Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Meeting : Cochlear Implants for Sensorineural Hearing Loss

Susan Miller, M.D.
Coverage and Analysis Group, OCSQ
Centers for Medicare and Medicaid Services

National Coverage Determination (NCD) for Cochlear Implantation (effective 4/4/2005)

- Effective for services performed on or after April 4, 2005, **cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition**.

National Coverage Determination (NCD) for Cochlear Implantation (effective 4/4/2005)

Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and **with hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.**

Purpose of the MEDCAC:

- To examine the clinical evidence that has been recently developed in the field of cochlear implantation for both unilateral and bilateral devices and to determine how these advances affect health outcomes for the Medicare population

National Coverage Determination (NCD) for Cochlear Implantation (effective 4/4/2005)

- Medicare coverage is provided only for those patients who meet all of the following selection guidelines.

  - Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
  - Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
  - Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
  - No contraindications to surgery; and
  - The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling