CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11875	**Date: February 23, 2023**
	Change Request 13073

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.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (CFR) section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

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	1/50/3/Cochlear Implantation

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

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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 - 03.1	Contractors shall be in compliance with the updates to CMS Internet Only Manual (IOM) Publication 100-03, Chapter 1 and Part 1, Section	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	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 - 03.2	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): 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) , William Ruiz, William.Ruiz@cms.hhs.gov (Institutional Billing) , 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: 1

50.3 - Cochlear Implantation

(Rev.11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

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

Effective for services performed on or after September 26, 2022, 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 *60*% correct in the best-aided listening condition on *recorded* tests of open-set sentence *re*cognition. *P*atients *must* meet all of the following *criteria*.

- 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.

C. Nationally Non-Covered Indications

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed *in Section B* are deemed not eligible for Medicare coverage *except as described in Section D below.*

D. Other

CMS may provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed in Section B 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 Determinations Manual titled Routine Costs in Clinical Trials.

(This NCD last reviewed September 2022)

NCD:	50.3
NCD Title:	Cochlear Implantation
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf#page=70
MCD:	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&bc=AgAAgAAAAAAA&

CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.

ICD-10 CM	ICD-10 DX Description
	****For FI only and only patients in a clinical trial. A second dx should also be reported.**
Z00.6**	Encounter for examination for normal comparison and control in clinical research program
	For all patients (in a clinical trial or not in a clinical trial)
H90.3	Sensorineural hearing loss, bilateral
H90.5	Unspecified sensorineural hearing loss
Z45.321	Examination for adjustment and management of cochlear device

NCD:	50.3
NCD Title:	Cochlear Implantation
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf#page=70
MCD:	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&bc=AgAAgAAAAAAA&

CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.

ICD-10 PCS	ICD-10 PCS Description
	Insertion Only
09HD05Z	Insertion of Single Channel Cochlear Prosthesis into Right Inner Ear, Open Approach
09HD06Z	Insertion of Multiple Channel Cochlear Prosthesis into Right Inner Ear, Open Approach
09HD35Z	Insertion of Single Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Approach
09HD36Z	Insertion of Multiple Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Approach
09HD45Z	Insertion of Single Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Endoscopic Approach
09HD46Z	Insertion of Multiple Channel Cochlear Prosthesis into Right Inner Ear, Percutaneous Endoscopic Approach
09HE05Z	Insertion of Single Channel Cochlear Prosthesis into Left Inner Ear, Open Approach
09HE06Z	Insertion of Multiple Channel Cochlear Prosthesis into Left Inner Ear, Open Approach
09HE35Z	Insertion of Single Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous Approach
09HE36Z	Insertion of Multiple Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous Approach
09HE45Z	Insertion of Single Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous Endoscopic Approach
09HE46Z	Insertion of Multiple Channel Cochlear Prosthesis into Left Inner Ear, Percutaneous Endoscopic Approach
	Other Related Cochlear Codes ***not all inclusive
F00Z19Z	Speech Threshold Assessment using Cochlear Implant Equipment
F00Z29Z	Speech/Word Recognition Assessment using Cochlear Implant Equipment
F00Z59Z	Synthetic Sentence Identification Assessment using Cochlear Implant Equipment
F0BZ01Z	Cochlear Implant Rehabilitation Treatment using Audiometer
F0BZ02Z	Cochlear Implant Rehabilitation Treatment using Sound Field / Booth
F0BZ09Z	Cochlear Implant Rehabilitation Treatment using Cochlear Implant Equipment
F0BZ0KZ	Cochlear Implant Rehabilitation Treatment using Audiovisual Equipment
F0BZ0PZ	Cochlear Implant Rehabilitation Treatment using Computer
F0BZ0YZ	Cochlear Implant Rehabilitation Treatment using Other Equipment
F13Z09Z	Hearing Screening Assessment using Cochlear Implant Equipment
F13ZP9Z	Aural Rehabilitation Status Assessment using Cochlear Implant Equipment
F14Z01Z	Cochlear Implant Assessment using Audiometer
F14Z02Z	Cochlear Implant Assessment using Sound Field / Booth
F14Z03Z	Cochlear Implant Assessment using Tympanometer
F14Z04Z	Cochlear Implant Assessment using Electroacoustic Immitance / Acoustic Reflex Equipment
F14Z05Z	Cochlear Implant Assessment using Hearing Aid Selection / Fitting / Test Equipment
F14Z07Z	Cochlear Implant Assessment using Electrophysiologic Equipment
F14Z09Z	Cochlear Implant Assessment using Cochlear Implant Equipment
F14Z0KZ	Cochlear Implant Assessment using Audiovisual Equipment
F14Z0LZ	Cochlear Implant Assessment using Assistive Listening Equipment
F14Z0PZ	Cochlear Implant Assessment using Computer
F14Z0YZ	Cochlear Implant Assessment using Other Equipment
F14Z0ZZ	Cochlear Implant Assessment

This dx code list/translation was approved by CMS/Coverage. It may or may not be a complete list of covered indications/dx codes for this NCD policy. As this policy indicates, individual A/B MACs within their jurisdictions have the discretion to cover additional indications/dx codes they deem reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

NCD:	50.3
NCD Title:	Cochlear Implantation (CR 3796, CR8197, CR8691, CR9087, CR9631, CR11905, CR13073)
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf#page=116
MCD:	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&bc=AgAAgAAAAAAA&

Part A	Rule Description Part A	Proposed HCPCS/CPT Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifier Part A	Provider Specialty	Proposed MSN Message Part A	Proposed CARC Message Part A	Proposed RARC Message Part A
Part A	All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered remain at local contractor discretion.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Part A	**A/MACs** shall accept claims 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; expanded to ≤ 60% effective 9/26/22. **A/MACs** shall pay claims with the TOBs noted for cochlear implantation services.	92521 92522 92523 92524 92507 92601 92602 92603 92604 L7510 L8614 L8619	N/A	11X 12X (except surgical procedures) 13X 85X	N/A	N/A	N/A	15.20	50	N386
Part A	**A/MACs** shall accept claims for cochlear implantation devices/services for beneficiaries with moderate-to-profound hearing loss in patients with hearing test scores ≤ 40% through 9/25/22; expanded to ≤ 60% effective 9/26/22. **A/MACs** shall pay claims with the TOBs noted for cochlear implantation services.	69930 **see ICD-10 procedures tab	N/A	11X 12X (except surgical procedures) 13X 85X	N/A	N/A	N/A	15.20	50	N386
Part A	**For IP Part B & OP bills**: • For patients in an approved clinical trial with hearing test scores > 40% to ≤ 60% hearing (end-dated 9/25/22), expanded to >60% (effective 9/25/22), the -Q0 modifier must be reported with the cochlear implantation device and all other related costs or; • For patients in an approved clinical trial under the clinical trial policy with hearing test scores > 60% hearing, the -Q1 modifier must be billed for routine costs and not the device itself. **A/MACs** shall pay claims with the TOBs noted for cochlear implantation services. (-QR/-QV modifiers expired 12/31/07; Replaced by-Q0/-Q1 respectively).	69930 L7510 L8614 L8619	N/A	11X 12X (except 69930) 13X 85X	N/A	-Q0 -Q1	N/A	15.20	50	N386

NCD:	50.3								
NCD Title:	Cochlear Implantation (CR 3796, CR8197, CR8691, CR9087, CR9631, CR11905, CR13073)								
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf#page=116								
MCD:	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&bc=AgAAgAAAAAAA&								
Part A	**For IP billing:** A/MACs shall instruct providers to report dx code Z00.6 (Examination of participant in clinical trial) along with the appropriate principal dx code for patients in a clinical trial. **A/MACs** shall pay claims with the TOBs noted for cochlear implantation services.	69930 92507 92601 92602 92603 92604 92521 92522 92523 92524 L7510 L8614 L8619		11X 12X (except surgical procedures) 13X 85X	N/A	N/A	N/A	15.20	50	N386
Part A	**A/MACs** shall pay for any covered dx audiology/therapy services related to cochlear implantation. **The -Q0/-Q1 modifier does not need to be applied to these services (92601-92604, 92507, 92521-92524 or any applicable audiology codes).** **A/MACs** shall pay claims with the TOBs noted for cochlear implantation services.	92601 92602 92603 92604 92507 92521 92522 92523 92524	N/A	11X 12X (except for surgical procedure) 13X 85X	N/A	N/A	N/A	15.20	50	N386

NCD:	50.3
NCD Title:	Cochlear Implantation (CR 3796, CR8197, CR8691, CR9087, CR9631, CR11905, CR13073)
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf#page=116
MCD:	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=245&ncdver=2&bc=AgAAgAAAAAAA&

Part B	Rule Description Part B	Proposed HCPCS/CPT Part B	Frequency Limitations	POS (Part B)	n/a	Modifier Part B	Provider Specialty	Proposed MSN Message Part B	Proposed CARC Message Part B	Proposed RARC Message Part B
										N386
Part B	All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered remain at local contractor discretion.	N/A	N/A	N/A	N/A	N/A	N/A	15.20	50	N386
Part B	**B/MACs** shall accept claims 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; expanded to ≤ 60% effective 9/26/22.	92521 92522 92523 92524 69930 92507 92601 92602 92603 92604 L7510 L8614 L8619	N/A	N/A	N/A	N/A	N/A	15.20	50	N386
Part B	**For IP Part B andOP bills**: • For patients in an approved clinical trial with hearing test scores > 40% to ≤ 60% hearing (end-dated 9/25/22), expanded to >60% (effective 9/25/22), the -Q0 modifier must be reported with the cochlear implantation device and all other related costs or; • For patients in an approved clinical trial under the clinical trial policy with hearing test scores > 60% hearing, the -Q1 modifier must be billed for routine costs and not the device itself. (-QR/-QV modifiers expired 12/31/07; Replaced by -Q0/-Q1 respectively).	69930 L7510 L8614 L8619	N/A	N/A	N/A	Q0 Q1	N/A	15.20	50	N386
Part B	**B/MACs** shall accept 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, 92507, 92521-92524 or any applicable audiology codes).**	92601 92602 92603 92604 92507 92521 92522 92523 92524	N/A	N/A	N/A	N/A	N/A	15.20	50	N386

Revision History Date	Revision History Explanation	Reason(s) for Change
	CR8691: Remove expired code L7500 (exp 12/31/11): Remove TOB 83X invalid 2/13. Removed expired items. Remove expired CPT 92506. Remove MSN, CARC and RARC combination codes leaving only those evident in related NCD documents. Expired CPT; Invalid CARC combinations	
	CR9631: MACs can override FISS RCs 59134, 59135 for CPT 92507, 92521, 92522, 92523, 92524 when it conflicts with speech language pathology LCD claims processing. MACs can also reactivate RC 59134, 59135 with the implementation of this CR.	
	CR11905: Add ICD-10 dx Z45.321 effective 1/1/2021.	
	CR13073: Effective 9/26/22, patient criteria expands to ≤ 60% hearing test scores outside of clinical trial. Instructions regarding exceptions for Modifer Q0/Q1 clarified and duplicate instructions removed.	

50.3 - Cochlear Implantation

(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

A. General

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B. Nationally Covered Indications

Effective for services performed on or after September 26, 2022, 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 *60*% correct in the best-aided listening condition on *recorded* tests of open-set sentence *re*cognition. *P*atients *must* meet all of the following *criteria.*

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
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(This NCD last reviewed September 2022)