CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2365	**Date: September 27, 2019**
	Change Request 11244

NOTE: This Transmittal is no longer sensitive and is being re-communicated December 3, 2019. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: Discontinuing the Erythropoietin Stimulating Agent (ESA) Monitoring Policy System Edits under the End Stage Renal Dialysis Prospective Payment System (ESRD PPS)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to remove the monitoring policy system edits implemented for Erythropoietin Stimulating Agents (ESA) under the End Stage Renal Disease Prospective Payment System (ESRD PPS.)

EFFECTIVE DATE: January 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 6, 2020

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: In fall 2003, the Centers for Medicare & Medicaid Services (CMS) solicited input from the End-Stage Renal Disease (ESRD) community in order to develop a national claims monitoring policy for Erythropoiesis Stimulating Agents (ESAs), administered to ESRD patients receiving dialysis in a renal dialysis facility. Following input from the ESRD community, CMS implemented the first iteration of the national ESA monitoring policy (EMP), effective for dates of service April 1, 2006, and later (Change Request (CR) 4135 dated November 10, 2005). This version instructed Medicare contractors to make payments based on a 25% reduction in the reported ESA dose on the claim when the hematocrit level exceeded 39.0% (or hemoglobin exceeded 13.0g/dL) unless the provider indicated, by appending a GS modifier to the claim, that the amount of ESA on the claim reflected a 25% dose reduction compared to the prior month. A Medically Unlikely Edit (MUE) was implemented for claims for Epoetin Alfa (EPO) over 500,000 units and Darbepoetin Alfa (Aranesp®) over 1500 micrograms in the billed month. Since amounts exceeding the MUE were assumed to be typographical errors, claims reporting amounts above the threshold were returned to providers for correction. We note that the MUE implemented under the EMP is separate and distinct from MUEs that are issued by the CMS National Correct Coding Initiative Program.

CR 5251, issued August 25, 2006, revised the EMP. In essence, the revision clarified claims processing systems instructions contained in CR 4135 for patients that receive home dialysis, and specified that effective for claims with dates of service on or after April 1, 2006, claims for patients that opt to receive home dialysis are not subject to the 25% dose reduction and are not required to report the GS modifier. The CR also redefined the GS modifier to indicate that the ESA dose had been reduced and maintained in response to high hematocrit or hemoglobin levels, without specifying the percentage of the reduction or when it occurred, effective for claims with dates of service on or after October 1, 2006.

CR 5700, issued July 20, 2007, further revised the EMP. CR 5700 broadened the application of the EMP to include all drugs categorized as ESAs and noted that future CRs would be issued to provide additional instructions as new drugs enter the market. This CR reduced the MUE threshold described in CRs 4135/5251 to 400,000 units from 500,000 for EPO and to 1200 mcg from 1500 for Aranesp. It also instructed systems to apply a 50 percent reduction to the reported dose on ESA claims for ESRD patients receiving their dialysis in ESRD facilities when the hematocrit has been above 39.0 percent (or hemoglobin above 13.0g/dL) for 3 or more consecutive billing cycles immediately prior to and including the current billing cycle.

Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) required the implementation of an ESRD PPS effective January 1, 2011. The ESRD PPS provides a single payment to ESRD facilities to cover all of the resources used in furnishing outpatient dialysis, including ESAs. In the Calendar Year (CY) 2011 ESRD Prospective Payment System (PPS) final rule, CMS implemented a final rule that adopted the EMP under the ESRD PPS. Specifically, for purposes of calculating the ESRD PPS

base rate and establishing the outlier policy's percentage and thresholds, dose limits were applied to ESAs consistent with the EMP. Additionally, for purposes of the outlier policy, we apply dosing reductions and ESA dose limits consistent with the EMP prior to any calculation of outlier eligibility.

CR 11392 increased the MUE threshold for Aranesp from 1200 mcg to 1500 mcg for dates of service July 1, 2017 through December 31, 2019.

B. Policy: Effective January 1, 2020, CMS will no longer apply the EMP under the ESRD PPS. Since the implementation of the ESRD PPS, ESA utilization has decreased significantly and the incentives to overuse these drugs and biologicals are no longer seen as a concern. Prescribing practitioners should continue to prescribe ESAs in accordance with ESA dosing guidelines and ESRD facilities should continue to report what they furnish.

The type of bill 72X (ESRD claim) will no longer be subject to dose reductions or ESA dose limitations. ESRD facilities will no longer be required to report the following modifiers:

1. GS - Dosage of erythropoietin stimulating agent has been reduced and maintained in response to hematocrit or hemoglobin level

2. ED - Hematocrit level has exceeded 39% (or hemoglobin level has exceeded 13.0 g/dl) for 3 or more consecutive billing cycles immediately prior to and including the current cycle

3. EE - Hematocrit level has not exceeded 39% (or hemoglobin level has not exceeded 13.0 g/dl) for 3 or more consecutive billing cycles immediately prior to and including the current cycle

CMS contractors will no longer apply edits to ESA dosing above the MUE threshold, that is, 400,000 units for EPO and 1500 mcg for Aranesp for ESRD PPS claims.

ESRD facilities must continue to report all necessary information for the ESRD Quality Incentive Program. CMS has in place a monitoring program that studies the trends and behaviors of ESRD facilities under the ESRD PPS and the health outcomes of the beneficiaries who receives their care. CMS will continue to monitor the utilization of ESAs and any changes in the outlier policy to determine if additional MUEs are necessary.

In order to assure that the system edits are updated correctly, CMS is requesting the contractors identify all systems edits related to the EMP as part of the October 2019 release and implementation will occur in the January 2020 release.

The requirements under this CR are subject to change due to rulemaking.

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	
11244.1	Medicare contractors shall no longer apply a 25% reduction for ESRD claims, Type of Bill (TOB) 72x containing EPO Healthcare Common Procedure Coding System (HCPCS) code Q4081 with or without modifier GS when: • Value code 49 amount is greater than 39.0 or • Value code 48 amount is greater than 13.0					X				
11244.1.1	Medicare contractors shall no longer assign a reason code when the units for ESRD claims, TOB 72x containing EPO HCPCS code Q4081 when the units exceed 400,000 per claim.					X				
11244.2	Medicare contractors shall no longer apply a 25% reduction for ESRD claims, TOB 72x containing Aranesp HCPCS code J0882 with or without modifier GS when: • Value code 49 amount is greater than 39.0 or • Value code 48 amount is greater than 13.0					X				
11244.2.1	Medicare contractors shall no longer assign a reason code when the units for Aranesp, HCPCS code J0882 exceed 1,500 per claim (note: 1 unit = 1 mcg)					X				
11244.3	Medicare contractors shall not assign a reason code when: • EPO HCPCS code Q4081 or Aranesp HCPCS code J0882 is present and • Value code 48 exceeds 13.0 and • Modifier ED or EE is not present on at least one of the line items.					X				
11244.4	Medicare contractors shall no longer assign a reason code when: • EPO HCPCS code Q4081 or Aranesp HCPCS code J0882 is present and • Value code 49 exceeds 39.0 and • Modifier ED or EE is not present on at least one of the line items.					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11244.5	Medicare contractors shall no longer apply the 50% reduction to ESRD claims, TOB 72x when: • Value code 49 exceeds 39.0 or • Value code 48 exceeds 13.0 and • HCPCS code Q4081 or J0882 is present with modifier ED.					X				
11244.5.1	Medicare contractors shall no longer apply the 25% reduction to ESRD claims, TOB 72x when: • Value code 49 exceeds 39.0 or • Value code 48 exceeds 13.0 and • HCPCS code Q4081 or J0882 is present with modifier EE and modifier GS is not present.					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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 , Wendy Tucker, Wendy.Tucker@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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