CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2192	**Date: November 2, 2018**
	Change Request 10851

Transmittal 2117, dated August 10, 2018, is being rescinded and replaced by Transmittal 2192, dated, November 2, 2018 to revise the background and policy sections and to remove business requirements 10851.9 and 10851.10. NOTE: This Transmittal is no longer sensitive and is being re-communicated November 2, 2018. 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 Healthcare Common Procedure Coding System (HCPCS) Code J3591 and Additional Changes for End Stage Renal Disease (ESRD) Claims

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) 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.)

EFFECTIVE DATE: January 1, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 7, 2019

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: Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) 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. Change Request (CR) 7064, Transmittal 2134, entitled "End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services" implemented the ESRD PPS.

Beginning January 1, 2017, ESRD facilities are able to furnish dialysis to Acute Kidney Injury (AKI) patients.

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) provide that ESRD PPS outlier services are those ESRD-related services 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 can be located on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html

Under the ESRD PPS drug designation process, 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). While these drugs are eligible for the TDAPA, they do not qualify toward outlier calculation. CR 10065, Transmittal 1999, entitled "Implementation of the Transitional Drug Add-On Payment Adjustment" implemented TDAPA. Information regarding TDAPA can be located on the CMS website: 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. 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 an outlier payment. Information regarding the HCPCS process can be located on the CMS website: 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. 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 Medicare Administrative Contractors.

B. Policy: Effective January 1, 2019, for new renal dialysis drugs and biologicals that are eligible for an outlier payment, CMS is implementing a 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 claims processing system will flag the code for manual pricing by the Medicare Administrative Contractor (MAC). The MAC will set the payment rate based on pricing methodologies under 1847A of the Act using the guidance in the Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, Section 20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology. 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.

We 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 payments 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 policy is 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, Medicare contractors should only consider those treatments that are reported and covered. Medicare contractors should mass adjust outlier claims reported with the CG modifier beginning with dates of service 10/1/2017. Medicare contractors should also mass adjust TDAPA claims reported with the CG modifier beginning with dates of service 1/1/18 to ensure appropriate Medicare payment.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility			
		A/B MAC	DME	Shared-System Maintainers	Other

		A	B	H H H	M A C	F I S S	M C S	V M S	C W F	
10851.1	Medicare contractors shall recognize on the ESRD, Type of Bill (TOB) 72x the new HCPCS code: J3591 - Unclassified drug or biological (for ESRD on dialysis)					X				IOCE
10851.2	Medicare contractors shall modify the HCPC load process to add the following on the contractor file for NOC (not otherwise classified) HCPCS code J3591 to be used on the ESRD, Type of Bill (TOB) 72x with the following: • HCPCS Indicator field = Y • ESRD Pricing Indicator field = Q • ESRD OVR field = 3.					X				
10851.2.1	Medicare contractors shall update reason code 36327 to add the ESRD Pricing Indicator field = Q as a valid value when HCPCS code J3591 is submitted with revenue code 0636 on the ESRD, Type of Bill (TOB) 72x.					X				
10851.3	Medicare contractors shall create a reason code to return to provider (RTP) ESRD claims type of bill (TOB) 72X with HCPCS code J3591 and the following are not present: • A valid NDC number (in the 11-digit format 5-4-2) • A valid NDC qualifier • NDC units **NOTE:** This does not apply to charges that are submitted as non-covered.					X				
10851.3.1	Medicare contractors shall RTP the claim.	X								
10851.4	Medicare contractors shall create a reason code to return to provider (RTP) ESRD claims type of bill (TOB) 72X with HCPCS code J3591 when the units are greater than one on claim page 3.					X				
10851.4.1	Medicare contractors shall RTP the claim.	X								
10851.5	Medicare contractors shall suspend ESRD claims, TOB 72X with HCPCS code J3591, valid NDC number, a valid NDC qualifier and NDC units for manual pricing based on the ESRD Pricing Indicator on the HCPC file MAP1201.	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10851.6	Medicare contractors shall calculate the payment amount for HCPCS code J3591 using the NDC number, the NDC qualifier and NDC units from claim page 33. This amount should be entered in the rate field on claim page 3. **NOTE:** This should be modeled after HCPCS code C9399.	X								
10851.7	Medicare Contractors shall not separately pay HCPCS code J3591 (not found on the consolidated billing list) for Type of Bill 72X. **NOTE:** Line should be indicated as covered. Separate payment is not made for these services when billed with modifier AY.					X				
10851.7.1	Medicare Contractors shall use the following ANSI information: 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. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.					X				
10851.8	Medicare contractors shall capture the claim total payment amount in value code 79 to be included in the outlier calculation for each covered service line reported on an ESRD claim, TOB 72X with the following: • Revenue code 0636 • HCPCS code J3591 • A valid NDC number • A valid NDC qualifier • NDC units • Without modifier AX					X				
10851.9	This business requirement has been deleted.					X				
10851.10	This business requirement has been deleted.					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10851.11	Medicare contractors shall send the following data from the 72x TOB to the ESRD PRICER in the claim file effective for dates of service on or after October 1, 2017: • Total number of covered (only) dialysis sessions on the claim for outlier and TDAPA calculation. Note: This data should be captured in the "B-CLAIM-NUM-DIALYSIS-SESSIONS" field.					X				ESRD Pricer
10851.12	Medicare contractors shall mass adjust ESRD claims, TOB 72x, for dates of service on or after October 1, 2017 through December 31, 2018 with: • Revenue code 0821 or 881 • HCPCS code 90999 and CG modifier is present with non-covered lines And • Value code 79 is present Mass adjustments should be completed within 90 days of the implementation date of this transmittal.	X								
10851.13	Medicare contractors shall mass adjust ESRD claims, TOB 72x, for dates of service on or after January 1, 2018 through December 31, 2018 with • Revenue code 0636; • HCPCS code J0604 or J0606 and; • Modifier AX • Value code Q8 And • Revenue code 0821 or 881 • HCPCS code 90999 and CG modifier is present with non-covered lines	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Mass adjustments should be completed within 90 days of the implementation date of this transmittal.									
10851.14	Medicare contractors shall create a reason code to return to the provider (RTP) any AKI claim billed with HCPCS code J3591. AKI claim = TOB 72x with condition code 84, CPT code G0491 and one of the following ICD-10 diagnosis codes: 1. N17.0 Acute kidney failure with tubular necrosis 2. N17.1 Acute kidney failure acute cortical necrosis 3. N17.2 Acute kidney failure with medullary necrosis 4. N17.8 Other acute kidney failure 5. N17.9 Acute kidney failure, unspecified 6. T79.5XXA Traumatic anuria, initial encounter 7. T79.5XXD Traumatic anuria, subsequent encounter 8. T79.5XXS Traumatic anuria, sequela 9. N99.0 Post-procedural (acute)(chronic) renal failure					X				
10851.14.1	Medicare contractors shall RTP the claim.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10851.15	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects	X				

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.					

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): Tracey Mackey, Tracey.Mackey@cms.hhs.gov , Cindy Pitts, Cindy.Pitts@cms.hhs.gov , Shauntari Cheely, Shauntari.Cheely@cms.hhs.gov

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: 0