

Epoetin alfa:

Epogen®; Procrit®; Retacrit®

(Subcutaneous/Intravenous)

NON-DIALYSIS

Document Number: IC-0243

Last Review Date: 05/04/2023 Date of Origin: 10/17/2008

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, 05/2021, 05/2022, 05/2023

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

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 1 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

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 Syndrome (MDS) ‡ 4,6,27

- Patient has symptomatic anemia; AND
 - o Patient has lower risk disease (defined as IPSS [Low/Intermediate-1]); AND
 - Used as a single agent for del(5q) mutation (excluding use in patients with cytogenetic abnormality involving chromosome 7); **OR**
 - o Patient has lower risk disease (defined as IPSS-R [Very Low, Low, Intermediate]); AND
 - Patient does not have del(5q) mutation; AND
 - Patient has a serum erythropoietin (EPO) ≤ 500 mU/mL; **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) following no response (despite adequate iron stores) or erythroid response followed by loss of response to an erythropoiesis-stimulating agent (ESA) alone; **OR**
 - Patient has ring sideroblasts ≥15% (or ring sideroblasts ≥5% with an SF3B1 mutation); AND
 - ❖ Used as a single agent; **OR**
 - ❖ Used in combination with a G-CSF

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

• Endogenous serum erythropoietin level of < 500 mUnits/mL

Anemia Due to Chemotherapy Treatment † 1-5,27

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

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-Treated, HIV-Infected Patients † (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); **\Phi** Orphan Drug

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 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 Treated, HIV-Infected Patients:

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

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

Coverage may not be renewed.

- * 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: Administer 50 units/kg intravenously or subcutaneously three times weekly 	
Anemia due to HIV in patients on zidovudine §	 Administer 100 units/kg intravenously or subcutaneously three times weekly May titrate up to 300 units/kg per dose 	
Anemia due to chemotherapy §	 Adult patients: 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	
Perioperative use	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	

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- 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-epbx, 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-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-хх
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

- 1. Procrit [package insert]. Horsham, PA; Janssen, LP; April 2023. Accessed April 2023.
- 2. Epogen [package insert]. Thousand Oaks, CA; Amgen, Inc.; July 2018. Accessed April 2023.
- 3. Retacrit [package insert]. Lake Forest, IL; Hospira, Inc.; August 2020. Accessed April 2023.
- 4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin alfa. National Comprehensive Cancer Network, 2023. 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 April 2023.
- 5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hematopoietic Growth Factors Management of Cancer-and Chemotherapy-Induced Anemia Version 2.2023. National Comprehensive Cancer Network, 2023. The NCCN



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- 6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myelodysplastic Syndrome Version 1.2023. National Comprehensive Cancer Network, 2023. 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 April 2023.
- 7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloproliferative Neoplasms Version 3.2022. National Comprehensive Cancer Network, 2023. 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 April 2023.
- 8. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO clinical practice guideline for anemia in chronic kidney disease. Kidney Int Suppl. 2012;2(suppl):279-335. https://kdigo.org/guidelines/anemia-in-ckd/. Published August 2012.
- 9. Piccoli A, Malagoli A, Komninos G, Pastori G. Subcutaneous epoetin-alpha every one, two, and three weeks in renal anemia. J Nephrol. 2002;15(5):565-574.
- 10. Provenzano R, Bhaduri S, Singh AK; PROMPT Study Group. Extended epoetin alfa dosing as maintenance treatment for the anemia of chronic kidney disease: the PROMPT study. Clin Nephrol. 2005;64(2):113-123.
- 11. Provenzano R, Garcia-Mayol L, Suchinda P, et al; POWER Study Group. Once-weekly epoetin alfa for treating the anemia of chronic kidney disease. Clin Nephrol. 2004;61(6):392-405.
- 12. Singh AJ, Szczech L, Tang Kl, et al, "Correction of Anemia With Epoetin Alfa in Chronic Kidney Disease," N Engl J Med, 2006, 355(20):2085-98.
- 13. Fishbane S, Spinowitz BS, Wisemandle WA, et al. Randomized Controlled Trial of Subcutaneous Epoetin Alfa-epbx Versus Epoetin Alfa in End-Stage Kidney Disease. Kidney Int Rep. 2019 May 22;4(9):1235-1247.
- 14. Thadhani R, Guilatco R, Hymes J, et al. Switching from Epoetin Alfa (Epogen®) to Epoetin Alfa-Epbx (RetacritTM) Using a Specified Dosing Algorithm: A Randomized, Non-Inferiority Study in Adults on Hemodialysis. Am J Nephrol. 2018;48(3):214-224.
- 15. Fishbane S, Singh B, Kumbhat S, et al. Intravenous Epoetin Alfa-epbx versus Epoetin Alfa for Treatment of Anemia in End-Stage Kidney Disease. Clin J Am Soc Nephrol. 2018 Aug 7;13(8):1204-1214.



- 16. US Food and Drug Administration. FDA briefing document. Oncologic Drugs Advisory Committee Meeting. BLA 125545: Epoetin Hospira, a proposed biosimilar to Epogen/Procrit (epoetin alfa). Hospira Inc., a Pfizer Company. May 25, 2017.
- 17. Fenaux P, Santini V, Spiriti MAA, et al. A phase 3 randomized, placebo-controlled study assessing the efficacy and safety of epoetin-α in anemic patients with low-risk MDS. Leukemia. 2018;32(12):2648-2658. doi: 10.1038/s41375-018-0118-9.
- 18. Park S, Greenberg P, Yucel A, et al. Clinical effectiveness and safety of erythropoietin-stimulating agents for the treatment of low- and intermediate-1-risk myelodysplastic syndrome: a systematic literature review. Br J Haematol. 2019;184(2):134-160. doi: 10.1111/bjh.15707
- 19. Greenberg PL, Sun Z, Miller KB, et al. Treatment of myelodysplastic syndrome patients with erythropoietin with or without granulocyte colony-stimulating factor: results of a prospective randomized phase 3 trial by the Eastern Cooperative Oncology Group (E1996). Blood. 2009;114(12):2393-2400.
- 20. Peeters, HR, Jongen-Lavrencic, M, Vreugdenhil, G, Swaak, AJ. Effect of recombinant human erythropoietin on anaemia and disease activity in patients with rheumatoid arthritis and anaemia of chronic disease: a randomized placebo controlled double blind 52 weeks clinical trial. Ann Rheum Dis 1996; 55:739.
- 21. Pincus T, Olsen NJ, Russell IJ, et al. Multicenter study of recombinant human erythropoietin in correction of anemia in rheumatoid arthritis. Am J Med 1990; 89:161-8.
- 22. Saag, MS, Bowers, P, Leitz, GJ, Levine, AM. Once-weekly epoetin alfa improves quality of life and increases hemoglobin in anemic HIV+ patients. AIDS Res Hum Retroviruses 2004; 20:1037.
- 23. Grossman, HA, Goon, B, Bowers, P, Leitz, G. Once-weekly epoetin alfa dosing is as effective as three times-weekly dosing in increasing hemoglobin levels and is associated with improved quality of life in anemic HIV-infected patients. J Acquir Immune Defic Syndr 2003; 34:368.
- 24. Cervantes F, Alvarez-Laran A, Hernandez-Boluda JC, et al. Erythropoietin treatment of the anaemia of myelofibrosis with myeloid metaplasia: results in 20 patients and review of the literature. British Journal of Haematology, 127: 399–403. doi:10.1111/j.1365-2141.2004.05229.x.
- 25. Shaffer CL, Ransom JL. Current and theoretical considerations of erythropoietin use in anemia of bronchopulmonary dysplasia. J of Pediatric Pharmacy Practice 1996; 1:23-29.
- 26. Reiter PD, Rosenberg AA, Valuck RJ. Factors associated with successful epoetin alfa therapy in premature infants. Ann Pharmacother 2000; 34:433-439.
- 27. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin alfa-epbx. National Comprehensive Cancer Network, 2023. 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 April 2023.
- 28. Tsiara SN, Chaidos A, Bourantas LK, et al. Recombinant human erythropoietin for the treatment of anaemia in patients with chronic idiopathic myelofibrosis. Acta Haematol. 2007;117(3):156-61. doi: 10.1159/000097463.
- 29. Mikhail A, Brown C, Williams JA, et al. Renal association clinical practice guideline on Anaemia of Chronic Kidney Disease. BMC Nephrol. 2017 Nov 30;18(1):345. doi: 10.1186/s12882-017-0688-1.
- 30. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Erythropoiesis Stimulating (ESAs) (L34633). Centers for Medicare & Medicaid Services, Inc. Updated on 06/22/2021 with effective dates 07/01/2021. Accessed April 2023.
- 31. CGS Administrators, LLC. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESA) (L34356). Centers for Medicare & Medicare Services. Updated on 02/23/2023 with effective dates 03/02/2023. Accessed April 2023.
- 32. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Centers for Medicare & Medicare Services, Inc. Updated 01/14/2021 with an effective date 07/30/2007. Accessed April 2023.
- 33. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article (LCA): Billing and Coding: Erythropoiesis Stimulating Agents (ESAs) (A56795). Centers for Medicare & Medicaid Services, Inc. Updated on 10/18/2022 with effective dates 10/01/2022. Accessed April 2023.
- 34. CGS Administrators, LLC. Local Coverage Article (LCA): Billing and Coding: Erythropoiesis Stimulating Agents (ESA) (A56462). Centers for Medicare & Medicaid Services. Updated on 02/28/2023 with effective dates 03/09/2023. Accessed April 2023.
- 35. Palmetto GBA. Local Coverage Article (LCA): Billing and Coding: Erythropoiesis Stimulating Agents (A58982). Centers for Medicare & Medicaid Services. Updated on 08/18/2022 with effective dates 10/01/2022. Accessed April 2023.

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)	
N18.9	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 OR bill D63.8 AND Z01.818
- Anemia due to zidovudine in HIV patients: must bill D61.1 AND B20 or B97.35
- 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 N18.9
- Anemia due to Chemotherapy: must bill D64.81 or D61.810 AND C-series, D-series or Q-series coding for NON-myeloid malignancies
- Anemia due to MDS: must bill D47.3 AND D75.81

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: https://www.cms.gov/medicare-coverage-database/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/LCA Document (s): 110.21

https://www.cms.gov/medicare-coverage-database/new-search/search-

results.aspx?keyword=110.21&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD

Jurisdiction(s): 5, 8 NCD/LCD/LCA Document (s): L34633

https://www.cms.gov/medicare-coverage-database/new-search/search-

 $\frac{results.aspx?keyword=l34633\&areaId=all\&docType=NCA\%2CCAL\%2CNCD\%2CMEDCAC\%2CTA\%2CMCD}{\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}$

Jurisdiction(s): 15 NCD/LCD/LCA Document (s): L34356

https://www.cms.gov/medicare-coverage-database/new-search/search-

 $\frac{results.aspx?keyword=l34356\&areaId=all\&docType=NCA\%2CCAL\%2CNCD\%2CMEDCAC\%2CTA\%2CMCD}{\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}$

Jurisdiction(s): 5, 8 NCD/LCD/LCA Document (s): A56795

https://www.cms.gov/medicare-coverage-database/new-search/search-

 $\frac{results.aspx?keyword=a56795\&areaId=all\&docType=NCA\%2CCAL\%2CNCD\%2CMEDCAC\%2CTA\%2CMCD\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}{D\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}$

Jurisdiction(s): 15 NCD/LCD/LCA Document (s): A56462

https://www.cms.gov/medicare-coverage-database/new-search/search-

 $\frac{results.aspx?keyword=a56462\&areaId=all\&docType=NCA\%2CCAL\%2CNCD\%2CMEDCAC\%2CTA\%2CMCD\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}{D\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}$

Jurisdiction(s): J. M NCD/LCD/LCA Document (s): A58982

https://www.cms.gov/medicare-coverage-database/new-search/search-

 $\frac{results.aspx?keyword=a58982\&areaId=all\&docType=NCA\%2CCAL\%2CNCD\%2CMEDCAC\%2CTA\%2CMCD\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}{D\%2C6\%2C3\%2C5\%2C1\%2CF\%2CP}$

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)	



Medicare Part B Administrative Contractor (MAC) Jurisdictions			
Jurisdiction	Applicable State/US Territory	Contractor	
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	



PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP.

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- · Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- · Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

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ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).
ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013)
LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).
XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).
CHÚ Ý: Nếu ban nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho ban. Goi số 1.800.940.5049 (TTY: 763.847.4013).
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1.800.940.5049 (TTY: 763.847.4013).
ማስታወሻ: የሚናንሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049
(መስጣት ለተሳናቸው: 763.847.4013 ).
ဟ်သူ၌ဟ်သး– နမ့်ကတိ၊ ကညီ ကျို်အယိ, နမၤန္ရ၊ ကျို်အတါမၤစၤလ၊ တလက်ဘူဉ်လက်စ္၊ နီတမံးဘဉ်သုန္၌လီ၊. ကိႏ 1.800.940.5049 (TTY: 763.847.4013).
ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY:
ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។
         ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).
ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).
주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1,800,940,5049 (TTY: 763,847,4013), 번으로 전화해 주십시오.
PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa
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PreferredOne Insurance Company Nondiscrimination Notice

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- Information written in other languages

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If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist PreferredOne Insurance Company PO Box 59212 Minneapolis, MN 55459-0212 Phone: 1.800.940.5049 (TTY: 763.847.4013) Fax: 763.847.4010 customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

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