Custom Criteria for
BlueCross Blue Shield of Rhode Island

ARANESP (darbepoetin alfa)

GPI CODING:

824010151120**

DESCRIPTION:

The purpose of this document is to provide approval criteria and guidelines for prior authorization of benefits (PAB) of Aranesp (darbepoetin alfa). Aranesp is used for the treatment of anemia. Claims submitted without obtaining prior authorization of benefits will reject on the Pharmacy Claim system.

APPROVAL DURATION:

Approval duration for initial and renewals: 2 months (8 weeks)
Requests will not be approved for longer than 2 months (8 weeks) at a time

CRITERIA FOR ARANESP

I. Patient has tried, failed or is intolerant to Procrit in the previous 180 days **AND**
II. Meets all the following:
   A. Hematocrit (HCT)/hemoglobin (Hgb) levels are less than 32%/10 g/dL prior to initiation of therapy (unless otherwise specified below)
   B. The patient's iron status, including transferrin saturation and serum ferritin is evaluated with transferrin saturation at least 20% and ferritin at least 100 ng/mL prior to initiation or during therapy
   C. For patients with uncontrolled hypertension, blood pressure is adequately controlled before initiation of therapy and closely monitored and controlled during therapy

AND

III. Meets one of the following:
   A. Treatment of anemia due to Chronic Renal Failure (CRF)
      1. Includes both patients on dialysis [end-stage renal disease (ESRD)], and patients not on dialysis with Hgb<10 g/dL
      2. In the absence of response, use of Aranesp® (darbepoetin alfa) may not be approved beyond 12 weeks
      3. Continued use of Aranesp® (darbepoetin alfa) may only be approved beyond 8 weeks if the hemoglobin does not exceed 12 g/dL
      4. Iron stores (including transferrin saturation and ferritin) are adequately maintained and monitored periodically during therapy

   OR

   B. Patient has anemia induced by chemotherapy or biological agents known to produce anemia in patients with a diagnosis of cancer, excluding acute leukemia;
      1. The continuation of Aranesp® (darbepoetin alfa) may not be approved beyond 8 weeks after therapy with chemotherapy or biological agent(s) known to produce the anemia is completed
      2. Aranesp® (darbepoetin alfa) may not be approved for the treatment of anemia in patients not induced by chemotherapy or biological agents

3. Continued use of Aranesp® (darbepoetin alfa) may only be approved beyond 8 weeks if the hemoglobin does not exceed 12 g/dL
4. Iron stores (including transferrin saturation and ferritin) are adequately maintained and monitored periodically during therapy

OR

C. Myelodysplastic syndrome

1. Aranesp® (darbepoetin alfa) may be approved for the treatment of anemia in patients with myelodysplastic syndrome with an endogenous erythropoietin level lessthan 500 mU/liter
2. In the absence of response, use of Aranesp® (darbepoetin alfa) may not be approved beyond 12 weeks
3. Continued use of Aranesp® (darbepoetin alfa) may only be approved beyond 8 weeks if the hemoglobin does not exceed 12 g/dL
4. Iron stores (including transferrin saturation and ferritin) are adequately maintained and monitored periodically during therapy

IV. Aranesp may not be approved if any of the following are present:

A. Anemia 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)
B. Sudden loss of response with severe anemia and low reticulocyte count
C. Increase in dosage at intervals more frequently than once a month