CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1581	**Date: AUGUST 29, 2008**
	Change Request 6133

Subject: Discarded Erythropoietin Stimulating Agents for Home Dialysis

I. SUMMARY OF CHANGES: This CR updates the manual to include specific instructions regarding discarded self-administered erythropoietin stimulating agents for Method I home dialysis patients.

New / Revised Material
Effective Date: December 1, 2008
Implementation Date: December 1, 2008

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 / 60.4.4.1 / Self Administered EPO Supply
R	8 / 60.7.4 / Darbepoetin Alfa (Aranesp) Furnished to Home Patients
R	17 / Table of Contents
N	17 / 40.1 / Discarded Erythropoietin Stimulating Agents for Home Dialysis

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: 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

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1581	Date: August 29, 2008	Change Request: 6133

SUBJECT: Discarded Erythropoietin Stimulating Agents for Method I Home Dialysis

Effective Date: December 1, 2008

Implementation Date: December 1, 2008

I. GENERAL INFORMATION

A. Background: Multiuse vials are generally not subject to payment for discarded amounts of drug or biological. An exception is applied specifically to self administered erythropoietin stimulating agents (ESAs) by Method I home dialysis patients.

B. Policy: The provider must bill the program using the modifier JW for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial because of interruption in the patient's plan of care or unused ESAs on hand after a patient's death. In these cases, the maximum 13 to 14 administrations generally allowed per month are not expected to all be administered to a patient. The provider must show the appropriately discarded amount on a separate line item with the modifier JW. The line item date of service should be the date of the last covered administration according to the plan of care or if the patient dies use the date of death.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6133.1	Contractors shall require the modifier JW on a single line item to identify appropriately discarded self administered erythropoietin stimulating agents for Method I home dialysis patients.	X		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6133.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X							

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):
For policy questions contact Cheryl Gilbreath, Cheryl.Gilbreath@cms.hhs.gov (410) 786-5919
For claims processing questions contact Wendy Tucker, Wendy.Tucker@cms.hhs.gov (410) 786-3004

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Intermediaries (RHHIs)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *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.

60.4.4.1 - Self Administered EPO Supply

(Rev. 1581; Issued: 08-29-08; Effective/Implementation Date: 12-01-08)

Initially, facilities may bill for up to a 2-month supply of EPO for Method I beneficiaries who meet the criteria for selection for self-administration. After the initial two months' supply, the facility will bill for one month's supply at a time. Condition code 70 is used to indicate payment requested for a supply of EPO furnished a beneficiary. Usually, revenue code 0635 would apply since the supply would be over 10,000 units. Facilities leave FL 46, Units of Service, blank since they are not administering the drug. For value code 68, they enter the total amount of the supply.

For claims with dates of service on or after January 1, 2008, supplies of EPO for self administration should be billed according to the pre-determined plan of care schedule provided to the beneficiary. Submit a separate line item for each date an administration is expected to be performed with the expected dosage. In the event that the schedule was changed, the provider should note the changes in the medical record and bill according to the revised schedule. For patients beginning to self administer EPO at home receiving an extra month supply of the drug, bill the one month reserve supply on one claim line and include modifier EM defined as "Emergency Reserve Supply (for ESRD benefit only)".

When billing for drug wastage in accordance with the policy in chapter 17 of this manual, section 40.1 the provider must show the wastage on a separate line item with the modifier JW. The line item date of service should be the date of the last covered administration according to the plan of care or if the patient dies use the date of death.

Condition code 70 should be reported on claims billing for home dialysis patients that self administer anemia management drugs including epoetin alfa and darbepoetin alfa.

60.7.4 – Darbepoetin Alfa (Aranesp) Furnished to Home Patients

(Rev. 1581; Issued: 08-29-08; Effective/Implementation Date: 12-01-08)

Medicare covers Aranesp for dialysis patients who use Aranesp in the home, when requirements for a patient care plan and patient selection as described in the Medicare Benefit Policy Manual, Chapter 11, are met.

When Aranesp is prescribed for a home patient, it may be either administered in a facility, e.g., the one shown on the Form CMS-382 (ESRD Beneficiary Method Selection Form) or furnished by a facility or Method II supplier for self-administration to a home patient determined to be competent to administer this drug. For Aranesp furnished for self-administration to Method I and Method II home patients determined to be competent, the renal facility bills its FI and the Method II supplier bills its DMERC. No additional payment is made for training a prospective self-administering patient or retraining an existing home patient to self-administer Aranesp.

When billing for drug wastage for Method 1 patients in accordance with the policy in chapter 17 of this manual, section 40.1 the provider must show the wastage on a separate line item with the modifier JW. The line item date of service should be the date of the last

covered administration according to the plan of care or if the patient dies use the date of death.

Method II home patients who self-administer may obtain Aranesp only from either their Method II supplier or a Medicare-certified ESRD facility.

In this case, the DMERC makes payment at the same rate that applies to facilities. Program payment may not be made for Aranesp furnished by a physician to a patient for self-administration.

The DMERCs pay for Aranesp for Method II ESRD beneficiaries only. DMERCs shall deny claims for Aranesp where the beneficiary is not a Method II home dialysis patient.

When denying line items for patients that are not Method II, use the following message on the remittance advice:

The ANSI message 7011: Claim not covered by this payer contractor. You must send the claim to the correct payer contractor.

When denying line items for patients that are not Method II, use the following message on the Medicare Summary Notice (MSN):

English: 8.59- Durable Medical Equipment Regional Carriers pay for Epoetin Alfa and Darbepoetin Alfa only for Method II End Stage Renal Disease home dialysis patients.

Spanish: 8.59- Las Empresas Regionales de Equipo Médico Duradero pagan por los medicamentos Epoetina Alfa y Darbepoetina Alfa sólo a pacientes del Método II de diálisis con enfermedad renal en etapa final que están confinados al hogar.

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

Table of Contents

(Rev. 1581, 08-29-08)

40.1 – Discarded Erythropoietin Stimulating Agents for Home Dialysis

(Rev. 1581; Issued: 08-29-08; Effective/Implementation Date: 12-01-08)

Multiuse vials are not subject to payment for discarded amounts of drug or biological, with the exception of self administered erythropoietin stimulating agents (ESAs) by Method I home dialysis patients. The renal facility must bill the program using the modifier JW for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. Specific instructions are found in chapter 8 of this manual, §60.4.4.1 "Self Administered EPO Supply", and §60.7.4 "Darbepoetin Alfa (Aranesp) Furnished to Home Patients".

This applies only to home dialysis patients who meet the Method I conditions described in Pub 100-2 Benefits Policy Manual, chapter 11, §90 "Epoetin (EPO)", and does not apply to Method II home dialysis patients.

Supplies of ESAs for self administration are billed according to the pre-determined plan of care schedule provided to home dialysis patients that meet the criteria for self administered ESAs discussed in chapter 8 of this manual, §60.4 "Epoetin Alfa (EPO) For ESRD Patients" and §60.7 "Darbepoetin Alfa (Aranesp) for ESRD Patients". The renal facility, through the amounts prescribed in the plan of care, shall ensure the patient's ESA on hand at any time does not exceed a 2-month supply. CMS expects the facility to minimize excess dispensing of the ESAs for self administration based on the patient's plan of care.