blue california
Promise Health Plan

## darbepoetin alfa (Aranesp)

## Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

**Place of Service**

Home Infusion Administration
Hospital Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration
Self-Administration - *May be provided by the Pharmacy Benefit*

## Drug Details

**USP Category:** BLOOD PRODUCTS AND MODIFIERS
**Mechanism of Action:** a recombinant form of the renal glycoprotein hormone erythropoietin (EPO) and stimulates erythropoiesis by the same mechanism as endogenous EPO.
**HCPCS:**
J0881:Injection, darbepoetin alfa, 1 microgram (non-esrd use)
**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)

## Condition(s) listed in policy *(see coverage criteria for details)*

- Anemia due to Chronic Kidney Disease (CKD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

## Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

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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. |

## Coverage Criteria
**The following condition(s) require Prior Authorization/Preservice.**

**Anemia due to Chronic Kidney Disease (CKD)**

**Meets medical necessity if all the following are met:**

1. Inadequate response, intolerant, or 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
   b. Contraindication to Retacrit that is not a contraindication to Aranesp
   c. Side effect to Retacrit that would not be expected with Aranesp
   d. Has a religious belief objecting to treatment with a drug containing human albumin
2. Hemoglobin is less than 10 gm/dl
3. Both Primary and Secondary ICD-10 codes must be met

**Covered Doses:**
0.45 mcg/kg subcutaneously or intravenously at 4 week intervals or 0.75 mcg/kg once every 2 weeks

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

## References


1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Aranesp (darbepoetin alfa) Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; 12.2024
4. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2025). Available at http://www.nccn.com.
5. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 2.2025). Available at http://www.nccn.com.

6. National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 2.2025). Available at http://www.nccn.org.

**Review History**

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity

*Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee*