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

NON-DIALYSIS

Document Number: SHP-0243

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I. Length of Authorization

- Coverage will be provided for 60 days and may be renewed unless otherwise specified.
    - Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery: Coverage may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 2,000 U/mL single-dose vial: 3 vials per week
- 3,000 U/mL single-dose vial: 3 vials per week
- 4,000 U/ml single-dose vial: 3 vials per week
- 10,000 U/mL single-dose vial: 3 vials per week
- 10,000 U/mL 2 mL multi-dose vial: 3 vials per week
- 20,000 U/mL multi-dose vial: 3 vials per week
- 40,000 U/mL single-dose vial: 1 vial per week

B. 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]

- Patient must have a contraindication or intolerance to a trial of epoetin alfa-epbx (i.e., Retacrit™); **AND**

Coverage is provided in the following conditions:

- Patient is at least 18 years of age or older (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]

- 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 4 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 Secondary to Myelodysplastic Syndrome (MDS) ‡ [4,6]

- Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
- Patient has lower risk disease (*i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]*); **AND**
- Patient has symptomatic anemia

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

- Endogenous serum erythropoietin level of < 500 mUnits/mL

Anemia Secondary to Chemotherapy Treatment † [1-5]

- Patient is at least 5 years of age; **AND**
- Patient is receiving concomitant myelosuppressive chemotherapy; **AND**
- Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
- There are a minimum of two additional months of planned chemotherapy

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

- Patient is at least 1 month of age

Anemia Secondary to Zidovudine-Treated, HIV-Infected Patients † Φ [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 – *applicable to Procrit/Epogen only*

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

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**
- Previous dose was administered within the past 120 days; **AND**
- Anemia response 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 Secondary to Myelodysplastic Syndrome (MDS):

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

Anemia Secondary to Myeloproliferative Neoplasms - Myelofibrosis

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

Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery

- Coverage may not be renewed.

Anemia Secondary to Chemotherapy Treatment

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

Anemia Secondary to Zidovudine Treated, HIV-Infected Patients:

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

- Patient is receiving zidovudine administered at ≤ 4200 mg/week

Anemia Secondary to Chronic Kidney Disease:

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

* *Intravenous iron supplementation may be taken into account 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 [1-3,24,28]

Indication	Dose
Anemia due to CKD – non-dialysis§	• Adult patients: 50-100 units/kg intravenously or subcutaneously three times weekly • Pediatric patients: 50 units/kg intravenously or subcutaneously three times weekly
Anemia due to HIV on zidovudine§	• 100 units/kg intravenously or subcutaneously three times weekly • May titrate up to 300 units/kg per dose

Anemia due to chemotherapy§	• Adult patients: 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): 600 units/kg intravenously once weekly
	  ○ May titrate up to 900 units/kg intravenously once weekly

Perioperative use	• 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-** • 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§	• 40,000 to 60,000 units subcutaneously once to twice weekly
Anemia due to myeloproliferative neoplasms (MPN)§	• 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

§

– 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 3 to 4 months 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, 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, 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:

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

NDC:

Brand	HCPCS	Strength	MDV or SDV	MDV Size	NDC
Epogen	J0885	2,000 U/mL	SDV		55513-0126
Epogen	J0885	3,000 U/mL	SDV		55513-0267
Epogen	J0885	4,000 U/mL	SDV		55513-0148
Epogen	J0885	10,000 U/mL	SDV		55513-0144
Epogen	J0885	10,000 U/mL	MDV	2 mL	55513-0283
Epogen	J0885	20,000 U/mL	MDV	1 mL	55513-0478
Procrit	J0885	2,000 U/mL	SDV		59676-0302
Procrit	J0885	3,000 U/mL	SDV		59676-0303

Procrit	J0885	4,000 U/mL	SDV		59676-0304
Procrit	J0885	10,000 U/mL	SDV		59676-0310
Procrit	J0885	10,000 U/mL	MDV	2 mL	59676-0312
Procrit	J0885	20,000 U/mL	MDV	1 mL	59676-0320
Procrit	J0885	40,000 U/mL	SDV		59676-0340
Retacrit	Q5106	2,000 U/mL	SDV		00069-1305
Retacrit	Q5106	3,000 U/mL	SDV		00069-1306
Retacrit	Q5106	4,000 U/mL	SDV		00069-1307
Retacrit	Q5106	10,000 U/mL	SDV		00069-1308
Retacrit	Q5106	10,000 U/mL	MDV	2 mL	00069-1318
Retacrit	Q5106	20,000 U/mL	MDV	1 mL	00069-1311
Retacrit	Q5106	40,000 U/mL	SDV		00069-1309

VII. References

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2. Epogen [package insert]. Thousand Oaks, CA; Amgen, Inc; July 2018. Accessed April 2021.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
B20	Human immunodeficiency virus [HIV] disease
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	Malignant neoplasm of peripheral nerves of upper limb, including shoulder
D47.4	Malignant neoplasm of peripheral nerves of abdomen

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	Secondary polycythemia
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)
N18.9	Chronic kidney disease, unspecified
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 zidovudine in HIV patients: must bill D61.1 AND B20
- Anemia due to CKD (not on dialysis): must bill D63.1 AND N18.31, N18.32, or N18.4

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): ALL	**NCD/LCD Document (s):** NCD110.21
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=110.21&bc=gAAAAAAAAAAAAA%3d%3d&	

Jurisdiction(s): 5, 8	**NCD/LCD Document (s):** L34633
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34633&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): 15	NCD/LCD Document (s): L34356
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34356&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): N	NCD/LCD Document (s): L36276
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L36276&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): 5, 8	NCD/LCD Document (s): A56795
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56795&bc=gAAAAAAAAAAA	

Jurisdiction(s): N	NCD/LCD Document (s): A57628
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57628&bc=gAAAAAAAAAAA	

Jurisdiction(s): 15	NCD/LCD Document (s): A56462
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56462&bc=gAAAAAAAAAAA	

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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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