Local Coverage Determination (LCD) for Erythropoiesis Stimulating Agents (L29168)

Contractor Information

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09102

Contractor Type
MAC - Part B

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LCD Information

Document Information

LCD ID Number
L29168

Primary Geographic Jurisdiction
Florida

LCD Title
Erythropoiesis Stimulating Agents

Oversight Region
Region IV

Contractor's Determination Number
J0881

Original Determination Effective Date
For services performed on or after 02/02/2009

Original Determination Ending Date

Revision Effective Date
For services performed on or after 08/23/2011

Revision Ending Date

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). 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 represent quotation from one or more of the following CMS sources:

CMS Manual System, Pub 100-02, Medicare Benefit Policy, Chapter 11, Section 90

CMS Manual System, Pub 100-02, Medicare Benefit Policy, Chapter 15, Section 50


CMS Manual System, Pub 100-03, CMS National Coverage, Chapter 1, Part 2, Section 110.21

CMS Manual System, Pub 100-04, Medicare Claims Processing, Chapter 17, Section 80.8, 80.9, 80.10 and 80.12

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Erythropoietin is a specialized cytokine that is produced by the kidneys and stimulates the proliferation of red blood cells in the bone marrow. Erythropoietin is released into the bloodstream in response to hypoxia. In response to the hypoxia, the erythropoietin interacts with the progenitor cells to increase the production of red blood cells.

This LCD will outline the indications and limitations for Epoetin alfa and Darbepoetin alfa, also referred to as Erythropoesis stimulating agents (ESAs), for Renal and Non-renal indications.

**Indications:**

**Epoetin alfa (Procrit® and Epogen®)**

Medicare will cover Epoetin alfa for the following FDA approved, labeled, indications:

- **Anemia due to Chronic Kidney Disease.** Epoetin alfa is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.

- **Anemia due to Zidovudine in HIV-infected patients.** Epoetin alfa is indicated for the treatment of anemia due to zidovudine administered at ≤ 4200 mg/week HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL.

- **Reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery.** Epoetin alfa is indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin >10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood pre-operatively.

- **Anemia due to chemotherapy in patients with cancer.** Coverage for this indication is outlined in the NCD issued on 7/30/07 for ESAs in cancer and related neoplastic conditions and is summarized under the “limitations” section of this LCD.

In addition to the FDA labeled indications, Medicare will cover epoetin alfa for the following off-label indications:

- **For the treatment of anemia associated with myelodysplastic syndrome (MDS).** Patients usually present with variable clinical features depending on the MDS classification and the degree of disordered hematopoiesis with anemia. Common complaints or symptoms are fatigue, pallor, infection and bleeding or bruising. Diagnosis is usually confirmed by bone marrow aspiration and/or biopsy. For the purposes of this LCD, Chronic Myelomonocytic Leukemia (CMML) will be considered a form of MDS and as such the anemia associated with it may be eligible for coverage if the indications and limitations outlined in this LCD for MDS are met. Providers must use the ICD-9 codes listed in the LCD for MDS to code for CMML. If the physician cannot classify the patient with one of the MDS diagnosis codes, then the patient does not meet the criteria for CMML and coverage will not have been met.

- **For the treatment of anemia associated with the management of hepatitis C.** The use of epoetin alfa has been shown to be effective in treatment of anemia in patients with hepatitis C virus infection who are being treated with the combination of ribavirin and interferon alfa or ribavirin and peginterferon alfa

- **For the treatment of chronic anemia associated Rheumatoid Arthritis (RA).** The patient must have been previously diagnosed with RA using the American College of Rheumatology criteria. Patients are usually on antimetabolite (e.g., Methotrexate) which causes the anemia.
Darbepoetin alfa (Aranesp®)

Medicare will cover Darbepoetin alfa for the following FDA approved, labeled, indications:

- **Anemia due to chronic kidney disease (CKD).** Aranesp is indicated for the treatment of anemia due to CKD, including patients on dialysis and patients not on dialysis.

- **Anemia due to chemotherapy in patients with cancer.** Coverage for this indication is outlined in the NCD issued on 7/30/07 for ESAs in cancer and related neoplastic conditions and is summarized in the “limitations” section of this LCD.

In addition to the FDA labeled indications, Medicare will cover Darbepoetin alfa for the following off-label indications:

- **For the treatment of anemia associated with myelodysplastic syndrome (MDS).** Patients usually present with variable clinical features depending on the MDS classification and the degree of disordered hematopoiesis with anemia. Common complaints or symptoms are fatigue, pallor, infection and bleeding or bruising. Diagnosis is usually confirmed by bone marrow aspiration and/or biopsy. For the purposes of this LCD, Chronic Myelomonocytic Leukemia (CMML) will be considered a form of MDS and as such the anemia associated with it may be eligible for coverage if the indications and limitations outlined in this LCD for MDS are met. Providers must use the ICD-9 codes listed in the LCD for MDS to code for CMML. If the physician cannot classify the patient with one of the MDS diagnosis codes, then the patient does not meet the criteria for CMML and coverage will not have been met.

**Limitations**

ESAs are not indicated for use:

1.) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy
2.) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
3.) In patients scheduled for surgery who are willing to donate autologous blood (applies to epoetin alfa products only-Epogen and Procrit)
4.) In patients undergoing cardiac or vascular surgery (applies to epoetin alfa products only-Epogen and Procrit)
5.) As a substitute for RBC transfusions in patients who require immediate correction of anemia.

Prior to initiating ESA therapy, other causes of anemia should be ruled out and managed if present. Evaluate the iron status in all patients before and during treatment and maintain iron repletion. Correct or exclude other causes of anemia (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) Other causes could also be iron deficiency, underlying infectious, inflammatory or malignant processes, occult blood loss, underlying hematologic diseases, hemolysis, aluminum intoxication, osteitis fibrosa cystica or Pure Red Blood Cell Aplasia.

Both Epoetin alfa and Darbepoetin alfa are contraindicated in patients with uncontrolled hypertension. Epoetin alfa is also contraindicated in patients with known hypersensitivity to mammalian cell-derived products and to Albumin (Human). Darbepoetin alfa is contraindicated in patients with known hypersensitivity to the active substance or any of the excipients of darbepoetin alfa.

*For patients in the ESRD program: Generally, ESRD patients with symptomatic anemia considered for initiation of EPO/Aranesp therapy should have a hematocrit less than 30 or hemoglobin less than 10; ESRD patients who have been receiving EPO/Aranesp therapy should have a hematocrit between 30 and 36. Refer to Pub 100-02, Chapter 11, Section 90 and Pub 100-02, Chapter 15, Section 50.5.2 for further discussion.*

The FDA has issued a black box warning for ESAs. The Black Box Warning reads as follows:

**Chronic Kidney Disease:**

- In controlled trials, patients experienced greater risk for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.
- No trial has identified a hemoglobin target, ESA dose, or dosing strategy that does not increase these risks.
- Use the lowest epoetin alfa dose sufficient to reduce the need for red blood cell (RBC) transfusion.

**Cancer:**
• ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
• Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense epoetin alfa to patients with cancer.
• To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid RBC transfusions.
• Use ESAs only for anemia from myelosuppressive chemotherapy.
• ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
• Discontinue following the completion of a chemotherapy course.

**Perisurgery**

• Due to increased risk of deep vein thrombosis (DVT), DVT prophylaxis is recommended.

Renal failure: Patients experienced greater risk for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

CMS issued a National Coverage Decision for ESAs for non-ESRD use. The following limitations have been imposed by the NCD and are effective for services on or after 7/30/2007:

- ESA treatment is not reasonable and necessary for the following clinical conditions:
  - 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;
  - 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

CMS has also determined that ESA treatment for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is only reasonable and necessary under the following specified conditions:

1. The hemoglobin level immediately prior to initiation or maintenance of ESA treatment is <10 g/L (or the Hematocrit is <30%)

2. The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 U/kg/three times weekly for epoetin and 2.25 mcg/kg/weekly for Darbepoetin alfa. Equivalent doses may be given over other approved time periods.

3. Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL (or Hematocrit is <30%) 4 weeks after initiation of therapy and the rise in hemoglobin is ≥ 1 g/dL (or Hematocrit is ≥ 3%).

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4. For patients whose hemoglobin rise <1 g/dl (Hematocrit rise <3%) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains <10 g/dL after 4 weeks of treatment (or the hematocrit <30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable or necessary if the hemoglobin rises <1 g/dL (Hematocrit is <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 hemoglobin > 1g/dl (Hematocrit is <30%). Continuation and reinstitution of ESA therapy must include a dose reduction of 25% from the previously administered dose.

6. ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

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.

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<tr>
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<td>999x</td>
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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.

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CPT/HCPCS Codes

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<td>J0886</td>
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ICD-9 Codes that Support Medical Necessity

J0881 List 1

The diagnosis codes listed below require the use of the EC modifier when submitting claims for J0881. In addition, diagnosis codes marked with an * require a dual diagnosis. The dual diagnosis rule is outlined below.

Dual diagnosis rule:

1.) 403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 585.1, 585.2, 585.3, 585.4, 585.5 or 585.9 AND 285.21 must be billed together.

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<tr>
<th>ICD-9 Code</th>
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<td>238.71</td>
<td>ESSENTIAL THROMBOCYTHEMIA</td>
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<td>238.72</td>
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<td>238.73</td>
<td>HIGH GRADE MYELODYSPLASTIC SYNDROME LESIONS</td>
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238.74 MYELODYSPLASTIC SYNDROME WITH 5Q DELETION
238.75 MYELODYSPLASTIC SYNDROME, UNSPECIFIED
238.76 MYELOFIBROSIS WITH MYELOID METAPLASIA
273.3 MACROGLOBULINEMIA
285.21* ANEMIA IN CHRONIC KIDNEY DISEASE
403.01* HYPERTENSIVE CHRONIC KIDNEY DISEASE, MALIGNANT, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
403.11* HYPERTENSIVE CHRONIC KIDNEY DISEASE, BENIGN, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
403.91* HYPERTENSIVE CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
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
404.12* 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 WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
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 WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
585.1* CHRONIC KIDNEY DISEASE, STAGE I
585.2* CHRONIC KIDNEY DISEASE, STAGE II (MILD)
585.3* CHRONIC KIDNEY DISEASE, STAGE III (MODERATE)
585.4* CHRONIC KIDNEY DISEASE, STAGE IV (SEVERE)
585.5* CHRONIC KIDNEY DISEASE, STAGE V
585.9* CHRONIC KIDNEY DISEASE, UNSPECIFIED

* Diagnosis codes marked with an * require a dual diagnosis.

J0881 List 2

The following diagnosis codes require the use of the EA modifier when submitting claims for J0881. In addition, ALL diagnosis codes listed below require a dual diagnosis. The dual diagnosis rule is outlined below.

**Dual Diagnosis Rule**

1.) ALL diagnosis codes listed below for J0881 List 2 require a dual diagnosis in addition to the EA modifier. Diagnosis code 285.3 AND one of the malignancy codes listed below MUST be billed together. All codes listed below except for 285.3 are malignancy codes.

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
The diagnosis codes listed below require the use of the EC modifier when submitting claims for J0885. In addition, diagnosis codes marked with an * require a dual diagnosis. The dual diagnosis rules are outlined below.

Dual diagnosis rules:

1.) 403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 585.1, 585.2, 585.3, 585.4, 585.5 or 585.9 AND 285.21 must be billed together.

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2.) 042, 070.54, 070.70, V07.8 or 714.0 AND 285.29 or 285.9 must be billed together.

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
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<td>042*</td>
<td>HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE</td>
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<td>070.54*</td>
<td>CHRONIC HEPATITIS C WITHOUT HEPATIC COMA</td>
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<td>070.70*</td>
<td>UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA</td>
</tr>
<tr>
<td>238.71</td>
<td>ESSENTIAL THROMBOCYTHEMIA</td>
</tr>
<tr>
<td>238.72</td>
<td>LOW GRADE MYELODYSPLASTIC SYNDROME LESIONS</td>
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<td>238.73</td>
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<td>238.74</td>
<td>MYELODYSPLASTIC SYNDROME WITH 5Q DELETION</td>
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<td>238.75</td>
<td>MYELODYSPLASTIC SYNDROME, UNSPECIFIED</td>
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<td>238.76</td>
<td>MYELOFIBROSIS WITH MYELOID METAPLASIA</td>
</tr>
<tr>
<td>273.3</td>
<td>MACROGLOBULINEMIA</td>
</tr>
<tr>
<td>285.21*</td>
<td>ANEMIA IN CHRONIC KIDNEY DISEASE</td>
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<tr>
<td>285.29*</td>
<td>ANEMIA OF OTHER CHRONIC DISEASE</td>
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<td>285.9*</td>
<td>ANEMIA UNSPECIFIED</td>
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<td>404.03*</td>
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<td>404.12*</td>
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<td>404.13*</td>
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<td>404.93*</td>
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<td>585.1*</td>
<td>CHRONIC KIDNEY DISEASE, STAGE I</td>
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<td>585.3*</td>
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<td>585.9*</td>
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<td>714.0*</td>
<td>RHEUMATOID ARTHRITIS</td>
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<tr>
<td>V07.8*</td>
<td>OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE</td>
</tr>
</tbody>
</table>

* Diagnosis codes marked with an * require a dual diagnosis.

J0885 List 2

The following diagnosis codes require the use of the EA modifier when submitting claims for J0885. In addition, ALL diagnosis codes listed below require a dual diagnosis. The dual diagnosis rule is outlined below.

**Dual Diagnosis Rule**
1.) ALL diagnosis codes listed below for J0885 List 2 require a dual diagnosis in addition to the EA modifier. Diagnosis code 285.3 AND one of the malignancy codes listed below MUST be billed together. All codes listed below except for 285.3 are malignancy codes.

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Diagnosis Description</th>
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<tbody>
<tr>
<td>140.0 - 149.9</td>
<td>MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY</td>
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<td>150.0 - 159.9</td>
<td>MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE DIGESTIVE ORGANS AND PERITONEUM</td>
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<td>160.0 - 165.9</td>
<td>MALIGNANT NEOPLASM OF NASAL CAVITIES - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE RESPIRATORY SYSTEM</td>
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<tr>
<td>170.0 - 176.9</td>
<td>MALIGNANT NEOPLASM OF BONES OF SKULL AND FACE EXCEPT MANDIBLE - KAPOSI’S SARCOMA UNSPECIFIED SITE</td>
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<tr>
<td>179 - 189.9</td>
<td>MALIGNANT NEOPLASM OF UTERUS-PART UNS - MALIGNANT NEOPLASM OF URINARY ORGAN SITE UNSPECIFIED</td>
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<td>190.0 - 199.2</td>
<td>MALIGNANT NEOPLASM OF EYEBALL EXCEPT CONJUNCTIVA CORNEA RETINA AND CHOROID - MALIGNANT NEOPLASM ASSOCIATED WITH TRANSPLANT ORGAN</td>
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<td>200.00 - 200.88</td>
<td>RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES</td>
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<td>201.00 - 201.98</td>
<td>HODGKIN'S PARAGANULOMA UNSPECIFIED SITE - HODGKIN'S DISEASE UNSPECIFIED TYPE INVOLVING LYMPH NODES OF MULTIPLE SITES</td>
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<td>NODULAR LYMPHOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES</td>
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285.3 ANTINEOPLASTIC CHEMOTHERAPY INDUCED ANEMIA

The following list applies to J0882 and J0886 only. A dual diagnosis is required for all claims billing J0882 or J0886.

Dual Diagnosis Rule:

* 285.21 and 585.6 must be billed together.
285.21* ANEMIA IN CHRONIC KIDNEY DISEASE
585.6* END STAGE RENAL DISEASE

* Diagnosis codes marked with an * require a dual diagnosis.

Diagnoses that Support Medical Necessity
N/A

ICD-9 Codes that DO NOT Support Medical Necessity
Any diagnosis not listed under ICD-9 CM codes that support medical necessity

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ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
Any diagnosis not listed under ICD-9 CM codes that support medical necessity

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General Information

Documentation Requirements
This is not an all-inclusive list. Providers are responsible for ensuring that all requirements outlined in the LCD are documented clearly and support the medical necessity for ESA therapy.

The medical record must reflect that the patient meets all requirements for coverage outlined in this LCD. The medical record must contain a history and physical that includes the following information: most recent blood pressure and evidence that patients with elevated blood pressure are being adequately controlled, weight in Kg, date and results of Hct and Hgb level prior to the initiation of ESA therapy, assessment that rules out other causative factors of anemia or if causative factors are present, that they have been managed and that it is still necessary to initiate ESA therapy. The dosage and route of administration must be documented.

The medical record must support that Hgb and Hct levels are documented at the frequencies outlined for each indication and that doses are being titrated or withheld/re-initiated according to the indications, limitations and utilization guidelines outlined in the LCD.

In addition to the above, the following are documentation requirements that are specific to certain indications.

Prior to and during ESA therapy for CKD patients, the patient’s iron stores, including transferrin saturation and serum ferritin, should be evaluated. Transferrin saturation should be at least 20%, and ferritin should be at least 100 ng/mL.

For HIV-infected patients with anemia related to Zidovudine treatment, the medical record must contain the endogenous erythropoietin level (prior to transfusion). If levels are > 500mUnits.mL, patients are unlikely to respond to therapy with epoetin alfa. The patient’s current dose of Zidovudine should be documented in the medical record.

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For patients with anemia related to anemia of Hepatitis C, the medical record must support that the patient is being treated with the combination of ribavarin and interferon alfa or ribavarin and peginterferon alfa.

For patients with RA, the medical record must show that the patient has been diagnosed with RA using the American College of Rheumatology criteria. Patients are usually on an anti-metabolite (e.g., Methotrexate), which causes the anemia. If the anemia is caused by factors other than an anti-metabolite, the medical record should justify the initiation of ESA therapy and that the causative factor cannot be managed without ESA therapy.

For patients with MDS, the medical record must contain a bone marrow biopsy or aspiration report confirming a diagnosis of MDS.

For cancer patients with anemia related to chemotherapy, the date of the last chemotherapy treatment must be documented. A course of chemotherapy includes the 8 weeks following the last dose of chemotherapy for that course of treatment. After 8 weeks, ESA treatment is not medically necessary.

For cancer patients with anemia related to myelosuppressive chemotherapy, the medical record should support that the provider is enrolled in the ESA APPRISE Oncology Program and meets the program requirements.

Appendices

Utilization Guidelines It is expected that these drugs will be given in accordance with accepted standards of medical practice. It is also expected that these drugs will be given in accordance with the listed guidelines found on the FDA approved product labels, unless instructions are otherwise noted in this LCD. For additional prescribing information, refer to the FDA approved product labels.

For all patients with CKD receiving ESAs:

When initiating or adjusting therapy, monitor hemoglobin levels at least weekly until stable, then monitor at least monthly. When adjusting therapy consider hemoglobin rate of rise, rate of decline, ESA responsiveness and hemoglobin variability. A single hemoglobin excursion may not require a dosing change.

- Do not increase the dose more frequently than once every 4 weeks. Decrease in dose can occur more frequently. Avoid frequent dose adjustments.
- If the hemoglobin rises rapidly (e.g., more than 1 g/dL in any 2-week period), reduce the dose of ESA by 25% or more as needed to reduce rapid responses.
- For patients who do not respond adequately, if the hemoglobin has not increased by more than 1 g/dL after 4 weeks of therapy, increase the dose by 25%.
- For patients who do not respond adequately over a 12 week escalation period, increasing the ESA dose further is unlikely to improve response and may increase risks. Use the lowest dose that will maintain a hemoglobin level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue the ESA if responsiveness does not improve.

To initiate ESA therapy for other covered indications in this LCD, except for preoperative use and for anemia in cancer patients on chemotherapy, the patient must have a documented anemia as evidenced by symptoms and a Hct of < 33% or a Hgb < 11 g/dL, unless there is medical documentation showing the need for ESA therapy despite a Hct of > 32.9 or a Hgb > 10.9 g/dL. It may be medically necessary for a patient to initiate ESA therapy when the patient exhibits signs and symptoms such as extreme weakness and fatigue, cold intolerance, tachycardia, pulmonary distress, hypotension, angina, congestive heart failure, etc., which is caused by the anemic condition and Hct is > 32.9 % and the Hgb is > 10.9 g/dL.
For anemia in cancer patients on chemotherapy, please refer to the National Coverage Decision language found under the “limitations” section of this LCD for coverage requirements. In order to prescribe and/or dispense ESAs to patients with cancer and anemia due to myelosuppressive chemotherapy, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program requirements.

Dosage and Administration requirements:

**Epoetin alfa (Procrit and Epogen)**

**Treatment of anemia for CKD patients on dialysis:**

- Initiate Epoetin alfa treatment when the hemoglobin level is less than 10 g/dL.
- If the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of epoetin alfa.
- The recommended starting dose for adult patients is 50 to 100 Units/kg 3 times weekly intravenously or subcutaneously.
- The intravenous route is recommended for patients on dialysis.

**Treatment of anemia for CKD patients not on dialysis:**

- Consider initiating epoetin alfa treatment only when the hemoglobin level is less than 10 g/dL and the following considerations apply:
  - The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion and,
  - Reducing the risk of allimmunization and/or other RBC transfusion-related risks is a goal
- If the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of epoetin alfa, and use the lowest dose of epoetin alfa sufficient to reduce the need for RBC transfusions.
- The recommended starting dose for adult patients is 50-100 Units/kg 3 times weekly intravenously or subcutaneously.

**Treatment of anemia in Zidovudine-treated HIV-infected patients:**

**Starting Dose:**

The recommended starting dose in adults is 100 Units/kg as an intravenous or subcutaneous injection 3 times per week.

**Dose Adjustment:**

- If hemoglobin does not increase after 8 weeks of therapy, increase epoetin alfa dose by approximately 50-100 Units/kg at 4 to 8 week intervals until hemoglobin reaches a level needed to avoid RBC transfusions or 300 Units/kg.
- Withhold the epoetin alfa if hemoglobin exceeds 12 g/dL. Resume therapy at a dose 25% below the previous dose when hemoglobin declines to less than 11 g/dL.
- Discontinue epoetin alfa if an increase in hemoglobin is not achieved at a dose of 300 Units/kg for 8 weeks.

**Reduction of allogenic blood transfusions in surgery patients**

Prior to initiating epoetin alfa therapy a hemoglobin level should be obtained to establish that it is greater than 10 and less than or equal 13 g/dL. The recommended epoetin alfa regimens are:

- 300 Units/kg per day subcutaneously for 14 days total: administered daily for 10 days before surgery, on the day of surgery and for 4 days after surgery.
- 600 Units/kg subcutaneously in 4 doses administered 21, 14 and 7 days before surgery and on the day of surgery.

**Treatment of anemia in cancer patients on chemotherapy:**

- For therapy initiation, dose adjustments and maintenance doses see the National Coverage Decision language found under the limitations section of this LCD.
Anemia associated with myelodysplastic syndrome (MDS) and anemia associated with Rheumatoid Arthritis

- The recommended starting dose of epoetin alfa is 150 units/kg subcutaneously three times weekly or 40,000 units subcutaneously weekly.

- Dose modification three times weekly dosing:

  o Reduce dose by 25% when the hemoglobin approaches 12 g/dL or when the hemoglobin increases > 1 g/dL in any two week period.

  o Withhold the dose when the hemoglobin exceeds 12 g/dL, until the hemoglobin falls below 11 g/dL and restart the dose at 25% below the previous dose.

  o Increase the dose to 300 units/kg three times weekly if the response is not satisfactory (no reduction in transfusion requirements or rise in hemoglobin) after 8 weeks to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for red blood cell transfusion and not to exceed 12 g/dL.

- Dose modification weekly dosing:

  o Reduce dose by 25% when the hemoglobin approaches 12 g/dL or increases >1 g/dL in any 2 weeks

  o Withhold dose if the hemoglobin exceeds 12 g/dL, until the hemoglobin falls below 11 g/dL, and restart the dose at 25% below the previous dose.

  o The dose may be increased to 60,000 units subcutaneously weekly if the response is not satisfactory (no reduction in transfusion requirements or rise in hemoglobin) after 8 weeks to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for red blood cell transfusion and not to exceed 12 g/dL.

Medicare will cover the off-label maintenance dosing schedule for MDS patients:

- **120,000 units subcutaneously once every three weeks to maintain the target hemoglobin.** This dosing schedule must not be used as an initial dosing schedule. The hemoglobin should not exceed 12 g/dL. The patient should already be receiving epoetin alfa and responding to the therapy as evidenced by Hgb rising at least 2 g/dL, not exceeding 12 g/dL.

Treatment of chronic anemia associated with the management of Hepatitis C:

- The usual dose for this indication is 40,000 units subcutaneously once weekly.

Darbepoetin alfa (Aranesp)

Treatment of chronic kidney disease (CKD):

Patients on dialysis:

- Initiate Aranesp treatment when the hemoglobin level is less than 10 g/dL
- If the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of Aranesp.
- The recommended starting dose is 0.45 mcg/kg intravenously or subcutaneously as a weekly injection or 0.75 mcg/kg once every 2 weeks as appropriate. The intravenous route is recommended for patients on dialysis.

Patients not on dialysis:

- Consider initiating Aranesp treatment only when the hemoglobin level is less than 10 g/dL and the following considerations apply:
  o The rate of hemoglobin decline indicates the likelihood of reporting RBC transfusion and,
Reducing the risk of alloimmunization and/or other RBC transfusion-related risk is a goal.
- If the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of Aranesp, and use the lowest dose of Aranesp sufficient to reduce the need for RBC transfusion.
- The recommended starting dose is 0.45 mcg /kg body weight intravenously or subcutaneously given once at four weeks intervals as appropriate.

For conversion from Epoetin alfa to Aranesp for CKD patients on or off dialysis, refer to the Aranesp FDA approved product label for doses and tables.

Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy:
- For therapy initiation, dose adjustments and maintenance doses see the National Coverage Decision language found under the limitations section of this LCD.

Anemia associated with myelodysplastic syndrome (MDS):
- The recommended starting dose for MDS patients is similar to those for FDA approved indications found in the package insert and outlined in this LCD for darbepoetin alfa. Refer to the package insert for additional dose adjustment or maintenance dose schedules. Doses should be reduced to maintain Hgb levels ≤12 g/dL. Hemoglobin levels that increase to or approach 12 g/dL should be reduced by approximately 25%. If hemoglobin levels continue to increase above 12 g/dL, doses should be temporarily withheld until the hemoglobin begins to decrease, at which time the therapy can be reinitiated at a dose approximately 25% below the previous dose. A rise in hemoglobin >1 g/dL in any two week period requires the dose to be reduced by 25%.

Sources of Information and Basis for Decision
ACCC drug database (2007) Epoetin alfa (systemic)
Amgen (2011) Prescribing information, Darbepoetin alfa (Aranesp®) and Epogen®.

Advisory Committee Meeting Notes This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.
Florida Contractor Advisory Committee Meeting held on March 7, 2009.
Puerto Rico/U.S. Virgin Islands Contractor Advisory Meeting held on March 19, 2009
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Revision History Number 4

Revision History Explanation
Revision Number: 4  
Start Date of Comment Period: N/A  
Start Date of Notice Period: 09/01/2011  
Revised Effective Date: 08/23/2011  

LCR B2011-100  
August 2011 Connection

Explanation of Revision: The LCD has been revised based on newly approved FDA product labels. Indications, Limitations, utilization guidelines have all been revised according to revised product labels. These revisions will be effective for dates of service on or after June 24, 2011 for claims processed on or after 08/23/11.

Revision Number: 3  
Start Date of Comment Period: N/A  
Start Date of Notice Period: 10/01/2010  
Revised Effective Date: 10/01/2010

LCR B2010-071  
September 2010 Update

Explanation of Revision: Annual 2011 ICD-9-CM Update. Revised descriptor for ICD-9-CM code V07.8 found in list #1 for HCPCS code J0885. The effective date of this revision is based on date of service.

Revision Number: 2  
Start Date of Comment Period: N/A  
Start Date of Notice Period: 10/01/2009  
Revised Effective Date: 10/01/2009

LCR B2009-098  
September 2009 Update

Explanation of Revision: Annual 2010 ICD-9-CM Update. Added diagnosis codes 209.31-209.36, 209.70-209.79, and 285.3 for procedure codes J0881 List 2 and J0885 List 2. In addition, a dual diagnosis for J0881 List 2 and J0885 List 2 was added. The dual diagnosis rule is outlined at the beginning of each list. The effective date of this revision is based on date of service.

4-24-09 - deleted "285.29 or *285.9 and one of the following diagnosis codes must be billed: 238.71, 238.72, 238.73, 238.74, 238.75, 238.76, 273.3 or one of the malignancy codes listed below." from the "ICD-9 Codes that Support Medical Necessity" section for J0881 List 1 as this was erroneously left in the LCD during finalization.

Revision Number: 1  
Start Date of Comment Period: 02/20/2009  
Start Date of Notice Period: 05/01/2009  
Revised Effective Date: 06/30/2009

LCR B2009-068  
Printed on 11/22/2011. Page 15 of 16
April 2009 Update

Explanation of Revision: LCD being revised to revise ICD-9 CM coding requirements. In addition grammatical changes were made as needed. The effective date of this LCD revision is based on date of service.

Revision Number: Original
Start Date of Comment Period: N/A
Start Date of Notice Period: 12/04/2008
Revised Effective Date: 02/02/2009

LCR B2009-044FL
December 2008 Update

This LCD consolidates and replaces all previous policies and publications on this subject by the carrier predecessors of First Coast Service Options, Inc. (Triple S and FCSO).

For Florida (00590) this LCD (L29168) replaces LCD L5984 as the policy in notice. This document (L29168) is effective on 02/02/2009.

08/08/2009 - This policy was updated by the ICD-9 2009-2010 Annual Update.
09/06/2010 - This policy was updated by the ICD-9 2010-2011 Annual Update.

Reason for Change

Related Documents
Article(s)
A49092 - J0881 Erythropoiesis stimulating agents revision to the LCD
A48461 - J0881: Erythropoiesis Stimulating Agents–Clarification on correct modifier use

LCD Attachments
Coding Guidelines
Draft LCD Comment Summary

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Updated on 08/21/2011 with effective dates 08/23/2011 - N/A
Updated on 08/19/2011 with effective dates 08/23/2011 - N/A
Updated on 09/16/2010 with effective dates 10/01/2010 - 08/22/2011
Updated on 09/25/2009 with effective dates 10/01/2009 - 09/30/2010
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