

Darbepoetin alfa (Aranesp®)

Place of Service

Hospital Administration
Office Administration
Home Infusion Administration
Outpatient Facility Administration
Infusion Center Administration
Self-Administration

HCPCS:

J0881 per 1 mcg (*non-ESRD use*)

J0882 per 1 mcg (*for ESRD on dialysis*)

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.

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 \leq 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 \leq 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

PHP Medi-Cal

Darbepoetin (Aranesp®)

- 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 review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*