CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11929	**Date: March 27, 2023**
	Change Request 13073

Transmittal 11875 issued February 23, 2023, is being rescinded and replaced by Transmittal 11929, dated, March 27, 2023, to correct the Pub.100-04 Claims Processing Manual Chapter 32, Section 105 diagnostic code reference. This correction does not make any revisions to the companion Pubs. 100-03; all revisions are associated with Pub. 100-04. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) 50.3 - Cochlear Implantation Manual Update

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update the manuals with revised eligibility criteria for the cochlear implantation NCD policy that is expanding beneficiary coverage for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification.

EFFECTIVE DATE: September 26, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 24, 2023

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: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/100/Table of Contents
R	32/100/Billing Requirements for Expanded Coverage of Cochlear Implantation
R	32/100/1/A/B MACs (Part A) Billing Procedures
R	32/100/1/2/Special Billing Requirements for A/B MACs (A) for Inpatient Billing
R	32/100/3/ A/B MACs (Part B) Billing Procedures
R	32/100/4/Healthcare Common Procedural Coding System (HCPCS)
N	32/100/5/Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 11929	Date: March 27, 2023	Change Request: 13073

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SUBJECT: National Coverage Determination (NCD) 50.3 - Cochlear Implantation Manual Update

EFFECTIVE DATE: September 26, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 24, 2023

I. GENERAL INFORMATION

A. Background: The prevalence of hearing loss increases with age, and approximately two thirds of people 70 years of age or older in the United States exhibit hearing loss. At least 1.2 million adults in the United States live with severe or profound hearing loss — a level of impairment that is not sufficiently corrected with hearing aids. However, there are a number of other devices that can aid in the improvement of hearing, in the appropriate individual. Among them are cochlear implants. Cochlear implants bypass nonfunctional or missing cochlear hair cells and directly stimulate the surviving cells of the distal cochlear nerve. There are various cochlear implants available commercially, but the concept of their componentry is similar. In general, the hardware of the implant system consists of both external and internal components. The external components consist of a microphone that detects environmental sound and a speech processor that converts it to electronically encoded signals. The encoded signal is transmitted to the internal receiver across the skin and soft tissues. The transmitted signal continues to the electrode arrays that sit within the cochlea and send electrical stimuli to the cochlear nerve fibers.

B. Policy: Effective September 26, 2022, CMS is expanding beneficiary coverage 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 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition. The policy also provides coverage of cochlear implants for beneficiaries not meeting the coverage criteria when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201, or as a routine cost in clinical trials under section 310.1 of the National Coverage Determination (NCD) Manual titled Routine Costs in Clinical Trials.

Note: As a result of the revised eligibility criteria for this NCD, CMS is replacing the current text of Section 50.3 of the NCD Manual, Publication (Pub.) 100-03, Chapter 1, Part 1, and Chapter 32, Section 100 of the Claims Processing Manual, Pub. 100-04.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13073 - 04.1	Contractors shall be in compliance with the updates to	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	CMS Internet Only Manual (IOM) Publication 100-03, Chapter 1 and Part 1, Section 50.3 and Publication 100-04, Chapter 32, Section 100.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13073 - 04.2	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): William Ruiz, William.Ruiz@cms.hhs.gov (Institutional Billing) , Wanda Belle, Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Kimberly Long, Kimberly.Long@cms.hhs.gov (Coverage and Analysis) , Lisa Davis, Lisa.Davis@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-

Simons, Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis) , Wendy Knarr, Wendy.Knarr@cms.hhs.gov (Supplier Billing)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

(Rev. 11929; Issued: 03-27-23)

100 – Billing Requirements for Expanded Coverage of Cochlear Implantation

(Rev. 11929; Issued; 03-27-23; Effective: 09-26-22; Implementation: 03-24-23)

Effective for dates of services on and after *September 26, 2022*, the Centers for Medicare & Medicaid Services (CMS) has expanded the coverage for cochlear implantation to cover *bilateral pre- or post-linguistic, sensorineural*, moderate-to-profound hearing loss in individuals with hearing test scores equal to or less than *60%* correct in the best aided listening condition on *recorded tests of* open-set sentence recognition and who demonstrate limited benefit from amplification. (See Publication 100-03, Chapter 1, Section 50.3, for *complete* coverage criteria).

In addition, CMS is covering cochlear *implants for beneficiaries not meeting the coverage criteria listed under Publication 100-03, Chapter 1, Section 50.3 when performed in context with:*

- A Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial *as defined at 42 CFR 405.201*; or

- *As a routine cost in a clinical* trial under the CMS clinical trial policy (see Pub. 100-03, section 310.1).

100.1 – *A/B MACs (Part A)* Billing Procedures

(Rev. 11929; Issued; 03-27-23; Effective: 09-26-22; Implementation: 03-24-23)

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

100.1.2 – Special Billing Requirements for A/B MACs (A) for Inpatient Billing

(Rev. 11929; Issued; 03-27-23; Effective: 09-26-22; Implementation: 03-24-23)

- The second or subsequent diagnosis code must be ICD-10-CM Z00.6 (Encounter for exam for normal comparison and control in clinical research program). These diagnoses alert the claims processing system that this is a clinical trial.

- For patients in an FDA-approved category B IDE clinical trial the *-Q0* 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 the *-Q1* modifier must be billed for routine costs *and not for the device itself*

NOTE: *The -Q0/-Q1 modifiers do not need to be applied to these services (92601-92604, 92507 & 92521-92524).*

100.3 – *A/B MACs (Part B)* Billing Procedures

(Rev. 11929; Issued; 03-27-23; Effective: 09-26-22; Implementation: 03-24-23)

Effective for dates of service performed on and after *September 26*, 2022, the following applies:

A/B MACs (Part B) shall accept claims for cochlear implantation devices and services for beneficiaries *meeting the coverage criteria listed under Publication 100-03, Chapter 1, section 50.3*.

A/B MACs (Part B) shall accept claims for cochlear implantation devices and all related costs for beneficiaries *not meeting the coverage criteria listed under Publication 100-03, Chapter 1, Section 50.3* provided in an FDA-approved category B IDE clinical trial *or* a trial under the CMS Clinical Trial policy, that is billed with the *-Q0* modifier. The definition of the *-Q0* modifier is, "Item or service provided in a Medicare specified study."

A/B MACs (Part B) shall accept claims for routine costs pertaining to beneficiaries *not meeting the coverage criteria listed under Publication 100-03, Chapter 1, Section 50.3* who are in a clinical trial under the clinical trial policy that is billed with the -*Q1* modifier. The definition of the -*Q1* modifier is, "*Routine clinical service provided in a clinical research study that is in an approved clinical research study*"

A/B MACs (Part B) shall accept claims for evaluation and therapeutic services related to cochlear implantation.

NOTE: *The -Q0/-Q1 modifier does not need to be applied to these services (92601-92604, 92507 & 92521-92524).*

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. 11929; Issued; 03-27-23; Effective: 09-26-22; Implementation: 03-24-23)

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 service of 92507, by speech language pathologists.

69930 – Cochlear device implantation, with or without mastoidectomy

L8614 – Cochlear Device *includes all internal and external components*

L8619 – Cochlear implant external speech processor *and controller, integrated system,* replacement

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

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

92521 – Evaluation of speech fluency (e.g. stuttering, cluttering)

92522 – Evaluation of speech sound production (e.g. articulation, phonological process, apraxia, dysarthria)

92523 – Evaluation of speech sound production (e.g. articulation, phonological process, apraxia, dysarthria) with evaluation of language comprehension and expression (e.g. receptive and expressive language).

92524 – Behavioral and qualitive analysis of voice and resonance

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.

100.5 - Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages

(Rev. 11929; Issued; 03-27-23; Effective: 09-26-22; Implementation: 03-24-23)

Contractors shall use the appropriate claim adjustment reason codes (CARCs), remittance advice remark codes (RARCs), group codes, or Medicare summary notice (MSN) messages when denying payment for cochlear implantation devices and services for beneficiaries with moderate-to-profound hearing loss in patients with hearing test scores ≤ 40% through 9/25/22; ≤ 60% effective 9/26/22.

Use the following messages when denying services on claims:

- *submitted on a TOB other than 11X, 12X (except surgical procedures), 13X or 85X (For Part A only); or*
- *submitted without the Q0/Q1; or*
- *submitted without diagnostic code Z00.6 or*
- *submitted without one of the CPT/HCPCs listed (92521-92524, 92507, 92601- 92604, L7510, L8614, L8619, 69930)*

CARC 50 - "These are non-covered services because this is not deemed a 'medical necessity' by the payer"

RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

MSN 15.20 = "The following policies were used when we made this decision:
NCD 50. 3"

Spanish translation: "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 50.3")

Contractors processing institutional claims shall use the following MSN message in addition to MSN 15.20:

MSN 15.19 - Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD.

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

Group Code: CO (Contractual Obligation) assigning financial liability to the provider

A/B MACs (Part A) shall deny for any covered dx audiology/therapy services related to cochlear implantation with the following messages:

Use the following messages when denying services on claims:

- *Submitted on a TOB other than 11X, 12X (except surgical procedures), 13X or 85X (Part A only), or*
- *submitted without diagnostic code Z00.6*
- *submitted without one of the CPT/HCPCs listed (92521-92524, 92507, 92601- 92604, L7510, L8614, L8619, 69930)*

CARC 50 - "These are non-covered services because this is not deemed a 'medical necessity' by the payer"

RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

MSN 15.20 = "The following policies were used when we made this decision:
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Spanish translation: "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 50.3")

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Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

Group Code: CO (Contractual Obligation) assigning financial liability to the provider

A/B/MACs (Part B) shall deny claims for evaluation and therapeutic services related to cochlear implantation. NOTE: Modifiers -Q0/-Q1 do not need to be applied to these services (92601– 92604, 92521-92524 or any applicable audiology codes).

Use the following messages when denying services on claims:

- *Submitted without one of the CPT/HCPCs listed (92521-92524, 92507, 92601- 92604).*

CARC 50 - "These are non-covered services because this is not deemed a 'medical necessity' by the payer"

RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

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