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Medicare Coverage Database

Draft LCD for Erythropoietin Stimulating Agents (ESA) (DL27571)

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Contractor Information





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[Palmetto GBA](#)

Contractor Number [back to top](#)

01101

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MAC - Part A

LCD Information



LCD ID Number [back to top](#)

DL27571

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Erythropoietin Stimulating Agents (ESA)

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J1A-08-0015-L

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Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA), §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act (SSA), §1881(b)(1) allows payment for services furnished to individuals who have been determined to have end stage renal disease.

Title XVIII of the Social Security Act (SSA), §1881(b)(11)(B)(I) allows payment for erythropoietin provided by a physician.

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 1, §30 Drugs and Biologicals

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 6, §30 Drugs and Biologicals

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 11, §30.1 Frequency of Dialysis Sessions, §30.4 Drugs and Biologicals, §30.5 ESRD Composite Payment Rates Effective January 1, 2009 and §90 Epoetin (EPO)

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §50 Drugs and Biologicals, §50.1 Definition of Drug or Biological, §50.2 Determining Self-Administration of Drug or Biological, §50.3 Incident-to Requirements, §50.4.1 Approved Use of Drug, §50.4.3 Examples of Not Reasonable and Necessary, §50.5.2 Erythropoietin (EPO), §50.5.2.1 Requirements for Medicare Coverage for EPO and §50.5.2.2 Medicare Coverage of Epoetin Alfa (Procrit) for Preoperative Use

CMS Manual System, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §110.21 Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 6, §10.1 Consolidated Billing Requirement for SNFs, §20.2 Services Excluded from Part A PPS Payment ..., §20.2.1.1 ESRD Services and §20.2.1.2 Coding Applicable to Dialysis Services Provided in a Renal Dialysis Facility (RDF) or Home

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 8, §10.5 Hospital Services, §50 In-Facility Dialysis Bill Processing Procedures, §50.3 Required Information for In-Facility Claims Paid Under the Composite Rate, §60.2.3.1 Requirement For Providing Route of Administration Codes for Erythropoiesis Stimulating Agents(ESAs), §60.4 Epoetin Alfa (EPO), §60.4.1 Epoetin Alfa (EPO) Facility Billing Requirements, §60.4.3 Payment Amount for Epoetin Alfa (EPO), §60.4.3.2 Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments, §60.7 Darbepoetin Alfa (Aranesp®) for ESRD Patients, §60.7.1 Darbepoetin Alfa (Aranesp®) Facility Billing Requirements, §60.7.3 Payment Amount for Darbepoetin Alfa (Aranesp®), §60.7.3.2 Payment for Darbepoetin Alfa (Aranesp®) in the Hospital Outpatient Department, §80.2.1 Required Billing Information for Method I Claims, §90 Method II Billing, §90.5 Method II Support Services Billed to the Intermediary by the Facility, §90.5.1 Billable Revenue Codes Under Method II and §90.5.1.1 Unbillable Revenue Codes Under Method II

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, §10 Payment Rules for Drugs and Biologicals, §20.5.8 Injections Furnished to ESRD Beneficiaries, §80.9 Required Modifiers for ESAs Administered to Non-ESRD Patients and §80.10 Hospitals billing for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 25, §75 General Instructions for Completion of Form CMS-1450 for Billing (UB-04)

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 27, §80.8 ESRD Maintenance Transaction Error Codes

Medicare National Coverage Determinations/Decision Memo CAG-00383N, July 30, 2007.

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California - Entire State

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Region I

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For services performed on or after 08/20/2008

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Revision Effective Date [back to top](#)

For services performed on or after 06/25/2009

Revision Ending Date [back to top](#)**Indications and Limitations of Coverage and/or Medical Necessity** [back to top](#)

An erythropoietin stimulating agent (ESA) is an analog of erythropoietin. ESAs are biologically engineered hormones produced by recombinant DNA technology. Erythropoietin analogs contain the identical amino acid sequence as naturally occurring erythropoietin, and have the same biological effect. Primarily, the kidneys produce erythropoietin in response to hypoxia. Both erythropoietin and ESAs stimulate the bone marrow to form new red blood cells. They are used to treat anemia by elevating or maintaining the red blood cell level (as demonstrated by the hematocrit and/or hemoglobin levels), therefore decreasing anemia and the need for transfusions. Darbepoetin alfa (brand name Aranesp®), an erythropoietin analog, differs from recombinant human erythropoietin alfa (brand name Epogen® or Procrit®) in having two additional N-glycosylation sites, which slows its clearance and makes its half-life two-three times longer, allowing less frequent injections. This policy will apply to new ESAs as they are approved.

Since darbepoetin alfa and epoetin alfa have a similar mode of action and their structures differ only by the number of N-linked oligosaccharides on the protein, this policy does not distinguish differences for on or off-label indications and contraindications, except for pre treatment of selective surgery where blood loss is anticipated. Several off-label uses are well-accepted clinically, as indicated by inclusion in various compendia. However, a contraindication for either ESA is binding on both. In March 2007, the FDA issued new warnings against target Hgb levels above 12 g/dL (36% Hct) "for all patients." The FDA also issued specific warnings against off-label use in cancer patients whose anemia is not directly linked to chemotherapy. The FDA also reminded physicians that the main endpoint in studies for on-label indications has been avoidance or reduction in transfusions. The LCD contains descriptions of specific coverage guidelines and documentation that supports medical necessity for individual patients.

CMS has a national coverage decision on both renal and non-renal uses of ESAs. This local decision elaborates on the NCD and covers some additional indications.

Erythropoietin analogs are covered for the following indications:

1. *Treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis;*
2. *Treatment of significant anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy;*
3. *Treatment of anemia induced by AZT and/or other Nucleoside Reverse Transcriptase Inhibitors (NRTI) used in treatment of HIV/AIDS;*
4. *Treatment of selected patients with anemia related to myelodysplastic syndrome;*
5. *Preoperative adjuvant therapy (epoetin alfa only);*
6. *Treatment of anemia of selected chronic diseases: rheumatoid arthritis,*

systemic lupus erythematosus, inflammatory bowel diseases, and Hepatitis C undergoing treatment.

The following causes of anemia should be considered, documented, and corrected (when possible) before starting erythropoietin analog therapy for any of the covered indications:

- Iron deficiency
- Underlying infection or inflammatory process
- Underlying hematological disease
- Hemolysis
- Vitamin deficiencies (e.g. folic acid or B12)
- Blood loss
- Aluminum intoxication

The 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. These conditions include:

- *any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;*
- *the anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;*
- *the anemia of cancer not related to cancer treatment;*
- *any anemia associated only with radiotherapy;*
- *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.*

There are rare patients whose cardiac, pulmonary or other medical diseases warrant the use of ESAs to maintain a hemoglobin/hematocrit (Hgb/Hct) higher than the target level discussed in this LCD. Documentation to support this practice must be available upon request. This does not apply to ESA therapy for anemia related to cancer chemotherapy, which follows the rules mandated by the National Coverage Decision.

During therapy with an erythropoietin analog, many patients will eventually require supplemental iron. For these patients, stores of iron should be regularly monitored to ensure a transferrin saturation greater than 20% and/or serum ferritin levels greater than 100 ng/ml, in order to guide appropriate supplementation.

For patients receiving chemotherapy for non-myeloid malignancies, the goal of therapy is to maintain the Hgb/Hct at 10/30. ESA therapy will not be reimbursed when the Hgb/Hct is greater than 10/30. For all other indications, the goal of therapy is to maintain a stable Hgb/Hct, with a target of 10-12 g/dL / 30-36%. Doses must be titrated according to the patient's response. Erythropoietin analog therapy need not be stopped completely simply due to the achievement of the target Hgb/Hct. However, judicious, appropriately timed dose adjustments are expected to prevent inappropriate increases in Hgb/Hct levels.

ESAs may be administered by intravenous or subcutaneous routes. The dosage may be dependent on several factors including the availability of iron stores, the baseline Hgb/Hct, and the presence of concurrent medical problems.

Although subcutaneous medications are generally considered to be self-administered and therefore not covered, erythropoietin analogs are covered regardless of route of administration when used within the ESRD benefit.

Coverage Criteria:

A. For End Stage Renal Disease (ESRD) patients on dialysis:

1. Diagnosis of end stage renal disease;
2. Anemia of ESRD should be treated to maintain a Hgb level of 10-12 gm/dL or a Hct of 30%-36%.

B. For chronic kidney disease patients NOT on dialysis:

1. Anemia of chronic kidney disease should be treated to maintain the Hgb level of 10-12 gm/dl or a Hct of 30%-36%.
2. Serum creatinine equal to or greater than 3, creatinine clearance less than 60 ml/min, or glomerular filtration rate (GFR) less than 60 mL/min/1.73 m².

C. For patients with non-myeloid malignancies where anemia is due to the effect of chemotherapy:

1. Anemia with Hgb/Hct less than 10 / 30% at initiation of therapy.
2. The starting dose for ESA treatment is no more than 150 U/kg/three times weekly for epoetin and 2.25 mcg/kg/weekly for darbepoetin alpha. Equivalent doses may be given over other FDA approved time periods.
3. The maintenance dose of ESA therapy is the same as the starting dose if the Hgb/Hct level remains below 10/30 four weeks after initiation of therapy AND the rise in Hgb is $\geq 1\text{g/dl}$ (Hct $\geq 3\%$).
4. If Hgb/Hct rises $<1/3$ compared to pretreatment baseline over 4 weeks of therapy and Hgb/Hct level remains $<10/30$, the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the Hgb rises $<1\text{g/dl}$ (Hct rise $< 3\%$ compared to pretreatment baseline by 8 weeks of treatment).
5. Continued administration of the drug is not reasonable and necessary if there is a rapid rise in Hgb/Hct $>1/3$ over 2 weeks of treatment unless the Hgb/Hct remains below or subsequently falls to $<10/30$. Continuation and reinstatement of ESA therapy must include a dose reduction of 25% from previously administered dose.
6. The FDA labeling states that ESAs are indicated for treatment of anemia of malignancy when receiving concomitant chemotherapy, which means during an established course of planned chemotherapy. It will also cover ESAs for eight weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

D. For patients with anemia related to AZT and/or other Nucleoside Reverse Transcriptase Inhibitors (NRTI) therapy for HIV/AIDS:

1. Anemia should be treated to maintain the Hgb level of 10-12gm/dl or a Hct of 30%-36%.

E. For patients with myelodysplastic syndrome:

1. Low risk myelodysplasia
2. Pretreatment *erythropoietin levels of 500 or less
3. Anemia with Hgb/Hct less than 10 / 30% at initiation of therapy. If after two months of treatment, there is no significant increase in Hgb/Hct and/or a significant decrease in transfusion requirements, erythropoietin analogs therapy should be stopped.

*For ESA therapy initiated on or after 12/1/2007, this A/B MAC requires an EPO level less than or equal 500 IU/L.

F. Preoperative adjuvant therapy: epoetin alfa for patients who:

1. Are undergoing hip or knee surgery;
2. Have an anemia with a Hgb between 10 and 13 gm/dL;
3. Are not a candidate for autologous blood transfusion;
4. Are expected to lose more than two units of blood;
5. Have been evaluated to ensure that their anemia is due to chronic disease.

G. For patients with anemia of chronic disease:

1. Anemia with Hgb/Hct less than 10-12 / 30%-36%

The literature covering use of ESAs for anemia of chronic disease is mixed, though developing. Most reported studies are small, and positive effects must be balanced with newer data that shows some patients given ESAs with anemia of cancer have shorter survival times. Currently there is evidence of patient benefit using ESA therapy to reduce transfusions for selected patients with significant refractory and symptomatic anemia who have inflammatory diseases (rheumatoid arthritis, Crohn's disease, ulcerative colitis), and Hepatitis C with anemia due to the medication therapy. Until further publications show clear benefit, ESAs for anemia of other chronic diseases other than those listed above will not be covered. Use the lowest dose of an ESA that will gradually increase the Hgb concentration to the lowest level sufficient to avoid the need for red blood cell transfusion.

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Prescription Drugs

Coding Information



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Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)
22x	SNF-inpatient or home health visits (Part B only)
23x	SNF-outpatient (HHA-A also)
71x	Clinic-rural health
72x	Clinic-hospital based or independent renal dialysis facility
73x	Clinic-independent provider based FQHC (eff 10/91)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)

Revenue Codes: [back to top](#)

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the

policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

*Revenue code 0636 relates to HCPCS code. Indicate HCPCS code J0885 in Form Locator 44 of the UB-92 form. The specified units of service to be reported are to be in thousands (1000s), rounded to the nearest thousand.

Revenue codes only apply to providers who bill these services to the fiscal intermediary. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier.

0634	Drugs requiring specific identification-EPO under 10,000 units
0635	Drugs requiring specific identification-EPO 10,000 units or more
0636	Drugs requiring specific identification-detailed coding (eff 3/92)

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J0881	INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (NON-ESRD USE)
J0882	INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (FOR ESRD ON DIALYSIS)
J0885	INJECTION, EPOETIN ALFA, (FOR NON-ESRD USE), 1000 UNITS
J0886	INJECTION, EPOETIN ALFA, 1000 UNITS (FOR ESRD ON DIALYSIS)
Q4081	INJECTION, EPOETIN ALFA, 100 UNITS (FOR ESRD ON DIALYSIS)

ICD-9 Codes that Support Medical Necessity [back to top](#)

It is the responsibility of the provider to code to the highest level specified in the ICD-9-CM (e.g., to the fourth or fifth digit). The correct use of an ICD-9-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

For Patients on Dialysis (Both diagnoses must be on claim.)

285.21	ANEMIA IN CHRONIC KIDNEY DISEASE
585.6	END STAGE RENAL DISEASE

For patients with chronic kidney disease (not yet on dialysis) and

anemia – must include 285.21 and one other listed diagnosis

285.21	ANEMIA IN CHRONIC KIDNEY DISEASE
403.00*	HYPERTENSIVE CHRONIC KIDNEY DISEASE, MALIGNANT, WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
403.01	HYPERTENSIVE CHRONIC KIDNEY DISEASE, MALIGNANT, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
403.10*	HYPERTENSIVE CHRONIC KIDNEY DISEASE, BENIGN, WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
403.11	HYPERTENSIVE CHRONIC KIDNEY DISEASE, BENIGN, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
403.90*	HYPERTENSIVE CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
403.91	HYPERTENSIVE CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.00*	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.01*	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.02	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.03	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, MALIGNANT, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.10*	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.11*	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.12	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.13	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, BENIGN, WITH HEART FAILURE AND CHRONIC KIDNEY

DISEASE STAGE V OR END STAGE RENAL DISEASE	
404.90*	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.91*	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE I THROUGH STAGE IV, OR UNSPECIFIED
404.92	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITHOUT HEART FAILURE AND WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
404.93	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH HEART FAILURE AND CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
585.3	CHRONIC KIDNEY DISEASE, STAGE III (MODERATE)
585.4	CHRONIC KIDNEY DISEASE, STAGE IV (SEVERE)
585.5	CHRONIC KIDNEY DISEASE, STAGE V
*Note: Patients with stage I and II chronic kidney disease do not meet the creatinine clearance or GFR requirements in coverage criteria B.	

Patients with anemia related to treatment with zidovudine and/or other Nucleoside Reverse Transcriptase Inhibitors (NRTI) for HIV disease must have 284.89 (aplastic anemia due to drugs) and either 042 or 079.53 on claim.

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
079.53	HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 [HIV-2]
284.89	OTHER SPECIFIED APLASTIC ANEMIAS

For patients with anemia related to chemotherapy, claims must be reported with ICD-9-CM code 284.89 (representing the anemia related to chemotherapy) plus the non-myeloid malignancy for which the chemotherapy was administered. (Note: 205.00-205.91, 206.00-206.91, 207.00-208.91 are myeloid malignancies and are excluded from coverage.)

140.0 - 149.9	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY
150.0 - 159.9	MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE DIGESTIVE ORGANS AND PERITONEUM
160.0 - 165.9	MALIGNANT NEOPLASM OF NASAL CAVITIES - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE RESPIRATORY SYSTEM
170.0 - 176.9	MALIGNANT NEOPLASM OF BONES OF SKULL AND FACE EXCEPT MANDIBLE - KAPOSI'S SARCOMA UNSPECIFIED SITE

179 - 189.9	MALIGNANT NEOPLASM OF UTERUS-PART UNS - MALIGNANT NEOPLASM OF URINARY ORGAN SITE UNSPECIFIED
190.0 - 199.1	MALIGNANT NEOPLASM OF EYEBALL EXCEPT CONJUNCTIVA CORNEA RETINA AND CHOROID - OTHER MALIGNANT NEOPLASM OF UNSPECIFIED SITE
199.2	MALIGNANT NEOPLASM ASSOCIATED WITH TRANSPLANT ORGAN
200.00 - 202.98	RETICULOSARCOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES
203.00 - 203.81	MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER IMMUNOPROLIFERATIVE NEOPLASMS IN REMISSION
203.82	OTHER IMMUNOPROLIFERATIVE NEOPLASMS, IN RELAPSE
204.00 - 204.91	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED LYMPHOID LEUKEMIA IN REMISSION
204.92	UNSPECIFIED LYMPHOID LEUKEMIA, IN RELAPSE
209.00 - 209.30	MALIGNANT CARCINOID TUMOR OF THE SMALL INTESTINE, UNSPECIFIED PORTION - MALIGNANT POORLY DIFFERENTIATED NEUROENDOCRINE CARCINOMA, ANY SITE
233.30	CARCINOMA IN SITU, UNSPECIFIED FEMALE GENITAL ORGAN
233.31	CARCINOMA IN SITU, VAGINA
233.32	CARCINOMA IN SITU, VULVA
233.39	CARCINOMA IN SITU, OTHER FEMALE GENITAL ORGAN
235.0 - 235.9	NEOPLASM OF UNCERTAIN BEHAVIOR OF MAJOR SALIVARY GLANDS - NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER AND UNSPECIFIED RESPIRATORY ORGANS
236.0 - 236.99	NEOPLASM OF UNCERTAIN BEHAVIOR OF UTERUS - NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER AND UNSPECIFIED URINARY ORGANS
237.0 - 237.9	NEOPLASM OF UNCERTAIN BEHAVIOR OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT - NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER AND UNSPECIFIED PARTS OF NERVOUS SYSTEM
238.0	NEOPLASM OF UNCERTAIN BEHAVIOR OF BONE AND ARTICULAR CARTILAGE
238.1	NEOPLASM OF UNCERTAIN BEHAVIOR OF CONNECTIVE AND OTHER SOFT TISSUE
238.2	NEOPLASM OF UNCERTAIN BEHAVIOR OF SKIN
238.3	NEOPLASM OF UNCERTAIN BEHAVIOR OF BREAST
238.5	NEOPLASM OF UNCERTAIN BEHAVIOR OF HISTIOCYTIC AND MAST CELLS

238.6	NEOPLASM OF UNCERTAIN BEHAVIOR OF PLASMA CELLS
238.77	POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD)
238.79 - 238.9	OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES - NEOPLASM OF UNCERTAIN BEHAVIOR SITE UNSPECIFIED
239.0 - 239.9	NEOPLASM OF UNSPECIFIED NATURE OF DIGESTIVE SYSTEM - NEOPLASM OF UNSPECIFIED NATURE SITE UNSPECIFIED
273.3	MACROGLOBULINEMIA
284.89	OTHER SPECIFIED APLASTIC ANEMIAS
V58.11	ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY
V58.12	ENCOUNTER FOR IMMUNOTHERAPY FOR NEOPLASTIC CONDITION

Patients with anemia related to Myelodysplastic Syndrome

238.72	LOW GRADE MYELODYSPLASTIC SYNDROME LESIONS
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Preoperative use in specified patients. Must have an anemia diagnosis (Note: 285.29 or 285.9) and other specified prophylactic measure diagnosis. (Anemia must be primary diagnosis).

285.29	ANEMIA OF OTHER CHRONIC DISEASE
285.9	ANEMIA UNSPECIFIED
V07.8	NEED FOR OTHER SPECIFIED PROPHYLACTIC MEASURE

For patients with Hepatitis C and anemia of chronic inflammatory diseases. Include 285.29 (anemia of other chronic disease) and one other listed diagnosis.

070.41	ACUTE HEPATITIS C WITH HEPATIC COMA
070.44	CHRONIC HEPATITIS C WITH HEPATIC COMA
070.51	ACUTE HEPATITIS C WITHOUT MENTION OF HEPATIC COMA
070.54	CHRONIC HEPATITIS C WITHOUT HEPATIC COMA
070.70	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
070.71	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
555.0	REGIONAL ENTERITIS OF SMALL INTESTINE
555.1	REGIONAL ENTERITIS OF LARGE INTESTINE
555.2	REGIONAL ENTERITIS OF SMALL INTESTINE WITH LARGE INTESTINE
555.9	REGIONAL ENTERITIS OF UNSPECIFIED SITE
556.0	ULCERATIVE (CHRONIC) ENTEROCOLITIS
556.1	ULCERATIVE (CHRONIC) ILEOCOLITIS
556.2	ULCERATIVE (CHRONIC) PROCTITIS

556.3	ULCERATIVE (CHRONIC) PROCTOSIGMOIDITIS
556.4	PSEUDOPOLYPOSIS OF COLON
556.5	LEFT-SIDED ULCERATIVE (CHRONIC) COLITIS
556.6	UNIVERSAL ULCERATIVE (CHRONIC) COLITIS
556.8	OTHER ULCERATIVE COLITIS
556.9	ULCERATIVE COLITIS UNSPECIFIED
710.0	SYSTEMIC LUPUS ERYTHEMATOSUS
714.0	RHEUMATOID ARTHRITIS

Diagnoses that Support Medical Necessity [back to top](#)

Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity [back to top](#)

[205.00 - 205.91](#) ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED MYELOID LEUKEMIA IN REMISSION

[206.00 - 206.91](#) ACUTE MONOCYTIC LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED MONOCYTIC LEUKEMIA IN REMISSION

[207.00 - 207.81](#) ACUTE ERYTHREMIA AND ERYTHROLEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER SPECIFIED LEUKEMIA IN REMISSION

[208.00 - 208.91](#) ACUTE LEUKEMIA OF UNSPECIFIED CELL TYPE, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED LEUKEMIA IN REMISSION

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation [back to top](#)

Diagnoses that DO NOT Support Medical Necessity [back to top](#)

Not applicable

General Information





Documentation Requirements [back to top](#)

Listing of ICD-9-CM codes contained in this LCD does not assure coverage of the specific service. Coverage criteria specified in this LCD shall be applied to determine appropriate reimbursement.

Medical record documentation must be legible, maintained in the patient's medical record, and meet the criteria contained in this LCD.

Medical records such as physician's (or nonphysician practitioner's) order must be made available upon request of this A/B MAC. Documentation the provider is to maintain in the patient's medical record include: patient's weight in kilograms; erythropoietin analog units administered per kilogram of body weight; and medical justification for administration of erythropoietin analogs exceeding usual doses.

Documentation supporting the indication for erythropoietin analogs administration must be made available upon the request of this A/B MAC; for all patients, this includes Hgb/Hct and documentation of adequate iron stores. Additional information is determined by indication. Regular reporting of Hgb/Hct is needed to show monitoring of ESA dose.

- Dialysis Patients – dialysis schedule, Hgb/Hct immediately prior to billing period. For ESRD patients on home dialysis, the following additional information must be maintained in the medical record and available to this A/B MAC upon request: a care plan; evidence of home monitoring (including a record of the erythropoietin analog supplied to the patient and a record of dose administration); patient instructions; and patient selection protocol.
- Non-dialysis Patients:
Chronic renal failure patients: serum creatinine, creatinine clearance, or glomerular filtration rate (GFR) supporting a diagnosis of chronic renal failure. Patients with myelodysplastic syndrome: *bone marrow biopsy report, date of initiation of erythropoietin analog therapy, and response to erythropoietin analog administration (change in Hgb/Hct and/or transfusion requirements).
*For patients on ESA therapy for MDS, initiated prior to 12/01/2007, this A/B MAC requires that a physician's statement that the patient does have MDS be included in the medical record. For ESA therapy initiated on or after 12/01/2007, a copy of the actual bone marrow report must be included in the medical record. MDS cannot be diagnosed definitively until a bone marrow biopsy is performed to

confirm the diagnosis.

Appendices [back to top](#)

Not Applicable

Utilization Guidelines [back to top](#)

N/A

Sources of Information and Basis for Decision [back to top](#)

Aranesp ® [package insert]. Thousand Oaks, CA: Amgen, Inc; 2007.

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Brunkhorst R. Darbepoetin alpha effectively maintains hemoglobin concentrations at extended dose intervals relative to intravenous or subcutaneous recombinant human erythropoietin in dialysis patients. *Nephrology, Dialysis, Transplantation*. May 1, 2004;19(5): 1224-30.

Canon JL. Randomized, double-blind, active-controlled trial of every-3-week darbepoetin alfa for the treatment of chemotherapy-induced anemia. *Journal of the National Cancer Institute*. Feb 15,2006;98(4): 273-84.

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Kotasek D. Darbepoetin alpha administered every 3 weeks alleviates anemia in patients with solid tumors receiving chemotherapy; results of a double-blind, placebo-controlled, randomized study. *European Journal of Cancer*. Sep 1,2003; 39(14):2026-34.

NKF – K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2007.

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Parfrey P. Target Hemoglobin Level for EPO in CKD. *American Journal of Kidney Diseases*. January, 2006; 47(1).

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Schwartzberg LS. A randomized comparison of every 2-week Darbepoetin alpha and epoetin alpha for the treatment of chemotherapy-induced anemia in patients with breast, lung, or gynecological cancer. *Oncologist*. Jan 1,2004; 9(6): 696-707.

Singh AK, Szczeck L, Tang KL, et al. Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease. (CHOIR). *NEJM*. November 16, 2006; 355(20):2085-2098.

Stasi R. Management of cancer related anemia with erythropoietic agents: doubts, certainties, and concerns. *The Oncologist*. Aug 1,2005; 10(7):539-54.

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U.S. Food and Drug Administration Center for Drug Evaluation and Research. Information on Erythropoiesis Stimulating Agents (ESA). Feb 16, 2007.

Wintrobe's Clinical Hematology. 10th ed. Lippincott Williams & Wilkins. 1999;184-187.

Advisory Committee Meeting Notes [back to top](#)

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community.

Contractor Advisory Committee meeting dates:

California - March 18, 2009

Hawaii - March 6, 2009

Nevada - March 12, 2009

Start Date of Comment Period [back to top](#)

03/06/2009

End Date of Comment Period [back to top](#)

04/20/2009

Start Date of Notice Period [back to top](#)

Revision History Number [back to top](#)

Revision #3, 06/25/2009

Revision History Explanation [back to top](#)

Revision #3, 06/25/2009

Under CMS National Coverage Policy added (b) to the cited reference: Title

XVIII of the Social Security Act (SSA), §1881(11)(B)(I). Changed the date cited in the following reference :CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 11, §30.5 ESRD Composite Payment Rates Effective January 1, 2005 to now read January 1, 2009. Deleted the following reference: CMS Manual System, Medicare Coverage of Erythropoietin Stimulating Agents, <http://www.cms.hhs.gov/center/coverage.asp>. Under Indications and Limitations of Coverage and/or Medical Necessity in the 3rd paragraph deleted the url cited for the decision memo for ESA's for non-renal disease. Under Indications and Limitations of Coverage and/or Medical Necessity- # 5- Erythropoietin analogs are covered for the following indications- changed the word "perioperative" to "preoperative". Under Indications and Limitations of Coverage and/or Medical Necessity-Coverage Criteria A- changed #2 to read, "Anemia of ESRD should be treated to maintain a Hgb level of 10-12 gm/dL or a Hct of 30%-36%." Under Indications and Limitations of Coverage and/or Medical Necessity- Coverage Criteria B- changed #1 to read, "Anemia of chronic kidney disease should be treated to maintain the Hgb level of 10-12 gm/dl or a Hct of 30%-36%." Under Indications and Limitations of Coverage and/or Medical Necessity-Coverage Criteria C- corrected verbiage for #3 and #4 to read as per the CMS Manual System. Under Indications and Limitations of Coverage and/or Medical Necessity-Coverage Criteria D-#1 changed the verbiage. Under Indications and Limitations of Coverage and/or Medical Necessity-Coverage Criteria E-#1 deleted the verbiage, "with less than 5% blasts." Under the same section #2 changed the verbiage for pretreatment erythropoietin levels from 100 or less to now read 500 or less. Under Indications and Limitations of Coverage and/or Medical Necessity-Coverage Criteria E * changed the EPO level cited for "ESA therapy initiated on or after 12/1/2007...", from 100 IU/L to now read 500 IU/L. Under Indications and Limitations of Coverage and/or Medical Necessity-Coverage Criteria F- changed "perisurgical adjuvant therapy..." to now read "Preoperative adjuvant therapy..." Under Indications and Limitations of Coverage and/or Medical Necessity-Coverage Criteria G #1 the verbiage was changed. Under CPT/HCPCS Codes deleted HCPCS A4657. Under ICD-9 Codes That Support Medical Necessity-Group 4- For patients with anemia related to chemotherapy, deleted the verbiage regarding the use of "E" codes and deleted E930.7 and E933.1. Under ICD-9 Codes That Support Medical Necessity-Group 7-For patients with Hepatitis C, deleted E931.7. Under Utilization Guidelines deleted the verbiage. Under Sources of Information and Basis for Decision the references were placed in the AMA citation format. This revision becomes effective 06/25/2009.

Revision #2,10/01/2008

This LCD is being revised due to the annual FY 2009 ICD-9 CM code update. Under CMS National Coverage Policy added CMS Manual System, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 1, §110.21. Revised the section cited for CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, §20.2.1.4 to now read §20.2.1.2. Added §§50, 50.3, and 60.2.3.1 to CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 8. Added §§80.9 and 80.10 to CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 17. Revised the section cited for CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 25, §60 to now read §75. Deleted Change Requests 5480, 5216, 5251, 4135, 4108, 4103, 5545, 5700, and 5818 as these have been manualized. Under ICD-9 Codes That Support Medical Necessity- For Patients With Anemia Related to Chemotherapy...added ICD-9 codes 199.2; 203.02 and 203.12(in range 203.00-203.81); 203.82; 204.02, 204.12 204.22, and 204.82(in range 204.00-204.91); 204.92; 209.00-209.30 and 238.77. The verbiage was revised for ICD-9 codes 203.00, 203.10, and 203.80(in range 203.00-203.81), and 204.00, 204.10, 204.20, 204.80, and 204.90(in range 204.00-

204.91). Under ICD-9 Codes That Do Not Support Medical Necessity the verbiage was revised for ICD-9 codes 205.00, 205.10, 205.20, 205.30, 205.80, and 205.90(in range 205.00-205.91); 206.00,206.10, 206.20, 206.80, and 206.90(in range 206.00-206.91); 207.00, 207.10, 207.20, and 207.80(in range 207.00-207.81); and 208.00, 208.10, 208.20, 208.80, and 208.90(in range 208.00-208.91). Under Utilization Guidelines removed redundant referenced manual citations. Under Sources of Information and Basis for Decision the references were placed in the AMA citation format. This revision becomes effective 10/01/2008.

Revision #1, 08/20/2008

Changed the Original Determination Effective Date from 8-18-08 to 8-20-08 to comply with the date change of the J1 A/B MAC, Part A cutover date.

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Coverage Change (actual change in medical parameters)
Maintenance (annual review with new changes, formatting, etc.)
Narrative Change
Other
Typographical Correction

Last Reviewed On Date [back to top](#)

02/13/2009

Related Documents [back to top](#)

This LCD has no Related Documents.

LCD Attachments [back to top](#)

There are no attachments for this LCD.

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