| Darbepoetin alfa (Aranesp®) | Place of Service<br>Hospital Administration<br>Office Administration<br>Home Infusion Administration<br>Outpatient Facility Administration<br>Infusion Center Administration<br>Self-Administration<br><br>HCPCS: J0881 per 1 mcg (non-ESRD) |
|---|---|

Conditions listed in policy *(see criteria for details):*

- Anemia due to chronic renal failure
- Anemia in patients with cancer who are undergoing palliative treatment
- Anemia secondary to myelosuppressive chemotherapy in patients with cancer
- Myelodysplastic syndromes (MDS)
- Myelofibrosis-associated anemia

**AHFS therapeutic class:** Hematopoietic Agent

**Mechanism of action:** Darbepoetin alfa is a recombinant form of the renal glycoprotein hormone erythropoietin (EPO) and stimulates erythropoiesis by the same mechanism as endogenous EPO.

## (1) Special Instructions and Pertinent Information

**If covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax. **Please include medical rationale why medication cannot be home self-administered.**

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|---|
| Retacrit is the preferred erythropoiesis stimulating agent (ESA). For many indications, treatment failure, intolerance or contraindication to Retacrit (epoetin alfa-epbx) is required for members newly initiating ESA therapy. |

## (2) Prior Authorization/Medical Review is required for the following condition(s)

**All requests for Aranesp® (darbepoetin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**Anemia due to chronic renal failure**

1. **Patient has an inadequate response, is intolerant to, or is contraindicated to Retacrit** as defined by any one of the following:
    a. At the max dose of Retacrit for 8 weeks, patient does not meet Hgb target, or Hgb does not rise by at least 2g/dL
    b. Patient has a contraindication to Retacrit that is not also a contraindication of Aranesp
    c. Patient has known side effects to Retacrit that would not be expected with Aranesp
    d. Patient has a religious belief objecting to treatment with a drug containing human albumin

    **AND**
2. Hemoglobin is less than 10 g/dl, **AND**
3. Both Primary and Secondary ICD-10 codes must be met

**Covered Doses**
Up to 200 mcg IV/SC per week

**Coverage Period**
Initial: 1 year
Reauthorization: Cover yearly if Hgb ≤ 11 g/dL

**ICD-10:**
Primary: D63.1 (Anemia in ESRD)
Secondary: N18.1-N18.9 (CRF)

**Anemia in patients with cancer who are undergoing palliative treatment**

1. Patient has an inadequate response, is intolerant to, or is contraindicated to Retacrit as defined by any one of the following:
    a. Hgb does not meet target or is not maintained at a stable level at the max dose of Retacrit for 8 weeks, or
    b. Contraindication to Retacrit that is not a contraindication to Aranesp, or
    c. Side effect to Retacrit that would not be expected with Aranesp, or
    d. Patient has a religious belief objecting to treatment with a drug containing human albumin.

    **AND**
2. Physician attestation that the patient is undergoing palliative treatment, **AND**
3. Hgb < 10 gm/dl

**Covered Doses**
Up to 300 mcg SC per week

**Coverage Period**
Indefinite

**ICD-10:**
D63.0, D63.1, D64.81, D64.9, Z51.11, Z51.89

Anemia secondary to myelosuppressive chemotherapy in patients with cancer

1. **Patient has an inadequate response, is intolerant to, or is contraindicated to Retacrit** as defined by any one of the following:
    a. At the max dose of Retacrit for 8 weeks, patient does not meet Hgb target, or Hgb is not maintained at a stable or improved level.
    b. Patient has a contraindication to Retacrit that is not also a contraindication of Aranesp
    c. Patient has known side effects to Retacrit that would not be expected with Aranesp
    d. Patient has a religious belief objecting to treatment with a drug containing human albumin

    **AND**
2. Patient is currently on chemotherapy or has completed their last dose of chemotherapy within the past 8 weeks, or is currently on Revlimid (lenalidomide) therapy for multiple myeloma, **AND**
3. Hgb of less than 10 g/dL

**Covered Doses**
Up to 200 mcg IV/SC per week

**Coverage Period**
Indefinite

**ICD-10:**
D63.0, D64.81, Z51.11

Myelodysplastic syndromes (MDS)

1. **Patient has an inadequate response, is intolerant to, or is contraindicated to Retacrit** as defined by any one of the following:
    a. At the max dose of Retacrit for 8 weeks, patient does not meet Hgb target, or Hgb is not maintained at a stable or improved level
    b. Patient has a contraindication to Retacrit that is not also a contraindication of Aranesp
    c. Patient has known side effects to Retacrit that would not be expected with Aranesp
    d. Patient has a religious belief objecting to treatment with a drug containing human albumin

    **AND**
2. Baseline serum EPO ≤ 500 mU/ml drawn prior to Aranesp therapy, **AND**
3. Hgb less than 10 g/dL

**Covered Dose**

Up to 500 IV/SC mcg every other week

**Coverage Period**
Indefinite

**ICD-10:**
D46.0, D46.1, D46.2, D46.21, D46.4, D46.A, D46.B,D46.22, D46.C, D46.9, D46.Z

Myelofibrosis-associated anemia

1. Patient has failed, is intolerant to, or is contraindicated to Retacrit as defined by any one of the following:
    a. At the max dose of Retacrit for 8 weeks, patient does not meet Hgb target, or Hgb is not maintained at a stable or improved level
    b. Patient has a contraindication to Retacrit that is not also a contraindication of Aranesp
    c. Patient has known side effects to Retacrit that would not be expected with Aranesp
    d. Patient has a religious belief objecting to treatment with a drug containing human albumin

    **AND**
2. Baseline serum EPO < 500 mU/ml drawn prior to Aranesp therapy, **AND**
3. Hgb of less than 10 g/dL

**Covered Dose**
Up to 300 mcg IV/SC per week

**Coverage Period**
Indefinite

**ICD-10:**
C94.40-C94.42, D47.4, D75.81

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**
**All requests for Aranesp® (darbepoetin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s)**
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Treatment is not covered when Hgb > 12 g/dL or HCT > 36% for all indications
- (280.0) Iron deficiency anemias; secondary to blood loss (chronic)
- (280.9) Iron deficiency anemia, unspecified
- (281.9) Unspecified deficiency anemia
- (283.0) Autoimmune hemolytic anemias
- (284.9) Aplastic anemia, unspecified

- (285.9) Anemia, unspecified (except for EPO for preoperative use)
- (288.0) Agranulocytosis
- (289.9) Unspecified diseases of blood and blood forming organs
- (451.9) Phlebitis and thrombophlebitis; of deep vessels of lower extremities; other
- (V59.01) Donors; blood; whole blood
- (205.00-205.91) Myeloid leukemia
- (206.00-206.91) Monocytic leukemia
- (207.00-208.91) Other specified and unspecified leukemias
- (Z52.01-Z52.018) Future Autologous Transfusion

**Anemias due to:**

- Athletic performance management
- Beta thalassemia
- Blood transfusion reduction
- Cancer radiotherapy
- Cofactor deficiencies
- Congestive heart failure
- Folate deficiency anemia
- Hemolysis
- Hemorrhage
- HIV Treatment
- Insulin resistance
- Most patients with GI bleeding
- Nutritional deficiencies
- Porphyria
- Postpartum
- Prematurity
- Puerperium
- Sexual dysfunction
- Sickle-cell anemia
- Radiation
- Refractory anemia such as thalassemia or sickle cell disease
- Transfusional iron overload
- Untreated underlying infections

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

**How supplied**:

- 25, 40, 60, 100, 150, 200, 300, or 500 mcg (single-dose vials)
- 25, 40, 60, 100, 150, 200, 300, or 500 mcg (single-dose prefilled syringes and prefilled SureClick™ autoinjectors)

**Reference: Dose conversion from Epoetin alfa**

- If patient's previous epoetin alfa dose is administered 2-3 times weekly, darbepoetin should be administered once a week.
- If patient's previous epoetin alfa dose is administered once weekly, darbepoetin should be administered once every 2 weeks.
- The route of administration when treated with epoetin alfa should be maintained when converting to darbepoetin (IV or SC).

| Previous weekly epoetin alfa dose (units/week) | Starting weekly darbepoetin dose (mcg/week) |
|---|---|
| < 2500 | 6.25 |
| 2500-4999 | 12.5 |
| 5000-10,999 | 25 |
| 11,000-17,999 | 40 |
| 18,000-33,999 | 60 |
| 34,000-89,999 | 100 |
| >90,000 | 200 |

*Refer to Aranesp package insert for pediatric dosing conversion.*

Key:
**Hgb** = hemoglobin level, measured in grams per deciliter (g/dL)
**HCT** = hematocrit level, reported in %
**EPO** = Erythropoietin level, reported in microunits per milliliter (mU/ml)

Concurrent iron supplementation is recommended.

## (6) References


- AHFS®. Available by subscription at http://www.lexi.com
- Aranesp® (darbepoetin alfa) Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; 1/2019.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Erythropoiesis-Stimulating Agents (ESAs) in Chronic Kidney Disease: FDA Drug Safety Communication – Modified Dosing Recommendations. 6-24-11. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm260641.htm
- National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2022). Available at http://www.nccn.com.
- National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 3.2022). Available at http://www.nccn.com.
- National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 2.2022). Available at http://www.nccn.org.
- Rizzo JD, Brouwers M, Hurley P et al. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. J Clin Oncol. 2010;28(33):4996-5010.
- Tsiara SN, Chaidos A, Bourantas LK et al. Recombinant human erythropoietin for the treatment of anemia in patients with chronic myelofibrosis. Acta Haematol 2007; 117(3): 156-61.


## (7) Policy Update

Date of last revision: 2Q2023
Date of next review: 3Q2023
Changes from previous policy version:

- No clinical change to policy following revision.