

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1413</b>	<b>Date: JANUARY 14, 2008</b>
	<b>Change Request 5818</b>

**SUBJECT: Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions**

**I. SUMMARY OF CHANGES:** CMS has determined that ESA treatment is reasonable and necessary for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia under specified conditions. CMS has also determined that ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use.

**NEW / REVISED MATERIAL**

**EFFECTIVE DATE: JULY 30, 2007**

**IMPLEMENTATION DATE: APRIL 7, 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**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	17/Table of Contents
<b>N</b>	17/80.12/Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy

**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: 1413	Date: January 14, 2008	Change Request: 5818
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**SUBJECT: Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions**

**Effective Date: NCD: July 30, 2007**  
**Modifiers: January 1, 2008**  
**Implementation Date: April 7, 2008**

## I. GENERAL INFORMATION

**A. Background:** The United States Food and Drug Administration (FDA) recently issued alerts and warnings for ESAs administered for a number of clinical conditions, including cancer and renal disease. Recently published studies report a higher risk of serious and life-threatening events associated with the use of ESAs in various clinical applications. As a result, on March 14, 2007, CMS opened a National Coverage Analysis (NCA) to evaluate the uses of ESAs in non-renal disease applications. On July 30, 2007, CMS issued a Decision Memorandum for the uses of ESAs in non-renal disease applications, specifically narrowed to the use of ESAs in cancer and other neoplastic conditions. This change request (CR) communicates the findings resulting from the NCA and the coverage policy listed in the National Coverage Determination (NCD).

In addition, the Tax Relief and Health Care Act of 2006 requires providers to report a recent hemoglobin or hematocrit level on claims for anti-anemia drugs administered in connection with the treatment of cancer beginning January 1, 2008. To implement this requirement, CMS issued CR 5699, transmittal 1412, dated January 11, 2008 that instructs providers to report a hematocrit or hemoglobin for all non-ESRD anti-anemia claims, inclusive of ESAs. CR 5699 instructs providers to report one of three modifiers (EA, EB or EC). The definitions of the modifiers are: EA: ESA, anemia, chemo-induced; EB: ESA, anemia, radio-induced and EC: ESA, anemia, non-chemo/radio. Refer to CR 5699 for further reporting requirement details.

**B. NCD Policy:** The Centers for Medicare & Medicaid Services (CMS) reviewed the evidence and determined that ESA treatment is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia under specified conditions. ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use. The complete NCD can be accessed at section 110.21 of Publication (Pub.) 100-03, NCD Manual, and claims processing instructions can be accessed at Pub. 100-04, Claims Processing Manual, chapter 17, sections 80.8-80.12. The HCPCS codes specific to non-ESRD ESA use are J0881 and J0885. Claims processed with dates of service July 30, 2007, through December 31, 2007, do not have to include the ESA modifiers as they are not effective until January 1, 2008.

## II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement*

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A	D	F	C	R	Shared-System Maintainers				OTHER
		/	M	I	A	H	F	M	V	C	
		B	E		R	H	I	S	S	M	W
		M	M		I			S		S	F
		A	A		E						
		C	C		R						

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER	
							F I S S	M C S	V M S	C W F		
5818.1	<p>Effective for claims with dates of service on and after January 1, 2008, standard systems maintainers (SSMs) shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) when any one of the following diagnosis codes is present on the claim:</p> <p>-any anemia in cancer or cancer treatment patients due to folate deficiency (281.2),</p> <p>B-12 deficiency (281.1, 281.3),</p> <p>iron deficiency (280.0-280.9),</p> <p>hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9-283.10, 283.19), or</p> <p>bleeding (280.0, 285.1),</p> <p>-anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91), or,</p> <p>erythroid cancers (207.00-207.81).</p>						X	X				
5818.1.1	<p>Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) for:</p> <p>-any anemia in cancer or cancer treatment patients due to bone marrow fibrosis,</p> <p>-anemia of cancer not related to cancer treatment,</p> <p>-prophylactic use to prevent chemotherapy-induced anemia,</p> <p>-prophylactic use to reduce tumor hypoxia,</p> <p>-patients with erythropoietin-type resistance due to neutralizing antibodies, and</p> <p>-anemia due to cancer treatment if patients have uncontrolled hypertension.</p>	X		X	X	X						
5818.2	Effective for claims with dates of service on and after						X	X				

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	January 1, 2008, SSMs shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EB (ESA, anemia, radio-induced).										
5818.3	Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EA (ESA, anemia, chemo-induced) for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia when a hemoglobin 10.0g/dL or greater or hematocrit 30.0% or greater is reported.  NOTE: ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regime.	X		X	X	X					
5818.4	Effective for claims with dates of service on and after January 1, 2008, Medicare contractors shall have discretion to establish local coverage policies for those indications not included in NCD 110.21	X		X	X	X					
5818.5	Contractors shall deny non-ESRD ESA services for cancer and related neoplastic indications included in NCD 110.21 based on reasonable and necessary determinations. A provider may have the beneficiary sign an Advance Beneficiary Notice, making the beneficiary liable for services not covered by Medicare.	X		X	X	X					
5818.5.1	Denials are subject to appeal and SSMs shall allow for medical review override of denials for appeal purposes.						X	X			
5818.5.2	SSMs shall assign liability for the denied charges to the provider unless documentation of the ABN is present on the claim.						X	X			
5818.5.3	Contractors shall use MSN message 15.20, The following policies [NCD 110.21] were used when we made this decision, and remittance reason code 50, These are non-covered services because this is not deemed a `medical necessity' by the payer, for medical necessity denials of non-ESRD ESA claims for cancer and related neoplastic indications included in NCD 110.21.	X		X	X	X	X				
5818.6	Claims processed prior to April 7, 2008, shall not be searched for adjustment. However, contractors shall adjust claims if brought to their attention.	X		X	X	X					

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
5818.7	<p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles">http://www.cms.hhs.gov/MLNMattersArticles</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>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.</p>	X		X	X	X					

### IV. SUPPORTING INFORMATION

**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 this space:**

### V. CONTACTS

**Pre-Implementation Contact(s):**

National Coverage Determination: Maria Ciccanti, [maria.ciccanti@cms.hhs.gov](mailto:maria.ciccanti@cms.hhs.gov), 410-786-3107,  
 Pat Brocato-Simons, [patricia.brocatosimons@cms.hhs.gov](mailto:patricia.brocatosimons@cms.hhs.gov), 410-786-0261,  
 Kim Long, [kimberly.long@cms.hhs.gov](mailto:kimberly.long@cms.hhs.gov), 410-786-5702  
 Institutional Claims Processing: Sherry Murray, [sherry.murray@cms.hhs.gov](mailto:sherry.murray@cms.hhs.gov), 410-786-6145  
 Practitioner Claims Processing: Melvia Page-Lasowski, [melvia.pagelasowski@cms.hhs.gov](mailto:melvia.pagelasowski@cms.hhs.gov), 410-786-4727

**Post-Implementation Contact(s):** Appropriate RO

### VI. FUNDING

**A. For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC):**

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

**B. For Medicare Administrative Contractors (MACs):**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does 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 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.

# Medicare Claims Processing Manual

## Chapter 17 - Drugs and Biologicals

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### Table of Contents *(Rev. 1413, 01-14-08)*

*80.12 – Claims Processing Rules for ESAs Administered to Cancer Patients  
for Anti-Anemia Therapy*

**80.12 – Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy**  
**(Rev. 1413; Issued: 01-14-08; Effective: 07-30-07; Implementation: 04-07-08)**

*The national coverage determination (NCD) titled, “The Use of ESAs in Cancer and Other Neoplastic Conditions” lists coverage criteria for the use of ESAs in patients who have cancer and experience anemia as a result of chemotherapy or as a result of the cancer itself. The full NCD can be viewed in Publication 100-03 of the NCD Manual, section 110.21.*

*Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) shall be denied when any one of the following diagnosis codes is present on the claim:*

- *any anemia in cancer or cancer treatment patients due to folate deficiency (281.2),*
- *B-12 deficiency (281.1, 281.3),*
- *iron deficiency (280.0-280.9),*
- *hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9-283.10, 283.19), or*
- *bleeding (280.0, 285.1),*
- *anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91); or*
- *erythroid cancers (207.00-207.81).*

*Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) for:*

- *any anemia in cancer or cancer treatment patients due to bone marrow fibrosis,*
- *anemia of cancer not related to cancer treatment,*
- *prophylactic use to prevent chemotherapy-induced anemia,*
- *prophylactic use to reduce tumor hypoxia,*
- *patients with erythropoietin-type resistance due to neutralizing antibodies; and*
- *anemia due to cancer treatment if patients have uncontrolled hypertension.*

*Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EB (ESA, anemia, radio-induced), shall be denied.*

*Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EA (ESA, anemia, chemo-induced) for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia when a hemoglobin 10.0g/dL or greater or hematocrit 30.0% or greater is reported.*

***NOTE:*** *ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regime.*

*Effective for claims with dates of service on and after January 1, 2008, Medicare contractors shall have discretion to establish local coverage policies for those indications not included in NCD 110.21*

*Denials of claims for ESAs are based on reasonable and necessary determinations established by NCD 110.21. A provider may have the beneficiary sign an Advanced Beneficiary Notice, making the beneficiary liable for services not deemed reasonable and necessary and thus not covered by Medicare.*

*Report Medicare Summary Notice message 15.20, “The following policies [NCD 110.21] were used when we made this decision”, and remittance reason code 50, “These are non-covered services because this is not deemed a `medical necessity' by the payer” for denied ESA claims.*

*Medicare contractors have the discretion to conduct medical review of claims and reverse the automated adjudication if the medical review results in a determination of clinical necessity.*