CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11166	Date: December 21, 2021
	Change Request 12347

Transmittal 10933, dated August 11, 2021, is being rescinded and replaced by Transmittal 11166, dated, December 17, 2021 to provide clarifying language to the policy section that Capital Related Assets (CRA) reported on the claim cannot exceed the number of treatments billed. Business requirement 12347.5.2 is updated to require claims reporting more CRA than treatments be returned to the provider. All other information remains the same.

SUBJECT: Implementation of the Capital Related Assets Adjustment (CRA) for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End Stage Renal Disease Prospective Payment System (ESRD PPS)

I. SUMMARY OF CHANGES: This Change Request will create the system changes necessary to implement the ESRD PPS add-on payment Capital Related Assets Adjustment (CRA) for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). In addition to implementing the CRA for TPNIES, value code QH— Total TPNIES CRA Amount is to be used to capture the add-on payment.

EFFECTIVE DATE: January 1, 2022

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

IMPLEMENTATION DATE: January 3, 2022

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: 11166 Date: December 21, 2021 Change Request: 12347

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I. GENERAL INFORMATION

A. Background: Effective January 1, 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) based on the requirements of section 1881(b)(14) of the Social Security Act (the Act). The ESRD PPS provides a single per treatment payment to ESRD facilities that covers all of the resources used in furnishing an outpatient dialysis treatment.

To support the uptake of new and innovative renal dialysis equipment and supplies, effective January 1, 2020, the ESRD PPS provides the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for these new and innovative renal dialysis equipment and supplies that qualify under § 413.236. Although CMS began the process of reviewing applications for supplies and equipment to determine eligibility for TPNIES in CY 2021, both applications received for CY 2021 payment were determined ineligible for TPNIES payment.

Beginning January 1, 2021, the TPNIES policy was expanded to include certain capital-related assets (CRA) that are home dialysis machines when used in the home for a single patient.

For eligible CRAs that are home dialysis machines, ESRD facilities will be paid the CRA for TPNIES beginning January 1, 2022.

The CRA for TPNIES is based on 65 percent of the Medicare Administrative Contractor (MAC) determined price. The MACs, on behalf of CMS, establish prices for new and innovative renal dialysis equipment and supplies, including certain CRA that are home dialysis machines, that meet the TPNIES eligibility criteria using verifiable information from the following sources, if available: (1) the invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

The CRA for TPNIES is paid for 2 calendar years, beginning on January 1 and ending on December 31. Following payment of the CRA for TPNIES, the ESRD PPS base rate will not be modified and the new CRA that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

B. Policy: CRA for TPNIES

For CRAs that are home dialysis machines used in the home for a single patient, the MACs will calculate the annual allowance and the pre-adjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate. The CY 2022 average per treatment TPNIES for CRA offset amount is subject to rulemaking.

ESRD facilities will report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for the CRA that is eligible to receive CRA for TPNIES. When a HCPCS code on the TPNIES CRA list is reported with the AX modifier and one of the following revenue codes, the CRA for TPNIES instructions will apply:

- 0823, Hemodialysis Home Equipment
- 0833, Peritoneal Home Equipment
- 0843, Continuous Ambulatory Peritoneal Dialysis (CAPD) Home Equipment
- 0853, Continuous Cycling Peritoneal Dialysis (CCPD) Home Equipment
- 0889, Other Miscellaneous Dialysis (to be used for ultrafiltration home equipment).

This CR also implements the CRA for TPNIES value code QH— Total TPNIES CRA Amount, to be used to capture the add-on payment.

The CRA for TPNIES offset amount applies to maintenance dialysis treatments within the three times per week limit. The number of dialysis treatments for the month used in the CRA for TPNIES calculation, is limited to the 13 to 14 allowable monthly treatments that are deemed medically necessary. Dialysis treatments exceeding 13 to 14 per month (3 treatments per week) that are determined reasonable and necessary by the Medicare contractors are payable; however, treatments that exceed 13 to 14 per month shall not be considered for separate pricing for CRA for TPNIES. Providers should not bill separate line items for CRA for TPNIES in excess of 13 to 14 treatments per month. Regardless of the number of treatments given per month, the adjusted CRA TPNIES per treatment amount will equal the adjusted CRA TPNIES Per Treatment amount that is calculated for 13 treatments per month. MACs shall not allow CRA for TPNIES in excess of 156 treatments per calendar year.

Pricer puts a payment at the dialysis line so that it is a per treatment payment. Therefore, pricer will perform a calculation to divide 65 percent of QH by the total number of dialysis treatments and then that per treatment amount is added to each dialysis line.

CRA for TPNIES 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).

Example Calculation (amounts listed are for illustrative purposes only):

Annual Allowance

A CRA priced at 40,000 amortized over 5 years = 8,000/year

Pre-adjusted CRA TPNIES Per Treatment Amount

8,000/year/156 treatments per year = 51.28 per treatment

QH is assigned \$51.28 ((1 * \$51.28) * 13 = \$666.64)

Number of dialysis treatments for month = 13

Adjusted ESRD PPS base rate = \$250.00

QIP reduction = 0.985

(65 percent of the MAC-determined CRA for TPNIES amount)/ number of dialysis treatments for the month = pre-adjusted CRA for TPNIES per treatment amount

$$33.33 = (.65 * 666.64)/13$$

\$33.33 = 433.32/13

Adjusted CRA TPNIES Per Treatment Amount

\$24.33 = (\$33.33 – \$9.00) [NOTE: Regardless of the number of treatments given per month, the adjusted CRA TPNIES per treatment amount will equal the adjusted CRA TPNIES Per Treatment amount that is calculated for 13 treatments per month.]

Final Per Treatment Payment Amount

(Adjusted ESRD PPS base rate + adjusted CRA TPNIES per treatment amount) * QIP reduction

$$270.22 = (250.00 + 24.33) * 0.985$$

\$270.22 = 274.33 * 0.985

The final per treatment payment amount is \$270.22.

The ESRD facility would report the approved CRA for TPNIES on the claim with its assigned HCPCS code that will be on the TPNIES CRA list.

1/1/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/1/2022 REV 821

1/3/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/3/2022 REV 821

1/5/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/5/2022 REV 821

1/8/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/8/2022 REV 821

1/10/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/10/2022 REV 821

1/12/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/12/2022 REV 821

1/15/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/15/2022 REV 821

1/17/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/17/2022 REV 821

1/19/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/19/2022 REV 821

1/22/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/22/2022 REV 821

1/24/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/24/2022 REV 821

1/26/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/26/2022 REV 821

1/29/2022 REV 823, HCPCS for CRA TPNIES, AX, 1 unit

1/29/2022 REV 821

Additional instructions for ESRD facilities and contractors regarding the TPNIES CRA policy, manual pricing, and the per treatment offset amount will be provided in the ESRD PPS January 2022 recurring update notice (RUN) and subsequent quarterly updates.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility									
		A	/B I	MAC	DME	Share	d-Syste	m Main	tainers	Other	
		A	В	ННН		FISS	MCS	VMS	CWF		
					MAC						
12347.1	Medicare shared systems shall remove the logic for reason code 36226 that requires the AX modifier for lines with HCPCS that qualify for Transitional Drug Addon Payment Adjustment (TDAPA).					X					
12347.1.1	If the AX modifier is not present on a line item with a HCPCS that is eligible for TDAPA, TPNIES or CRA TPNIES Medicare shared systems shall process the					X					

Number	Requirement	Responsibility								
				MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	line item as bundled service without the addon.									
12347.2	Medicare contractors shall allow the AX modifier to be reported on the type of bill (TOB) 072X for CRA TPNIES HCPCS. Note: CRA TPNIES	X				X				
	HCPCS approved for this transitional add-on will be provided in the ESRD PPS January Recurring Update (RUN), and subsequent quarterly updates.									
12347.3	Medicare contractors shall accept the following revenue codes for reporting CRA TPNIES HCPCS on type of bill 072X: 0823 – Hemodialysis Home Equipment 0833 – Peritoneal Home Equipment 0843 – Continuous	X				X				
	Ambulatory Peritoneal Dialysis (CAPD) Home Equipment 0853 – Continuous Cycling Peritoneal Dialysis (CCPD) Home Equipment 0889 - Other Miscellaneous Dialysis (to be used for ultrafiltration home equipment).									

Number	Requirement	Re								
		A	/B I	MAC	DME		tainers	Other		
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
12347.4	Medicare contractors shall create an overridable reason code if the units reported on a TPNIES or a CRA TPNIES line exceed 1.					X				
12347.4.1	Medicare contractors shall return to the provider (RTP) claims billing for TPNIES or a CRA TPNIES when units on the line exceed 1.	X								
12347.5	Medicare contractors shall create a new or update an existing overridable reason code to allow for contractor pricing when TOB 072X reporting a CRA TPNIES HCPCS billed with the AX modifier and any one of the above allowable revenue codes is billed. Note: MACs shall override when rate has been added to the claim line. This does not apply to charges that are submitted as non-covered.					X				
12347.5.1	Medicare contractors shall set the reason code to suspend the claim for manual pricing. Note: Contractors should update the external reason code narrative to inform the provider that additional information is needed for pricing the line item. Instructions for pricing CRA TPNIES will be provided in the	X								

Number	Requirement	Re								
		A	/B I	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	ESRD PPS January RUN and future quarterly recurring updates.									
12347.5.2	Medicare contractors shall return the claim to the provider if the provider is billing for more than the allowed monthly 13/14 payment add-on's for CRA or if the claim is reporting more CRA line items than treatments billed. Note: Even if the MAC deems additional treatments over 13/14 per month are reasonable and necessary, the CRA add-on is not applicable for extra treatments and the provider is not allowed to bill for more than the 13/14 allowed.	X								
12347.6	Medicare contractors shall recognize QH as a valid payer only value code. Note: Value code QH shall not be passed to BCRC.					X				HIGLAS, NCH
12347.7	Medicare contractors shall capture the total CRA TPNIES by multiplying the rate by the units reported and summing the total of all CRA lines in the payer only value code QH for each covered CRA TPNIES service line reported on the claim.					X				

Number	Requirement	Re								
		A	/B I	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	Note: Medicare contractors shall not include services billed with the AX modifier (for transitional add-on payments) in the outlier value code 79.,and shall not include in the QH payer only value code AKI claims with condition code 84 reported.									
12347.7.1	Medicare contractors shall update reason code 36229 to include TPNIES CRA HCPCS billed with the AX modifier shall not be reported on an AKI claim (condition code 84).					X				
12347.8	When value code QH is manually entered on the claim, the Medicare shared system shall systemically remove the value code and bypass reason code 10405.					X				
12347.9	Medicare contractors shall not make separate payment on ESRD claims, TOB 72X for service lines containing CRA TPNIES HCPCS with the AX modifier with/ or without the AY modifier.					X				
	Medicare contractors shall ensure that lines billed as covered will remain covered services even though separate									

Number	Requirement	Re								
		A	/B I	MAC	DME	Share	Other			
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	payment is not made.									
12347.9.1	Medicare contractors shall use the following ANSI information for the line:					X				
	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. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present									
12347.10	Medicare contractors shall pass the total CRA TPNIES to the ESRD Pricer in payer-only value code QH. Refer to Attachment "ESRD Java Pricer 22 – new variables" Note: This shall be performed by FISS but is informational only for the ESRD Pricer and PS&R.					X				ESRD Pricer, PS&R
12347.10.1	ESRD Pricer shall accept the QH payer only value code amount field for the CRA TPNIES.									ESRD Pricer

Number	Requirement	Re								
		Α	/B I	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	Layout and Variable: B-PAYER-ONLY-VC-QH-AMT PIC 9(07)V9(04)									
12347.11	ESRD Pricer shall calculate the CRA TPNIES and include it with final payment.									ESRD Pricer
12347.12	Medicare contractors shall accept the new CRA TPNIES from the ESRD PRICER. Required field size: CRA-TPNIES-RETURN PIC 9(07)V9(04)					X				ESRD Pricer
12347.12.1	The Medicare contractor shall create a line level field to house the new CRA TPNIES from the ESRD Pricer. Required field size: CRA-TPNIES-RETURN PIC 9(07)V9(04)					X			X	
12347.12.2	The Medicare contractor shall pass the new field for CRA TPNIES to CWF, IDR and PS&R.					X			X	IDR, PS&R
12347.12.3	CWF shall accept the new fields from FISS.								X	

Number	Requirement	Re								
		Α	/B 1	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
12347.12.4	Field lengths required: PIC 9(07)V9(04) CWF shall ensure that the new field is passed to the downstream systems. CWF shall carry the new				MAC				X	FPS, NCH
12347.12.5	field on the claim history for OUTH in HIMR. Shared system					X				
	maintainers shall make any necessary updates that are needed by the CWF HIMR expansion being made under HIMR Main menu CLMH for OUTH to expand a new page (no new ID) to add the new field for the TPNIES CRA amount. Note: MCS and VMS indicated no impact.									
12347.13	CWF and FISS shall perform integrated testing during the ALPHA period of this CR.					X			X	
12347.14	FISS shall modify documentation to perform the following tasks with recurring Rxxx05A/Rxxx59Q to include HCPCS for the new CRA TPNIES addon adjustments:					X				

Number	Requirement	Re								
	•			MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН		FISS	MCS	VMS	CWF	
	Modify reason codes as necessary to include CRA TPNIES instruction in this CR. Add all new CRA				MAC					
	TPNIES HCPCS codes to the process for calculating the Line Level CRA TPNIES amount for populating the value code QH.									
	• Ensure all new CRA TPNIES HCPCS listed in the CR and billed with the AX modifier do not apply towards outlier, value code 79.									
	• Ensure new CRA TPNIES HCPCS listed in the CR are added to the process to not make separate payments for service lines reported with a CRA TPNIES HCPCS and 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;									

Number	Requirement	Re								
		Α	/B 1	MAC	DME	Share	d-Syste	m Main	tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	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 CRA TPNIES HCPCS eligible for the add-on shall be effective based on the future CR's effective date using the claims from date. In the event that there are no codes on the list of eligible TPNIES, CRA TPNIES or TDAPA ensure any previous codes are end-dated effective based on the future CR's effective date using the claims from date.									
12347.15	FISS shall estimate the recurring hours for this instruction under recurring updates Rxxx05A/Rxxx59Q and post them in the estimates attachment section of eChimp.					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	Responsibility				
			A/B MAC		DME MAC	CEDI	
		A	В	ННН			
12347.16	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X					

IV. SUPPORTING INFORMATION

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

[&]quot;Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

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

V. CONTACTS

Pre-Implementation Contact(s): Teira Canty, teira.canty@cms.hhs.gov (For claims processing inquiries), Wendy Jones, wendy.jones@cms.hhs.gov (For claims processing inquiries), Brenda Hudson, Brenda.hudson@cms.hhs.gov (For policy inquiries)

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: 1

Input to the ESRD Pricer -

• Payer-only value code QH amount; for Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Capital Related Assets (CRA): PIC 9(07)V9(04) **ESRD Pricer API Request:**

Variable Name: payerOnlyValueCodeQHAmount

Output from the ESRD Pricer -

• TPNIES return amount for CRA: PIC 9(07)V9(04) **ESRD Pricer API Response:**

Variable Name: craTpniesReturn

API Contract for the new fields (these will be added to the end of the API request and response).

```
"payerOnlyValueCodeQHAmount" : {
            "maximum" : 9999999.9999,
            "exclusiveMaximum" : false,
            "minimum" : 0,
            "exclusiveMinimum" : false,
            "type" : "number",
            "description" : "Payer-only value code QH amount; for TPNIES
capital-related assets.",
            "example" : 2354.9812,
            "x-cobol-declaration" : {
              "B-PAYER-ONLY-VC-QH-AMT" : "PIC 9(07) V9(04)"
            }
          }
          "craTpniesReturn" : {
            "maximum" : 9999999.9999,
            "exclusiveMaximum" : false,
            "minimum" : 0,
            "exclusiveMinimum" : false,
            "type" : "number",
            "description" : "The Transitional Add-on Payment Adjustment
for New and Innovative Equipment and Supplies (TPNIES) return amount for
capital-related assets.",
            "example" : 468752.8461,
            "x-cobol-declaration" : {
              "CRA-TPNIES-RETURN": "PIC 9(07)V9(04)"
          }
```