Clinical Policy: Darbepoetin alfa (Aranesp)

Reference Number: PA.CP.PHAR.236
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for darbepoetin alfa (Aranesp®).

FDA Approved Indication(s)
Aranesp is indicated for the treatment of:

- Anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.
- Anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Limitation(s) of use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion.
- As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Aranesp is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Anemia due to Chronic Kidney Disease (must meet all):

1. Diagnosis of anemia of chronic kidney disease (CKD) (dialysis and non-dialysis members);
2. Prescribed by or in consultation with a hematologist or nephrologist;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%;
4. Pretreatment hemoglobin level < 10g/dL;

Approval Duration: 12 weeks

B. Anemia due to Chemotherapy in Patients with Cancer (must meet all):

1. Diagnosis of anemia due to chemotherapy;
2. Prescribed by or in consultation with a hematologist or oncologist;

3. Age ≥ 18 years;
4. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%;
5. Pretreatment hemoglobin < 10g/dL;

Approval Duration: 6 months

C. Anemia Associated with Myelodysplastic Syndrome (must meet all):

1. Diagnosis of anemia from myelodysplastic syndrome (MDS);
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Current (within the last 3 months) Serum erythropoietin (EPO) ≤ 500 mU/mL;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%;
6. Pretreatment hemoglobin < 10g/dL;

Approval Duration: 6 months

D. Myelofibrosis-Associated Anemia (off-label) (must meet all)**:**

7. Diagnosis of anemia associated with myelofibrosis;
8. Prescribed by or in consultation with a hematologist or oncologist;
9. Current (within the last 3 months) serum EPO < 500 mU/mL;
10. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.

Approval duration: 6 months

E. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

1. Additional Aranesp uses outlined in the NCCN compendium, and which meet NCCN category 12a, or 2b are covered for the following indications per the PA.CP.PHAR.57 Global Biopharm Policy:
   a. Myelofibrosis-associated anemia with serum EPO < 500 mU/mL in members with adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%.

II. Continued Approval

A. Anemia due to CKD (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies;
2. Hemoglobin is responsive to erythropoiesis-stimulating agent (ESA) therapy;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%;

Approval Duration: 6 months

B. Anemia due to Chemotherapy in Patients with Cancer (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies;
2. Continuation of ESA therapy is concurrent with myelosuppressive chemotherapy;
3. Length of therapy is one of the following:
   a. Has received < 8 weeks of ESA therapy;
   b. Has received ≥ 8 weeks of ESA therapy and both of the following:
      i. Documented evidence of response to therapy as measured by rise in hemoglobin levels > 1g/dL;
      ii. No red blood cell transfusions are required;
4. Current hemoglobin < 10g/dL;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%.

Approval Duration:
6 months or until the completion of chemotherapy course, whichever is less

C. Anemia Associated with Myelodysplastic Syndrome (must meet all):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies;
2. Member is responding positively to therapy
3. Current hemoglobin < 12g/dL;
4. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%.

Approval Duration: 6 months

D. Myelofibrosis-Associated Anemia (off-label) (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies;
2. Member is responding positively to therapy;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.

Approval duration: 6 months

E. Other diagnoses/indications: (1 or 2)
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies;

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:
Darbepoetin alfa is an erythropoiesis-stimulant agent (ESA). It stimulates erythropoiesis by the same mechanism as endogenous erythropoietin.

Formulations:
Single-dose vials
Injection: 25 mcg, 40 mcg, 60 mcg, 100 mcg, 200 mcg, 300 mcg, and 500 mcg/1 mL, and 150 mcg/0.75 mL

Single-dose prefilled syringes
Injection: 10 mcg/0.4 mL, 25 mcg/0.42 mL, 40 mcg/0.4 mL, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL, 200 mcg/0.4 mL, 300 mcg/0.6 mL, and 500 mcg/1 mL

Appendices

Appendix A: Abbreviation Key

CKD: chronic kidney disease
EPO: erythropoietin
ESA: erythropoiesis-stimulating agent
MDS: myelodysplastic syndromes
PRCA: pure red cell aplasia

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0881	Injection, darbepoetin alfa, 1 mcg (non- ESRD use)
J0882	Injection, darbepoetin alfa, 1 mcg (for-ESRD on dialysis)

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added age where relevant approval duration modified to allow no less than 6 months for initial/continued approval; anemia associated with MDS/MF: clarified that the lab for serum EPO should be current (within the past 3 months); added requirement for positive response to therapy on re-auth; references reviewed and updated.	02.06.18	

References

1. Aranesp Prescribing Information. Thousand Oaks, CA: Amgen Inc.; April 2017. Available at http://www.aranesp.com/. Accessed December 18, 2017.

2. Rizzo, JD., Brouwers, M., Hurley, P., et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. Blood, 116(20), 4045-4059. Accessed January 4, 2018. https://doi.org/10.1182/blood-2010-08-300541.
3. Darbepoetin alfa. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed December 18, 2017.
4. Myelodysplastic Syndromes (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed December 18, 2017.
5. Myeloproliferative Neoplasms (Version 2.2018). In National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed December 18, 2017.
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 4, 2018.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.