Erythropoiesis Stimulating Agents (ESA)

Line(s) of Business: HMO; PPO; QUEST Integration
Akamai Advantage

Original Effective Date: 04/15/2007
Current Effective Date: 10/01/2015

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Table 1. Erythropoiesis Stimulating Agents

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>FDA Approved Indications</th>
</tr>
</thead>
</table>
| Aranesp®   | darbepoetin alfa | • Treatment of anemia due to CKD in patients on dialysis and patients not on dialysis  
• Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy |
| Epogen® Procrit® | epoetin alfa | Treatment of anemia due to  
• CKD in patients on dialysis and not on dialysis  
• Zidovudine in HIV-infected patients  
• The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy  
• Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery |

Abbreviations: CKD = chronic kidney disease; HIV = human immunodeficiency virus; RBC = red blood cell.
B. REQUIRED DOCUMENTATION

- Laboratory report with hemoglobin (obtained within the past 30 days and excluding any values due to a recent blood transfusion)
- For myelodysplastic syndrome (MDS):
  o Laboratory report with endogenous erythropoietin level
  o International Prognostic Scoring System (IPSS) score and any other documentation supporting low or intermediate-1 risk MDS
  o Clinical notes demonstrating transfusion dependency

C. CRITERIA FOR APPROVAL – INITIATION OF THERAPY

1. Chronic Kidney Disease
   Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criterion is met:
   a. Pretreatment hemoglobin < 10 g/dL

2. Cancer Patients Receiving Chemotherapy
   Authorization for 3 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criteria are met:
   a. Currently receiving concomitant myelosuppressive chemotherapy
   b. Diagnosis of a non-myeloid malignancy
   c. Expected to receive at least 2 more months of chemotherapy
   d. Pretreatment hemoglobin < 10 g/dL

3. HIV Patients Receiving Zidovudine (AZT)
   Authorization for 3 months may be granted for members who are prescribed Epogen/Procrit when the following criteria are met:
   a. Currently receiving ≤ 4200 mg per week of zidovudine (AZT)
   b. Pretreatment hemoglobin < 10 g/dL
   c. Pretreatment endogenous erythropoietin level ≤ 500 mU/mL

4. Myelodysplastic Syndromes (MDS)
   Authorization for 3 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criteria are met:
   a. International Prognostic Scoring System (IPSS) low or intermediate-1 risk MDS
   b. Pretreatment hemoglobin ≤ 10 g/dL or member is dependent on blood transfusions
   c. Pretreatment endogenous erythropoietin level ≤ 500 mU/mL

5. Reduce Allogeneic Blood Transfusions Prior to Elective Surgery
   Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit when the following criteria are met:
   a. Pretreatment hemoglobin > 10 to ≤ 13 g/dL
   b. Elective, non-cardiac, non-vascular surgery scheduled
   c. High risk for peri-operative blood transfusions with significant anticipated blood loss (eg, member is expected to require > 2 units of blood)
6. **Anemia in Congestive Heart Failure**  
Authorization for 3 months may be granted for members who are prescribed Epogen/Procrit when the following criterion is met:  
   a. Pretreatment hemoglobin < 9 g/dL

7. **Anemia in Rheumatoid Arthritis**  
Authorization for 3 months may be granted for members who are prescribed Epogen/Procrit when the following criterion is met:  
   a. Pretreatment hemoglobin < 10 g/dL

8. **Anemia Associated With Hepatitis C Management**  
Authorization for 3 months may be granted for members who are prescribed Epogen/Procrit when the following criteria are met:  
   a. Currently receiving a hepatitis C regimen that contains interferon alfa/peginterferon alfa and/or ribavirin  
   b. Pretreatment hemoglobin < 11 g/dL or member has a comorbid condition requiring treatment of mild to moderate anemia (eg, cirrhosis, heart failure, COPD)

9. **Anemia in Members with Religious Beliefs That Forbid Blood Transfusions**  
Authorization for 3 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criterion is met:  
   a. Pretreatment hemoglobin < 10 g/dL

D. **CONTINUATION OF THERAPY**

1. **Chronic Kidney Disease**  
Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criteria are met:  
   a. Response to initial ESA therapy as demonstrated by a rise in Hgb of at least 1 g/dL after at least 3 months of ESA therapy  
   b. EITHER of the following:  
      i. Member is currently on hemodialysis; and  
         1) Current hemoglobin ≤ 11 g/dL; or  
         2) Current hemoglobin > 11 g/dL to ≤ 12 g/dL and prescriber will interrupt or decrease dose to the lowest dose sufficient to reduce the need for red blood cell transfusions  
      ii. Member is NOT currently on dialysis; and  
         1) Current hemoglobin ≤ 10 g/dL; or  
         2) Current hemoglobin > 10 g/dL to ≤ 12 g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for red blood cell transfusions

2. **Cancer Patients Receiving Chemotherapy**  
Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criteria are met:  
   a. Currently receiving concomitant myelosuppressive chemotherapy  
   b. Diagnosis of a non-myeloid malignancy  
   c. Expected to receive at least 2 more months of chemotherapy
d. Response to initial ESA therapy as demonstrated by a rise in Hgb of at least 1 g/dL after at least 3 months of therapy

e. Current hemoglobin < 11 g/dL

3. **Myelodysplastic Syndromes**
Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criteria are met:

a. International Prognostic Scoring System (IPSS) low or intermediate-1 risk MDS

b. Response to initial ESA therapy as demonstrated by a rise in Hgb of at least 1 g/dL after at least 3 months of ESA therapy

c. EITHER of the following:
   i. Current hemoglobin ≤ 11 g/dL; or
   ii. Current hemoglobin > 11 g/dL to ≤ 12 g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for red blood cell transfusions

4. **HIV Patients Receiving Zidovudine (AZT), Anemia in Congestive Heart Failure, and Anemia in Rheumatoid Arthritis,**
Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit when the following criteria are met:

a. Response to initial ESA therapy as demonstrated by a rise in Hgb of at least 1 g/dL after at least 3 months of ESA therapy

b. EITHER of the following:
   i. Current hemoglobin ≤ 11 g/dL; or
   ii. Current hemoglobin > 11 g/dL to ≤ 12 g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for red blood cell transfusions

5. **Anemia Associated with Hepatitis C Management**
Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit when the following criteria are met:

a. Currently receiving a hepatitis C regimen that contains interferon alfa/peginterferon alfa and/or ribavirin

b. Response to initial ESA therapy as demonstrated by a rise in Hgb of at least 1 g/dL after at least 3 months of ESA therapy

c. EITHER of the following:
   i. Current hemoglobin ≤ 11 g/dL; or
   ii. Current hemoglobin > 11 g/dL to ≤ 12 g/dL and prescriber will interrupt or decrease dosing to the lowest dose sufficient to reduce the need for red blood cell transfusions

6. **Anemia in Members with Religious Beliefs that Forbid Blood Transfusions**
Authorization for 12 months may be granted for members who are prescribed Epogen/Procrit or Aranesp when the following criteria are met:

a. Response to initial ESA therapy as demonstrated by a rise in Hgb of at least 1 g/dL after at least 3 months of ESA therapy

b. EITHER of the following:
   i. Current hemoglobin ≤ 11 g/dL; or
E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. PROGRAM EXCEPTION – AKAMAI ADVANTAGE
For Akamai Advantage members, the following Local Coverage Determination (LCD) applies:
• Erythropoietin Stimulating Agents (ESA) (L33525).

G. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES