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Implementation of Healthcare Common Procedure Coding System (HCPCS) Code J3591 and Additional Changes for End Stage Renal Disease (ESRD) Claims

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Related Change Request (CR) Number: 10851
Related CR Release Date: November 2, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R2192OTN
Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for End-Stage Renal Disease (ESRD) facilities that submit claims to Medicare Administrative Contractors (MACs) for ESRD services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

The purpose of Change Request (CR) 10851 is to implement a new unclassified drug or biological for End Stage Renal Disease (ESRD) and to make additional changes for the 72X Type of Bill (TOB). Make sure your billing staffs are aware of these changes.

BACKGROUND

The Medicare Improvements for Patients and Providers Act (MIPPA; Section 153(b); https://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf) required the implementation of an End Stage Renal Disease Prospective Payment System (ESRD PPS), effective January 1, 2011. The ESRD PPS provides a per treatment payment amount to ESRD facilities that covers all of the resources used in furnishing an outpatient dialysis treatment.

CR7064 implemented the ESRD PPS (Transmittal 2134; see related article at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7064.pdf) entitled End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services.

The ESRD PPS provides outlier payments, if applicable, for high cost patients due to unusual variations in the type or amount of medically necessary care. Medicare regulations at 42 CFR §413.237(a)(1)(i)(https://www.gpo.gov/fdsys/pkg/CFR-2012-title42-vol2/pdf/CFR-2012-title42-vol2-sec413-237.pdf) provide that ESRD PPS outlier services are those ESRD-related services

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that were or would have been considered separately billable under Medicare Part B or would have been separately payable drugs under Medicare Part D (excluding renal dialysis oral-only drugs), for renal dialysis services furnished prior to January 1, 2011. Information regarding the ESRD PPS outlier policy is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html.

Under the ESRD PPS drug designation process, the Centers for Medicare & Medicaid Services (CMS) provides payment using a Transitional Drug Add-on Payment Adjustment (TDAPA) for new renal dialysis drugs and biologicals that qualify under 42 CFR 413.234(c) (https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol2/pdf/CFR-2016-title42-vol2-sec413-234-.pdf). While these drugs are eligible for the TDAPA, they do not qualify toward outlier calculation. Until January 1, 2019, calcimimetics were the only drugs that qualify for payment using the TDAPA. CR10065 (Transmittal 1999; see related article at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf) entitled Implementation of the Transitional Drug Add-On Payment Adjustment implemented TDAPA, and information regarding TDAPA is available https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html.

New United States Food and Drug Administration approved renal dialysis drugs and biologicals can come to market at any point of the year, and the Healthcare Common Procedure Coding System (HCPCS) process has an annual release schedule. There is often a timeframe wherein a drug manufacturer has submitted a HCPCS application yet still awaiting a permanent code to be used by providers for billing Medicare. New drugs and biologicals could potentially be eligible for TDAPA, and this policy could also be applicable for outlier eligible services. CMS provides more information regarding the HCPCS process at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html.

In order to accurately capture all treatments provided to a beneficiary, CMS implemented the CG modifier in CR9989 (see related article at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9989.pdf). Modifier CG – Policy Criteria Applied for the 72x type of bill is used to identify dialysis treatments (CPT 90999) in excess of 13 or 14 per month that do not meet medical justification requirements as defined by the MACs.

Effective January 1, 2019, for new renal dialysis drugs and biologicals that are eligible for outlier or TDAPA, CMS is implementing the following new HCPCS code:

- J3591 - Unclassified drug or biological (for ESRD on dialysis)

End Stage Renal Disease Prospective Payment System (ESRD PPS) Outlier Policy

For new injectable renal dialysis drugs and biologicals that are eligible outlier services, ESRD facilities should report J3591 with the National Drug Code (NDC) in the 11-digit format 5-4-2. The Medicare claims processing system will flag the code for manual pricing by the MAC. The MAC will set the payment rate based on pricing methodologies under 1847A of the Social Security Act using guidance in the Medicare Claims Processing Manual, Chapter 17, Section

20.1.3. The final pricing information will be passed to value code 79 to be included in the outlier calculation. Oral equivalent renal dialysis drugs and biologicals that are eligible outlier services will follow the existing processes.

CMS will issue guidance to advise when to use the code for an outlier drug.

Acute Kidney Injury (AKI) Claims

Outlier payment eligibility are payment policies under the ESRD PPS that are only applicable to ESRD beneficiaries. Therefore, J3591 is not billable on an AKI claim.

J3591 is used to facilitate potential outlier payment or the TDAPA to ESRD facilities when a new renal dialysis service is available but before it has been assigned its own HCPCS code (if applicable). The outlier and TDAPA policies are for renal dialysis services (drugs and biologicals used for the treatment of ESRD) only.

Since ESRD facilities use the AY modifier when an item or service is furnished for reasons other than the treatment of ESRD to facilitate separate payment under Medicare Part B, ESRD facilities should not receive separate payment for J3591 either with or without the AY modifier and the MACs shall process the line item as covered with no separate payment under the ESRD PPS.

Calculation of the Transitional Drug Add-on Payment Adjustment (TDAPA) and Outlier

Dialysis treatments reported with the CG modifier and non-covered dialysis treatments should not be used for purposes of the TDAPA or outlier calculations. For purposes of the number of dialysis treatments for the month used in the TDAPA and outlier calculations, MACs should only consider those treatments that are reported and covered. MACs should mass adjust outlier claims reported with the CG modifier beginning with dates of service October 1, 2017. MACs should also mass adjust TDAPA claims reported with the CG modifier beginning with dates of service January 1, 2018 to ensure appropriate Medicare payment.

ADDITIONAL INFORMATION

The official instruction, CR10086, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R2192OTN.pdf.

Chapter 17 of the Medicare Claims Processing Manual is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
November 6, 2018	Initial article released.