

CMS Manual System

Department of Health &
Human Services

Pub 100-03 Medicare National Coverage Determinations

Center for Medicare and &
Medicaid Services

Transmittal 42

Date: JULY 1, 2005

CHANGE REQUEST 3796

SUBJECT: Cochlear Implantation

NOTE: Transmittal 39, dated June 24, 2005 is rescinded and replaced with Transmittal 42, dated July 1, 2005. The implementation date was change to July 25, 2005. All other information remains the same.

I. SUMMARY OF CHANGES: Effective for services performed on and after April 4, 2005, the Centers for Medicare & Medicaid Services (CMS) has expanded the coverage for cochlear implantation to cover moderate-to-profound hearing loss in individuals with hearing test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification. Also, CMS is covering cochlear implantation for individuals with open-set sentence recognition test scores of greater than 40% to less than or equal to 60% correct, where device was implanted in an acceptable clinical trial. (See Publication 100-03, chapter 1, section 50.3, for the specific coverage criteria.)

This revision to section 50.3 to Pub. 100-03 is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR section 405.1064, effective May 1, 2005). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL :

EFFECTIVE DATE : April 4, 2005

IMPLEMENTATION DATE : July 25, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/50.3/Cochlear Implantation (Effective April 4, 2005)

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

Table of Contents

(Rev. 42, 07-01-05)

50.3 – Cochlear Implantation *(Effective April 4, 2005)*

50.3 - Cochlear Implantation (Effective April 4, 2005)
(Rev. 42, Issued: 06/24/05; Effective: 04/04/05; Implementation: 07/25/05)

A. General

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

B. Nationally Covered Indications

- 1. 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 cognition.** 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.
- 2. 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.**

C. Nationally Noncovered Indications

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed are deemed not eligible for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act.

D. Other

All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered above remain at local contractor discretion.

(This NCD last reviewed May 2005.)