## CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 10399

Department of Health \&
Human Services (DHHS)
Centers for Medicare \& Medicaid Services (CMS)

Date: October 16, 2020
Change Request 11869

Transmittal 10267, dated August 6, 2020, is being rescinded and replaced by Transmittal 10399, dated, October 16, 2020 to include revised recurring update numbers in business requirements 11869.9 and 11869.9.1. All other information remains the same.

NOTE: This Transmittal is no longer sensitive and is being re-communicated November 10, 2020. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: Implementation of 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 transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES). In addition, it will establish a quarterly recurring update for the Healthcare Common Procedure Coding System (HCPCS) codes eligible for the TPNIES. The TPNIES payment policy, including the codes eligible for the TPNIES will be provided in a separate instruction included with the annual January ESRD PPS Recurring Update.

EFFECTIVE DATE: January 1, 2021
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: January 4, 2021
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. 100-04 | Transmittal: 10399 | Date: October 16, 2020 | Change Request: 11869 |
| :--- | :--- | :--- | :--- |

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## EFFECTIVE DATE: January 1, 2021

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IMPLEMENTATION DATE: January 4, 2021

## 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.

Beginning January 1, 2016, the ESRD PPS provides the 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. CR 10065, Transmittal 1999, issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018. The TDAPA policy was refined in CR 11514, Transmittal 2392, issued on November 8, 2019.

Beginning January 1, 2020, the ESRD PPS provides the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for new and innovative renal dialysis equipment and supplies that qualify under § 413.236. CMS began the process in January 2020 of collecting information on supplies and equipment to determine eligibility for TPNIES. If eligible, the ESRD facilities would be paid TPNIES for the eligible items beginning January 1, 2021. The TPNIES payment 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 that meet the TPNIES eligibility criteria using verifiable information from the following sources of information, 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 TPNIES is paid for 2 calendar years, beginning on January 1 and ending on December 31. While the TPNIES applies to a new and innovative equipment or supply, the equipment or supply is not considered an outlier service.

In this Change Request (CR), the existing TDAPA Recurring Update Notification (RUN) is being modified to also include the TPNIES. That is, this CR establishes one RUN for the ESRD PPS transitional add-on payment adjustments with 2 sets of codes, that is, one code set for the TDAPA and another for the TPNIES.

## B. Policy: TDAPA

There is no change in the mechanics of how the TDAPA is applied. When a HCPCS code on the TDAPA list is reported with the AX modifier and revenue code 0636, the TDAPA instructions will apply.

## TPNIES

ESRD facilities will report the AX modifier (item furnished in conjunction with dialysis services) with the HCPCS code for the equipment or supply eligible to receive the TPNIES. When a HCPCS code on the TPNIES list is reported with the AX modifier and revenue code 027X, the TPNIES instructions will apply. This CR also implements the payer only value code QG - Total TPNIES Amount, to be used to capture the add-on payment.

Dialysis treatments reported with the CG modifier and non-covered dialysis treatments should not be used for purposes of the TPNIES. For purposes of the number of dialysis treatments for the month used in the TPNIES calculation, Medicare contractors should only consider those treatments that are reported and covered.

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 QG by the total number of dialysis treatments and then that per treatment amount is added to each dialysis line.

## Z Supply Example Calculation:

Patient is furnished Z Supply for each hemodialysis treatment. The MAC-determined price is $\$ 10.00$ per each Z Supply. The ESRD facility would report Z Supply on the claim with its assigned HCPCS code that will be on the TPNIES list.

1/1/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/1/2021 REV 821
1/3/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/3/2021 REV 821
1/5/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/5/2021 REV 821
1/8/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/8/2021 REV 821
1/10/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/10/2021 REV 821
1/12/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/12/2021 REV 821
1/15/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit

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1/17/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
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1/19/2021 REV 821
1/22/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/22/2021 REV 821
1/24/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/24/2021 REV 821
1/26/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/26/2021 REV 821
1/29/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/29/2021 REV 821
1/31/2021 REV 27X, HCPCS for Z Supply, AX, 1 unit
1/31/2021 REV 821
QG is assigned $\$ 140((1 * \$ 10.00) * 14=\$ 140.00)$
Number of dialysis treatments for month $=14$
Adjusted ESRD PPS base rate $=\$ 250.00$
QIP reduction $=0.985$
(65 percent of the MAC-determined TPNIES amount)/ number of dialysis treatments for the month = TPNIES per treatment payment
$\$ 6.50=(.65 * \$ 140.00) / 14$
$\$ 6.50=\$ 91.00 / 14$
Final Payment Rate $=($ Adjusted ESRD PPS base rate + TPNIES per treatment payment $)$ * QIP reduction
$\$ 252.65=(\$ 250.00+\$ 6.50) * 0.985$
$\$ 252.65=\$ 256.50 * 0.985$
The final per treatment payment amount is $\$ 252.65$
Additional instructions for ESRD facilities and contractors regarding the TPNIES policy will be provided in the ESRD PPS January 2021 RUN and subsequent quarterly updates.

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).

## II. BUSINESS REQUIREMENTS TABLE

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



| Number | Requirement | Responsibility |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | $\begin{gathered} \text { A/B } \\ \text { MAC } \end{gathered}$ |  |  | $\begin{aligned} & \mathrm{D} \\ & \mathrm{M} \\ & \mathrm{E} \end{aligned}$ |  | Shared- <br> System <br> Maintainers |  |  | Other |
|  |  | A | B | H | $\begin{aligned} & \mathrm{M} \\ & \mathrm{~A} \\ & \mathrm{C} \end{aligned}$ | $\begin{array}{\|c\|} \hline \text { F } \\ \text { I } \\ \text { S } \\ \mathrm{S} \end{array}$ | $\begin{aligned} & \mathrm{M} \\ & \mathrm{C} \\ & \mathrm{~S} \end{aligned}$ | $\begin{aligned} & \mathrm{V} \\ & \mathrm{M} \\ & \mathrm{~S} \end{aligned}$ | $\begin{array}{\|l\|} \hline \mathrm{C} \\ \mathrm{~W} \\ \mathrm{~F} \end{array}$ |  |
|  | Refer to Attachment "Revised ESRD PRICER Layout 01012021". |  |  |  |  |  |  |  |  |  |
| 11869.6.1 | ESRD Pricer shall accept payer only value code QG for the TPNIES. <br> Layout and Variable: <br> B-PAYER-ONLY-VALUE-CODE PIC X(02) <br> B-PAYER-ONLY-VC-QG-AMT PIC 9(07)V9(04) |  |  |  |  |  |  |  |  | ESRD Pricer |
| 11869.7 | ESRD Pricer shall calculate the TPNIES and include it with final payment. |  |  |  |  |  |  |  |  | ESRD Pricer |
| 11869.8 | Medicare contractors shall accept the new TPNIES from the ESRD PRICER. |  |  |  |  | X |  |  |  | ESRD Pricer |
| 11869.8.1 | The Medicare contractor shall create a line level field to house the new TPNIES from the ESRD Pricer. <br> Required field size: TPNIES-RETURN PIC 9(07)V9(04) |  |  |  |  | X |  |  | X |  |
| $\begin{aligned} & \hline 11869.8 .1 \\ & .1 \end{aligned}$ | The Medicare contractor shall pass the new field to CWF, IDR and PS\&R. |  |  |  |  | X |  |  | X | IDR, PS\&R |
| $\begin{aligned} & 11869.8 .1 \\ & .2 \end{aligned}$ | CWF shall accept the new field from FISS. <br> Field length required: <br> PIC 9(07)V9(04) |  |  |  |  |  |  |  | X |  |
| $\begin{aligned} & 11869.8 .1 \\ & .3 \end{aligned}$ | CWF shall ensure that the new field is passed to the downstream systems. CWF will carry the new field on the claim history for OUTH in HIMR. <br> NOTE: The NCH will not begin storing the TPNIES Adjustment Amount to the line level until the April 2021 release. The NCH has frozen its code to work on their Version 'L' release which will be implemented January 2021, so no new elements can be added to the copybook until after the Version ' $L$ ' implementation. |  |  |  |  |  |  |  | X | FPS, NCH |




## III. PROVIDER EDUCATION TABLE



## IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

| X-Ref <br> Requirement <br> Number | Recommendations or other supporting information: |
| :--- | :--- |

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

## V. CONTACTS

Pre-Implementation Contact(s): Wendy Jones, wendy.jones@cms.hhs.gov (For claims processing inquiries.) , Michelle Cruse, michelle.cruse@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



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009800* The following variables are from the old pricer and are used fo
009900*testing purposes, displaying within the manager main program what
010000*went on in the calculating subroutine.
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