Utilization Review Policy 211B

POLICY: Erythropoiesis-Stimulating Agents – Epoetin Alfa Products Utilization Management Medical Policy

- Epogen® (epoetin alfa intravenous or subcutaneous injection – Amgen)
- Procrit® (epoetin alfa intravenous or subcutaneous injection – Janssen)

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 07/25/2025

COVERAGE CRITERIA FOR: UCare Medicare Plans Only (UCare Medicare, EssentiaCare, Group Plans, MSHO, Connect + Medicare, UCare Your Choice)

OVERVIEW

Epoetin alfa (Epogen, Procrit, Retacrit), an erythropoiesis-stimulating agent (ESA), is indicated for the following uses:[1-3]

- Anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis to decrease the need for red blood cell (RBC) transfusions.
- Anemia due to chemotherapy in patients with cancer, in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
- Anemia due to zidovudine, in patients with human immunodeficiency virus (HIV) infection.
- Reduction of allogeneic RBC transfusions, in patients with perioperative hemoglobin (Hb) > 10.0 to ≤ 13.0 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery.

Retacrit is a biosimilar to Epogen/Procrit.[3]

Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being.[1-3] Epoetin alfa is not indicated for the following uses:

- Patients with cancer receiving hormonal agents, biologic products, or radiotherapy unless also receiving concomitant myelosuppressive chemotherapy.
- Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- Patients with cancer receiving myelosuppressive chemotherapy in whom anemia can be managed by transfusion.
- Patients scheduled for surgery who are willing to donate autologous blood.
- Patients undergoing cardiac or vascular surgery.
- As a substitute for RBC transfusions in those who require immediate correction of anemia.

The iron status should be evaluated in all patients before and during treatment with ESAs.[1-3] Therapy should be initiated for **adults with CKD on dialysis** when the Hb level is < 10.0 g/dL and if the Hb level approaches or exceeds 11.0 g/dL, reduce or interrupt the dose of epoetin alfa. For **adults with CKD who are not on dialysis**, consider initiating epoetin alfa only when the Hb is < 10.0 g/dL and other considerations apply (e.g., rate of Hb decline indicates patient is likely to need RBC transfusion and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal). If the Hb exceeds 10.0 g/dL, reduce or interrupt the epoetin alfa dose and use the lowest dose sufficient to reduce the

need for RBC transfusions. For **pediatric patients with CKD**, initiate epoetin alfa when the Hb < 10.0 g/dL and if the Hb level approaches 12.0 g/dL, reduce or interrupt the dose of epoetin alfa. Initiate epoetin alfa for **patients on cancer chemotherapy** only if the Hb is < 10.0 g/dL. Epoetin alfa is indicated for the treatment of **anemia due to zidovudine** given at ≤ 4,200 mg per week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mU/mL. It is recommended to withhold epoetin alfa if Hb exceeds 12.0 g/dL. Data show that epoetin alfa elevated or maintained Hb and/or hematocrit and decreased transfusions in anemic patients (Hb < 10.0 g/dL) who were receiving zidovudine. Patients with baseline endogenous serum erythropoietin levels ≤ 500 mU/mL derived greater benefit with epoetin alfa (e.g., achievement of higher hematocrit, reduction in transfusion requirements) compared with those having levels greater than this threshold.

Dosing Information

Doses of epoetin alfa are titrated based on hemoglobin values. Refer to the prescribing information regarding increasing, reducing, interrupting, or conversion dosing. Use the lowest dose sufficient to reduce the need for RBC transfusions.

Guidelines

The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for anemia in CKD (2025) provide recommendations for the use of ESAs.[2] Guidelines recommend addressing all correctable causes of anemia (i.e. iron deficiency, malignancy, infection, etc.) before initiating treatment with an ESA or hypoxia-inducible factor-prolyl hydroxylase inhibitor (HIF-PHI). After all correctable causes of anemia are addressed, KDIGO suggests using ESAs as first-line therapy for treating anemia in patients with CKD rather than HIF-PHIs. Although clinical trials have revealed noninferiority of HIF-PHIs versus ESAs for efficacy as treatment for anemia, some studies suggested a higher risk of major adverse cardiovascular events with HIF-PHIs compared to ESAs in at least some CKD populations. For patients with CKD on dialysis, the guidelines recommend ESA therapy should be initiated when the Hb level is ≤ 9.0 to 10.0 g/dL. For patients with CKD who are not on dialysis, the decision to initiate ESA therapy should be individualized based on many factors (e.g., rate of Hb decline, prior response to iron therapy, transfusion risk, patient symptoms). In adults with anemia and CKD who are being treated with an ESA, ESA therapy should not be used to maintain Hb concentrations above 11.5 g/dL. For pediatric patients with anemia and CKD, the selection of an Hb target for ESA maintenance therapy should be individualized considering potential benefits and harms. Baseline and periodic monitoring (e.g., iron, total iron-binding capacity, transferrin saturation, or ferritin levels) and instituting iron replacement when needed may be useful in limiting the need for ESAs, maximizing symptomatic improvement in patients, and determining the reason for inadequate response to ESAs. Iron deficiency can occur following continued ESA use. Therefore, ongoing iron supplementation is often required in most patients to maintain an optimal response.

Epoetin alfa is recommended in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Hematopoietic Growth Factors:** NCCN guidelines (version 1.2025 – October 11, 2024) indicate Aranesp and epoetin alfa with or without iron supplementation may be warranted for the long-term management of anemia in high-risk patients or in asymptomatic patients with comorbidities receiving myelosuppressive chemotherapy where are cure is not anticipated.[5]
- **Myelodysplastic Syndrome (MDS):** NCCN guidelines (version 2.2025 – January 17, 2025) list Aranesp and epoetin alfa products as having utility in anemic, symptomatic patients with MDS if serum erythropoietin levels are ≤ 500 mU/mL.[6] Iron stores should be adequate. Due to safety issues, the guidelines suggest that ESAs be used in the management of symptomatic anemia in patients with MDS and to aim for a target Hb range of 10 to 12.0 g/dL but not to exceed 12.0 g/dL.
- **Myeloproliferative Neoplasms:** The NCCN guidelines (version 1.2025 – February 21, 2025) address Aranesp and epoetin alfa products as options for treatment of patients with anemia related

to myelofibrosis having a serum erythropoietin level < 500 mU/mL.[7] Iron stores should be adequate. The guidelines also advise that ESAs are generally less effective for the management of transfusion-dependent anemia.

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of epoetin alfa products in patients with conditions other than CKD who are on dialysis. The intent of this policy is to provide recommendations for uses other than anemia in patients with CKD who are on dialysis. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are for the duration documented below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Epogen/Procrit is recommended for request meeting both the preferred product step therapy requirements and indication requirements.

Preferred Product(s): Retacrit, Aranesp
Non-Preferred Products(s): Epogen, Procrit

Step Therapy Requirements:

Authorization for a non-preferred biologic product or biosimilar will be granted if the patient meets any *one of the items listed below (A, B, C, D or E)*. *Chart notes documenting* the issue must be provided at time of request:

A. The patient is *not* considered a new start to the non-preferred product (new start is defined as no use of the requested product in the previous 365 days) OR

B. Allergic reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR

C. Adverse reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR

D. Therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure during an adequate trial of all preferred biologic products or biosimilars which allowed sufficient time for a positive treatment outcome documented by medical chart notes OR

E. The patient has a diagnosis not included in the FDA-approved indications of all preferred products, but is included in the FDA-approved indications of the non-preferred product

Please note:

- Factors such as patient or prescriber preference or healthcare facility's or pharmacy's inability or unwillingness to order or stock the preferred product(s) will not be considered
- Common side effects to all products and infusion-related reactions are not considered documented allergic reactions to a preferred product as they would be expected with the innovator and biosimilar products.

- Generally, an adequate trial of a drug is considered to be three months or longer in order to allow time for efficacy to be established

FDA-Approved Indications

1. Anemia in Patients with Chronic Kidney Disease (CKD) who are on Dialysis. @ Approve for 3 years.

2. Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis. @

Criteria. Approve for 1 year if the patient meets the following criteria (A or B):

A) Initial Therapy. Approve if the patient meets the following criteria (i and ii):
- **i.** The patient meets one of the following (a or b):
  - **a.** The patient is ≥ 18 years of age with a hemoglobin < 10.0 g/dL; OR
  - **b.** The patient is < 18 years of age with a hemoglobin ≤ 11.0 g/dL; AND
- **ii.** The patient meets one of the following (a or b):
  - **a.** The patient is currently receiving iron therapy; OR
  - **b.** The patient has adequate iron stores according to the prescriber; OR

B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Approve if the patient meets the following criteria (i and ii):
- **i.** Patient has a hemoglobin ≤ 12.0 g/dL; AND
- **ii.** The patient meets one of the following (a or b):
  - **a.** The patient is currently receiving iron therapy; OR
  - **b.** The patient has adequate iron stores according to the prescriber.

Dosing. Approve if the doses are equivalent to ≤ 60,000 units total per month.

3. Patients with Anemia and Human Immunodeficiency Virus (HIV) who are Receiving Zidovudine. @

Criteria. Approve for 1 year if the patient meets the following criteria (A or B):

A) Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
- **i.** The patient meets one of the following (a or b):
  - **a)** The patient has a hemoglobin < 10.0 g/dL; OR
  - **b)** The patient has a serum erythropoietin level is ≤ 500 mU/mL; AND
- **ii.** The patient is currently receiving zidovudine therapy; AND
- **iii.** The patient meets one of the following (a or b):
  - **a)** The patient is currently receiving iron therapy; OR
  - **b)** The patient has adequate iron stores according to the prescriber; OR

B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp). Approve if the patient meets the following criteria (i, ii, and iii):
- **i.** The patient has a hemoglobin ≤ 12.0 g/dL; AND
- **ii.** The patient is currently receiving zidovudine therapy; AND
- **iii.** The patient meets one of the following (a or b):
  - **a)** The patient is currently receiving iron therapy; OR

b) The patient has adequate iron stores according to the prescriber.

Dosing. Approve the following dosing regimens (A or B):
A. Patients ≥ 18 years of age. Approve if the dose meets the following (i and ii):
i. Each dose is ≤ 300 Units/kg; AND
ii. Each dose is given no more frequently than 3 times per week; OR
B. Patients < 18 years of age. Approve if the dose meets the following (i and ii):
i. Each dose is ≤ 400 Units/kg; AND
ii. Each dose is given no more frequently than 3 times per week.

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4. Anemia in Patients with Cancer due to Cancer Chemotherapy. ^ *eviCore*

Criteria. Approve if the patient meets the following criteria (A or B):
A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):
i. The patient has a hemoglobin < 10.0 g/dL (or hematocrit < 30%); AND
ii. Patient meets BOTH of the following (a and b):
a. Patient is currently receiving myelosuppressive chemotherapy; IC-ISGP AND
b. According to the prescriber, myelosuppressive chemotherapy is considered non-curative; IC-ISGP AND
iii. Patient meets one of the following (a or b):
a. Patient is currently receiving iron therapy; IC-ISGP OR
b. Patient has adequate iron stores according to the prescriber. IC-ISGP
B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp). Approve for 6 months if the patient meets the following criteria (i, ii and iii):
i. The patient has a hemoglobin ≤ 12.0 g/dL (or hematocrit < 30%); IC-ISGP AND
ii. Patient meets BOTH of the following (a and b):
a. Patient is currently receiving myelosuppressive chemotherapy; IC-ISGP AND
b. According to the prescriber, myelosuppressive chemotherapy is considered non-curative; IC-ISGP AND
iii. Patient meets one of the following (a or b):
a. Patient is currently receiving iron therapy; IC-ISGP OR
b. Patient has adequate iron stores according to the prescriber. IC-ISGP

Dosing. Approve the following dosing regimens (A or B):
A. Patients ≥ 18 years of age. Approve if the dose meets the following (i and ii):
i. Each dose is ≤ 300 Units/kg; AND
ii. Each dose is given no more frequently than 3 times a week; OR
B. Patients < 18 years of age. Approve if the dose meets the following (i, ii, and iii):
i. Each dose is ≤ 900 Units/kg; AND
ii. Each dose is ≤ 60,000 Units (Maximum Dose); AND
iii. Each dose is given no more frequently than once weekly.

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5. Reduction of Allogeneic Red Blood Cell (RBC) Transfusions in Patients Undergoing Surgery. @

Criteria. Approve for 1 month if the patient meets the following criteria (A, B, C and D):

A) Hemoglobin is ≤ 13.0 g/dL; AND
B) The surgery is elective, nonvascular and noncardiac; AND
C) The patient is not willing or able to donate autologous blood prior to surgery; AND
D) The patient meets one of the following (i or ii):
  i. The patient is currently receiving iron therapy; OR
  ii. The patient has adequate iron stores according to the prescriber.

Dosing. Approve the following dosing regimens (A or B):
A) Approve if the dose meets the following (i and ii):
  i. Each dose is ≤ 300 Units/kg per day; AND
  ii. The total amount of doses is ≤ 15; OR
B) Approve if the dose meets the following (i and ii):
  i. Each dose is ≤ 600 Units/kg per day; AND
  ii. The total amount of doses is ≤ 4.

Other Uses with Supportive Evidence

6. Anemia Associated with Myelodysplastic Syndromes (MDS). *@ eviCore*

Criteria. Approve for 1 year if the patient meets the following criteria (A or B):
A) Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
  i. Patient is ≥ 18 years of age; AND
  ii. The patient meets one of the following (a or b):
    a) The patient has a hemoglobin < 10.0 g/dL; OR
    b) The patient has a serum erythropoietin level is ≤ 500 mU/mL; AND
  iii. The patient meets one of the following (a or b):
    a) The patient is currently receiving iron therapy; OR
    b) The patient has adequate iron stores according to the prescriber; OR
B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp). Approve if the patient meets the following criteria (i, ii, and iii):
  i. Patient is ≥ 18 years of age; AND
  ii. The patient has a hemoglobin ≤ 12.0 g/dL; AND
  iii. The patient meets one of the following (a or b):
    a) The patient is currently receiving iron therapy; OR
    b) The patient has adequate iron stores according to the prescriber.

Dosing. Approve if the dose meets the following (A and B):
A. Each dose is ≤ 60,000 Units; AND
B. Each dose is given no more frequently than 2 times a week.

7. Anemia Associated with Myelofibrosis. *@ eviCore*

Criteria. Approve for the duration noted below if the patient meets the following criteria (A or B):
A) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i and ii):
  i. The patient meets one of the following (a or b):
    a) The patient has a hemoglobin < 10.0 g/dL; OR
    b) The patient has a serum erythropoietin level is ≤ 500 mU/mL; AND

ii. The patient meets one of the following (a or b):
  a) The patient is currently receiving iron therapy; OR
  b) The patient has adequate iron stores according to the prescriber; OR

B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA) therapy. Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), or a darbepoetin alfa product (e.g., Aranesp). Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
  i. The patient has a hemoglobin ≤ 12.0 g/dL; AND
  ii. The patient meets one of the following (a or b):
    a) The patient is currently receiving iron therapy; OR
    b) The patient has adequate iron stores according to the prescriber; AND
  iii. The patient has had a response according to the prescriber of Hb ≥ 10 g/dL or an increase of ≥ 2 g/dL.

Dosing. Approve if the dose meets the following (A and B):
A. Each dose is ≤ 60,000 Units; AND
B. Each dose is given no more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Epoetin alfa is not recommended in the following situations:

1. **Anemia Associated with Cancer in Patients not Receiving Cancer Chemotherapy.** *eviCore* Epoetin alfa is not indicated in cancer patients who are not receiving cancer chemotherapy. The American Society of Clinical Oncology (ASCO)/American Society of Hematology (ASH) guidelines for the use of epoetin alfa and Aranesp in adult patients with cancer recommend that ESAs not be used in treatment of anemia associated with malignancy in those who are not receiving concurrent myelosuppressive chemotherapy.

2. **Anemia Associated with Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML) or other Myeloid/Erythroid Cancers.** *eviCore* Epoetin alfa is indicated for use in non-myeloid cancers. AML and CML are examples of myeloid cancers.

3. **Anemia Associated with Radiotherapy in Cancer.** *eviCore* Epoetin alfa is not indicated for use in patients with cancer who are only given radiation therapy.

4. **To Enhance Athletic Performance.** Epoetin alfa is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

5. **Anemia in Patients due to Acute Blood Loss.** Use of epoetin alfa is not appropriate in these types of situations.

6. **Non-Anemic Patients (Hemoglobin [Hb] > 13.0 g/dL) prior to Surgery.** Although studies have been done that involved non-anemic patients undergoing various surgeries receiving epoetin alfa preoperatively and sometimes postoperatively to prevent transfusions or subsequent anemia, the overall benefit of this therapy in those with relatively normal preoperative Hb level is questionable.

7. Coverage is not recommended for circumstances not listed in the Recommended Authorization criteria. Criteria will be updated as new published data are available.

SOURCES OF INFORMATION

1. Procrit® intravenous or subcutaneous injection [prescribing information]. Horsham, PA: Janssen; May 2024.
2. Epogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2024.
3. Retacrit® subcutaneous or intravenous injection [prescribing information]. Lake Forest, IL: Pfizer; June 2024.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease (2025). Public Review Draft; November 2024. Accessed on: June 17, 2025. Available at: https://kdigo.org/guidelines/anemia-in-ckd/
5. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 7, 2025.
6. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 2.2025 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 7, 2025.
7. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 1.2025 – February 21, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 7, 2025.
8. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). [Version Number 1, Effective date of version: 7/30/2007. Revision date: 10/2024. Accessed July 25, 2025].

HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Medical Policy	06/10/2020
Policy revision	**Anemia in a Patient with Chronic Kidney Disease who is <u>not</u> on Dialysis:** Dosing was changed to approve if the doses are equivalent to ≤ 60,000 units total per month.	07/11/2022
UCare Revision	Added "Epogen/Procrit is being prescribed due to a documented Retacrit drug shortage" due to the expected Retacrit supply disruption during Q2-4 2022.	2/14/2022
Policy revision	**Anemia in a Patient with Cancer due to Cancer Chemotherapy:** A non-curative treatment, according to the prescriber was added to the criterion for a patient to be currently receiving myelosuppressive chemotherapy.	10/13/2022
Policy revision	**Anemia in a Patient with Cancer due to Cancer Chemotherapy:** A non-curative treatment, according to the prescriber was added to the criterion for a patient to be currently receiving myelosuppressive chemotherapy.	10/13/2022
Policy revision	**Anemia in a Patient with Chronic Kidney Disease who is <u>not</u> on Dialysis:** For a Patient Currently Receiving an Erythropoiesis-Stimulating Agent, the criterion regarding a patient who is ≥18 years of age, the hemoglobin level was changed from < 11.5 to ≤12.0 g/dL. Since the criterion is now the same as a patient < 18 years of age, the delineation of age was also removed from criteria.	04/17/2023
Selected UCare Revision	Adding Aranesp as a preferred product to the Preferred Product Step Therapy Requirement (For New Starts Only)	03/20/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Selected UCare Revision	Removing the option "Epogen or Procrit is being prescribed due to a documented Retacrit drug shortage." In the preferred product step therapy section as the Retacrit manufacturer (Pfizer) has communicated sufficient stock is now available.	12/26/2024
Policy review	No criteria changes. Review based on NCD surveillance review.	01/06/2025
UCare Update	Updated step therapy criteria to require clinical need for non-preferred product over the preferred products including chart note documentation to support the need for a non-preferred product.	05/08/2025
Policy revision	No criteria changes. Formatting and notation updates.	03/10/2025
Policy review	No criteria changes Review based on commercial policy annual review	07/25/2025

UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process.	09/15/2025