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Implementation of the Transitional Drug Add-On Payment Adjustment

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Related Change Request (CR) Number: CR 10065
Related CR Release Date: January 10, 2018
Effective Date: January 1, 2018
Related CR Transmittal Number: R1999OTN
Implementation Date: January 2, 2018

Note: This article was revised on January 10, 2018 to reflect the revised CR10065 issued on that date. The CR was revised to provide more descriptive examples for Parsabiv and Sensipar. These examples were added to the article. In addition, the CR release date, transmittal number and the Web address for accessing the CR were revised. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for End-Stage Renal Disease (ESRD) facilities submitting claims to Medicare Administrative Contractors (MACs) for certain ESRD drugs provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs you about Change Request (CR) 10065, which directs the MACS to implement the Transitional Drug Add-On Payment Adjustment (TDAPA). Please be sure your billing staffs are informed of this change.

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 ESRD Prospective Payment System (PPS). Under the drug designation process, CMS provides payment using a TDAPA for new injectable or intravenous drugs and biologicals that qualify under 42 Code of Federal Regulations (CFR) 413.234(c)(1).

To be considered a new injectable or intravenous product, the product must be approved by the Food and Drug Administration (FDA), commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service. CMS considers the new injectable or intravenous product to be included in the ESRD PPS

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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 TDAPA, if the new injectable or intravenous product is used to treat or manage a condition for which there is not an existing ESRD PPS functional category. While calcimimetics are included in the bone and mineral metabolism ESRD PPS functional category, they are an exception to the drug designation process as discussed in the Calendar Year (CY) 2016 ESRD PPS final rule (80 FR 69025, 69027). CMS bases the TDAPA on payment methodologies under section 1847A of the Social Security Act which are discussed in the "Medicare Claims Processing Manual", 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.

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 to receive payment for these drugs using the TDAPA. While these drugs are eligible for the TDAPA, they do not qualify toward outlier calculation. Currently, calcimimetics are the only drugs that qualify for payment using the TDAPA. **ESRD facilities should not use the AX modifier for any other drug until notified by CMS**.

Effective January 1, 2018, MACs will return to provider (RTP) ESRD claims (TOB 72X) when:

- HCPCS code J0604 or J0606 is present without modifier AX or
- Modifier AX is present without HCPCS code J0604 or J0606

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 MACs will 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.

CR 10065 also implements the payer only value code Q8 – Total TDAPA Amount, to be used to capture the add-on payment adjustment. CR 10065 has an example of the calculation used in PRICER.

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

Oral or Other Forms of Injectable Drugs and Biologicals

ESRD facilities are responsible for furnishing renal dialysis services either directly or under arrangement. The one exception to this policy is oral-only drugs and biologicals that are not paid under the ESRD PPS until January 1, 2025.

CMS recognizes that ESRD facilities may have unique circumstances with regard to furnishing oral and other forms of injectable drugs and biologicals when the medication cannot be administered in the ESRD facility. For example, a pharmacy may, under arrangement with the ESRD facility, dispense the medication and provide the patient with instructions on how to self-administer the drug. In this situation, the ESRD facility is responsible for developing contractual arrangements with pharmacies and ensuring that appropriate delivery and billing of the drug is completed in accordance with the beneficiary's plan of care.

CMS Pub. 100-02, chapter 11, section 20.3.C provides the reporting guidance for oral or other forms of renal dialysis drugs that are filled at the pharmacy or furnished directly by an ESRD facility for home use. ESRD facilities are instructed to report one line item per prescription, but only for the quantity of the drug expected to be taken during the claim billing period, that is, calendar month. ESRD facilities should use the best information they have to determine the amount expected to be taken in a given calendar month, including prescription fill information

from the pharmacy and the patient's plan of care (80 FR 37838).

ESRD facility claims include only the items and services used during the calendar month. CMS does not expect facilities to physically administer the drug to the patient, however, CMS does expect facilities to be aware of the patient's plan of care and know the medications the patient was instructed to take for the claim's time period, and ensure the claim reflects that plan of care.

With the implementation of TDAPA, facilities are now responsible for reporting an oral calcimimetic (J0604) on the ESRD claim. The ESRD PPS is built and operationalized around the monthly reporting of items and services that are furnished. However, we recognize that continuity of therapy may be unpredictable. For example, beneficiaries can be hospitalized, switch facilities, or change dosages all within the same calendar month. CMS recognizes that these situations may be beyond the control of the ESRD facility and that they can impact payment. ESRD facilities will need to determine the most appropriate way to furnish drugs and biologicals that ensures patients receive their required medications, while mitigating the facilities' risk for drug costs.

Again, with regard to reporting for the oral calcimimetic (J0604), CMS expects that ESRD facilities will report the quantity of the drug expected to be taken during the calendar month using the best information available as discussed above. CMS does not expect the date of the line on the claim for the oral calcimimetic to correspond to a treatment date or the specific day that the patient received the supply of medication, however, the facility's recordkeeping (for example, the patient's medical record) should be consistent with the claim.

CMS expects all providers and suppliers to supply and administer all patient drugs and biologicals in a clinically approved, efficient and economical manner. CMS will closely monitor the utilization of renal dialysis services and the use of TDAPA to analyze trends, behaviors and require appropriate corrective action when necessary.

ADDITIONAL INFORMATION

The official instruction, CR 10065, issued to your MAC regarding this change, is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf.

The CY 2016 ESRD PPS Final Rule is available at https://www.gpo.gov/fdsys/pkg/FR-2015-11-06/pdf/2015-27928.pdf.

If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/ on the CMS website.

DOCUMENT HISTORY

Date of Change	Description
January 10, 2018	The article was revised to provide more descriptive examples in the Background section for Parsabiv and Sensipar. The CR release date, transmittal number and the Web address for accessing the CR were revised also. All other information remains the same.
December 29, 2017	The article was revised in order to add the section entitled “Oral or Other Forms of Injectable Drugs and Biologicals” starting on page 2.
August 9, 2017	Initial article released.