologic CI candidacy assessments, counseling the patient and family, programming the device after implantation, and providing extensive training and rehabilitation to the patient.

b. Audiologists' training and experience will be reviewed during the initial Cochlear Implant Center or Cochlear Implant Programming Center application process. Audiologists who begin participating in CI activities after a Cochlear Implant Center or Cochlear Implant Programming Center has been approved will submit their training and experience to the VHA CI Advisory Board for review.

c. Each Cochlear Implant Center 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 is responsible for the management of medical and surgical aspects of evaluation and treatment.

d. The cochlear implant team is an interdisciplinary 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, Audiology, Medicine, Otolaryngology, Prosthetics, Neurology, Psychology, Social Work, Speech-language Pathology, Radiology, and ancillary services.

3. Training and Experience

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

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

c. The cochlear implant audiologist will demonstrate not less than .5 CEU (5 contact hours) per year in cochlear implant management or related areas.

d. In addition to manufacturer training, each prospective cochlear implant audiologist will demonstrate recent observation of at least ten cochlear implant programming sessions and CI candidacy evaluations to initially be certified as an implant audiologist. Prospective cochlear implant surgeons will demonstrate recent involvement with ten cochlear implant surgeries. After the Cochlear

Implant Center has been approved, it is recommended that providers perform at least ten new cochlear implants each year to maintain their expertise.

4. Evaluation and Documentation

   a. Each site will maintain thorough medical documentation in CPRS and cochlear implant programming software.

   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. Each site will enter speech recognition and outcome data for cochlear implant patients in ROES.

   d. CI Candidacy:

      i. Prior to completing preoperative testing, the hearing aid fitting will be evaluated using probe microphone measures. Optimized fitting parameters will be achieved and results documented.

      ii. Pre-operative CNC word and AzBio sentence tests will be presented in quiet in sound field at 0˚ azimuth at a level of 60 dBA while the Veteran is fit with optimal amplification. Testing will be completed with right ear aided, left ear aided and binaurally aided. When testing individual ears, the contralateral ear should be occluded when any unaided pure tone threshold is better than 50 dB HL.

      iii. Balance testing should be performed pre-operatively as needed, especially for patients who have a history of dizziness.

      iv. Refer to section III. C. for audiologic cochlear implant candidacy criteria.

   e. Post-operatively, CNC word and AzBio sentence tests will be presented in sound field at 0˚ azimuth at a level of 60 dBA while the Veteran is using the best map in the sound processor. At minimum, the post-operative testing will be conducted at six months post-activation and at annual evaluations. These measures are the minimum testing required for VHA reporting purposes. Post-operatively, clinicians are encouraged to also test patients with speech in noise and bimodally, if appropriate.

   f. Bilateral cochlear implant candidacy will be assessed using the Cochlear Implant Advisory Board-approved Bilateral Protocol (See ASPS SharePoint site). Submitting bilateral cases to the CI Advisory Board is optional, but is welcomed if the CI site would like the case to be reviewed.

   g. Each site will administer the IOI-CI outcome measure, both pre-operatively and at one year post-operatively, as well as other outcome measures, such as the Tinnitus Handicap Inventory, the Dizziness Handicap Inventory, and the Spatial Hearing Questionnaire, as appropriate (See ASPS SharePoint site).

C. Cochlear Implant Advisory Board

1. The Audiology and Speech Pathology National 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. Determine approval for new implant centers and monitor clinical practices and outcomes at implant sites. Periodic site visits may also be conducted at established centers to review personnel, equipment, and documentation to ensure compliance and VHA policy.

    c. Provide guidance to the Denver Acquisition and Logistics Center (DALC) to establish and maintain a cochlear implant registry.

    d. Act as a resource for problem cases and questions related to patient candidacy, surgery and management issues.

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

    a. Two VA audiologists with experience in cochlear implants.

    b. Two VA 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 these Clinical Practice Recommendations, 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 as well as 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. Travel costs will be paid in accordance with VHA Policy on travel and lodging for patients, spouses and significant others.

4. Cochlear implant equipment and replacement parts will be ordered through ROES. 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 funds. Only approved VHA Cochlear Implant Centers have the authority to purchase internal cochlear implants through the Denver Acquisition and Logistic Center. Only approved VHA Cochlear Implant Centers and Programming Centers may purchase sound processors. Any VHA audiology clinic may purchase cochlear implant accessories and batteries.

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 within 30 days following surgery.

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

CPT CODES FOR COCHLEAR IMPLANT PROCEDURES

CPT Code	COCHLEAR IMPLANT EVALUATION
92557	Comprehensive Audio
92567	Tympanometry
92550	Tymp, ipsi & contr reflex
V5020	Real ear measurements
92593	Hearing aid check, binaural
92595	Electroacoustic analysis, binaural
V5014	Hearing aid repair
92626	Evaluation of auditory status, including speech perception testing, 1st 60 min
92627	Evaluation of auditory status, additional 15 min
	OR MONITORING
95940	Intraoperative monitoring direct in operating room, each 15 minutes
95941	Continuous IOM, from outside the O.R., per hour
92584	NRT in OR
	COCHLEAR IMPLANT SURGERY
69930	Cochlear device implantation, with or without mastoidectomy
	COCHLEAR IMPLANT ACTIVATION
92603	Initial activation and mapping, includes speech perception testing
98960	Device orientation, each 30 mins
92633	Aural Rehabilitation
	COCHLEAR IMPLANT FOLLOW-UP
92604	Subsequent programming, includes speech perception testing
92633	Aural Rehabilitation
L7510	Repair of Prosthetic Device
92626/27	Evaluation of rehab status
V5299	Outcome measures

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