

darbepoetin alfa (Aranesp)

Commercial Medical Benefit Drug Policy

For oncology-related indications, medical necessity criteria can be found here: [Blue Shield Oncology-Related Medication Policies](#).

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's [CarePro Provider Portal](#) to submit your request.

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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Aranesp given as a subcutaneous injection at home: Refer to the "Self-Administered Drugs" Medical Benefit drug policy.

Aranesp given as an intravenous injection is managed under the Medical Benefit. Please submit clinical information for prior authorization review.

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. Not on hemodialysis or peritoneal dialysis (if patient is on hemodialysis or peritoneal dialysis, the dialysis center must supply and administer the drug)
2. Hemoglobin is less than 10 g/d
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 meets the below

1. Not on hemodialysis or peritoneal dialysis
2. Hgb \leq 11 g/dL

ICD-10:

Primary: D63.1 (Anemia in ESRD), Secondary: N18.1-N18.9 (CRF)

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, medical necessity criteria can be found here: [Blue Shield Oncology-Related Medication Policies](#).
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*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*