SUBJECT: Darbepoetin alfa (Aranesp®), Epoetin alfa (Procrit® & Epogen®)
INDEX TITLE: Clinical Pharmacy Services
ORIGINAL DATE: 7/2005

This policy applies to the following lines of business: (Check those that apply.)

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I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy and Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs Darbepoetin alfa (Aranesp) and Epoetin alfa (Procrit and Epogen) are subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the prior authorization process for Darbepoetin alfa (Aranesp) and Epoetin alfa (Procrit and Epogen).

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. PROCEDURE

Criteria for Darbepoetin alfa and Epoetin alfa:

1. Darbepoetin alfa
   a. Darbepoetin alfa is indicated for the following:
      i. Treatment of anemia of chronic renal failure, including members on dialysis (end stage renal disease [ESRD]) and members not on dialysis.
      ii. Treatment of anemia due to concomitant chemotherapy when a cure of cancer is not anticipated in patients with non-myeloid malignancies. Darbepoetin alfa is not indicated for use in patients receiving only the following therapies:
         a. Hormonal agents
         b. Therapeutic biological products
         c. Radiotherapy
   b. Darbepoetin alfa will be covered for members who meet all of the following criteria:
      i. Member must have ONE of the following diagnoses:
         a. Anemia of chronic renal failure and on renal dialysis when Hgb <10 g/dL; or
         b. Anemia of chronic renal failure, not requiring dialysis when Hgb < 10g/dL; or
         c. Anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy (Hgb <10 g/dL) ; or
         d. Anemia associated with the use of ribavirin when Hgb < 10 g/dL or a 2 g/dL decrease from baseline Hgb; or
         e. Anemia associated with myelodysplastic syndrome when Hgb < 10 g/dL.
      ii. Iron status must be evaluated by the provider for all members before and during treatment. Supplemental iron therapy is required for all members whose serum ferritin is below 100 mcg/L (<300 mcg/L in members with chronic kidney disease) or whose serum transferrin saturation is below 20%.
      iii. Member must not have uncontrolled hypertension.
      iv. Member must not have a known hypersensitivity to the active substance or any of the excipients of the product.
      v. Prescribed dose must be within the recommended dosing guidelines.

   If clinical documentation confirms the above criteria are met, UPMC Health Plan will initially approve Darbepoetin alfa for a 1-month trial.

   c. Continuation/Discontinuation criteria for Darbepoetin alfa:
      i. A clinical and lab reassessment will be conducted after an initial 1-month trial and every 6 months thereafter to determine if the authorization may be
extended. For members on ribavirin therapy, the reassessment will be monthly.
ii. An increase of Hgb > 12g/dl for all members will result in discontinuation of therapy. Authorization extension will be denied.

2. Epoetin alfa
   a. Procrit® (epoetin alfa) is indicated for the following:
      i. Treatment of anemia of chronic renal failure, including members on dialysis (end stage renal disease [ESRD]) and members not on dialysis
      ii. Treatment of anemia of HIV members
      iii. Treatment of anemia due to concomitant chemotherapy when a cure of cancer is not anticipated in patients with non-myeloid malignancies. Epoetin alfa is not indicated for us in patients receiving only the following therapies
         o Hormonal agents
         o Therapeutic biological products
         o Radiotherapy
      iv. Reduction in allogeneic blood transfusion in surgery members
   b. Epogen® (epoetin alfa) is indicated for the following:
      i. Treatment of anemia of chronic renal failure members, including members on dialysis (end stage renal disease [ESRD]) and members not requiring dialysis.
   c. Even though the indications differ for Procrit® and Epogen®, the two drugs are considered therapeutically interchangeable.
   d. Epoetin alfa will be covered for members who meet the following criteria:
      i. Member must have ONE of the following:
         a. Anemia of chronic renal failure and on renal dialysis when Hgb <10 g/dL; or
         b. Anemia of chronic renal failure not requiring dialysis when Hgb <10 g/dL; or
         c. Zidovudine treatment-induced anemia in HIV members when lab value showing Hgb<10 g/dL; or
         d. Anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy when Hgb <10 g/dL; or
         e. Anemic members with lab value showing Hgb >10 and \leq 13g/dL, who are at high risk for perioperative transfusions secondary to significant, and anticipated blood loss and are scheduled to undergo elective, noncardiac, or nonvascular surgery to reduce the risk for allogenic blood transfusions; or
         f. Anemia associated with the use of ribavirin when Hgb < 10 g/dL or a 2 g/dL decrease from baseline Hgb; or
         g. Anemia associated with myelodysplastic syndrome when Hgb < 10 g/dL.
ii. Iron status must be evaluated by the provider for all members before and during treatment. Supplemental iron therapy is required for all members whose serum ferritin is below 100 mcg/L (<300 mcg/L in members with chronic kidney disease) or whose serum transferrin saturation is below 20%.

iii. Member must not have uncontrolled hypertension.

iv. Member must not have a known hypersensitivity to the active substance or any of the excipients of the product.

v. Prescribed dose must be within the recommended dosing guidelines.

If clinical documentation confirms the above criteria are met, UPMC Health Plan will initially approve epoetin alfa for a one-month trial.

e. Continuation/Discontinuation criteria for epoetin alfa
   i. A clinical and lab reassessment will be conducted after an initial 1 month trial and every 6 months thereafter to determine if the authorization may be extended.
   ii. An increase of Hgb > 12 g/dl for all members will result in discontinuation of therapy. Authorization extension will be denied.

Limitations:
If the established criteria are not met, the prior authorization request will be referred to the UPMC Health Plan Medical Director.

VI. BIBLIOGRAPHY

32. Grossman HA, Goon B, Leitz G, and the 010 Study Group. Once-weekly epoetin alfa dosing is as effective as three-times-weekly dosing in increasing hemoglobin levels and is associated with...


