

**Blue Cross and Blue Shield of Vermont and The Vermont Health Plan  
Prior Approval Guidelines  
Aranesp®(darbepoetin alpha)**

**Description:** Epoetin alpha is a hematopoietic agent used in the treatment of anemic patients to elevate or maintain red blood cell levels as determined by hematocrit or hemoglobin analysis. Darbepoetin alpha differs from epoetin alpha in that it contains two additional carbohydrate chains in its molecular structure. This results in a longer duration of action.

**Indications:** Darbepoetin alpha is indicated for treatment of CRF-associated anemia and for cancer patients on long-term chemotherapy.

**Warnings/  
Precautions:** Use with caution in patients with hypertension or a history of seizures. Darbepoetin alpha can reduce dialysis efficiency which may result in a need for dialysis adjustment. Evaluate any patient with loss of response to darbepoetin alpha for pure red cell aplasia (PRCA). Iron stores should be evaluated before and during therapy. The dose should be adjusted for each patient to achieve and maintain a target hemoglobin not to exceed 12 g/dL, rises in hemoglobin should not exceed 1.0g/dL in a two week period.

**Reasons for Prior Authorization:**  Cost  Potential for misuse  
 Toxicity

**Criteria for Approval:** 1) Diagnosis is an FDA-Labeled Indication **and**  
2) Patient has no contraindications to treatment (See Below)

**Reasons for Denial of Benefit:** 1) Patient has the following **contraindications**  
a) History of hypersensitivity to mammalian cell-derived products or to human albumin.  
b) Uncontrolled hypertension.  
c) Hemoglobin  $\geq$  12g/dL  
2) Patient does not meet criteria

**Benefit Approval**

Initial approval will be for 4 months at which time patient should be evaluated for response to therapy. If patient is responding to therapy, an additional 3 months will be approved in 30 days supplies. Dispensed in no greater than 30 days supplies

**References:** 1) Aranesp product package information. Amgen, Inc. Thousand Oaks, CA. 2001.  
2) Lacy, FL, Armstrong, LL, Goldman, MP, et al. Epoetin alpha. Drug Information Handbook. Hudson. 2003. p.474-7.  
3) Olin BR, ed. Epoetin alpha, recombinant. Hematopoietic agents. Drug Facts and Comparisons (Updated Monthly). St. Louis, July 2003. p.135.