

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: Erythropoietic Agents Policy

Drug(s): ARANESP (darbepoetin alfa), EPOGEN (epoetin alfa)

Covered Uses: All FDA-approved indications not otherwise excluded from Part D or determined that coverage is not or should not be available under Medicare Part B benefits based on Medicare Part B coverage policies. All criteria in "other criteria" section must be met for coverage.

Required Medical Information: Documentation must include all current complete blood count (CBC) with differential and iron studies (e.g. ferritin, serum iron, transferrin saturation, total iron binding capacity (TIBC), etc. before initiating therapy and at least quarterly thereafter. Treatment plan of iron supplementation. Transfusion records. Endogenous epoetin and Zidovudine dose (HIV on Zidovudine). Surgical procedure and date of surgery (for pre-surgical treatment). Bone marrow biopsy (for MDS). ICD-9 supporting use of erythropoiesis stimulating agent (ESA). Name, dose and frequency of requested drug, kidney function test results. Response to treatment.

Age Restrictions: ESAs restricted to 5 years and older for anemia due to chemo.

Prescriber Restrictions: Restricted to oncologists, hematologists, and nephrologists.

Other Criteria:

Based on ASCO/ASH Guidelines, specific recommendations are provided when patients are diagnosed with myeloma, non-Hodgkins lymphoma, or chronic lymphocytic leukemia. Erythropoietin should not be initiated until after the start of chemotherapy and/or high dose corticosteroids and until hemoglobin levels have fallen, as in these cancer types, hemoglobin goal levels have the possibility of being achieved solely through tumor reduction.

Darbepoetin, will be covered only in those members whose Hct/Hgb have been stabilized for at least two months while on erythropoietin.

Must have bone marrow potentially responsive to erythropoietin therapy.

ESA for anemia secondary to chemotherapy of at least 8 weeks in solid tumors, multiple myeloma, lymphoma and lymphocytic leukemia is covered under the following conditions:

- Hgb level immediately prior to initiation or maintenance of ESA is less than 10 g/dL.
- FDA label starting dose must be followed.

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- If Hgb rises less than 1 g/dl compared to baseline over 4 wks and Hgb level remains less than 10 g/dL after 4 wks, the starting dose may be increased once by 25%.
- Anemia related to zidovudine, MDS, and renal failure HGB must be less than 10 gm/dL at start of therapy and maintained at 10-12.
- HIV patients receiving Zidovudine: dose of Zidovudine less than 4200mg/wk and endogenous epoetin level less than 500mUnits/ml and anemia must be causing one of the following symptoms for coverage:
 - fatigue,
 - shortness of breath,
 - tachycardia,
 - tachypnea,
 - or palpitations on exertion.
- MDS criteria: low risk myelodysplasia with less than 5% blasts, epoetin level less than or equal to 100 IU/L, HGB less than 10 g/dL, must not yet be transfusion dependent, anemia must be causing one of the following symptoms for coverage:
 - fatigue,
 - shortness of breath,
 - tachycardia,
 - tachypnea or palpitations on exertion.
- Pre-surgical ESA criteria:
 - elective, noncardiac, nonvascular surgery and,
 - not able to donate autologous blood, and
 - HGB must be greater than 10 gm/dL and less than 13 gm/dL at start of therapy, and
 - must be at high risk for perioperative transfusions with anticipated blood loss greater than 2 units.
- Anemia associated with chronic renal failure (CRF) criteria: serum creatinine greater than 3mg/dl, crcl less than 60ml/min, or GFR less than 60 ml/min/1.73m².
- HGB/HCT less than 10/30% at start of therapy.
- Based on currently available data, the hematocrit (Hct) should be maintained between 33% (Hgb 11g/dl) and 36% (Hgb 12g/dL). At times, the Hct/Hgb may be above this target range.
- The erythropoietin/darbepoetin dose or dose frequency should be decreased to bring the Hct in the target range.
- For continued approvals: titrate dose to achieve and maintain the lowest HGB level sufficient to avoid the need for transfusion and not to exceed 12 gm/dL.
- Response to ESA should be measured via Hct/Hgb levels Q 1-2 wks until a stable dose has been achieved, then monitor every 2-4 weeks. Monitoring could be extended to monthly or quarterly if member is receiving stable doses or demonstrates stable renal function.
- If Hgb increased by more than 1g/dL in a 2 week period, dose should be reduced by 25% (reduce darbepoetin dose by 40% for chemo induced anemia).

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- If Hgb exceeds 12g/dL, hold therapy. Reinitiate therapy if hemoglobin falls below 12g/dL at 25% dose reduction of prior dose. For chemo induced anemia, reduce darbepoetin dose by 40%.
- Maintenance dose of ESA therapy is the starting dose if the HGB level remains below 10 g/dL 4 wks after initiation of therapy and the rise in HGB greater than 1g/dL

Exclusion Criteria:

- Transferrin Saturation less than 20%,
- Ferritin less than 100ng/mL,
- HGB more than 10 g/dL at start (except for pre-surgical).
- For anemia secondary to chemo:
 - HGB rises less than 1 g/dl compared to baseline by 8 wks.
 - Rapid rise in HGB more than 1g/dl over 2 wks unless the HGB remains below 10 g/dL.
 - After 2 months there is no increase in HGB.

For all diseases, EPO is not covered:

- if HGB higher than 12 grams/dL,
- after 8 wks of chemo completion,
- anemia due to the following:
 - folate deficiency,
 - B-12 deficiency,
 - iron deficiency,
 - hemolysis,
 - bleeding, or bone marrow fibrosis,
 - anemia assoc with the treatment of CML, AML, or erythroid cancers, --
 - anemia of cancer not related to cancer treatment,
 - anemia assoc only w/radiotherapy,
 - prophylactic use to prevent chemo-induced anemia,
 - prophylactic use to reduce tumor hypoxia,
 - epo-type resistance due to neutralizing antibodies,
 - in uncontrolled HTN.
- When iron stores are adequate if HGB has not increased by 1-2gm/dl after 8 wks of treatment for epoetin or 6 weeks for darbepoetin at max doses to achieve HGB of 11-12 gm/dL.
- MDS if the member is receiving max doses of ESA and the member has not demonstrated a 50% reduction in transfusion requirements or if the HGB has not normalized at more than 10 gm/dL.
- Pre-operative epo for anemic patients who are able to donate autologous blood. Religious affiliations will not be considered medically necessary.
- Dosing increases more frequently than monthly.
- Anemia related to :
 - Acute or Chronic blood loss (including GI bleeding),
 - Anemia requiring immediate correction,
 - Infectious or inflammatory disease,

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- Hypothyroidism,
- Liver disease,
- Malignant conditions,
- Malnutrition,
- Hemoglobinopathies,
- Osteitis fibrosa cystica,
- Drug-induced anemia (other than those described in this policy),
- conditions other than MDS who received routine administration of blood transfusions to maintain Hct while receiving epoetin or darbepoetin.
- Epo/Darbe doses exceeding package labeling.
- diseases not listed in this policy including fatigue.

Coverage Duration: Initial 3 month approval, followed by approvals up to 6 months