

Epoetin alfa:

Epogen®; Procrit®; Retacrit™ (Subcutaneous/Intravenous)

DIALYSIS

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I. Length of Authorization

- Coverage will be provided for 12 months and may be renewed.

II. Dosing Limits

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

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

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

- All other indications: 400 billable units every 7 days

III. Initial Approval Criteria¹⁻¹²

Coverage is provided in the following condition(s):

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 Chronic Kidney Disease (dialysis patients) †

- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) $< 30\%$; **AND**

† 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 indentified in section III; **AND**
- Previous dose was administered withing 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), “gaspings syndrome” (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.; **AND**

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

Indication	Dose
Anemia due to CKD - 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
<u>Conversion from Epoetin alfa to Aranesp in patients with CKD on dialysis</u>	

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Aranesp is administered less frequently than epoetin alfa.

- Administer Aranesp once weekly in patients who were receiving epoetin alfa 2 to 3 times weekly.
- Administer Aranesp once every 2 weeks in patients who were receiving epoetin alfa once weekly.

Maintain the route of administration (intravenous or subcutaneous injection).

§

- 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.

VI. Billing Code/Availability Information

HCPCS code:

- Q4081 - Injection, epoetin alfa, 100 units (for esrd on dialysis); 1 billable unit = 100 units
- Q5105 – Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units; 1 billable unit = 100 units

NDC:

Brand	HCPCS	Strength	MDV or SDV	MDV Size	NDC
Epogen	Q4081	2,000 U/mL	SDV		55513-0126
Epogen	Q4081	3,000 U/mL	SDV		55513-0267
Epogen	Q4081	4,000 U/mL	SDV		55513-0148
Epogen	Q4081	10,000 U/mL	SDV		55513-0144
Epogen	Q4081	10,000 U/mL	MDV	2 mL	55513-0283
Epogen	Q4081	20,000 U/mL	MDV	1 mL	55513-0478
Procrit	Q4081	2,000 U/mL	SDV		59676-0302
Procrit	Q4081	3,000 U/mL	SDV		59676-0303
Procrit	Q4081	4,000 U/mL	SDV		59676-0304
Procrit	Q4081	10,000 U/mL	SDV		59676-0310
Procrit	Q4081	10,000 U/mL	MDV	2 mL	59676-0312
Procrit	Q4081	20,000 U/mL	MDV	1 mL	59676-0320
Procrit	Q4081	40,000 U/mL	SDV		59676-0340
Retacrit	Q5105	2,000 U/mL	SDV		00069-1305
Retacrit	Q5105	3,000 U/mL	SDV		00069-1306
Retacrit	Q5105	4,000 U/mL	SDV		00069-1307

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Retacrit	Q5105	10,000 U/mL	SDV		00069-1308
Retacrit	Q5105	40,000 U/mL	SDV		00069-1309

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D63.1	Anemia in chronic kidney disease
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease

Dual coding requirements:

- Anemia due to CKD (on dialysis): must bill D63.1 AND N18.6

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): 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
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<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