FUTURE Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESA) (L33617)

Please note: Future Effective Date.

Contractor Information

Contractor Name	Contract Number	Contract Type	Jurisdiction
National Government Services, Inc. opens in new window	13201	A and B and HHH MAC	J - K

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LCD Information

Document Information

LCD ID
L33617

Original ICD-9 LCD ID
L25211

LCD Title
Erythropoiesis Stimulating Agents (ESA)

Jurisdiction
New York - Entire State

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For services performed on or after 10/01/2015

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N/A

CMS National Coverage Policy Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs), and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (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 Section 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):

Section 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.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Section 1881(b)(1) allows payment for services furnished to individuals who have been determined to have end stage renal disease.

Section 1881(11)(B)(I) allows payment for erythropoietin provided by a physician.

CMS Publications:

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 1:
30 Drugs and Biologicals

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 6:
30 Drugs and Biologicals

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 7:
Administration of Medications

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 11:
30.1 Frequency of Dialysis Sessions
30.4 Drugs and Biologicals
30.5 New ESRD Composite Payment Rates Effective January 1, 2005
90 Epoetin (EPO)

CMS Publication 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 [home use]
50.5.2.2 Medicare Coverage of Epoetin Alfa (Procrit) for Preoperative Use

CMS Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1:
110.21 Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

CMS Publication 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
20.2.1.4 Coding Applicable to EPO Services

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 8:
10.5 Hospital Services
60.4 Separately Billable ESRD Items and Services – Erythropoietin
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 Department
60.7 Darbepoetin Alfa (Aranesp®) for ESRD Patients
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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 UB-04 Revenue Codes Under Method II
90.5.1.1 Unbillable UB-04 Revenue Codes Under Method II

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 17:
80.8 Reporting of Hematocrit and/or Hemoglobin Levels
80.9 Required Modifiers for ESAs Administered to Non-ESRD Patients
80.10 Hospitals Billing for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients
80.11 Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)
80.12 Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 25:
60 General Instructions for Completion of Form CMS-1450 for Billing

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 27:
80.8 ESRD Maintenance Transaction Error Codes.

CMS Publication, *Medicare Coverage of Erythropoietin Stimulating Agents,*
http://www.cms.gov/center/coverage.asp.

CMS Publication 100-04, *Medicare Claims Processing Manual,* Transmittal No 2450, Change Request 7831, April 26, 2012, Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes – July 2012 Update.

CMS Publication 100-04, *Medicare Claims Processing Manual,* Transmittal No 2311, Change Request 7460, September 23, 2011, Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims.

CMS Publication 100-04, *Medicare Claims Processing Manual*, Transmittal No. 1307, Change Request # 5700, July 20, 2007, Modification to the National Monitoring Policy for Erythropoietic Stimulating Agents (ESAs) for End-Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

An erythropoiesis stimulating agent (ESA) is an analog of erythropoietin. ESAs are biologically engineered hormones produced by recombinant DNA technology. ESAs 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 [Hct] and/or hemoglobin [Hgb] levels), therefore decreasing anemia and the need for transfusions. Darbepoetin alfa (brand name Aranesp®), differs from epoetin (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 LCD applies to both darbepoetin alfa and epoetin alfa.

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 certain specific pre-operative uses (see "Coverage Criteria" bullet F). 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.

CMS has issued a national coverage decision for both renal and non-renal uses of ESAs. The Decision Memo for ESAs for non-renal disease indications (CAG-00383N) is located at http://www.cms.gov/center/coverage.asp. This local decision elaborates on the NCD and covers some additional indications.
ESAs 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. Perisurgical 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 ESA therapy for any of the covered indications:

1. Iron deficiency;
2. Underlying infection or inflammatory process;
3. Underlying hematological disease;
4. Hemolysis;
5. Vitamin deficiencies (e.g. folic acid or B12);
6. Blood loss;
7. 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 conditions warrant the use of ESAs to maintain a 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 ESA, 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. Coverage guidelines for administration of supplemental iron are found in National Government Services' coverage article A48420,[Iron Sucrose, Iron Dextran, Ferumoxytol and Sodium Ferric Gluconate, (Intravenous Iron Therapy) – Related to LCD L25820], located on the http://www.cms.gov/mcd/overview.asp.

For patients receiving chemotherapy for non-myeloid malignancies, the goal of therapy is to avoid transfusions. ESA therapy will be reimbursed only when the Hgb is less than 10 g/dL or the Hct is less than 30%. For all other indications, the goal of therapy is to maintain a stable Hgb and Hct, with target ranges of 10-12 g/dL and 30-36% respectively. Doses must be titrated according to the patient's response. ESA therapy need not be stopped completely simply due to the achievement of the target Hgb and/or Hct. However, judicious, appropriately timed

dose adjustments are expected to prevent inappropriate increases in Hgb and 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 and/or Hct, and the presence of concurrent medical problems.

Coverage Criteria:

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

1. Diagnosis of end stage renal disease
2. Anemia of ESRD with a Hgb less than 10 g/dL or a Hct of less than 30% at initiation of therapy

B. For chronic kidney disease patients NOT on dialysis

1. Anemia of ESRD with a Hgb less than 10 g/dL or a Hct of less than 30% at initiation of therapy
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 less than 10 g/dL or a Hct of less than 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 darbopoetin 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 or Hct remains below 10 g/dL or 30% four weeks after initiation of therapy AND the rise in Hgb or Hct is greater than or equal to 1 g/dL or 3%.
4. If Hgb or Hct rises less than1 g/dL and/or 3% compared to baseline after 4 weeks of therapy and Hgb or Hct remains less than 10 g/dL and/or 30%, the above starting dose may be increased by 25%. Continued use of the drug is not reasonable and necessary if the Hgb/Hct rises less than1 g/dL/3% after 8 weeks of treatment.
5. Continued administration of the drug is not reasonable and necessary if there is a rapid rise in Hgb and Hct greater than1 g/dL or 3% over 2 weeks of treatment unless the Hgb or Hct remains below or subsequently falls to less than 10 g/dL or 30%. Continuation and reinstitution 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 with Hgb less than 10 g/dL or a Hct of less than 30% at initiation of therapy

E. For patients with myelodysplastic syndrome

1. Myelodysplasia with less than 10% blasts
2. Pretreatment erythropoietin levels of 500 or less
3. Anemia with Hgb less than 10 g/dL or a Hct of less than 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.

F. Perisurgical adjuvant therapy: (epoetin alfa only) for patients who

1. *Are undergoing hip or knee surgery*
2. *Have an anemia with a Hgb between 10 and 13 g/dL*
3. *Are not a candidate for autologous blood transfusion*
4. *Are expected to lose more than two units of blood* Medicare Benefit Policy Manual, Chapter 15, Section 50.5.2.2)
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 less than 10 g/dL or a Hct of less than 30% at initiation of therapy

The literature covering the 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 regimen. 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.

Limitations Specified by CMS:

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.

Other Comments:

ESRD facilities will be required to submit the following on **ALL** ESRD claims:

- hemoglobin and/or hematocrit values,
- identify the route of administration using the JA or JB modifier code for any claim indicating the administration of erythropoiesis stimulating agents (ESAs),
- use a specified formula to calculate the Kt/V for the measurement of dialysis adequacy.

Bill type codes for Home Health services are not listed in the LCD for Erythropoiesis Stimulating Agents (ESAs) because "drugs and biologicals are specifically excluded from coverage by the statute section 1861(m)(5) of the Act."

The administration of an ESA may be a qualifying service for Home Health services. The beneficiary must be receiving the ESA for a covered indication, as specified in this LCD.

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Coding Information

Bill Type Codes:

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.

011x Hospital Inpatient (Including Medicare Part A)
012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
071x Clinic - Rural Health
072x Clinic - Hospital Based or Independent Renal Dialysis Center
073x Clinic - Freestanding
077x Clinic - Federally Qualified Health Center (FQHC)
085x Critical Access Hospital

Revenue Codes:

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 codes. Indicate HCPCS code J0885 in Form Locator 44 of the UB-04 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 Part A MAC. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the Part B MAC.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

All revenue codes billed on the inpatient claim for the dates of service in question may be subject to review.

0634 Pharmacy - Erythropoietin (EPO)<10,000 units
0635 Pharmacy - Erythropoietin (EPO)>=10,000 Units

CPT/HCPCS Codes
Group 1 Paragraph: N/A

Group 1 Codes:

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)
J0890	INJECTION, PEGINESATIDE, 0.1 MG (FOR ESRD ON DIALYSIS)
Q4081	INJECTION, EPOETIN ALFA, 100 UNITS (FOR ESRD ON DIALYSIS)

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: The correct use of an ICD-10-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 ICD-10-CM codes must be on the claim.) HCPCS code J0882, J0886, J0890 or Q4081 should be reported for this indication.

Group 1 Codes:

ICD-10 Codes	Description
D63.1	Anemia in chronic kidney disease
N18.6	End stage renal disease

Group 2 Paragraph: For patients with chronic kidney disease (not yet on dialysis) and anemia. ICD-10-CM code D63.1 and one other listed ICD-10-CM code must be reported on the claim.

Group 2 Codes:

ICD-10 Codes	Description
D63.1	Anemia in chronic kidney disease
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5

Group 3 Paragraph: Patients with anemia related to treatment with zidovudine (AZT) and/or other Nucleoside Reverse Transcriptase Inhibitors (NRTI) for HIV disease. ICD-10-CM code D61.1, D61.2, D61.3, D61.89 (aplastic anemia due to drugs) and ICD-10-CM code B20 or B97.35 must be reported on the claim.

Group 3 Codes:

ICD-10 Codes	Description
B20	Human immunodeficiency virus [HIV] disease
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
D61.1	Drug-induced aplastic anemia

ICD-10 Codes	Description
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes

Group 4 Paragraph: For patients with anemia related to chemotherapy, claims must be reported with ICD-10-CM code D64.81 (antineoplastic chemotherapy induced anemia) representing the anemia related to chemotherapy. Note: ICD-10-CM codes C92.00-C92.21, C92.40-C92.62, C92.90-C92.91, C92.A0-C92.Z2, C94.00 -C94.31, C94.80-C94.81 and D45 are myeloid malignancies and are excluded from coverage.)

Group 4 Codes:

ICD-10 Codes	Description
D64.81	Anemia due to antineoplastic chemotherapy

Group 5 Paragraph: Patients with anemia related to myelodysplastic syndrome

Group 5 Codes:

ICD-10 Codes	Description
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.21	Refractory anemia with excess of blasts 1
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality

Group 6 Paragraph: Preoperative use in specified patients. ICD-10-CM code D63.8 or D64.9(primary diagnosis) and other specified prophylactic measure(ICD-10-CM code Z41.8) must be reported on the claim.

Group 6 Codes:

ICD-10 Codes	Description
D63.8	Anemia in other chronic diseases classified elsewhere
D64.9	Anemia, unspecified
Z41.8	Encounter for other procedures for purposes other than remedying health state

Group 7 Paragraph: For patients with anemia of chronic disease. ICD-10-CM code D63.8 (anemia of other chronic disease) and one other listed diagnosis must be reported on the claim.

Group 7 Codes:

ICD-10 Codes	Description
B17.10	Acute hepatitis C without hepatic coma
B17.11	Acute hepatitis C with hepatic coma
B18.2	Chronic viral hepatitis C
D63.8	Anemia in other chronic diseases classified elsewhere
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication

ICD-10 Codes	Description
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
M06.9	Rheumatoid arthritis, unspecified
M32.19	Other organ or system involvement in systemic lupus erythematosus
M32.8	Other forms of systemic lupus erythematosus
T37.5X5A	Adverse effect of antiviral drugs, initial encounter
T37.5X5S	Adverse effect of antiviral drugs, sequela

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.41	Acute promyelocytic leukemia, in remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified in remission
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.Z2	Other myeloid leukemia, in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
D45	Polycythemia vera

ICD-10 Additional Information

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General Information

Associated Information

Documentation Requirements:

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Listing of ICD-10-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 non-physician practitioner's) order must be made available upon request of NGS. Documentation the provider is to maintain in the patient's medical record includes: patient's weight in kilograms, ESA units administered per kilogram of body weight, and medical justification for administration of ESAs exceeding usual doses.

Documentation supporting the indication for ESA administration must be made available upon the request of NGS; 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
  Documentation must include 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 NGS upon request: a care plan, evidence of home monitoring (including a record of the ESA supplied to the patient and a record of dose administered), patient instructions and patient selection protocol.

- Non-dialysis Patients
  For chronic kidney disease (CKD) patients: documentation must include serum creatinine, creatinine clearance, or GFR.

Patients with myelodysplastic syndrome: bone marrow biopsy report*, date of initiation of ESA therapy, and response to ESA administration (change in Hgb/Hct and/or transfusion requirements).

Utilization Guidelines:

Literature describes a significant increase in risk associated with Hct greater than 36 %. Prompt and judicious dose adjustments are anticipated in response to reaching the target Hgb or Hct (delayed reductions or reductions of less than 25% must be justified in the medical record). The medical record must support the necessity of a target Hgb greater than 12 g/dL or Hct greater than 36 %.

Appendices:

Not applicable

Sources of Information and Basis for Decision
This bibliography presents those sources that were obtained during the development of this policy. National Government Services is not responsible for the continuing viability of Web site addresses listed below.

AHA Coding Clinic Guidelines. 1st Qtr 2009.

Aranesp® [package insert]. Thousand Oaks, CA: Amgen, Inc. 06/2011.

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Arndt U, Kaltwasser JP, Gottschalk R, et al. Correction of iron-deficient erythropoiesis in the treatment of anemia of chronic disease with recombinant human erythropoietin. *Ann Hematol.* 2005;84(3):159-166.

Brunkhorst R. Darbepoetin alpha effectively maintains haemoglobin concentrations at extended dose intervals relative to intravenous or subcutaneous recombinant human erythropoetin in dialysis patients. *Nephrology, Dialysis, Transplantation.* 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.* 2006;98(4):273-284.

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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.* 2003;39(14):2026-2034.

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

OMONTYS® (peginesatide) Injection [Prescribing Information]. Marketed by: Affymax, Inc. Palo Alto, CA 94304. Distributed and Marketed by: Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015.

Other Medicare contractors, specialty societies, and specialty consultants.

Parfrey P. Target hemoglobin level for EPO in CKD. *American Journal of Kidney Diseases.* 2006;47(1):24-36.

Park S, Grabar S, Kelaidi G, et al. Predictive factors of response and survival in myelodysplastic syndrome treated with erythropoietin and G-CSF: the GFM experience. *Blood.* 2008;111:574-582.

Pujade-Lauraine E. Erythropoietic agents in anemic patients with cancer: a retrospective observational survey of epoetin alpha, epoetin beta and darbepoetin alpha use in routine clinical practice. *Oncology Reports.* 2005;14(4):1037-1044.

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Singh AK, Szczeck L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease CHOIR). *The New England Journal of Medicine.* 2006;355(20):2085-2098.

Stasi R. Management of cancer related anemia with erythropoietic agents: doubts, certainties, and concerns. *The Oncologist.* 2005;10(7):539-540.

Stein RS, Abels RI, Krantz SB, et al. Pharmacologic doses of recombinant human erythropoetin in the treatment of myelodysplastic syndromes. *Blood.* 1991;78:1658-1663.

The American Society of Hematology (ASH) Comments to The Center for Medicare and Medicaid Services on Coverage for Erythropoiesis Stimulating Agents (ESAs) filed electronically on April 12, 2007.

U.S. Food and Drug Administration Center for Drug Evaluation and Research, "Information on Erythropoiesis Stimulating Agents (ESA)", (published 2/16/07).

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

The following sources were added as a result of a reconsideration request received on February 10, 2011:

Kelaidi C, Park S, Brechignac S, et al. Treatment of myelodysplastic syndromes with 5q deletion before the lenalidomide era; the GFM experience with EPO and thalidomide. *Leukemia Research.* 2008;32:1049–1053.

NCCN Drugs and Biologics Compendium accessed at: http://www.nccn.org/

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Revision History Information

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2015	R1	Added HCPCS code J0882 and Q4081 to the Group 1 explanatory note section. Removed information regarding the requirement for a secondary ICD-10-CM code from the Group 4 explanatory note section.	• Typographical Error

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A52856 - Erythropoiesis Stimulating Agents (ESA) – Supplemental Instructions Article opens in new window

Related National Coverage Documents N/A

Public Version(s) Updated on 10/03/2014 with effective dates 10/01/2015 - N/A Updated on 04/02/2014 with effective dates 10/01/2015 - N/A Back to Top

Keywords

- EPO

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