CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2392	**Date: November 8, 2019**
	Change Request 11514

SUBJECT: Refinement of the Transitional Drug Add-on Payment Adjustment (TDAPA)

I. SUMMARY OF CHANGES: This CR expands the list of new renal dialysis drugs and biological products that are eligible for TDAPA and creates a new recurring process.

EFFECTIVE DATE: April 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 6, 2020

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	

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

Pub. 100-20	Transmittal: 2392	Date: November 8, 2019	Change Request: 11514

SUBJECT: Refinement of the Transitional Drug Add-on Payment Adjustment (TDAPA)

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I. GENERAL INFORMATION

A. Background: Under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) drug designation process, the Centers for Medicare & Medicaid Services (CMS) provides payment using a Transitional Drug Add-on Payment Adjustment (TDAPA) for new renal dialysis drugs and biological products that qualify under 42 Code of Federal Regulations (CFR) 413.234. Change Request (CR) 10065, Transmittal 1999, entitled "Implementation of the Transitional Drug Add-On Payment Adjustment" implemented TDAPA for calcimimetics. Information regarding TDAPA can be located on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html.

B. Policy: Effective January 1, 2020, CMS will no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of Average Sales Price (ASP) data within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for that product. That is, CMS will no longer apply the TDAPA for a new renal dialysis drug or biological product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. For example, if CMS begins applying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data for that product has not been made available to CMS by October 30, 2021 (30 days after the last day of the 3rd quarter of paying the TDAPA), CMS would stop applying the TDAPA for that product no later than March 31, 2022 (2 quarters after the 3rd quarter of paying the TDAPA).

In addition, CMS will no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS stops receiving the latest full calendar quarter of ASP data for the product during the applicable time period specified in 42 CFR 413.234(c)(1) or (c)(2), beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available. For example, if CMS begins applying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after the close of the 3rd quarter of applying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of applying the TDAPA), we would stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of applying the TDAPA).

There is no change in the mechanics of how the TDAPA is applied. ESRD facilities should continue to report the AX modifier (item furnished in conjunction with dialysis services) with the Healthcare Common Procedure Coding System (HCPCS) for new renal dialysis drugs and biological products eligible to receive payment using the TDAPA with revenue code 0636. New renal dialysis drugs or biological products eligible for the TDAPA do not qualify toward outlier calculation.

We note that calcimimetics are currently the only drug class that qualifies for payment using the TDAPA and ESRD facilities should not use the AX modifier for any other drug until notified by CMS.

TDAPA is not applicable to the per treatment payment amount that is paid to ESRD facilities for furnishing dialysis to individuals with Acute Kidney Injury (AKI).

II. 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	
11514.1	FISS shall create documentation to perform the following tasks for new recurring CR R87Q. • Modify reason codes to add new renal dialysis drugs or biological products eligible for the TDAPA. • Add all TDAPA new renal dialysis drugs or biological products HCPCS codes to the process for calculating the Line Level TDAPA amount for populating the value code Q8. • Ensure all TDAPA new renal dialysis drugs or biological products listed in the CR do not apply towards outlier, value code 79. • Ensure TDAPA new renal dialysis drugs or biological products are added to the process to not make separate payments for service lines reported with Revenue Code 0636, modifier AX with or without modifier AY on ESRD claims (72X TOB). The following line level ANSI information shall be used: Group code: CO Contractual Adjustment Amount; Claim Adjustment Reason Code: CARC 97 - The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. **NOTE:** All of the above tasks to update the list of new renal dialysis drugs or biological products eligible for the TDAPA shall be effective based on the future CR's effective date using the claims from date.					X				
11514.2	FISS shall estimate the recurring hours and post them in the estimates attachment section of eChimp by 1/31/2020.					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	CR10065 and CR10281

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

V. CONTACTS

Pre-Implementation Contact(s): Tracey Mackey, 410-786-5736 or Tracey.Mackey@cms.hhs.gov , Wendy Tucker, 410-786-3004 or Wendy.Tucker@cms.hhs.gov

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