

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11533	Date: July 29, 2022
	Change Request 12347

Transmittal 11166, dated December 21, 2021, is being rescinded and replaced by Transmittal 11533, dated, July 29, 2022 to provide clarifying language to the background and policy sections to present the policy as described in the regulation and to update the sequence of events in the example calculation. This correction clarifies that the offset adjustment is subtracted from the per treatment amount before the application of the 65 percent adjustment. 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

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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.

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. CMS approved payment for the first eligible CRA for TPNIES in CY 2022. Therefore, for eligible CRAs that are home dialysis machines, ESRD facilities are being paid the CRA for TPNIES as of January 1, 2022.

For CRA for TPNIES only, CMS includes an offset adjustment to offset the costs already paid for dialysis machines in the ESRD PPS bundle. Effective January 1, 2022, CMS annually updates the offset adjustment amount by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor.

The payment for CRA for TPNIES is based on 65 percent of the Medicare Administrative Contractor (MAC) determined price, reduced by the offset adjustment amount described above. 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. The MACs establish these prices 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 of the approval year and ending on December 31 the following year. 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:

Beginning January 1, 2021, ESRD facilities report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for the CRA that is eligible to receive payment for CRA for TPNIES. The CRA for TPNIES pricing instructions apply when a HCPCS code on the TPNIES CRA list is reported with the AX modifier and one of the following revenue codes:

- 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).

Pricing Instructions:

For CRAs that are home dialysis machines used in the home for a single patient, the MACs shall divide the annual allowance by the expected number of treatments to calculate the annual allowance and the per treatment amount. The expected number of treatments is always 156 per year. MACs shall assign an amount to value code QH (Total TPNIES CRA amount) which totals the CRA for TPNIES per treatment amount multiplied by the number of treatments on that claim.

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. ESRD facilities 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 for TPNIES per treatment amount will equal the adjusted CRA for 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 calculates the adjusted per treatment amount that is added to each dialysis line by: 1) dividing QH by the total number of administered dialysis treatments, 2) subtracting the applicable offset amount, and 3) multiplying by 65 percent.

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 Claim Submission (for illustrative purposes only):

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

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

Step 1: Calculate Annual Allowance (MACs)

A CRA priced by the MACs at \$40,000 amortized over 5 years.

Annual Allowance = \$40,000 / 5 years

Annual Allowance = \$8,000/year

Step 2: Calculate Per Treatment Amount (MACs)

Divide the annual allowance by the expected number of treatments.

Per treatment amount = \$8,000 / 156 treatments per calendar year

Per treatment amount = \$51.28 per treatment

[NOTE: Regardless of the number of treatments given per month, the adjusted CRA for TPNIES per treatment amount will equal the adjusted CRA for TPNIES per treatment amount that is calculated for 13 treatments per month.]

Step 3: Assign Value Code QH (FISS)

For each claim, the FISS assigns the value of QH based on the per treatment amount and the number of treatments on the claim. The number of dialysis treatments for the month is limited to the 13 to 14 allowable monthly treatments that are deemed medically necessary. MACs shall not allow CRA for TPNIES in excess of 156 treatments per calendar year. In this example, there are 13 allowable treatments for the month.

Value Code QH = \$51.28 * 13 allowable CRA TPNIES lines for the month

Value Code QH = \$666.64

Step 4: Calculate Adjusted Per Treatment Amount on the Claim (PRICER)

Pricer first calculates the per treatment amount for each claim by dividing QH by the number of administered treatments.

Per treatment amount = \$666.64 / 13 allowable treatments for the month

Per treatment amount = \$51.28

Pricer then subtracts the offset amount from the per treatment amount. The annual offset amount shall be provided each year in the ESRD recurring update CR. In this example, the offset amount is \$9.00.

Pre-adjusted per treatment amount = \$51.28 - \$9.00

Pre-adjusted per treatment amount = \$42.28

Lastly, Pricer multiplies the pre-adjusted per treatment amount by 65 percent.

Adjusted per treatment amount = \$42.28 * 0.65

Adjusted per treatment amount = \$27.48

Step 5: Calculate Final Per Treatment Payment Amount (PRICER)

Pricer calculates the final per treatment payment amount, which is the sum of the adjusted ESRD PPS base rate and the adjusted CRA for TPNIES per treatment amount, multiplied by the QIP reduction. In this example the adjusted ESRD PPS base rate is \$250.00 and the QIP reduction is 1.5 percent.

Final Per Treatment Payment Amount = (Adjusted ESRD PPS base rate + Adjusted per treatment amount) * QIP Reduction

Final Per Treatment Payment Amount = (\$250.00 + \$27.48) * 0.985

Final per treatment payment amount = \$277.48 * 0.985

Final per treatment payment amount = \$273.32

The final per treatment payment amount for each of the 13 treatments on the claim is \$273.32.

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 MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
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 Add-on 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 line item as bundled service without the add-on.					X				
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 HCPCS approved for this transitional add-on will be provided in the ESRD	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	PPS January Recurring Update (RUN), and subsequent quarterly updates.									
12347.3	<p>Medicare contractors shall accept the following revenue codes for reporting CRA TPNIES HCPCS on type of bill 072X:</p> <p>0823 – Hemodialysis Home Equipment</p> <p>0833 – Peritoneal Home Equipment</p> <p>0843 – Continuous Ambulatory Peritoneal Dialysis (CAPD) Home Equipment</p> <p>0853 – Continuous Cycling Peritoneal Dialysis (CCPD) Home Equipment</p> <p>0889 - Other Miscellaneous Dialysis (to be used for ultrafiltration home equipment).</p>	X				X				
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					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>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.</p> <p>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.</p>									
12347.5.1	<p>Medicare contractors shall set the reason code to suspend the claim for manual pricing.</p> <p>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 ESRD PPS January RUN and future quarterly recurring updates.</p>	X								
12347.5.2	<p>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.</p>	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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.									
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. 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.					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
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	<p>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.</p> <p>Medicare contractors shall ensure that lines billed as covered will remain covered services even though separate payment is not made.</p>					X				
12347.9.1	<p>Medicare contractors shall use the following ANSI information for the line:</p> <p>Group code: CO (Contractual Obligation)</p> <p>CARC 97: The benefit for this service is included in the</p>					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12347.12	<p>Medicare contractors shall accept the new CRA TPNIES from the ESRD PRICER.</p> <p>Required field size: CRA-TPNIES-RETURN PIC 9(07)V9(04)</p>					X				ESRD Pricer
12347.12.1	<p>The Medicare contractor shall create a line level field to house the new CRA TPNIES from the ESRD Pricer.</p> <p>Required field size: CRA-TPNIES-RETURN PIC 9(07)V9(04)</p>					X			X	
12347.12.2	<p>The Medicare contractor shall pass the new field for CRA TPNIES to CWF, IDR and PS&R.</p>					X			X	IDR, PS&R
12347.12.3	<p>CWF shall accept the new fields from FISS.</p> <p>Field lengths required: PIC 9(07)V9(04)</p>								X	
12347.12.4	<p>CWF shall ensure that the new field is passed to the downstream systems. CWF shall carry the new field on the claim history for OUTH in HIMR.</p>								X	FPS, NCH

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12347.12.5	<p>Shared system 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.</p> <p>Note: MCS and VMS indicated no impact.</p>					X				
12347.13	CWF and FISS shall perform integrated testing during the ALPHA period of this CR.					X			X	
12347.14	<p>FISS shall modify documentation to perform the following tasks with recurring Rxxx05A/Rxxx59Q to include HCPCS for the new CRA TPNIES add-on adjustments:</p> <ul style="list-style-type: none"> • Modify reason codes as necessary to include CRA TPNIES instruction in this CR. • Add all new CRA TPNIES HCPCS codes to the process for calculating the Line Level CRA TPNIES amount for populating 					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>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.</p>									
12347.15	<p>FISS shall estimate the recurring hours for this instruction under recurring updates Rxxx05A/Rxxx59Q and post them in the estimates attachment section of eChimp.</p>					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12347.16	<p>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</p>	X				

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	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.					

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): 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):

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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)"
  }
}
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