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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-20 One-Time Notification | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 12881 | Date: October 10, 2024 |
| | Change Request 13667 |

Transmittal 12698 issued June 27, 2024, is being rescinded and replaced by Transmittal 12881, dated October 10, 2024, to revise the Summary of Changes section of the CR has been updated to encompass the reporting on the subscribed Line 55.03 as well as some updates to the Background section. Additionally, business requirement (BR) 13367.1 now includes additional language, and BRs 13667.4 and 13667.5 were added to the CR. All other information remains the same.

NOTE: This Transmittal is no longer sensitive and is being re-communicated. This instruction may now be posted to the Internet.

SUBJECT: Tax Equity and Fiscal Responsibility Act (TEFRA) Reimbursement to Inpatient Prospective Payment System (IPPS) -Excluded Hospitals for Excess Costs Related to Providing CAR T-cell Therapy

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform the MACs, when CAR T-cell therapy provided to Medicare patients, in an inpatient setting, results in a TEFRA hospital's costs exceeding its rate-of-increase ceiling, MACs and providers must not utilize cost report Worksheet E-3 Part I, Line 17 or its subscripts to report CAR T-cell therapy costs. Instead, for cost reporting periods beginning before October 1, 2022, the costs, charges, and statistics for CAR T-cell therapy should be separately reported on the cost report using a subscript of Line 73 (Drugs Charged to Patients). Any amounts equal to interim payments received by the provider related to CAR T-cell therapy must be reported on the added subscribed Line 55.03, (CAR T-cell amount paid as an interim payment) on Worksheet D-1, Part II

EFFECTIVE DATE: July 29, 2024

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

IMPLEMENTATION DATE: July 29, 2024

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 purpose of this Change Request (CR) is to inform the MACS that Certain hospitals excluded from a prospective payment system, including 11 IPPS-excluded cancer hospitals, receive payment for inpatient hospital services they furnish to Medicare patients on the basis of reasonable costs, subject to a rate-of-increase ceiling under the TEFRA payment system. A per discharge limit, as defined under the TEFRA provisions in § 413.40(a) of the regulations, is set for each hospital based on the hospital's own cost experience in its base year and updated annually by a rate-of-increase percentage. When a hospital incurs inpatient operating costs in a cost reporting period that exceed the ceiling and those excess costs are reasonable, justified, and directly related to patient care services, the hospital may request an adjustment to the payment allowed under the rate-of-increase ceiling.

Chimeric Antigen Receptor T-cell therapy (CAR T-cell therapy) is a relatively newly developed immunotherapy treatment for certain types of cancers. Any excess costs related to providing CAR T-cell therapy may be the basis for an adjustment to a hospital's TEFRA rate-of-increase ceiling (target amount). In May of 2019 MACs were instructed to reach out to TEFRA hospitals to remind each hospital that it may request an adjustment to its interim payment rate in advance of making a request for an adjustment to its TEFRA ceiling (which may require adjustment to the hospital's periodic interim payments). Effective for cost reporting periods beginning on or after October 1, 2022, CAR T-cell therapy cost has a dedicated line on the Medicare cost report (Line 78, CAR T-Cell Immunotherapy), and is included in ancillary costs on Worksheet D-1, Part II, line 48 for comparison to the TEFRA ceiling. CAR T-cell is not a pass-through

cost; however, we have been made aware that certain TEFRA hospitals and MACs have been treating CAR T-cell therapy costs as a pass-through cost by reporting it on Worksheet E-3, Part I, Line 17 and its subscripts, as an “other adjustment.”

When CAR T-cell therapy provided to Medicare patients, in an inpatient setting, results in a TEFRA hospital’s costs exceeding its rate-of-increase ceiling, MACs and providers must not utilize cost report Worksheet E-3 Part I, Line 17 or its subscripts to report CAR T-cell therapy costs. Instead, for cost reporting periods beginning before October 1, 2022, the costs, charges, and statistics for CAR T-cell therapy should be separately reported on the cost report using a subscript of Line 73 (Drugs Charged to Patients), and if applicable, any amounts equal to interim payments received by the provider related to CAR T-cell therapy must be reported on the added subscripted Line 55.03 (CAR T-cell amount paid as an interim payment) on Worksheet D-1, Part II.

For cost reporting periods beginning on or after October 1, 2022, the costs, charges, and statistics for CAR T-cell therapy should be reported on Line 78, CAR T-Cell Immunotherapy and subscripted line 73, Drugs Charged to Patients should no longer be used, and if applicable, any amounts equal to interim payments received by the provider related to CAR T-cell therapy must be reported on the added subscripted Line 55.03 (CAR T-cell amount paid as an interim payment) on Worksheet D-1, Part II.

T-20 instructions for cost report line 78:

Line 78 (CAR T-Cell Immunotherapy) --Effective for cost reporting periods beginning on or after October 1, 2022, enter the hospital costs for procuring, storing, and processing chimeric antigen receptor T-cells (CAR T-cell) for immunotherapy infusion (FDA-approved CAR T-cell immunotherapies only). This includes the cost of the CAR T-cell manufactured biologic (i.e., the cost paid to the manufacturer). Do not include costs for CAR T-cell immunotherapy transplants or the medication cost of the non-CAR T-cell drugs used for CAR T-cell immunotherapy complications, e.g., cytokine release syndrome, on this line.

All open or reopenable Cancer hospital cost reports with a TEFRA adjustment request for costs related to CAR T-cell therapy treatment, for cost reporting periods beginning before October 1, 2022, must report those CAR T-cell therapy costs by subscribing Line 73 (Drugs Charged to Patients). Additionally, MACs must ensure adjustment amounts are not included on Worksheet E-3, Part I, lines 17 and its subscripts. All CAR-T cell therapy adjustment amounts that were included on Worksheet E-3, part I, line 17 and subscripts must be removed in order for the adjustment amount to be determined (if applicable). Any amounts equal to interim payments received by the provider related to CAR T-cell therapy must be reported on the added subscripted Line 55.03, (CAR T-cell amount paid as an interim payment) on Worksheet D-1, Part II. MACs must also accept amended cost reports for this purpose.

B. Policy: TEFRA payment policy is codified in the regulations at 42 CFR 413.40.

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 | |
| 13667.1 | MACs shall contact each IPPS-excluded cancer hospital to specify: <ul style="list-style-type: none"> CAR T-cell therapy costs cannot be reported on Worksheet | X | | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---------|--|----------------|---|-----|------------|---------------------------|-----|-----|-----|-------|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| | subscripts, associated with CAR T-cell therapy on any open or reopenable cost reports. | | | | | | | | | |
| 13667.3 | For all submitted (open or reopenable) IPPS-excluded hospitals' cost reports beginning before October 1, 2022 with a TEFRA adjustment request for the costs related to CAR T-cell therapy treatment, MACs shall make an adjustment to the reporting of costs, charges, and statistics for CAR T-cell therapy on the cost report Line 73, Drugs Charged to Patients, as a subscribed line throughout the cost report (following the same instructions as line 78 for cost reports beginning on or after October 1, 2022). | X | | | | | | | | |
| 13667.4 | MACs shall ensure any CAR T-cell amounts equal to interim payments received by the provider related to CAR T-cell therapy are reported on the added subscribed Line 55.03, (CAR T-cell amount paid as an interim payment) on Worksheet D-1, Part II. | X | | | | | | | | |
| 13667.5 | Once a final determination is made on the TEFRA adjustment(s) the MAC shall remove any amount reported on worksheet D-1, Part II, Line 55.03 and any approved adjustment shall be included in the TEFRA adjustment(s) reported on worksheet D-1, Part II, Line 55.02 or Line 55.01. | X | | | | | | | | |

IV. PROVIDER EDUCATION

None

Impacted Contractors: None

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

Pre-Implementation Contact(s): Ayub ibrahim, 410-786-5596 or ayub.ibrahim@cms.hhs.gov

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

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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ATTACHMENTS: 0