CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1999	**Date: January 10, 2018**
	Change Request 10065

Transmittal 1889, dated August 4, 2017, is being rescinded and replaced by Transmittal 1999 dated, January 10, 2018 to provide more descriptive examples in the policy section for Parsabiv and Sensipar. All other information remains the same.

SUBJECT: Implementation of the Transitional Drug Add-On Payment Adjustment

I. SUMMARY OF CHANGES: This Change Request (CR) implements the Transitional Drug Add-on Payment Adjustment.

EFFECTIVE DATE: January 1, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2018

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

Pub. 100-20	Transmittal: 1999	Date: January 10, 2018	Change Request: 10065

Transmittal 1889, dated August 4, 2017, is being rescinded and replaced by Transmittal 1999 dated, January 10, 2018 to provide more descriptive examples in the policy section for Parsabiv and Sensipar. All other information remains the same.

SUBJECT: Implementation of the Transitional Drug Add-On Payment Adjustment

EFFECTIVE DATE: January 1, 2018
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IMPLEMENTATION DATE: January 2, 2018

I. GENERAL INFORMATION

A. Background: In accordance with section 217(c) of the Protecting Access to Medicare Act, the Centers for Medicare & Medicaid Services (CMS) implemented a drug designation process for: (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the End Stage Renal Disease Prospective Payment System (ESRD PPS). Under the drug designation process, CMS provides payment using a Transitional Drug Add-on Payment Adjustment (TDAPA) for new injectable or intravenous drugs and biologicals that qualify under 42 CFR 413.234(c)(1).

To be considered a new injectable or intravenous product, the drug should be approved by the Food and Drug Administration, commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service.

The CMS considers the new injectable or intravenous drug to be included in the ESRD PPS bundled payment (with no separate payment available) if used to treat or manage a condition for which there is an ESRD PPS functional category. CMS will pay for the drug or biological using a transitional drug add-on payment adjustment, if the new injectable or intravenous drug or biological is used to treat or manage a condition for which there is not an existing ESRD PPS functional category. CMS bases the TDAPA on payment methodologies under section 1847A of the Social Security Act which are discussed in Pub. 100-04, Chapter 17, Section 20. This payment is applicable for a period of 2 years. While the TDAPA applies to a new injectable or intravenous drug or biological, the drug or biological is not considered an outlier service.

The ESRD PPS includes consolidated billing (CB) requirements for limited Part B services included in the ESRD facility's bundled payment. CMS periodically updates the lists of items and services that are subject to Part B consolidated billing and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

B. Policy: Transitional Drug Add-On Payment Adjustment

Effective January 1, 2018, injectable, intravenous, and oral calcimimetics qualify for the TDAPA. ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS for these drugs and biologicals to receive payment for these drugs using the TDAPA. While these drugs are eligible for the TDAPA, they do not qualify toward outlier calculation. We note that calcimimetics are 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.

J0604 Cinacalcet, oral, 1 mg, (for ESRD on dialysis)

J0606 Injection, etelcalcetide, 0.1 mg

J0604 and J0606 are drugs that are used for bone and mineral metabolism. Bone and mineral metabolism is an ESRD PPS functional category where drugs and biologicals that fall in this category are always considered to be used for the treatment of ESRD. ESRD facilities will not receive separate payment for J0604 and J0606 with or without the AY modifier and the claims shall process the line item as covered with no separate payment under the ESRD PPS. The ESRD PPS CB requirements will be updated to include J0604 and J0606. This CR also implements the payer only value code Q8 – Total TDAPA Amount, to be used to capture the add-on payment.

Example Calculation:

Pricer puts a payment at the dialysis line so that it is a per treatment payment. There is a calculation that happens in pricer to divide Q8 by the total number of dialysis treatments and then that per treatment amount is added to each dialysis line.

Parsabiv Example:

Patient is prescribed 5mg 3 times per week with a payment limit of $3.50 per 0.1 mg.

1/1/2018 HCPCS J0606, 50 units

1/1/2018 REV 821

1/3/2018 HCPCS J0606, 50 units

1/3/2018 REV 821

1/5/2018 HCPCS J0606, 50 units

1/5/2018 REV 821

1/8/2018 HCPCS J0606, 50 units

1/8/2018 REV 821

1/10/2018 HCPCS J0606, 50 units

1/10/2018 REV 821

1/12/2018 HCPCS J0606, 50 units

1/12/2018 REV 821

1/15/2018 HCPCS J0606, 50 units

1/15/2018 REV 821

1/17/2018 HCPCS J0606, 50 units

1/17/2018 REV 821

1/19/2018 HCPCS J0606, 50 units

1/19/2018 REV 821

1/22/2018 HCPCS J0606, 50 units

1/22/2018 REV 821

1/24/2018 HCPCS J0606, 50 units

1/24/2018 REV 821

1/26/2018 HCPCS J0606, 50 units

1/26/2018 REV 821

1/29/2018 HCPCS J0606, 50 units

1/29/2018 REV 821

1/31/2018 HCPCS J0606, 50 units

1/31/2018 REV 821

Q8 is assigned $2450 ((50 * 3.50) * 14 = $2450)

Number of dialysis treatments for month = 14

Adjusted ESRD PPS base rate = $250.00

QIP reduction = 0.985

Cost of TDAPA drug/ number of dialysis treatments for the month = TDAPA payment per treatment

$2450/ 14 = $175

Final Payment Rate = (Adjusted ESRD PPS base rate + TDAPA payment per treatment) * QIP reduction

$418.63 = ($250.00 + $175) * 0.985

$418.63 = $425 * 0.985

The final per treatment payment rate is $418.63

Sensipar Example:

Patient is prescribed 1-30mg tablet per day on January 10, 2018 with a payment limit of $1.00 per 1 mg.

1/1/2018 REV 821

1/3/2018 REV 821

1/5/2018 REV 821

1/8/2018 REV 821

1/10/2018 HCPCS J0604, 660 units

1/10/2018 REV 821

1/12/2018 REV 821

1/15/2018 REV 821

1/17/2018 REV 821

1/19/2018 REV 821

1/22/2018 REV 821

1/24/2018 REV 821

1/26/2018 REV 821

1/29/2018 REV 821

1/31/2018 REV 821

Q8 is assigned $660 ((660*1) = $660)

Number of dialysis treatments for month = 14

Adjusted ESRD PPS base rate = $250.00

QIP reduction = 0.985

Cost of TDAPA drug/ number of dialysis treatments for the month = TDAPA payment per treatment

$660/ 14 = $47.14

Final Payment Rate = (Adjusted ESRD PPS base rate + TDAPA payment per treatment) * QIP reduction

$292.68 = ($250.00 + $47.14) * 0.985

$292.68 = $297.14 * 0.985

The final per treatment payment rate is $292.68

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	
10065.1	Medicare contractors shall return to provider (RTP) ESRD claims type of bill (TOB) 72X when	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• HCPCS code J0604 (Cinacalcet, oral, 1 mg, (for ESRD on dialysis)) or J0606 (Injection, etelcalcetide, 0.1 mg) is not present; and • Modifier AX is present. Or • HCPCS code J0604 or J0606 is present; and Modifier AX is not present. NOTE: This does not apply to charges that are submitted as non-covered.									
10065.2	Medicare contractors shall use the rate from the Quarterly HCPCS File for HCPCS code J0604 and J0606. The rate should be multiplied by the units to calculate the TDAPA amount for each line when an ESRD claim, TOB 72x is billed with the following: • Revenue code 0636; • HCPCS code J0604 or J0606 and; • Modifier AX. NOTE: Pay the fee amount regardless of the charges.					X				
10065.3	Medicare contractors shall a create reason code to RTP ESRD claims, TOB 72X when HCPCS codes J0604 or J0606 is billed with modifier AX and the revenue code is not equal to 0636.					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10065.3.1	Medicare contractors shall capture the total TDAPA in payer only value code Q8 for each service line reported on an ESRD claim, TOB 72X with: • Revenue code 0636; • HCPCS code J0604 or J0606 and; • Modifier AX Note: This should not be included in the outlier payment, value code 79.					X				
10065.4	Medicare contractors shall recognize Q8 as a valid payer only value code. Note: Value code Q8 shall not be passed to BCRC.					X				
10065.5	Medicare contractors shall use reason code 10405 when a provider submits a 72x claim with the payer only value code Q8.					X				
10065.5.1	Medicare contractors shall return the claim to the provider.	X								
10065.6	Medicare contractors shall not make separate payment on ESRD claims, TOB 72X for service lines with: • Revenue code 0636; • HCPCS code J0604 or J0606 and; • Modifier AX NOTE: Separate payment is not made for these services when billed with modifier AY. Medicare contractors shall ensure that lines billed as covered will remain covered services even though					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	separate payment is not made.									
10065.6.1	Medicare contractors shall use the following ANSI information for the line: Group code: CO (Contractual Obligation) CARC 97: The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. This change is effective September 1, 2017: 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.					X				
10065.7	Medicare contractors shall pass the total TDAPA to the ESRD Pricer in payer-only value code Q8.					X				ESRD Pricer, PS&R
10065.8	ESRD Pricer shall accept payer only value code Q8 for the TDAPA. Layout and Variable Name: B-PAYER-ONLY-VC-Q89(07)V9(04)									ESRD Pricer
10065.9	ESRD Pricer shall calculate the TDAPA and include it with final payment.									ESRD Pricer
10065.10	Medicare contractors shall accept the new TDAPA from the ESRD PRICER.					X				ESRD Pricer

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10065.10.1	The Medicare contractor shall create a line level field to house the new TDAPA from the ESRD Pricer.					X				
10065.10.2	The Medicare contractor shall pass the new field to CWF, IDR and PS&R.					X			X	IDR, PS&R
10065.10.3	CWF shall accept the new field from FISS.								X	
10065.10.4	CWF shall ensure that the new field is passed to the downstream systems.								X	FPS, NCH

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10065.11	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	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): Shauntari Cheely, shauntari.cheely@cms.hhs.gov , Janae James, 410-786-0801 or janae.james@cms.hhs.gov , Michelle Cruse, 410-786-7540 or michelle.cruse@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 0