HEMATOPOIETIC AGENTS CRITERIA

Pharmacology:
Erythropoietin is a glycoprotein which stimulates red blood cell production. It is produced in the kidney and stimulates the division and differentiation of committed erythroid progenitors in the bone marrow.

Indication:
Procrit® and Epogen® are indicated in the treatment of anemia of chronic renal failure, zidovudine treated HIV infected patients, anemia in cancer patients on chemotherapy, and reduction of allogeneic blood transfusions in surgery patients.

Aranesp® is indicated in the treatment of anemia associated with chronic renal failure, including patients on dialysis and not on dialysis and for the treatment of anemia in patients with nonmyeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.

Mircera® is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis.

Medications:

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<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dosage Strengths</th>
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<tbody>
<tr>
<td>Aranesp®</td>
<td>darbepoetin alfa</td>
<td>25 mcg/ml, 40 mcg/ml, 60 mcg/ml, 100 mcg/ml, 150 mcg/ml, 200 mcg/ml, 300 mcg/ml, 500 mcg/ml</td>
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<td>Epogen®</td>
<td>epoetin alfa</td>
<td>2000 U/ml, 3000 U/ml, 4000 units/ml, 10,000 units/ml, 40000 units/ml</td>
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<td>Procrit®</td>
<td>epoetin alfa</td>
<td>2000 U/ml, 3000 U/ml, 4000 units/ml, 10,000 units/ml, 20000 units/ml, 40000 units/ml</td>
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<tr>
<td>Mircera®</td>
<td>methoxy polyethylene glycol-epoetin beta</td>
<td>30 mcg/0.3 ml, 50 mcg/0.3 ml, 75 mcg/0.3 ml, 100mcg/0.3 ml, 150 mcg/0.3 ml, 200 mcg/0.3 ml, 250 mcg/0.3 mL, 360mcg/0.6ml</td>
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Criteria For Approval:

A. A documented HCT < 30%, AND
B. A documented hg < 10 g/dL, AND
C. Iron levels performed (transferrin saturation ≥ 20%, ferritin ≥100ng/ml), AND
D. Lab data within 2 months of Prior Authorization (PA) submission

One of the following diagnoses:
A. Anemia associated with chronic kidney disease, predialysis or on dialysis, (this is the only diagnosis that can be approved for Mircera®), OR
B. Anemia associated with cancer chemotherapy, OR
C. Anemia in cancer patients who are not treated with chemotherapy but have anemia associated with any of the following: prior chemotherapy, prior radiation therapy, current treatment with radiation therapy, or malignancy, OR
D. Anemia in patients with HIV who are receiving zidovudine therapy (Procrit® or Epogen® only), OR
E. Reduction of allogeneic blood transfusions in surgery patients (Procrit® or Epogen® only), OR
F. Anemia in myelodysplastic syndromes (MDS), OR
G. Anemia in lymphoproliferative disease, OR
H. Anemia due to ribavirin use in patients infected with hepatitis C.
HEMATOPOIETIC AGENTS CRITERIA
(cont.)

Criteria For Denial:
A. Criteria for approval not met, OR
B. A documented HCT > 36%, AND
C. A documented hg > 12g/dl, OR

One of the following diagnoses:
A. Pruritis (uremic), OR
B. Patients requiring immediate correction of severe anemia, OR
C. Anemia in patients with rheumatoid arthritis, OR
D. Anemia of prematurity, OR
E. Anemia in women with postpartum iron deficiency anemia, OR
F. Sickle-cell anemia in patients who do not respond to hydroxyurea, OR
G. Patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy or in whom anemia can be managed by transfusion (Procrit®, Epogen® or Aranesp® only), OR
H. Anemia due to cancer chemotherapy (Mircera® only).

Criteria for Denial of Renewal:
A. Appropriate dose increase did not produce >1g/dl in Hg, OR
B. A documented HCT >36%, AND
C. A documented hg > 12g/dl

Length of Approval: 6 months

References:
Available upon request.

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<th>Reviewed by</th>
<th>Reason for Review</th>
<th>Date Approved</th>
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