



Epoetin alfa:

Epogen[®]; Procrit[®]; Retacrit[™]

(Subcutaneous/Intravenous)

NON-DIALYSIS

Document Number: IC-0243

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Dates Reviewed: 11/2008, 06/2009, 12/2009, 09/2010, 12/2010, 02/2011, 03/2011, 06/2011, 08/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 10/2012, 12/2012, 03/2013, 05/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 04/2017, 8/2017, 11/2017, 12/2017, 05/2018, 06/2018, 04/2019, 04/2020

I. Length of Authorization

- Coverage will be provided for 45 days and may 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 and MPN: 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 Criteria¹⁻²⁴

Coverage is provided in the following condition(s):

- Patient is 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

- 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) $\geq 20\%$ (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 Secondary to Myelodysplastic Syndrome (MDS) ‡

- 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 ‡

- Endogenous serum erythropoietin level of < 500 mUnits/mL

Anemia Secondary to Rheumatoid Arthritis ‡

Anemia Secondary to Chemotherapy Treatment †

- Patient is 5 years of age or older; **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) †

- Patient age is 1 month or older

Anemia Secondary to Zidovudine-Treated, HIV-Infected Patients †

- Patient is 8 months or older; **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 †

- Hemoglobin (Hb) >10 g/dL and ≤ 13 g/dL and/or Hematocrit (Hct) $>30\%$ and $\leq 39\%$; **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)

IV. Renewal Criteria¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal criteria identified in section III; **AND**
- Previous dose was administered within the past 60 days; **AND**
- Anemia response compared to pretreatment baseline; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe cardiovascular events (stroke, myocardial infarction, thromboembolism, uncontrolled hypertension), tumor progression or recurrence in patients with cancer, seizures, pure red cell aplasia, severe cutaneous reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis), “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 (MF, Post-PV Myelofibrosis, Post-ET Myelofibrosis)

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

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

- Hemoglobin(Hb) > 10 g/dL and ≤13 g/dL and/or Hematocrit(Hct) between 30% and 39%

Anemia Secondary to Chemotherapy Treatment

- Refer to initial criteria (age met initially) for this indication

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%

Anemia Secondary to Rheumatoid Arthritis:

- Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

* Intravenous iron supplementation may be taken into account when evaluating iron status

**Epoetin alfa (Epogen[®]; Procrit[®]; Retacrit[™])
Non-Dialysis Prior Auth Criteria**

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- 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

Indication	Dose
Anemia due to CKD – non-dialysis §	<ul style="list-style-type: none"> • Adults: 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	<ul style="list-style-type: none"> • 100 units/kg three times weekly • May titrate up to 300 units/kg
Anemia due to chemotherapy§	<ul style="list-style-type: none"> • Adults: 150 units/kg intravenously or subcutaneously three times weekly or 40,000 units once weekly <ul style="list-style-type: none"> ○ May titrate up to 300 units/kg three times weekly or 60,000 units once weekly • Pediatric patients (5-18 years): 600 units/kg intravenously or subcutaneously once weekly <ul style="list-style-type: none"> ○ May titrate up to 900 units/kg once weekly
Perioperative use	<ul style="list-style-type: none"> • 300 units/kg/day subcutaneously for 10 days before surgery, on the day of surgery, and for 4 days after surgery (15 days total) • 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/MPN	<ul style="list-style-type: none"> • 150-300 units/kg intravenously or subcutaneously three times weekly • 40,000 to 60,000 units once to twice weekly
Rheumatoid Arthritis	Dosing varies; generally up to 150 units/kg intravenously or subcutaneously three times weekly
Most commonly initiated dose	40,000 units weekly

§

- 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.
- For patients with CKD,
 - 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 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 until the hemoglobin reaches levels need to avoid transfusion or max dosing 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	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 March 2020.
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4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin alfa. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2020.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cancer and Chemotherapy-Induced Anemia Version 2.2020. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2020.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myelodysplastic Syndrome Version 2.2020. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2020.
7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloproliferative Neoplasms Version 4.2019. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2020.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
B20	Human immunodeficiency virus [HIV] disease

Epoetin alfa (Epogen®; Procrit®; Retacrit™)
Non-Dialysis Prior Auth Criteria

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
M05.10 - M06.9	Rheumatoid lung disease with rheumatoid arthritis of unspecified site - Rheumatoid arthritis, unspecified
N18.3	Chronic kidney disease, stage 3 (moderate)
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 RA: must bill D63.8 AND an eligible M series code
- 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 I12.9, I13.0, I13.10, N18.3, N18.4, or N18.9

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):

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=gAAAAAAAAAAAAAA%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=gAAAAAAAAAAAAAA==	
Jurisdiction(s): 15	NCD/LCD Document (s): L34356
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34356&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): N	NCD/LCD Document (s): L36276
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L36276&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): 5, 8	NCD/LCD Document (s): A56795
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56795&bc=gAAAAAAAAAAAAAA	
Jurisdiction(s): N	NCD/LCD Document (s): A57628
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57628&bc=gAAAAAAAAAAAAAA	
Jurisdiction(s): 15	NCD/LCD Document (s): A56462
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56462&bc=gAAAAAAAAAAAAAA	

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