Clinical Policy Title:	epoetin alfa, epoetin alfa-epbx
Policy Number:	RxA.265
Drug(s) Applied:	Epogen®, Procrit®, Retacrit®
Original Policy Date:	02/07/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All line of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Anemia due to chronic kidney disease (must meet all):

1. Diagnosis of anemia of chronic kidney disease (dialysis and non-dialysis members);
2. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
3. Pre-treatment hemoglobin level < 10 g/dL;
4. If Epogen or Procrit is requested, failure of Retacrit unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Anemia due to zidovudine in HIV-infected patients (must meet all):

1. Diagnosis of zidovudine-induced anemia;
2. Member is human immunodeficiency virus-positive;
3. Dose of zidovudine is ≤ 4,200 mg/week;
4. Endogenous serum erythropoietin levels ≤ 500 mU/mL;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
6. Pre-treatment hemoglobin level < 10 g/dL;
7. If Epogen or Procrit is requested, failure of Retacrit unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

C. Anemia due to chemotherapy in patients with cancer (must meet all):

1. Request is for use in solid or non-myeloid malignancies in members receiving myelosuppressive chemotherapy without curative intent;
2. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
3. Pre-treatment hemoglobin level < 10 g/dL;
4. If Epogen® or Procrit® is requested, failure of Retacrit® unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): Until the completion of chemotherapy course or 6 months, whichever is longer

D. Reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery (must meet all):
1. Member is at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery;
2. Perioperative hemoglobin ≥ 10 to ≤ 13 g/dL;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
4. Member is unwilling or unable to donate autologous blood pre-operatively;
5. If Epogen or Procrit is requested, failure of Retacrit unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 15 days (for 300 Units/kg daily) or 21 days (for 600 Units/kg in 4 doses)

E. Anemia Associated with myelodysplastic syndromes (off-label) (must meet all):
1. Diagnosis of anemia from myelodysplastic syndrome (MDS);
2. Current (within the last 3 months) endogenous serum erythropoietin ≤ 500 mU/mL;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
4. Pre-treatment hemoglobin level < 10 g/dL;
5. If Epoge or Procrit® is requested, failure of Retacrit unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 6 months

F. Myelofibrosis-associated anemia (off-label) (must meet all):
1. Diagnosis of anemia associated with myelofibrosis;
2. Current (within the last 3 months) endogenous serum erythropoietin < 500 mU/ml;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
4. If Epogen or Procrit is requested, failure of Retacrit unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
3. If the diagnosis is anemia due to zidovudine or myelodysplastic syndrome, current hemoglobin level ≤ 12 g/dL;
4. If the diagnosis is anemia due to chemotherapy, member meets the following (a, b, and c):
   a. Currently hemoglobin level ≤ 10 g/dL;
   b. Continuation of ESA therapy is concurrent with myelosuppressive chemotherapy;

c. If the member has received ≥ 8 weeks of ESA therapy, member meets the following (i and ii):
   i. Documented evidence of response to therapy as evidenced by rise in hemoglobin levels > 1 g/dL;
   ii. No RBC transfusions are required.

Approval Duration
All Lines of Business (except Medicare): 6 months

B. Reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular Surgery:
1. Re-authorization is not permitted.

Approval Duration
Not Applicable

References

1. Rizzo JD, Brouwers M, Hurley P, et al (2010). 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 2010; 116(20):4045-4059. Available at: https://doi.org/10.1182/blood-2010-08-300541. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Myelodysplastic Syndromes. Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Myeloproliferative Neoplasms. Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed August 28, 2024.
4. National Comprehensive Cancer Network. Hematopoietic Growth Factors. Version 3.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy Reviewed. 1. Formatting updated. 2. References updated. 3. Clinical policy title updated. 4. Drug(s) Applied updated. 5. Line of Business updated. 6. Continued therapy criteria updated.	06/30/2020	9/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.C.2 was updated to include “Diagnosis of moderate to severe chronic kidney disease”. 2. Initial Approval criteria I.C.3 was updated to include “Member is undergoing palliative treatment and refused blood transfusions”. 3. Initial Approval Criteria I.C.4 was updated to include “Member has a minimum of two additional months of planned chemotherapy”.	07/14/2021	09/14/2021

4. Initial Approval Criteria I.C Approval Durations for Commercial and Medicaid were updated from “until the completion of chemotherapy course or 6 months, whichever is long” to “6 months”. 5. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. Continued Therapy Approval Criteria II.B.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 7. Continued Therapy Approval Criteria II.C.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 8. Continued Therapy Approval Criteria II.E.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 9. Continued Therapy Approval Criteria II.F.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 10. References were reviewed and updated.		
Policy was reviewed: 1. References were reviewed and updated.	03/15/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B.5: Updated to remove "Current (within the last 3 months)" from prior lab value criteria. 2. Initial Approval Criteria, I.C.1: Updated diagnostic criteria from Diagnosis of anemia due to chemotherapy to Request is for use in solid or non-myeloid malignancies in members receiving myelosuppressive chemotherapy without curative intent. 3. Initial Approval Criteria, I.C.2: Updated to remove prior diagnostic criteria "Diagnosis of moderate to severe chronic kidney disease."	4/14/2023	7/13/2023

4. Initial Approval Criteria, I.C.3: Updated to remove prior criteria pertaining to indication Anemia due to chemotherapy in patients with cancer, "Member is undergoing palliative treatment and refused blood transfusions." 5. Initial Approval Criteria, I.C.4: Updated to remove prior criteria pertaining to indication Anemia due to chemotherapy in patients with cancer, "Member has a minimum of two additional months of planned chemotherapy." 6. Initial Approval Criteria, I.C: Updated approval duration from 6 months to Until the completion of chemotherapy course or 6 months, whichever is longer. 7. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 4. Reauthorization criteria for all the diagnosis merged under “All Indications in Section I”. 5. Removed reauthorization requirements for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024