Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran™

PROCRIT® & EPOGEN® (epoetin alfa)

GPI CODING:

82401020******

DESCRIPTION:

Epoetin alfa is a recombinant erythropoietin that stimulates red blood cell production. Procrit and Epogen are indicated for the treatment of anemia related to chronic renal failure, chemotherapy in cancer patients, and zidovudine therapy for human immunodeficiency virus infection. Procrit and Epogen are also indicated to reduce allogeneic blood transfusion requirements in surgery patients.

APPROVAL DURATION:

Initial Therapy: 2 months (8 weeks)
Continued Use: 2 months (8 weeks)
Request will not be approved for longer than 2 months (8 weeks) at a time

CRITERIA FOR PROCRIT AND EPOGEN

I. For requests for Epogen, patient has tried, failed or is intolerant to Procrit

II. Patient must meet all of the following criteria:
   A. Hematocrit (Hct)/hemoglobin (Hgb) levels are less than 32%/10g/dl, prior to initiation of therapy
   B. Prior to and during therapy, the patient's iron status, including transferrin saturation and serum ferritin is evaluated with transferring saturation at least 20% and ferritin at least 100ng/mL prior to initiation of therapy;
   C. For patients with uncontrolled hypertension, blood pressure is adequately controlled

III. For the treatment of Anemia of Chronic Renal Failure (CRF)
   1. Procrit or Epogen is considered medically necessary for the treatment of anemia associated with CRF, including both patients on dialysis [end-stage renal disease (ESRD)], and patients not on dialysis with Hgb < 10g/dL
   2. In the absence of response, use of Procrit or Epogen is considered NOT medically necessary beyond 8-12 weeks in patients
   3. Continued use of Procrit or Epogen is considered NOT medically necessary when the hemoglobin level exceeds 12g/dL **AND**
   4. Continued use of Procrit or Epogen may only be approved beyond 8 weeks if the hemoglobin does not exceed 12g/dL **AND**
   5. Iron stores (including transferring saturation and ferritin) are adequately maintained and monitored periodically during therapy

IV. For the treatment of Anemia in Cancer Patients on Chemotherapy
   1. Procrit or Epogen is considered medically necessary for the treatment of anemia induced by concomitantly administered chemotherapy known to produce anemia in patients with a diagnosis of cancer other than acute leukemia

2. Procrit or Epogen is considered NOT medically necessary for the treatment of anemia in patients with cancer not treated by chemotherapy known to produce anemia
3. Continued use of Procrit or Epogen is considered NOT medically necessary when the hemoglobin level exceeds 12g/dL **AND**
4. The continuation of Procrit or Epogen is considered NOT medically necessary beyond 8 weeks after therapy with chemotherapy known to produce anemia is completed.
5. Continued use of Procrit or Epogen (epoetin alfa) may only be approved beyond 8 weeks if the hemoglobin does not exceed 12g/dL **AND**
6. Iron stores (including transferring saturation and ferritin) are adequately maintained and monitored periodically during therapy

V. Treatment of Anemia in Myelodysplastic Syndrome
1. Procrit or Epogen is considered medically necessary for the treatment of anemia in patients with myelodysplastic syndrome with an endogenous erythropoietin level less than 500mU/liter
2. In the absence of response, use of Procrit or Epogen is considered NOT medically necessary beyond 8-12 weeks
3. Continued use of Procrit or Epogen is considered not medically necessary when the hemoglobin level exceeds 12g/dL unless otherwise specified above **AND**
4. Continued use of Procrit or Epogen may only be approved beyond 8 weeks if the hemoglobin does not exceed 12g/dL **AND**
5. Iron stores (including transferring saturation and ferritin) are adequately maintained and monitored periodically during therapy

VI. Treatment of Anemia in Zidovudine-treated HIV-infected Patients
1. Procrit or Epogen is considered medically necessary for the treatment of anemia related to therapy with zidovudine in HIV-infected patients when the endogenous serum erythropoietin level is ≤ 500mUnits/mL and when the dose of zidovudine is ≤ 4200mg/week.
2. Continued use of Procrit or Epogen is considered not medically necessary when the hemoglobin level exceeds 12g/dL unless otherwise specified above **AND**
3. Continued use of Procrit or Epogen may only be approved beyond 8 weeks if the hemoglobin does not exceed 12g/dL **AND**
4. Iron stores (including transferring saturation and ferritin) are adequately maintained and monitored periodically during the therapy

VII. Treatment of Anemia and Reduction of Allogeneic Blood Transfusion in Pre-Operative Surgery Patients
1. Procrit or Epogen is considered medically necessary for the treatment of preoperative anemia to reduce the need for allogeneic blood transfusions when the patient meets all of the following:
   i. Patient's hemoglobin > 10 to ≤ 13g/dL
   ii. Patient is scheduled to undergo elective, noncardiac, nonvascular surgery
   iii. Patient at high risk for perioperative transfusions with significant, anticipated blood loss
   iv. Patient is unable or unwilling to donate autologous blood
   v. Antithrombotic prophylaxis has been considered

VIII. Treatment of Anemia in Patients being treated for Hepatitis C Virus Infection
1. Procrit or Epogen is considered medically necessary for the treatment of anemia in patients with hepatitis C virus infection who are being concomitantly treated with the combination of ribavirin and interferon alfa, or ribavirin and peginterferon alfa

2. Continued use of epoetin alfa may only be approved beyond 8 weeks if the hemoglobin does not exceed 12g/dL **AND**
3. Iron stores (including transferring saturation and ferritin) are adequately maintained and monitored periodically during therapy

IX. Treatment of Anemia in Patients with Chronic Inflammatory Disease on Chemotherapy
1. Procrit or Epogen is considered medically necessary for the treatment of anemia induced by concomitantly administered chemotherapy known to produce anemia in patients with a diagnosis of a chronic inflammatory disease
2. Continued use of epoetin alfa may only be approved beyond 8 weeks if the hemoglobin does not exceed 12g/dL **AND**
3. Iron stores (including transferring saturation and ferritin) are adequately maintained and monitored periodically during therapy

X. Allogeneic Bone Marrow Transplantation
1. Procrit or Epogen is considered medically necessary for patients following allogeneic bone marrow transplantation
2. Continued use of Procrit or Epogen is considered NOT medically necessary when the hemoglobin level exceeds 12g/dL unless otherwise specified above **AND**
3. The continuation of Procrit or Epogen is considered NOT medically necessary beyond 8 weeks after therapy with chemotherapy known to produce anemia is completed
4. Continued use of epoetin alfa may only be approved beyond 8 weeks if the hemoglobin does not exceed 12g/dL **AND**
5. Iron stores (including transferring saturation and ferritin) are adequately maintained and monitored periodically during therapy

XI. Procrit or Epogen is considered NOT medically necessary if any of the following are present:
1. Anemia in patients due to other factors such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic diseases (such as sickle cell anemia, thalassemia, and porphyria)
2. Sudden loss of response with severe anemia and low reticulocyte count
3. Increase in dosage at intervals more frequently than once a month