darbepoetin alfa (Aranesp)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
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.
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 Renal Failure
- Anemia Secondary to Myelosuppressive Anticancer Chemotherapy
- Myelodysplastic Syndromes (MDS)
- Myelofibrosis-Associated Anemia

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Anemia due to Chronic Renal Failure

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:
200 mcg given intravenously or subcutaneously once weekly

Coverage Period:
Initial: 1 year
Reauthorization: Cover yearly if meets the below

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

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

ICD-10:
D63.1

Anemia Secondary to Myelosuppressive Anticancer Chemotherapy

Meets medical necessity if all the following are met:
Requirements listed within the National Coverage Determination (NCD) 110.2: Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

Covered Doses:
Not to exceed the FDA-approved maximum

Coverage Period:
Up to two months after length of chemotherapy

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

Myelodysplastic Syndromes (MDS)

Meets medical necessity if all the following are met:

1. ONE of the following (a or b):
   a. Patient has isolated 5q chromosome deletion [del(5q)]
   b. Patient has a baseline serum EPO ≤ 500 mU/ml drawn prior to Aranesp therapy
2. Symptomatic anemia (Hgb of less than 10 g/dL)

Covered Doses:
500 mcg given intravenously or subcutaneously every other week

Coverage Period:

yearly

ICD-10:
D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z

Myelofibrosis-Associated Anemia
Meets medical necessity if all the following are met:
1. Baseline serum EPO < 500 mU/ml drawn prior to Aranesp therapy
2. Symptomatic anemia (Hgb of less than 10 g/dL)

Covered Doses:
300 mcg given intravenously or subcutaneously once weekly

Coverage Period:
yearly

ICD-10:
C94.40, C94.41, C94.42, D47.4, D75.81

Additional Information

Summary of Evidence
The contents of this policy were created after examining the following resources:
1. The prescribing information for Aranesp
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
   a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
   b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
   c. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category 1 or 2A
   d. Lexi-Drugs – "Use: Off-Label" and rated as "Evidence Level A" (cancer indications only)
   e. Clinical Pharmacology - supportive narrative text (cancer indications only)
3. National Coverage Determination (NCD): NCD 110.21 Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions
4. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
5. NCCN Guidelines: Hematopoietic Growth Factors
6. NCCN Guidelines: Myelodysplastic Syndromes
7. NCCN Guidelines: Myeloproliferative Neoplasms

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Aranesp are covered in addition to the following:
- Myelodysplastic syndromes (MDS)
- Myelofibrosis-associated anemia

Explanation of Rationale:
- Support for FDA-approved indications can be found in the manufacturer's prescribing information.

- Support for using darbepoetin alfa for myelodysplastic syndromes (MDS) is found in the National Comprehensive Cancer Network's guideline for MDS. The NCCN Guideline for MDS supports the use of darbepoetin and epoetin alfa for 1) Treatment of lower risk (IPSS low/intermediate-1) disease associated with symptomatic anemia, with del(5q), with or without one other cytogenetic abnormality (except those involving chromosome 7) and serum erythropoietin ≤500 mU/mL; 2) Treatment of lower risk [IPSS-R (Very Low, Low, Intermediate)] disease associated with symptomatic anemia, with no del(5q), with or without other cytogenetic abnormalities with ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation), with serum erythropoietin ≤500 mU/mL either as a single agent (preferred) or in combination with either lenalidomide or a granulocyte-colony stimulating factor (G-CSF) following no response (despite adequate iron stores) to either an erythropoiesis-stimulating agent (ESA) alone or luspatercept-aamt; and 3) Treatment of lower risk [IPSS-R (Very Low, Low, Intermediate)] disease associated with symptomatic anemia, with no del(5q), with or without other cytogenetic abnormalities with ring sideroblasts ≥15% (or ring sideroblasts ≥5% with an SF3B1 mutation), with serum erythropoietin ≤500 mU/mL following no response to luspatercept-aamt either as a single agent or in combination with a granulocyte-colony stimulating factor (G-CSF).
- Support for using darbepoetin alfa for myelofibrosis-associated anemia is found in the National Comprehensive Cancer Network's guideline for Myeloproliferative Neoplasms. The NCCN Guideline for Myeloproliferative Neoplasms supports the use of darbepoetin and epoetin alfa for the management of myelofibrosis-associated anemia with serum EPO <500 mU/mL either with presence of symptomatic splenomegaly and/or constitutional symptoms currently controlled on a JAK inhibitor, to be given in combination with ruxolitinib or with no symptomatic splenomegaly and/or constitutional symptoms.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at http://www.lexi.com
5. Aranesp (darbepoetin alfa) Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; 1/2019.
6. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
7. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 3.2024). Available at http://www.nccn.com.
8. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 3.2024). Available at http://www.nccn.com.
9. National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 1.2024). Available at http://www.nccn.org.

Review History

Date of Last Annual Review: 3Q2024

Changes from previous policy version:

- New Part B policy

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

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