CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13043	**Date: January 10, 2025**
	Change Request 13926

SUBJECT: Fiscal Intermediary Shared System (FISS) Changes to Automate the Application of Condition Code ZC for Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapy Cases Involving a Clinical Trial of a Different Product

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to automate the application of payer-only condition code ZC 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 purchased in the usual manner, but the case involves the clinical trial of a different product. Condition code ZC is used to indicate to the Inpatient Prospective Payment System (IPPS) Pricer that the payment adjustment factor is not to be applied to the case.

This CR automates the process that was previously implemented as a Medicare Administrative Contractor (MAC) manual workaround under CR 11879. This CR also creates new edits to assign on claims mapping to MS-DRG 018, when submitted with clinical trial data or for Expanded Access (EA) approval, when charges in excess of $1.00 in revenue centers 0891 and/or 0892 are submitted on the claim.

EFFECTIVE DATE: October 1, 2020 - Effective for claims with discharge dates on or after October 1, 2020.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 7, 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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This CR automates the process that was previously implemented as a Medicare Administrative Contractor (MAC) manual workaround under CR 11879. This CR also creates new edits to assign on claims mapping to MS-DRG 018, when submitted with clinical trial data or for Expanded Access (EA) approval, when charges in excess of $1.00 in revenue centers 0891 and/or 0892 are submitted on the claim.

II. GENERAL INFORMATION

A. Background: MS-DRG 018 "Chimeric Antigen Receptor (CAR) T-Cell Immunotherapy" was created in Fiscal Year (FY) 2021 for cases that include procedures describing CAR-T cell therapies. In 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 CAR-T cell and other immunotherapy product is not purchased in the usual manner. However, when the CAR T-cell or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment is not applied in calculating the payment for the case. CR 11879 implemented a mechanism for providers to notify their MACs of such cases (International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM (diagnosis code Z00.6 on the claim). Providers may enter a Billing Note NTE02 “Diff Prod Clin Trial” on the electronic claim 837I or a remark “Diff Prod Clin Trial” on a Direct Data Entry (DDE) or paper claim, and MACs were instructed to add payer-only condition code ZC so that the Pricer will not apply the payment adjustment in calculating the payment for the case.

In clinical trial cases that group to MS-DRG 018 that do not include this billing note, revenue codes 0891 and 0892 would not be expected to contain line-item covered charges greater than a token charge of $1.00, since the provider does not purchase the product in the usual manner. Claims that contain revenue code 0891 or 0892 and line-item covered charges greater than a token charge of $1.00 may be missing the billing note indicating that the case involves a clinical trial of a different product, the line-item charges in revenue code 0891 or 0892 may be billed incorrectly, or the billing with the clinical trial coding may be in error.

The Centers for Medicare & Medicaid Services (CMS) was made aware of processing issues wherein the payment adjustment was not being applied consistently when the billing note was submitted on the claim. In order to ensure accurate program payments and streamline processing, this CR shall now automate the

process to apply the condition code in FISS. CMS was also made aware of cases where the billing note was not included on the claim and the claim contained revenue code 0891 with line-item covered charges greater than a token charge of $1.00.

B. Policy: No new 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.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13926.1	The Shared System Maintainer (SSM) shall populate payer-only condition code ZC to the claim when all of the following criteria are met: • Bill type is 11X, • Discharge date is on or after October 1, 2020, • The claim is mapped to MS-DRG 018, • ICD-10-CM Diagnosis Code Z00.6 is present, and • Billing Note NTE02 "Diff Prod Clin Trial" is present on the electronic claim 837I or a remark "Diff Prod Clin Trial" is present on a Direct Data Entry (DDE) or paper claim.					X				
13926.2	The Medicare Contractors shall no longer manually apply condition code ZC when billing note "Diff Prod Clin Trial" is present, upon the successful implementation of the automated FISS process. Contractors should continue to append the condition code as necessary, for additional claim development, appeals, reopens, or redeterminations.	X								
13926.2.1	The Medicare Contractors shall emphasize the importance of submitting the billing note "Diff Prod Clin Trial" verbatim on the claim, when developing provider education materials. The automation of the condition code ZC is dependent upon accurate billing note/claim remarks submission.	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13926.3	The Medicare Contractors shall adjust claims that were processed under the payment adjustment factor incorrectly when brought to their attention.	X								
13926.4	The SSM shall create a new claim level reason code to assign on inpatient clinical trial claims reporting CAR-T Cell or other Immunotherapy services with charges in revenue codes 0891 or 0892 as follows: • Bill type is 11X, • Discharge date is on or after October 1, 2020, • Revenue Code 0891 and/ or 0892 is present with line-item covered charges greater than a token charge of $1.00, • The claim is mapped to MS-DRG 018, • Condition Code ZC is *not* present, • ICD-10-CM Diagnosis Code Z00.6 is present, and • Billing Note NTE02 "Diff Prod Clin Trial" is *not* present on the electronic claim 837I or a remark "Diff Prod Clin Trial" is *not* present on a DDE or paper claim.					X				
13926.4.1	The SSM shall allow Medicare Contractors the functionality to override the new reason code.					X				
13926.4.2	The Medicare Contractors shall reject claims receiving the new reason code with instructions for providers to resubmit the claim by correcting one of the following: • Correction of charges in revenue code 0891 and/or 0892, OR • Submission of Billing Note NTE02/remark "Diff Prod Clin Trial", OR • Verification of and/or removal of clinical trial coding from the	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	claim.									
13926.4.2.1	The Medicare Contractors shall use the following provider remit messaging for the new reject reason code: • Group Code: **CO** (Contractual Obligation) • Claim Adjustment Reason Code (CARC): **16** "Claim/service lacks information or has submission/billing error(s)." • Remittance Advice Remark Code (RARC): **MA69** "Missing/incomplete/invalid remarks."	X								
13926.5	The SSM shall create a new claim level reason code to assign on inpatient claims reporting CAR-T Cell or other Immunotherapy services with charges in revenue codes 0891 or 0892 as follows: • Bill type is 11X, • Discharge date is on or after October 1, 2020, • Revenue Code 0891 and/or 0892 is present with line-item covered charges greater than a token charge of $1.00, • The claim is mapped to MS-DRG 018, • ICD-10-CM Diagnosis Code Z00.6 is *not* present, and • Condition Code 90 is present.					X				
13926.5.1	The SSM shall allow Medicare Contractors the functionality to override the new reason code.					X				
13926.5.2	The Medicare Contractors shall Return-To-Provider (RTP) claims receiving the new reason code with instructions for providers to resubmit the claim by correcting one of the following:	X								

	• Correction of charges in revenue codes 0891 and/or 0892, OR • Removal of condition code 90.									

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:

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

Section A: For Medicare Administrative Contractors (MACs):
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