

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13174	Date: April 17, 2025
	Change Request 14028

NOTE: This Transmittal is no longer sensitive and is being re-communicated August 27, 2025. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: Continuation of System Changes to Automate Processing of Inpatient Claims for Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapy Cases

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to continue system changes for the automation of inpatient claims processing for Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapy Cases. Upon implementation of this CR, the Fiscal Intermediary Shared System (FISS) Maintainer shall automate the application of payer-only condition code ZD to the claim for CAR-T cell and other immunotherapy cases mapping to Medicare Severity Diagnosis Related Group (MS-DRG) 018, where the product was not purchased in the usual manner. Condition code ZD is used to indicate to the Inpatient Prospective Payment System (IPPS) Pricer that the payment adjustment factor is to be applied to the case.

EFFECTIVE DATE: October 1, 2025

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

IMPLEMENTATION DATE: October 6, 2025

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
N/A	N/A

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:

One Time Notification

Attachment - One-Time Notification

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II. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) created MS-DRG 018 "Chimeric Antigen Receptor (CAR) T-Cell Immunotherapy" in Fiscal Year (FY) 2021 for cases that include procedures describing CAR-T cell therapies. Beginning FY 2022, the title was revised to "Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies". A DRG weight adjustment factor is applied to claims that group to MS-DRG 018 for clinical trial and expanded access use immunotherapy cases, where the immunotherapy product is not purchased in the usual manner.

CMS recently became aware that there are other instances in which the immunotherapy product is not purchased in the usual manner, such as provided at no cost. Beginning in FY 2026, in cases where the immunotherapy product is not purchased in the usual manner, such as provided at no cost, the payment adjustment will be applied.

To notify the Medicare Administrative Contractor (MAC) of a case where the immunotherapy product is not purchased in the usual manner, such as provided at no cost, the provider may enter billing note "PROD NO COST" on the electronic claim 837I or a remark "PROD NO COST" on a paper or Direct Data Entry (DDE) claim, and the Shared System Maintainer (SSM) shall populate condition code ZD so that the Inpatient Prospective Payment System (IPPS) Pricer will apply the payment adjustment in calculating the payment for the case.

B. Policy: These technical changes apply to existing policy as described in §412.85.

III. BUSINESS REQUIREMENTS TABLE

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

[illegible]

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared- System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	access use of immunotherapy case payment adjustment factor when determining the payment for the claim when condition code ZD is present.									
14028.5	The Medicare contractors shall emphasize the importance of submitting the billing note "PROD NO COST" verbatim on the claim, when developing provider education materials. The automation of the condition code ZD is dependent upon accurate billing note/claim remarks submission.	X								

IV. PROVIDER EDUCATION

CR as Provider Education: MACs shall use the content in the CR to develop relevant education material. Provide a link to the entire instruction in the education content. You can also supplement with local information that would help your provider community bill and administer the Medicare Program correctly. You don't need to separately track and report on this education.

Impacted Contractors: A/B MAC Part A

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

VI. CONTACTS

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

VII. FUNDING

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ATTACHMENTS: 1

Attachment A-NUBC Code Table

Record Type	Code	Effective Date	Termination date	Date Type Field	Payer Only Code	CWF	Narrative
C	ZD	10/01/2025		R	Y	Y	Product not purchased in usual manner- provided at no cost.