Department:	Pharmacy Management	**Original Approval:**	01/20/2016
Policy No:	PM136	**Last Approval:**	05/15/2026
Policy Title:	Epoetin Products Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for Epoetin alfa History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Labs/Diagnostics -Medication list (current and past) -Dosing and duration requested -Weight -Initial/Extended approval -Age -Prescribed by or in consultation with a specialist, when indicated.

Background

Endogenous erythropoietin (EPO) is used to stimulate red blood cell (RBC) production in the bone marrow. Suppression of erythropoietin production or suppression of the bone marrow response to erythropoietin results in anemia in several disease processes, including chronic kidney disease (CKD), many types of cancer treatment, other chronic diseases, and use of certain drugs.

For Medicare: 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 References 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 Reference 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.

Definitions

None.

Indications/Criteria

Medicaid	***Continue to criteria for approval below.*** ***Criteria based on Washington State Health Care Authority Medical policy no. 82.40.10 Hematopoietic Agents: Erythropoiesis-Stimulating Agents (ESAs)*** ***Preferred Products: Retacrit, Aranesp*** ***Non-Preferred Products: Procrit, Epogen, Mircera*** ***Please note: Prior authorization is NOT required if the requested medication is being administered at a kidney center/dialysis center.***
Individual & Family (Cascade Select) Members	***Preferred Products: Aranesp, Procrit, Retacrit*** ***Non-Preferred Products: Epogen, Mircera (Mircera only indicated for anemia in a patient with chronic kidney disease who is either on dialysis or not on dialysis)***
Medicare Members	***Preferred Products: Aranesp, Procrit, Retacrit*** ***Non-Preferred Products: Epogen, Mircera (Mircera only indicated for anemia in a patient with chronic***

	kidney disease who is either on dialysis or not on dialysis)

Coverage of epoetin alfa is recommended in those who meet one of the following criteria.

Recommended Authorization Criteria

Erythropoiesis-Stimulating Agents may be considered medically necessary when used for ONE of the following conditions:

1. Treatment of anemia of prematurity for less than 6 months of age; OR
2. Treatment of anemia associated with chronic kidney disease (CKD) – (including patients on dialysis and not on dialysis); OR
3. Anemia associated with zidovudine-treated HIV-infected patients; OR
4. Treatment of anemia of cancer patients on chemotherapy, where the intent of treatment is palliative; OR
5. Treatment of anemia associated with myelodysplastic syndrome to reduce transfusion dependency; OR
6. Treatment of patients after allogeneic bone marrow transplantation; OR
7. Treatment of anemia due to ribavirin in patients who did not experience an improvement in hemoglobin level with ribavirin dose reduction; OR
8. To reduce the need for blood transfusions in anemic patients scheduled to undergo high-risk surgery who are at increased risk or intolerant to transfusions; OR
9. Special circumstance patients who will not or cannot receive whole blood or components as replacement for traumatic or surgical loss.

Medicaid Criteria

Note: Prior authorization is NOT required if the requested medication is being administered at a kidney center/dialysis center.

1. Approve the requested medication for 1 year if the patient meets all of the following:
   - **A)** The medication is being used for an FDA-approved indication or an indications supported by Centers for Medicare and Medicaid Services (CMS) Compendia
   - **B)** Patient meets one of the following:
     - **i.** Patient is using Retacrit
     - **ii.** Patient has tried and failed both Retacrit and Aranesp.

Cascade Select and Medicare Criteria

1. **Anemia in Patients with Chronic Kidney Disease (CKD) who are on Dialysis.** Approve for 1 year.
2. **Anemia in Patients with Chronic Kidney Disease (CKD) who are not on dialysis.** 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)** **For Epogen, Procrit, Retacrit, and Mircera.** The patient is ≥ 18 years of age with a hemoglobin < 10.0 g/dL; OR
       - **b)** **For Epogen, Procrit, and Retacrit only**. 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)** Patient is currently receiving iron therapy; OR
       - **b)** The patient has adequate iron stores according to the prescriber; AND
     - **iii.** For non-preferred products (i.e., Epogen and Mircera), the patient meets one of the following criteria (a or b):
       - **a)** The patient meets both of the following ((1) and (2))
         - **(1)** The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND
         - **(2)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
       - **b)** For Medicare patients, the patient is currently taking the non-preferred product or has previously taken non-preferred product within the past 365 days.
   - **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, ii, and iii):
     - **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; AND

iii. For non-preferred products (i.e., Epogen and Mircera), the patient meets one of the following criteria (a or b):

a) The patient meets both of the following ((1) and (2))

(1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred within the past 365 days.

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

Mircera Dosing. Approve the following dosing regimen (A or B):

A) Approve if the dose meets the following (i and ii):

i. Each dose is ≤ 180 mcg; AND

ii. Each dose is given no more frequently than once every 2 weeks; OR

B) Approve if the dose meets the following (i and ii):

i. Each dose is ≤ 360 mcg; AND

ii. Each dose is given no more frequently than once monthly.

3. Patients with Anemia and Human Immunodeficiency Virus (HIV) who are Receiving Zidovudine (Epogen, Procrit, and Retacrit only). 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, iii and iv):

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) Patient is currently receiving iron therapy; OR

b) Patient has adequate iron stores according to the prescriber; AND

iv. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):

a) The patient meets both of the following ((1) and (2))
(1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND
(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days.

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, iii, and iv):

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) Patient is currently receiving iron therapy; OR
b) Patient has adequate iron stores according to the prescriber; AND
iv. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):
a) The patient meets both of the following ((1) and (2))
(1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND
(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days.

Dosing. Approve the following dosing regimen (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.

4. **Anemia in Patients with Cancer due to Cancer Chemotherapy (Epogen, Procrit, and Retacrit only).** 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, iii and iv):
      i. The patient has a hemoglobin < 10.0 g/dL (or hematocrit <30%); AND
      ii. The patient is currently receiving myelosuppressive chemotherapy; AND
      iii. The patient meets one of the following (a or b):
         a) Patient is currently receiving iron therapy; OR
         b) Patient has adequate iron stores according to the prescriber; AND
      iv. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):
         a) The patient meets both of the following ((1) and (2))
            (1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND
            (2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
         b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days.
   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, iii, and iv):
      i. The patient has a hemoglobin ≤ 12.0 g/dL (or hematocrit <30%); AND
      ii. The patient is currently receiving myelosuppressive chemotherapy; AND
      iii. The patient meets one of the following (a or b):
         a) Patient is currently receiving iron therapy; OR
         b) Patient has adequate iron stores according to the prescriber; AND
      iv. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):
         a) The patient meets both of the following ((1) and (2))
            (1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days.

Dosing. Approve the following dosing regimen (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 and ii):

i. Each dose is ≤ 900 Units/kg; AND

ii. Each dose is ≤ 60,000 Unit/kg; AND

iii. Each dose is given no more frequently than once weekly.

5. **Reduction of Allogenic Red Blood Cell (RBC) Transfusions in Patients Undergoing Surgery (Epogen, Procrit, and Retacrit only).** Approve for 1 month if the patient meets the following criteria (A, B, C, D, and E):

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. Patient has adequate iron stores according to the prescriber; AND

E) For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (i or ii):

i. The patient meets both of the following (a and b)

a) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND

b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

ii. For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days.

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 Syndrome (MDS) (Epogen, Procrit, and Retacrit only).** 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, iii and iv):

i. The patient ≥ 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) Patient is currently receiving iron therapy; OR

b) Patient has adequate iron stores according to the prescriber; AND

iv. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):

a) The patient meets both of the following ((1) and (2))

(1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days; 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, iii, and iv):

i. The patient ≥ 18 years of age; AND

ii. The patient has a hemoglobin <12.0 g/dL; OR

iii. The patient meets one of the following (a or b):

a) Patient is currently receiving iron therapy; OR

b) Patient has adequate iron stores according to the prescriber; AND

iv. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):

a) The patient meets both of the following ((1) and (2))

(1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days.

Dosing. Approve the following dosing regimen (A or 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 (Epogen, Procrit, and Retacrit only). Approve for the duration noted below if the patient meets the follow criteria (A or B):

A) Initial Therapy. Approve for 3 months 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 meets one of the following (a or b):

a) Patient is currently receiving iron therapy; OR

b) Patient has adequate iron stores according to the prescriber; AND

iii. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):

a) The patient meets both of the following ((1) and (2)):

(1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in

stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days; 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, iii, and iv):

i. The patient has a hemoglobin <12.0 g/dL; OR

ii. The patient meets one of the following (a or b):

a) Patient is currently receiving iron therapy; OR

b) Patient has adequate iron stores according to the prescriber; AND

iii. The patient has responded to therapy defined as Hb ≥ 10 g/dL or a Hb increase of ≥ 2 g/dL.

iv. For non-preferred products (i.e., Epogen only), the patient meets one of the following criteria (a or b):

a) The patient meets both of the following ((1) and (2)):

(1) The patient has tried ONE of Aranesp, Procrit, or Retacrit; AND

(2) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR

b) For Medicare patients, the patient is currently taking the non-preferred product or has previously taken the non-preferred product within the past 365 days.

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.

Drug Name	Dose and Quantity Limits
J0885	60 billing units (60,000-unit dose) per DOS

J0886	600 billing units (60,000-unit dose) per week
J0887	360 billing units (360 mcg) per DOS
J0888	360 billing units (360 mcg) per DOS
Q4081	100 billing units (10,000 units) per DOS
Q5105	600 billing units (60,000 units) per week
Q5106	60 billing units (60,000 units) per week

Waste Management for All Indications.

Single-dose vials and multidose vials are available in many different strengths. The dose should be calculated, and the number of vials needed assessed. Refer to the package insert for more information.

Conditions Not Recommended for Approval

Epoetin alfa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Anemia Associated with Cancer in Patients not Receiving Myelosuppressive Cancer Chemotherapy.** Epoetin alfa and Mircera are not indicated in cancer patients who are not receiving cancer chemotherapy.[1-3] 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.[6]

2. **Anemia Associated with Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML) or other Myeloid Cancers.** Epoetin alfa is indicated for use in non-myeloid cancers. AML and CML are examples of myeloid cancers.[1-3]

3. **Anemia Associated with Radiotherapy in Cancer.** Epoetin alfa is indicated for use in patients with cancer who are only given radiation therapy.[1-3]

4. **To Enhance Athletic Performance.** Epoetin alfa and Mircera are 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 and Mircera are 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.

Special Considerations

None.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Individual & Family (Cascade Select)	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

List of Appendices

None.

Citations & References

CFR	42 CFR § 438.210

WAC	WAC 284-43-2050	
RCW		
LOB & Contract Citation	☐ **WAHIMC**	
	☐ **BHSO**	
	☐ **Wraparound**	
	☐ **SMAC**	
	☐ **HH**	
	☐ **AHE**	
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	1. Product Information: ARANESP® intravenous injection, subcutaneous injection, darbepoetin alfa intravenous injection, subcutaneous injection. Amgen Inc (per FDA), Thousand Oaks, CA, March 2026. 2. Product Information: Epogen® intravenous injection, subcutaneous injection, epoetin alfa intravenous injection, subcutaneous injection. Amgen Inc (per FDA), Thousand Oaks, CA, November 2025. 3. Product Information: Procrit® intravenous injection, subcutaneous injection, epoetin alfa intravenous injection, subcutaneous injection. Janssen Products LP (per FDA), Horsham, PA, April 2025. 4. Product Information: RETACRIT™ intravenous, subcutaneous injection, epoetin alfa-epbx intravenous,subcutaneous injection. Hospira, Inc (per FDA), Lake Forest, IL, June 2025. 5. Product Information: Mircera® intravenous injection, subcutaneous injection, methoxy polyethylene glycol epoetin beta intravenous injection, subcutaneous injection. Hoffmann-La Roche Inc. (per FDA),South San Francisco, CA, June 2024. 6. KDIGO Clinical Practice Guidelines for Anemia in Chronic Kidney Disease. Kidney International Supplements. 2012; 2(4): 279-335. 7. 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. Accessed April 17, 2023].	

Revision History

Revision Date	Revision Description	Revision Made By
01/13/2016	New	Kelly Force; Yusuf Rashid, RPh
01/20/2016	Approval	MMLT
01/12/2017	No revisions	Fran McGaugh
01/13/2017	Approval	MMLT
07/24/2017	Criteria completely updated and revised	Michael Sporck, Pharmacy Intern; Sophia Yun, PharmD
07/25/2017	Approved	MMLT
03/09/2018	Reassigned from UM148 to PM136	Cindy Bush
05/07/2018	Transferred to new template	Cindy Bush
05/23/2018	No revisions	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee
08/16/2018	Revised and addition of SPDL status	Jennifer Farley, PharmD
11/28/2018	Minor Revision	Jennifer Farley, PharmD
12/12/2018	Approval	UM Committee
07/08/2019	Annual review and update	Ivan Figueira, PharmD
07/11/2019	Approval	UM Pharmacy Subcommittee
06/09/2020	Annual review. No changes	Jennifer Farley, PharmD
06/18/2020	Approval	UM Pharmacy Subcommittee
04/23/2021	Annual review. No criteria changes	Jennifer Farley, PharmD
05/06/2021	Approval	UM Pharmacy Subcommittee
02/28/2022	Annual review. No criteria changes	Alan Gabot, PharmD
03/02/2022	Approval	UM Pharmacy Subcommittee

11/30/2022	Early update. New criteria added to apply to Medicare LOB. Preferred and non-preferred products specified for Medicaid LOB.	Alan Gabot, PharmD
12/02/2022	Approved	UM Pharmacy Subcommittee
01/31/2023	Early update. Clarified criteria for non-preferred products. Allowed for approvals for both preferred and non-preferred products for anemia in patients with CKD who are on dialysis.	Alan Gabot, PharmD
02/01/2023	Approval	UM Pharmacy Subcommittee
11/01/2023	Annual review. For Chronic Kidney Disease who is not on Dialysis" under Medicare, the hemoglobin requirement for patients currently receiving an erythropoiesis-stimulating agent is now ≤ 12.0 g/dL for all ages. Updated dosing regimen for same indication, where epoetin alfa dosing should be equivalent to ≤ 60,000 units total per month.	Alan Gabot, PharmD
11/02/2023	Approval	UM Pharmacy Subcommittee
12/12/2023	Early update. Added description noting that the policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).	Alan Gabot, PharmD
12/18/2023	Approval	UM Pharmacy Subcommittee
02/26/2024	Early update. Created separate criteria for Cascade Select. Aranesp is now listed as preferred product for both Cascade Select and Medicare.	Alan Gabot, PharmD
02/28/2024	Approval	UM Criteria Subcommittee
09/10/2024	Early update. Updated criteria section for non-preferred products. In addition to requiring that the member try one of the preferred product (Aranesp, Procrit, Retacrit), there must be documentation on that the patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which,	Alan Gabot, PharmD

	according to the prescriber, would result in a significant allergy or serious adverse reaction. Added label to specify what section is the Medicaid criteria.	
09/11/2024	Approval	UM Criteria Subcommittee
07/03/2025	Annual review. Noted that requests under Medicaid do not require prior authorization if the medication is administered at a kidney/dialysis center.	Alan Gabot, PharmD
07/09/2025	Approval	UM Criteria Subcommittee
05/14/2026	Early update. For Cascade Select/Medicare Criteria, clarified that the following criteria is only applicable to Medicare: "The patient is currently taking the requested non-preferred product or had previously taken the non-preferred product within the past 365 days." For Medicaid, updated criteria where the requested medication may be approved if the medication is being used for an FDA-approved indication. Also required non-preferred products to try and fail both Retacrit and Aranesp.	Alan Gabot, PharmD
05/15/2026	Approval	UM Criteria Subcommittee