



**ERYTHROPOIESIS STIMULATING AGENTS (ESAs)  
MEDICAL NECESSITY CRITERIA**

J0881	Darbepoetin alfa injection; non-ESRD, 1 mcg ( <i>Aranesp</i> )
J0882	Darbepoetin alfa injection; for ESRD on dialysis, 1 mcg ( <i>Aranesp</i> )
J0885	Epoetin alfa injection); non-ESRD), 1000 units ( <i>Epogen, Procrit</i> )
J0886	Epoetin alfa injection); for ESRD on dialysis, 1000 units ( <i>Epogen, Procrit</i> )
Q4081	Epogen, Procrit (Epoetin alfa injection), 100 units: for ESRD on dialysis ( <i>Epogen, Procrit</i> )

Epoetin alfa and darbepoetin alfa are administered for the purpose of elevating or maintaining red blood cells (as manifested by hemoglobin and hematocrit determinations) and/or to decrease the need for blood transfusions.

Prior to initiating erythropoietin therapy, appropriate diagnostic work-up must be done to rule out other causes for anemia such as iron deficiency, folate/B12 deficiency, hemolysis, or gastrointestinal bleeding, etc.

Adequate iron stores must be demonstrated by means of bone marrow iron or serum ferritin levels or serum iron saturation studies. Iron supplementation therapy is at the discretion of the treating physician.

Prior to initiating erythropoietin therapy with epoetin alfa or darbepoetin alfa, blood pressure should be adequately controlled and must be closely monitored and controlled during therapy.

## I. Criteria for initial treatment

- A. Therapy with epoetin alfa or darbepoetin alfa for the treatment of anemia will be considered where the following conditions have been documented and the pretreatment hemoglobin is  $\leq$  10 grams/dL:
  1. Non-myeloid cancer receiving chemotherapy
  2. Chronic renal failure
  3. HIV receiving antiretrovirals
  4. Hepatitis C receiving antiviral therapy
  5. Myelodysplastic syndrome
  6. Anemia of chronic disease (secondary underlying chronic disease must be stipulated and coverage is limited to anemia related to rheumatoid arthritis and inflammatory bowel disease)
- B. Therapy with epoetin alfa or darbepoetin alfa for the treatment of anemia will be considered where the following conditions have been documented:
  1. Members scheduled to undergo elective, non-cardiac, non-vascular surgery, at high risk for significant anticipated blood loss and perioperative transfusions when they are unable to donate a sufficient quantity of autologous blood and the pretreatment hemoglobin is  $\leq$  13 grams/dL

2. Members with severe cardio-pulmonary or cerebrovascular co-morbidities or those at increased risk of or intolerant to transfusions and the pretreatment hemoglobin is  $\leq$  12 grams/dL
- C. Therapy with epoetin alfa or darbepoetin alfa for the treatment of anemia will be considered where for members with prematurity of less than 33 weeks or birth weight less than 1500 grams:
  1. Treatment as stipulated by member's provider

## **II. Criteria for continued treatment**

- A. Following initiation of therapy further treatment will not be approved if the hemoglobin level has failed to rise by 1 gram/dL within sixteen (16) weeks.
- B. The hemoglobin must be less than or equal to 12 grams/dL for continued approval.

If the criteria are met approval will be given for intervals of eight (8) weeks, with eight (8) doses authorized for epoetin alfa and four (4) doses authorized for darbepoetin alfa.

For clinical circumstances not described above, or for questions related to alternative dosing schedules refer to designated Medical Director for review and/or peer-to-peer discussion.

This policy is based in part on the following references:

National Comprehensive Cancer Network Practice Guidelines in Oncology – v.2.2007 Cancer and Treatment Related Anemia  
American Society of Clinical Oncology, Practice Guidelines - Use of Epoetin in Patients with Cancer

Seidenfeld J, Aronson M, Piper MA, et al: Use of erythropoietin for anemia in oncology: Evidence Report Technology Assessment No 30 (ARHQ Publ No 01-E009)

**Horizon BCBS NJ Medicare Plan Only**

J0881	Darbepoetin alfa injection; non-ESRD, 1 mcg ( <i>Aranesp</i> )
J0882	Darbepoetin alfa injection; for ESRD on dialysis, 1 mcg ( <i>Aranesp</i> )
J0885	Epoetin alfa injection); non-ESRD), 1000 units ( <i>Epogen, Procrit</i> )
J0886	Epoetin alfa injection); for ESRD on dialysis, 1000 units ( <i>Epogen, Procrit</i> )
Q4081	Epogen, Procrit (Epoetin alfa injection), 100 units: for ESRD on dialysis ( <i>Epogen, Procrit</i> )

Epoetin alfa and darbepoetin alfa are administered for the purpose of elevating or maintaining red blood cells (as manifested by hemoglobin and hematocrit determinations) and/or to decrease the need for blood transfusions.

Prior to initiating erythropoietin therapy appropriate diagnostic work-up must be done to rule out other causes for anemia such as iron deficiency, folate/B12 deficiency, hemolysis, gastrointestinal bleeding, etc.

Adequate iron stores must be demonstrated by means of bone marrow iron or serum ferritin levels or serum iron saturation studies. Iron supplementation therapy is at the discretion of the treating physician.

Prior to initiating erythropoietin therapy with epoetin alfa or darbepoetin alfa, blood pressure should be adequately controlled and must be closely monitored and controlled during therapy.

**I. Criteria for initial therapy**

- A. Anemia associated with chronic kidney disease (CKD) regardless of whether they are on dialysis when the pretreatment hemoglobin is  $\leq 11$  g/dL and glomerular filtration rate  $< 60$  mL/min
- B. Treatment of symptomatic anemia will be considered where the following conditions have been documented and the pretreatment hemoglobin is  $\leq 10$  grams/dL:
  1. Anemia associated with concomitant chemotherapy in cancer members
  2. Severe anemia associated with antiviral therapy in human immunodeficiency virus (HIV) infected members
  3. Symptomatic anemia associated with the treatment of ribavirin/interferon alfa-2b for chronic hepatitis C
  4. Treatment of anemia following allogeneic bone marrow transplantation (BMT)
  5. Treatment of anemia associated with myelodysplastic syndromes
  6. Treatment of anemia associated with chronic diseases excluding malignancy (e.g., rheumatoid arthritis, inflammatory bowel diseases)
- C. Reduction of allogeneic blood transfusions in anemic members who are at high risk for perioperative transfusions with significant anticipated blood loss and are scheduled to undergo elective, non cardiac, non-vascular surgery, where the hemoglobin is  $\leq 13$  g/dL

**II. Criteria for continued treatment**

- A. Following initiation of therapy, further treatment will not be approved if the hemoglobin level has failed to rise by 1 gram/dL within twelve (12) weeks of therapy.
- B. The hemoglobin must be  $\leq$  12 grams/dL for continued approval.

If the criteria are met, approval will be given for intervals of eight (8) weeks, with eight (8) doses authorized for epoetin alfa and four (4) doses authorized for darbepoetin alfa.

For clinical circumstances not described above or for questions related to alternative dosing schedules, refer to designated Medical Director for review and/or peer-to-peer discussion.

**Horizon BCBS NJ Commercial Plan Only**

J0881	Darbepoetin alfa injection; non-ESRD, 1 mcg ( <i>Aranesp</i> )
J0882	Darbepoetin alfa injection; for ESRD on dialysis, 1 mcg ( <i>Aranesp</i> )
J0885	Epoetin alfa injection); non-ESRD), 1000 units ( <i>Epogen, Procrit</i> )
J0886	Epoetin alfa injection); for ESRD on dialysis, 1000 units ( <i>Epogen, Procrit</i> )
Q4081	Epogen, Procrit (Epoetin alfa injection), 100 units: for ESRD on dialysis ( <i>Epogen, Procrit</i> )

Epoetin alfa and darbepoetin alfa are administered for the purpose of elevating or maintaining red blood cells (as manifested by hemoglobin and hematocrit determinations) and/or to decrease the need for blood transfusions.

Prior to initiating erythropoietin therapy, appropriate diagnostic work-up must be done to rule out other causes for anemia such as iron deficiency, folate/B12 deficiency, hemolysis, gastrointestinal bleeding, etc.

Adequate iron stores must be demonstrated by means of bone marrow iron or serum ferritin levels or serum iron saturation studies. Iron supplementation therapy is at the discretion of the treating physician.

Prior to initiating erythropoietin therapy with epoetin alfa or darbepoetin alfa, blood pressure should be adequately controlled and must be closely monitored and controlled during therapy.

**II. Criteria for initial therapy**

- A. Anemia associated with chronic kidney disease (CKD) regardless of whether they are on dialysis when the pretreatment hemoglobin is  $\leq 11$  g/dL and glomerular filtration rate  $< 60$  mL/min
- B. Treatment of symptomatic anemia will be considered where the following conditions have been documented and the pretreatment hemoglobin is  $\leq 10$  grams/dL:
  1. Anemia associated with concomitant chemotherapy in cancer members
  2. Severe anemia associated with antiviral therapy in human immunodeficiency virus (HIV) infected members
  3. Symptomatic anemia associated with the treatment of ribavirin/interferon alfa-2b for chronic hepatitis C
  4. Treatment of anemia following allogeneic bone marrow transplantation (BMT)
  5. Treatment of anemia associated with myelodysplastic syndromes
  6. Treatment of anemia associated with chronic diseases excluding malignancy (e.g., rheumatoid arthritis, inflammatory bowel diseases)
- C. Reduction of allogeneic blood transfusions in anemic members who are at high risk for perioperative transfusions with significant anticipated blood loss and are scheduled to undergo elective, non cardiac, non-vascular surgery, where the hemoglobin is  $\leq 13$  g/dL

**II. Criteria for continued treatment**

- A. Following initiation of therapy further treatment will not be approved if the hemoglobin level has failed to rise by 1 gram/dL within twelve (12) weeks of therapy.
- B. The hemoglobin must be  $\leq$  12 grams/dL for continued approval.

If the criteria are met, approval will be given for intervals of eight (8) weeks, with eight (8) doses authorized for epoetin alfa and four (4) doses authorized for darbepoetin alfa.

For clinical circumstances not described above or for questions related to alternative dosing schedules, refer to designated Medical Director for review and/or peer-to-peer discussion.