Epoetin Alfa for ESRD (Dialysis)

DESCRIPTION

Erythropoietin is a glycoprotein produced in the kidneys responsible for the stimulation of red blood cell production.

Epoetin alfa is a 165-amino acid erythropoiesis-stimulating glycoprotein manufactured by recombinant DNA technology. It is manufactured in the identical amino acid sequence of isolated natural erythropoietin. Like the endogenous hormone, it stimulates increased production of red blood cells in individuals with functioning erythropoiesis and is referred to as an erythropoietin-stimulating agent or an ESA.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

- Epoetin Alfa (Epogen/Procrit/Epogen®) for the treatment or prevention of anemia is considered **medically necessary** if the medical appropriateness criteria are met. (See Medical Appropriateness below.)
- Epoetin Alfa (Epogen/Procrit/Epogen®) for the treatment of other conditions/diseases is considered **investigational**.

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Epoetin Alfa (Epogen/Procrit/Epogen®) for the treatment or prevention of anemia is considered **medically appropriate** if **ALL** of the following criteria are met:
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated)
  - Adequate iron stores are demonstrated prior to therapy by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (Intravenous iron supplementation may be taken into account when evaluating iron status)
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30% (unless otherwise specified)
  - Other causes of anemia have been ruled out (e.g. hemolysis, bleeding, vitamin deficiency, etc.)
  - **Individual does not have uncontrolled hypertension**
  - Diagnosis of anemia secondary to chronic kidney disease (dialysis)

RENEWAL CRITERIA

- Epoetin Alfa (Epogen/Procrit/Epogen®) is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Last dose less than 60 days ago
  - Disease response
  - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe cardiovascular events (stroke, myocardial infarction, thromboembolism, uncontrolled hypertension), seizures, pure red cell aplasia, severe cutaneous reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis), “gasping syndrome” (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated)
  - Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months (Intravenous iron supplementation may be taken into account when evaluating iron status)
  - Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out
  - Diagnosis of anemia secondary to chronic kidney disease and **ANY ONE** of the following
    - Pediatric patients: Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
    - Adults: Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%
### INDICATION(S)

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<th>Anemia due to CKD-dialysis**</th>
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### DOSAGE & ADMINISTRATION

- Adults: 50-100 units/kg intravenously or subcutaneously three times weekly
- Pediatric patients: 50 units/kg intravenously or subcutaneously three times weekly

**Conversion from Epoetin alfa to Aranesp in patients with CKD on dialysis**

- Aranesp is administered less frequently than epoetin alfa
  - Administer Aranesp once weekly in patients who were receiving epoetin alfa 2 to 3 times weekly.
  - Administer Aranesp once every 2 weeks in patients who were receiving epoetin alfa once weekly.
  - Maintain the route of administration (intravenous or subcutaneous injection).

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- Dose increases of 25% can be considered if after 4 weeks of initial therapy the hemoglobin has increased less than 1 g/dL and the current hemoglobin level is less than the indication specific level noted above
- Dose decreases of 25% or more can be considered if the hemoglobin rises rapidly by more than 1 g/dL in any 2-week period
- Dose and frequency requested are the minimum necessary for the patient to avoid RBC transfusions.
- Avoid frequent dose adjustments. Do not increase the dose more frequently than once every 4 weeks; decreases can occur more frequently.
- If patients fail to respond over a 12-week dose escalation period, further doses increases are unlikely to improve response and discontinuation of therapy should be considered.

### LENGTH OF AUTHORIZATION

ESRD: Coverage will be provided for 12 months and may be renewed.

Refer to DOSAGE LIMITS below

### APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee’s Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

### IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

### ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice...
Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES


EFFECTIVE DATE

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