CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 601 | **Date: JULY 1, 2005**

CHANGE REQUEST 3796

NOTE: Transmittal 589, dated June 24, 2005 is rescinded and replaced with Transmittal 601, dated July 1, 2005. The implementation date was change to July 25, 2005. All other information remains the same.

SUBJECT: Cochlear Implantation

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 of 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 instruction announces the billing requirements for cochlear implantation when billing fiscal intermediaries and carriers.

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 to the red italicized material only. 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	32/Table of Contents
N	32/100/Billing Requirements for Expanded Coverage of Cochlear Implantation
N	32/100.1/Intermediary Billing Procedures
N	32/100.1.1/Applicable Bill Types
N	32/100.1.2/Special Billing Requirements for Intermediaries
N	32/100.2/Intermediary Payment Requirements
N	32/100.3/Carrier Billing Procedures
N	32/100.4/Healthcare Common Procedural Coding System (HCPCS)

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:

x	**Business Requirements**
x	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 601	Date: July 1, 2005	Change Request: 3796

***NOTE:** Transmittal 589, dated June 24, 2005 is rescinded and replaced with Transmittal 601, dated July 1, 2005. The implementation date was change to July 25, 2005. All other information remains the same.*

SUBJECT: Cochlear Implantation

I. GENERAL INFORMATION

A. Background: Existing national coverage states that in order to qualify for cochlear implantation, prelinguistically, perilinguistically, and postlinguistically deafened adults must have test scores of equal to or less than 30 percent correct on sentence recognition scores from tape recorded tests in the patient's best listening condition. In addition, cochlear implants may be covered for prelinguistically and postlinguistically deaf children aged 2 through 17.

B. Policy: Effective for dates of service on or after April 4, 2005, the national coverage determination (NCD) states that cochlear implantation is reasonable and necessary for treatment of bilateral pre-or-postlinguistic, sensorineural, moderate-to-profound hearing loss in individuals with test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition.

In addition, the NCD allows Medicare coverage for cochlear implantation that is reasonable and necessary for individuals with hearing test scores greater than 40% to less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either:

- A Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial; or
- A trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy (see NCD Manual, Pub. 100.3, section 310.1); or
- A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for national coverage analyses (NCA) and meeting specific quality standards.

The CMS will ensure that use and disclosure of information for any future data collection system be made in compliance with the Standard for Privacy of Individually Identifiable Health Information and that all issues related to patient confidentiality, privacy, and compliance with other Federal laws will be resolved prior to the collection of any data.

Under the new cochlear implantation policy at NCD Manual, section 50.3, payment provided in connection with implantation will be made for patients qualifying for implantation of the cochlear device by enrollment in a FDA-approved category B IDE clinical trial, a trial under the CMS clinical trial policy, or a prospective, controlled comparative trial approved by CMS as consistent with evidentiary requirements for NCA and meeting specific quality standards. The QR modifier must be used to identify the charge for the device being billed to the Medicare program for these patients.

II. BUSINESS REQUIREMENTS

“Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	**Requirements**	**Responsibility (“X” indicates the columns that apply)**								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3796.1	Effective for dates of service performed on or after April 4, 2005, FIs shall pay claims with the following TOBs for cochlear implantation services: • 11x • 12x (except for surgical procedure) • 13x • 83x (for non-OPPS providers) • 85x	X								
3796.2	Effective for dates of service performed on and after April 4, 2005, Medicare contractors shall pay for cochlear implantation devices and services for moderate-to-profound hearing loss in patients with hearing test scores equal to or less than 40%.	X		X						
3796.3	Effective for dates of service performed on and after April 4, 2005, Medicare contractors shall pay for cochlear implantation 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.	X		X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3796.4	Effective for dates of service performed on and after April 4, 2005, Medicare contractors shall pay for routine costs related to cochlear implantation and not the device itself for patients with hearing test scores not qualifying under this NCD, e.g., greater than 60% hearing, who are in a clinical trial meeting the criteria described in NCD manual section 310.1, which the provider will identify with a QV modifier.	X		X						
3796.5	Effective for dates of service performed on or after April 4, 2005, FIs shall instruct providers to 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.	X								
3796.6	Effective for dates of service performed on or after April 4, 2005, contractors shall pay for any covered diagnostic audiology or therapy services related to cochlear implantation. The QR or QV modifier does not need to be applied to these services (92601-92604 and 92506 and 92507).	X		X						
3796.7	Contractors already recognize and pay for the following HCPCS codes that can be used for billing various services related to cochlear implantation: 69930 L8614 L8619 L7500 L7510 92601 through 92604 92506 and 92507.	X		X	X					

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3796.8	Contractors may adjust claims back to April 4, 2005, if brought to their attention.	X		X	X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3796.9	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X					

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: April 4, 2005 **Implementation Date:** July 25, 2005 **Pre-Implementation Contact(s): F**rancina Spencer (coverage policy) 410-786-4614, Mel Page-Lasowski (Part B claims processing) 410-786-4727, Jason Kerr (Part A claims processing), 410-786-2123 **Post-Implementation Contact(s):** Regional office	**Medicare contractors shall implement these instructions within their current operating budgets.**

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

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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(Rev. 601, 07-01-05)

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100 - Billing Requirements for Expanded Coverage of Cochlear Implantation
(Rev. 601, Issued: 07/01/05; Effective: 04/04/05; Implementation: 07/25/05)

Effective for dates of services 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. (See Publication 100-3, chapter 1, section 50.3, for specific coverage criteria).

In addition 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 but only when the provider is participating in, and patients are enrolled in, either:

- *A Food and Drug Administration(FDA)-approved category B investigational device exemption (IDE) clinical trial; or*
- *A trial under the CMS clinical trial policy (see Pub. 100.3, section 310.1); or*
- *A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for national coverage analyses and meeting specific quality standards.*

100.1 – Intermediary Billing Procedures
(Rev. 601, Issued: 07/01/05; Effective: 04/04/05; Implementation: 07/25/05)

100.1.1 – Applicable Bill Types
(Rev. 601, Issued: 07/01/05; Effective: 04/04/05; Implementation: 07/25/05)

11X, 12X (see note below), 13X, 83X, 85X

Note: Surgical procedures are not acceptable on 12x bill types.

100.1.2 – Special Billing Requirements for Intermediaries
(Rev. 601, Issued: 07/01/05; Effective: 04/04/05; Implementation: 07/25/05)

For inpatient billing:

- *The second or subsequent diagnosis code must be V70.7 (examination of participant or control in clinical research). V70.7 alerts the claims processing system that this is a clinical trial.*

For inpatient Part B and outpatient bills:

- *For patients in an approved clinical trial with hearing test scores greater than 40% to less than or equal to 60% hearing, the QR modifier must be reported with the cochlear implantation device and all other related costs or; (see note below)*

- *For patients in an approved clinical trial under the clinical trial policy with hearing test scores greater than 60% hearing, the QV modifier must be billed for routine costs.*

NOTE: *The QR or QV modifier does not need to be applied to HCPCS 92601-92604 or any applicable audiology codes.*

100.2 – Intermediary Payment Requirements

(Rev. 601, Issued: 07/01/05; Effective: 04/04/05; Implementation: 07/25/05)

There are no special payment methods. Existing payment methods shall apply.

100.3 – Carrier Billing Procedures

(Rev. 601, Issued: 07/01/05; Effective: 04/04/05; Implementation: 07/25/05)

Effective for dates of service performed on and after April 4, 2005, the following applies:

Carriers shall accept claims for cochlear implantation devices and services for beneficiaries with moderate-to-profound hearing loss with hearing test scores equal to or less than 40%.

Carriers shall accept claims for cochlear implantation devices and all related costs for beneficiaries with hearing test scores of greater than 40% to less than or equal to 60% hearing provided in an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial policy, or a prospective, controlled comparative trial approved by CMS that is billed with the QR modifier. The definition of the QR modifier is, "Item or service provided in a Medicare specified study."

Carriers shall accept claims for routine costs pertaining to beneficiaries with hearing test scores of greater than 60% hearing who are in a clinical trial under the clinical trial policy that is billed with the QV modifier. The definition of the QV modifier is, "Item or service provided as routine care in a Medicare qualifying clinical trial."

Carriers shall accept claims for evaluation and therapeutic services related to cochlear implantation.

NOTE: *Modifiers QR or QV do not need to be applied to these services (92601– 92604 or any applicable audiology codes).*

These services should be billed on an approved electronic claim form or a paper CMS form 1500.

100.4 - Healthcare Common Procedural Coding System (HCPCS)
(Rev. 601, Issued: 07/01/05; Effective: 04/04/05; Implementation: 07/25/05)

The following HCPCS codes are some of those available for use when billing for cochlear implantation services and devices provided by audiologists or physicians, and for the services of 92506 and 92507, by speech language pathologists.

69930 – Cochlear device implantation, with or without mastoidectomy

L8614 – Cochlear Device/System

L8619 – Cochlear implant external speech processor, replacement

L7500 – Repair of prosthetic device, hourly rate (excludes V5335 repair of oral laryngeal prosthesis or artificial larynx)

L7510 – Repair of prosthetic device, repair or replace minor parts

92506 – Evaluation of speech, language, voice, communication, auditory processing, and/or aural rehabilitation status

92507 – Treatment of speech, language, voice, communication, and/or auditory processing disorder (includes aural rehabilitation); individual

92601 – Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming

(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.)

92602 – Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent programming. (Do not report 92602 in addition to 92601.)

92603 – Diagnostic analysis of cochlear implant, age 7 years or older; with programming

92604 – Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

A complete list of audiology codes can be found in Pub 100-4, chapter12, section 30.3.