CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1212	**Date: MARCH 30, 2007**
	Change Request 5480

Subject: Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)

I. SUMMARY OF CHANGES: This CR instructs all providers and suppliers on new requirements for providing route of administration codes on claims for erythropoiesis stimulating agents (ESAs) administered to end stage renal disease (ESRD) patients.

New / Revised Material
Effective Date: January 1, 2007
Implementation Date: June 29, 2007

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/ Table of Content
N	8/60/60.2.3.1 Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)
R	17/Table of content
N	17/80/80.11 Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)

III. FUNDING:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1212	Date: March 30, 2007	Change Request:5480

SUBJECT: New Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)

Effective Date: January 1, 2007

Implementation Date: June 29, 2007

I. GENERAL INFORMATION

A. Background: Patients with end stage renal disease (ESRD) receiving administrations of Erythropoiesis Stimulating Agents (ESA), such as epoetin alfa (EPO) and darbepoetin alfa (Aranesp) for the treatment of anemia may receive intravenous administrations or subcutaneous administrations of the ESA. Current claims processing requirements do not provide for reporting the method of administration used in providing ESA to patients with ESRD. In order to study the efficacy of both methods of administration, the Centers for Medicare and Medicaid Services (CMS) shall begin requesting providers to voluntarily report modifiers which will indicate the method of administration used in providing the ESA.

At a future date, the shared system modification will be completed and reporting of the route of administration shall be a requirement. Additional instructions will be issued when the shared system changes are completed. Until then, a claim for an ESA that does not report the route of administration shall be paid the same as a claim that does report the route of administration. At this time, a claim for an ESA that does not report and route of administration will not be returned to the provider.

B. Policy: Route of administration modifiers were published and effective January 1, 2007. Consequently, some providers have submitted claims for ESAs reporting the route of administration modifiers. CMS' expects that within 90 days of publication of this instruction, all contractors have encouraged providers to report route of administration on claims for ESAs. Effective for claims submitted on or after *February 1, 2007* with dates of services on or after *January 1, 2007*, all providers billing for injections of ESA for ESRD beneficiaries are encouraged to include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. At this time, reporting these modifiers is voluntary. Contractors do not need to reprocess claims submitted without a reported route of administration modifier.

All providers billing for injections of ESAs for ESRD beneficiaries will be required to include route of administration when claims processing system changes are completed. Renal dialysis facility claims including charges for administrations of the ESA by both methods must report separate lines to identify the number of administrations provided using each method.

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	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5480.1	For dates of service on or after January 1, 2007, all providers are encouraged to include route of administration modifiers, JA for intravenous administration and JB for subcutaneous administration, on claims billing Q4081,J0882 or J0886 for ESRD beneficiaries. Future instructions will be given making inclusion of route of administration modifiers on claims billing Q4081, J0882 or J0886 a requirement for ESRD beneficiaries.	X	X	X	X	X	X					
5480.2	Contractors shall not reject or return claims that do not report the route of administration on claims billing Q4081, J0882 or J0886 for ESRD beneficiaries.	X	X	X	X	X	X					
5480.3	Contractors should encourage providers to begin using the modifiers for claims with dates of service on or after January 1, 2007 and that are billed on or after February 1, 2007. Contractors shall be aware that future instructions will be given making inclusion of route of administration modifiers on claims billing Q4081, J0882 or J0886 a requirement for ESRD beneficiaries.	X	X	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5480.3	A provider education article related to this instruction will be available at 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 1 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	X	X	X					

IV. SUPPORTING INFORMATION

Route of Administration Modifier Definitions:
JA-administered intravenously;
JB-administered subcutaneously

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s):
Policy: Maria Ciccanti 410-786-3107;
Institutional Claims: Wendy Tucker 410-786-3004;
Physician Claims: Melvia Page-Lasowski 410-786-4727

Post-Implementation Contact(s): Policy: Maria Ciccanti 410-786-3107;
Institutional Claim: Wendy Tucker 410-786-3004;
Physician Claims: Melvia Page-Lasowski 410-786-4727;

VI. FUNDING

A. *For TITLE XVIII Contractors*, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. *For Medicare Administrative Contractors (MAC)*, use only one of the following statements:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. We do not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.

Medicare Claims Processing Manual
Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

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(Rev. 1212, 03-30-07)

60.2.3.1 - Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)

(Rev. 1212; Issued: 03-30-07; Effective: 01-01-07; Implementation: 06-29-07)

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA), such as epoetin alfa (EPO) and Darbepoetin alfa (Aranesp) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA.

Effective for claims submitted on or after February 1, 2007 with dates of services on or after January 1, 2007, all providers billing for injections of ESA for ESRD beneficiaries are encouraged to include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. All providers billing for injections of ESAs for ESRD beneficiaries will be required to include route of administration when claims processing system changes are completed. 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.

Medicare Claims Processing Manual
Chapter 17 - Drugs and Biologicals

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(Rev. 1212, 03-30-07)

80.11 - Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)

(Rev. 1212; Issued: 03-30-07; Effective: 01-01-07; Implementation: 06-29-07)

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA), such as epoetin alfa (EPO) and Darbepoetin alfa (Aranesp) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA.

Effective for claims submitted on or after February 1, 2007 with dates of services on or after January 1, 2007, all providers billing for injections of ESA for ESRD beneficiaries are encouraged to include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. All providers billing for injections of ESAs for ESRD beneficiaries will be required to include route of administration when claims processing system changes are completed. 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.