CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4105	**Date: August 3, 2018**
	Change Request 10839

SUBJECT: System Changes to Implement Epoetin Alfa Biosimilar, Retacrit for End Stage Renal Disease (ESRD) and Acute Kidney Injury (AKI) Claims

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make system changes for End Stage Renal Disease (ESRD) and Acute Kidney Injury (AKI) claims.

The CR will also make revisions to the following manuals:

Publication 100-02, Chapter 11, Section 100.6 - Applicability of Specific ESRD PPS Policies to AKI Dialysis, of the Medicare Benefits Policy manual.

Publication 100-04, Chapter 8, Section 60.4.2 - Facility Billing Requirements for ESAs, of the Medicare Claims Processing manual.

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
R	8/60/60.4.2/Facility Billing Requirements for ESAs

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:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4105	Date: August 3, 2018	Change Request: 10839

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I. GENERAL INFORMATION

A. Background: On June 29, 2015, the Trade Preferences Extension Act of 2015 was enacted in which section 808 amended Section 1861(s)(2)(F) of the Social Security Act (42 U.S.C. 1395x(s)(2)(F)) by extending renal dialysis services paid under section 1881(b)(14) to beneficiaries with acute kidney injury (AKI), effective January 1, 2017.

Change Requests (CRs) 9598 and 9814 implemented the initial requirements for this legislation

B. Policy: <u>Billing for consolidated renal dialysis services for beneficiaries with Acute Kidney Injury</u>
This Change Request (CR) updates the list of supplies, drugs, and labs included in the ESRD consolidated billing list and therefore included in the base rate payment for AKI. This includes erythropoietin stimulating agents billed with the ESRD-specific HCPCS or the non-ESRD specific HCPCS.

With this CR, we are adding Q5106 - Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units to the list established in CR 9987:

Claims that include Q5106 with dates of service between July 1, 2018 and December 31, 2018 will need to be reprocessed.

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	
10839 - 04.1	Medicare contractors shall not separately pay HCPCS code Q5106 (not found on the consolidated billing list) for AKI claims for dates of service on or after July 1, 2018. AKI claims = Type of Bill 72X, submitted with condition code 84, CPT code G0491 and one of the following ICD-10 diagnosis codes:					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	1. N17.0 Acute kidney failure with tubular necrosis 2. N17.1 Acute kidney failure with 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 NOTE: Line should be indicated as covered. Lines billed with modifier AY should not receive separate payment.									
10839 - 04.1.1	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				
10839 -	Medicare contractors shall mass adjust AKI claims	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
04.2	where HCPCS code Q5106 is present for dates of service on or after July 1, 2018 through December 31, 2018. Mass adjustment should be completed within 90 days of the implementation date of this transmittal.									
10839 - 04.3	Medicare contractors shall update reason code 31643 to include HCPCS codes Q5105when submitted with revenue codes 634/635 on type of bill 12X, 13X, 72X and 85X, effective for dates of service on or after July 1, 2018,					X				
10839 - 04.4	Medicare contractors shall establish recurring hours to update the list of services not separately payable on Acute Kidney Injury claims.					X				
10839 - 04.5	Medicare contractors shall be aware of revisions to Pub. 100-04, Chapter 8, Section 60.4.2 - Facility Billing Requirements for ESAs, of the Medicare Claims Processing manual.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10839 - 04.6	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 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.	X				

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

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

60.4.2 - Facility Billing Requirements for ESAs

(Rev.4105, Issued: 08- 03-18, Effective: 01-01-19, Implementation: 01-07-19)

Hematocrit and Hemoglobin Levels

Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48.

To report a hemoglobin or hematocrit reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of epoetin alfa. The provider may use results documented on form CMS 2728 or the patient's medical records from a transferring facility.

Effective January 1, 2012, ESRD facilities are required to report hematocrit or hemoglobin levels on all ESRD claims. Reporting the value 99.99 is not permitted when billing for an ESA.

The revenue codes for reporting Epoetin Alfa are 0634 and 0635. All other ESAs are reported using revenue code 0636. The HCPCS code for the ESA must be included:

HCPCS	HCPCS Description	Dates of Service
Q4055	Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0886	Injection, Epoetin Alfa, 1,000 units (for ESRD on Dialysis)	1/1/2006 through 12/31/2006
Q4081	Injection, Epoetin alfa, 100 units (for ESRD on Dialysis)	1/1/2007 to present
Q4054	Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0882	Injection, Darbepoetin Alfa, 1mcg (for ESRD on Dialysis)	1/1/2006 to present
J0890	Injection, Peginesatide, 0.1 mg (for ESRD on Dialysis)	1/1/2013 *through 7/1/2015*
Q5105	*Injection, epoetin alfa, biosimilar, (Retacrit) (For ESRD on Dialysis), 100 units*	*7/1/2018 to present*

Each administration of an ESA is reported on a separate line item with the units reported used as a multiplier by the dosage description in the HCPCS to arrive at the dosage per administration.

Route of Administration Modifiers

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA. Effective for claims with dates of services on or after January 1, 2012, all facilities billing for injections of ESA for ESRD beneficiaries must include the modifier JA on the claim to indicate an intravenous administration

or modifier JB to indicate a subcutaneous administration. ESRD claims containing ESA administrations that are submitted without the route of administration modifiers will be returned to the provider for correction. Renal dialysis facilities claim including charges for administrations of the ESA by both methods must report separate lines to identify the number of administration provided using each method.

Effective July 1, 2013, providers must identify when a drug is administered via the dialysate by appending the modifier JE (administered via dialysate).

ESA Monitoring Policy Modifiers
Append modifiers ED, EE and GS as applicable, see instructions in section 60.4.1.

Maximum Allowable Administrations
The maximum number of administrations of EPO for a billing cycle is 13 times in 30 days and 14 times in 31 days.

The maximum number of administrations of Aranesp for a billing cycle is 5 times in 30/ 31days.

The maximum number of administrations of Peginesatide is 1 time in 30/ 31days.