Epoetin alfa:
Epogen®; Procrit®; Retacrit®
(Subcutaneous/Intravenous)

NON-DIALYSIS

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I. Length of Authorization

Coverage will be provided for 45 days and may be renewed unless otherwise specified.

- Coverage for Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery may not be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- MDS: 120 billable units every 7 days
- Surgery patients: 600 billable units every 15 days
- All other indications: 60 billable units every 7 days

III. Initial Approval Criteria [1-3,6,7]

Retacrit is the preferred erythropoiesis stimulating agent (ESA) product.

- Patients must have a contraindication or intolerance to Retacrit prior to consideration of any other erythropoietin product.

Coverage is provided in the following condition(s):

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30% (unless otherwise specified); **AND**

Universal Criteria [1-3,5,8,29]

- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**

- Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
- Patient does not have uncontrolled hypertension; **AND**

Anemia Due to Myelodysplastic Syndromes (MDS) ‡ [4,6,27]

- Patient has symptomatic anemia; **AND**
- Patient has serum erythropoietin ≤ 500 mU/mL (unless otherwise specified); **AND**
- Patient has lower risk disease (defined as IPSS-R [Very Low, Low, Intermediate]); **AND**
  - Used as a single agent for del(5q) mutation *(excluding use in patients with cytogenetic abnormality involving chromosome 7)*; **OR**
  - Patient does not have del(5q) mutation; **AND**
    - Patient has ring sideroblasts < 15% (or < 5% with an SF3B1 mutation); **AND**
      - Used as a single agent; **OR**
      - Used in combination with either lenalidomide or a granulocyte-colony stimulating factor (G-CSF); **AND**
        - Patient had no response** (despite adequate iron stores) to or relapse after an erythropoiesis-stimulating agent (ESA) alone; **OR**
        - Patient had no response** to or relapse after luspatercept; **OR**
    - Patient has ring sideroblasts ≥15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation); **AND**
      - Used as a single agent; **AND**
        - Patient had no response** to or relapse after luspatercept; **OR**
        - Patient has a serum erythropoietin level < 200 mU/ml; **OR**
      - Used in combination with a G-CSF; **AND**
        - Patient had no response** to or relapse after luspatercept

*** **Note:** No response defined as a lack of ≥1.5 gm/dL rise in hemoglobin OR lack of a decrease in RBC transfusion requirement (within 6-8 weeks when treated with ESAs or within 3-6 months when treated with luspatercept).*

Anemia Due to Myeloproliferative Neoplasms (MPN) - Myelofibrosis ‡ [4,7,27]

- Patient has myelofibrosis-associated anemia with serum erythropoietin level of < 500 mU/mL; **AND**
  - Patient has symptomatic splenomegaly and/or constitutional symptoms currently controlled on a JAK inhibitor; **AND**
    - Used in combination with ruxolitinib; **OR**

- Patient has no symptomatic splenomegaly and/or constitutional symptoms; **AND**
  - Used as a single agent

Anemia Due to Chemotherapy Treatment † ‡ [1-5,27]

- Patient is at least 5 years of age; **AND**
- Patient has anemia due to concomitant myelosuppressive chemotherapy for a non-myeloid malignancy; **AND**
- Patient is receiving chemotherapy that is not intended to cure their disease (i.e., palliative treatment) **±**; **AND**
- There are a minimum of two additional months of planned chemotherapy

± ***Note:*** *Patients who are not undergoing palliative treatment and refuse blood transfusions may be reviewed on a case-by-case basis*

Anemia Due to Chronic Kidney Disease (Non-Dialysis Patients) † Φ [1-3,8,29]

- Patient is at least 1 month of age

Anemia Due to Zidovudine in Patients with HIV-Infection † (Φ – *applicable to Procrit/Epogen only)* [1-3]

- Patient is at least 8 months of age; **AND**
- Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
- Patient is receiving zidovudine administered at ≤ 4200 mg/week

Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery † [1-3]

- Hemoglobin (Hb) >10 g/dL and ≤ 13 g/dL and/or Hematocrit (Hct) > 30% and ≤ 39%; **AND**
- Patient is at high-risk of blood-loss from surgery that is elective, non-cardiac and non-vascular; **AND**
- Patient is unwilling or unable to participate in an autologous blood donation program prior to surgery

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1-3,6,7,30]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I);* **AND**
- Previous dose was administered within the past 60 days; **AND**

- Disease response with treatment as defined by improvement in anemia compared to pretreatment baseline; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, increased risk of tumor progression/ recurrence in patients with cancer, seizures, pure red cell aplasia, serious allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), "gasping syndrome" (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.; **AND**

Anemia Due to Myelodysplastic Syndrome (MDS)

- Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%

Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

- Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%

Anemia Due to Chemotherapy Treatment

- *Refer to Section III for criteria* (age was met initially)

Anemia Due to Chronic Kidney Disease (Non-Dialysis Patients)

- **Pediatric patients:** Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
- **Adult patients:** Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

Anemia Due to Zidovudine in Patients with HIV-Infection

- Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%; **AND**
- Patient is receiving zidovudine administered at ≤ 4200 mg/week

***** *Intravenous iron supplementation may be considered when evaluating iron status*
• Functional iron deficiency (i.e., adequate iron stores with an insufficient supply of available iron) may occur in patients with chronic diseases, cancer, and/or in those currently receiving ESAs. • Iron is not generally recommended in anemic patients with a Ferritin >500 ng/mL. • Anemic patients with a Ferritin ≤500 ng/mL AND TSAT <50% may derive benefit from IV iron therapy in conjunction with ESA.

V. Dosage/Administration [1-3,6,24,28]

Indication	Dose
Anemia due to Chronic Kidney Disease – Non-dialysis **§**	• **Adult patients:** Administer 50-100 units/kg intravenously or subcutaneously three times weekly

	• **Pediatric patients (1 month-17 years):** Administer 50 units/kg intravenously or subcutaneously three times weekly
Anemia due to zidovudine in patients with HIV-infection **§**	• **Adult patients:** Administer 100 units/kg intravenously or subcutaneously three times weekly ○ May titrate up to 300 units/kg per dose • **Pediatric patients (8 months-17 years):** Administer 50-400 units/kg intravenously or subcutaneously two to three times weekly

Anemia due to chemotherapy **§**	• **Adult patients (> 18 years):** Administer 150 units/kg subcutaneously three times weekly or 40,000 units subcutaneously once weekly
	  ○ May titrate up to 300 units/kg subcutaneously three times weekly or 60,000 units subcutaneously once weekly
	• **Pediatric patients (5-18 years):** Administer 600 units/kg intravenously once weekly
	  ○ May titrate up to 900 units/kg (maximum 60,000 units) intravenously once weekly

Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery	• Administer 300 units/kg/day subcutaneously for 10 days before surgery, on the day of surgery, and for 4 days after surgery (15 days total) -**OR-** • Administer 600 units/kg/dose subcutaneously on days 21, 14, and 7 before surgery plus 1 dose on the day of surgery (4 total doses)
Anemia due to MDS **§**	• Administer 40,000 to 60,000 units subcutaneously once to twice weekly
Anemia due to MPN **§**	• Administer 10,000 units subcutaneously three times weekly • May increase dose to 20,000 units subcutaneously three times weekly
Most commonly initiated dose	40,000 units weekly

§ Dose Adjustments and Discontinuation Guidance

– For patients with CKD:
- Dose increases of 25% can be considered if after 4 weeks of initial therapy the hemoglobin has increased less than 1 g/dL and the current hemoglobin level is less than the indication specific level noted above.
- Dose decreases of 25% or more can be considered if the hemoglobin rises rapidly by more than 1 g/dL in any 2-week period.
- Dose and frequency requested are the minimum necessary for the patient to avoid RBC transfusions.
- Avoid frequent dose adjustments. Do not increase the dose more frequently than once every 4 weeks; decreases can occur more frequently.
- If patients fail to respond over a 12-week dose escalation period, further doses increases are unlikely to improve response and discontinuation of therapy should be considered.

– For patients with MDS:
- After 8 weeks of therapy, if there is no response as measured by at least a 1.5 g/dL increase in hemoglobin or a decrease in RBC transfusions, change of regimen discontinuation of therapy should be considered.

– For patients with MPN:
- After 3 months of therapy, if there is no response as measured by at least a 2 g/dL increase in hemoglobin or a decrease in RBC transfusions, discontinuation of therapy should be considered.

– For patients on Cancer Chemotherapy:
- After 8 weeks of therapy, if there is no response as measured by hemoglobin levels or if RBC transfusions are still required or following completion of a chemotherapy course discontinue therapy.

– For zidovudine treated HIV infected patients:
  - If the patient fails to respond after 8 weeks of therapy, increase dose by approximately 50-100 U/kg at 4- to 8-week intervals until the hemoglobin reaches levels needed to avoid transfusion or max dose of 300 U/kg is reached.
  - If the hemoglobin exceeds the indication specific level noted above, withhold therapy and resume therapy once level declines to <11 g/dL, at a dose 25% below the previous dose.

VI. Billing Code/Availability Information

HCPCS code(s):

- J0885 – Injection, epoetin alfa, (for non-ESRD use), 1000 units; 1 billable unit = 1,000 units
- Q5106 – Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-ESRD use), 1000 units; 1 billable unit = 1,000 units

NDC(s):

Brand	HCPCS	Strength	MDV or SDV	MDV Size	NDC
Epogen	J0885	2,000 U/mL	SDV		55513-0126-xx
Epogen	J0885	3,000 U/mL	SDV		55513-0267-xx
Epogen	J0885	4,000 U/mL	SDV		55513-0148-xx
Epogen	J0885	10,000 U/mL	SDV		55513-0144-xx
Epogen	J0885	10,000 U/mL	MDV	2 mL	55513-0283-xx
Epogen	J0885	20,000 U/mL	MDV	1 mL	55513-0478-xx
Procrit	J0885	2,000 U/mL	SDV		59676-0302-xx
Procrit	J0885	3,000 U/mL	SDV		59676-0303-xx
Procrit	J0885	4,000 U/mL	SDV		59676-0304-xx
Procrit	J0885	10,000 U/mL	SDV		59676-0310-xx
Procrit	J0885	10,000 U/mL	MDV	2 mL	59676-0312-xx
Procrit	J0885	20,000 U/mL	MDV	1 mL	59676-0320-xx
Procrit	J0885	40,000 U/mL	SDV		59676-0340-xx
Retacrit	Q5106	2,000 U/mL	SDV		00069-1305-xx
Retacrit	Q5106	3,000 U/mL	SDV		00069-1306-xx
Retacrit	Q5106	4,000 U/mL	SDV		00069-1307-xx
Retacrit	Q5106	10,000 U/mL	SDV		00069-1308-xx
Retacrit	Q5106	10,000 U/mL	MDV	2 mL	00069-1318-xx
Retacrit	Q5106	20,000 U/mL	MDV	1 mL	00069-1311-xx
Retacrit	Q5106	40,000 U/mL	SDV		00069-1309-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C93.10	Chronic myelomonocytic leukemia, not having achieved remission
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis in remission
C94.42	Acute panmyelosis with myelofibrosis in relapse
C94.6	Myelodysplastic disease, not classified
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.4	Refractory anemia, unspecified

D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.Z	Other myelodysplastic syndromes
D47.1	Chronic myeloproliferative disease
D47.4	Osteomyelofibrosis
D61.1	Drug-induced aplastic anemia
D63.0	Anemia in neoplastic disease
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic diseases classified elsewhere
D64.81	Anemia due to antineoplastic chemotherapy
D64.9	Anemia unspecified
D75.81	Myelofibrosis
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
N18.30	Chronic kidney disease, stage 3 (moderate), unspecified
N18.31	Chronic kidney disease, stage 3a
N18.32	Chronic kidney disease, stage 3b
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z51.11	Encounter for antineoplastic chemotherapy
Z51.89	Encounter for other specified aftercare

Dual coding requirements:

- Preoperative use: must bill D63.8 or D64.9 AND Z41.8
- Anemia due to CKD (not on dialysis): must bill D63.1 AND I12.9, I13.0, I13.10, N18.30, N18.31, N18.32, N18.4 or N18.5

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
All	110.21	All
J,M	A58982	Palmetto GBA
15	A56462	CGS Administrators, LLC
5,8	A56795	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC