

Related Change Request (CR) #: 3796

MLN Matters Number: MM3796

Related CR Release Date: June 24, 2005

Related CR Transmittal #: 42 and 601

Effective Date: April 4, 2005

Implementation Date: July 25, 2005

Cochlear Implantation

Note: This article was revised to contain Web addresses that conform to the new CMS website and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected

Physicians and providers billing Medicare carriers and Fiscal Intermediaries (FIs) for cochlear implantation services to Medicare patients

Provider Action Needed



STOP – Impact to You

The coverage for cochlear implantation has expanded and is effective for services performed on or after April 4, 2005.



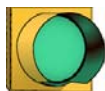
CAUTION – What You Need to Know

CMS will cover treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss for 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. More detailed coverage requirements are further listed in this article.

Additionally, CMS will cover cochlear implants of individuals with open-set sentence recognition test scores of greater than 40% to less than or equal to 60% correct, where the device was implanted in an acceptable clinical trial/study. See further details listed below.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.



GO – What You Need to Do

This revision is a binding national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. The remainder of this article provides more detailed billing instructions for these services.

Background

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. 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. Cochlear implant devices are available in single-channel and multi-channel models.

Additional Information

The information in this section outlines the policy guidelines for cochlear implantation coverage, the coverage criteria for an acceptable clinical trial/study, billing requirements for cochlear implantation, and a listing of Healthcare Common Procedural Coding System (HCPCS) associated with cochlear implantation.

Nationally Covered Indications

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 (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) 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.

Criteria for Acceptable Clinical Trials and Studies

The coverage criteria that allows for services for individuals meeting the above guidelines and with hearing test scores greater than 40% and less than or equal to 60% requires the provider to participate in and the patient to enroll in an acceptable clinical trial/study, which includes the following:

- Food and Drug Administration-approved category B investigational device exemption clinical trial as defined in 42 CFR 405.201;

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

- Trial under the CMS clinical trial policy as defined in Section 310.1 of the Medicare 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.

Billing Requirements for Cochlear Implantation When Billing FIs and Carriers

These services should be billed on an approved electronic claim form or a paper CMS form 1500. For services performed on and after April 4, 2005:

Medicare Contractors (FIs and Carriers) pay for:

1. Cochlear implant devices and services for moderate-to-profound hearing loss in patients with hearing test scores equal to or less than 40%.
2. Cochlear implant devices for patients with hearing test scores of greater than 40 % to less than or equal to 60% hearing provided in a clinical trial setting that is billed with the QR modifier.
3. Other services related to cochlear implantation, but not the device itself, for patients with hearing test scores of greater than 60% hearing who are in a clinical trial. (These services must be identified with a QV modifier.)
4. Services for patients with hearing test scores of greater than 40% to less than or equal to 60% hearing who are in a prospective, controlled comparative trial approved by CMS. (These services must be billed with the QR modifier.)
5. Any covered diagnostic audiology or therapy services related to the cochlear implant. (The QR or QV does not need to be applied to HCPCS 92601-92604 and 92506 and 92507)

Also, when billing FIs for cochlear implantations, follow these additional instructions:

1. Submit claims on the following bill types (TOB):
 - a. 11x
 - b. 12x
 - c. 13x
 - d. 83x (for non-OPPS providers)
 - e. 85x
2. Report diagnosis code V70.7 (Examination of participant in clinical trial) as the second or subsequent diagnosis code, along with the appropriate principal diagnosis code, for patients in a clinical trial.

HCPCS Associated with Cochlear Implantation

Some of the Healthcare Common Procedural Coding System (HCPCS) codes used when billing for cochlear implant services and devices provided by audiologists or physicians, and for the services of 92506 and 92507, by speech language pathologists include:

1. 69930 – Cochlear device implantation, with or without mastoidectomy.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

2. L8614 – Cochlear Device/System
3. L8619 – Cochlear implant external speech processor, replacement.
4. L7500 – Repair of prosthetic device, hourly rate (excludes V5335 repair of oral laryngeal prosthesis or artificial larynx).
5. L7510 – Repair of prosthetic device, repair or replace minor parts.
6. 92506 – Evaluation of speech, language, voice, communication, auditory processing, and/or aural rehabilitation status.
7. 92507 – Treatment of speech, language, voice, communication, and/or auditory processing disorder (includes aural rehabilitation); individual.
8. 92601 – Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming.
9. 92602 – Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent programming. (Do not report 92602 in addition to 92601).
10. 92603 – Diagnostic analysis of cochlear implant, age 7 years or older; with programming.

Note: Codes 92601 and 92603 describe post-operative analysis and fitting of previously placed external devices, connection to the cochlear implant, and programming of the stimulator.

Codes 92602 and 92604 describe subsequent sessions for measurements and adjustment of the external transmitter and re-programming of the internal stimulator.

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation specified above, or the specific coverage criteria for cochlear implantation in the context of a clinical trial/study, also specified above, are deemed not eligible for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act.

A National Coverage Determination revision is binding on all carriers, FIs, 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 405.732, 405.860). Because it expands coverage, the NCD 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.)

The official instruction issued to your FI or carrier regarding this change may be found by going to <http://www.cms.hhs.gov/Transmittals/downloads/R601CP.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R42NCD.pdf> on the CMS website.

The file with transmittal number 42 is the NCD itself and the file with transmittal number 601 contains the claims processing instructions.

For additional information relating to this issue, please refer to your local carrier or FI. To find the toll free phone number for your local carrier, go to <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.