curative

TITLE:	ERYTHROPOIESIS STIMULATING AGENTS (ESA) POLICY
POLICY #:	MM-PNP-035
VERSION #:	01
DEPARTMENT:	UTILIZATION REVIEW
ORIGINAL EFFECTIVE DATE:	12/01/2023
CURRENT REVISION DATE:	N/A

1. PURPOSE

This policy will be used to inform medical necessity decisions related to authorization requests for erythropoiesis stimulating agents (ESA) for the treatment of anemia.

Epoetin Alfa agents are used for:

- Anemia due to Chronic Kidney Disease (CKD), in patients on dialysis and those not on dialysis to decrease the need for red blood cell (RBC) transfusion
- Treatment of anemia due to zidovudine administered at less than or equal to 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of less than or equal to 500 mUnits/mL
- Anemia 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 2 additional months of planned chemotherapy
- Reduce the need of allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery

Limitations of Use:

- Retacrit has not been shown to improve quality of life, fatigue, or patient well-being

Retacrit is not indicated for use:

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

2. SCOPE

Medical and Pharmacy UM Department associates involved in the approval process.

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Brand Selection for Medically Necessary Indications

Health care services are not medically necessary when they are more costly than alternative services that are at least as likely to produce equivalent therapeutic or diagnostic results. **Epogen, Procrit, Aranesp, and Mircera** are more costly to Curative than other targeted immune modulators for certain indications. There is a lack of reliable evidence that **Epogen, Procrit, Aranesp, Mircera** are superior to the lower cost targeted **Retacrit**.

Preferred Agent

- **Preferred epoetin alfa containing agents:**
  - **Retacrit** (epoetin alfa-epbx)
- **All other agents are considered non-preferred.** Ex. Epogen, Procrit, Aranesp, Mircera

Evaluation

Preferred Agent(s) will be approved when **BOTH** of the following are met:

- The patient's hemoglobin was measured within the previous 4 weeks **AND**
- ONE of the following:
  - The patient will use the requested agent as part of dialysis AND ONE of the following:
    - The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR**
    - The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **OR**
  - **ALL** of the following:
    - **ONE** of the following:
      - The requested agent is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL **OR**
      - The requested agent is being prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND **ALL** of the following:
        - The requested agent is NOT Mircera **AND**
        - ONE of the following:
          - The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR**
          - The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **AND**

- The patient is concurrently treated with chemotherapy (with or without radiation) **AND**
- Chemotherapy is being used for palliative intent **AND**
- The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks AND BOTH of the following:
  - The patient's serum ferritin is NOT greater than 800 ng/mL AND
  - The patient's transferrin saturation is NOT greater than 50% OR

- The requested agent is being prescribed for anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:
  - ONE of the following:
    - The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL OR
    - The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL AND
  - The rate of hemoglobin decline is likely to result in a red blood cell (RBC) transfusion AND
  - The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks OR
- The requested agent is being prescribed for anemia due to myelodysplastic syndrome, or for anemia resulting from zidovudine treatment of HIV infection AND ONE of the following:
  - The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 12 g/dL **OR**
  - The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **OR**
- The requested agent is being prescribed for another FDA approved indication or another indication that is supported in compendia AND the patient's hemoglobin level is within the FDA labeling or compendia recommended range for the requested indication for patients initiating ESA therapy OR for patients stabilized on therapy for the requested indication **AND**
  - The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks **AND** ONE of the following:
    - The patient's serum ferritin is greater than or equal to 100 ng/mL AND the patient's transferrin saturation is greater than or equal to 20% **OR**
    - The patient has started supplemental iron therapy **AND**

    - If the patient has an FDA approved indication, ONE of the following:
        - The patient's age is within FDA labeling for the requested indication for the requested agent OR
        - The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
    - If the requested agent is Epogen or Procrit ONE of the following:
        - The patient has tried and had an inadequate response to ONE preferred agent (listed below) (medical records required) OR
        - The patient has an intolerance or hypersensitivity to ONE preferred agent that is NOT expected to occur with the requested agent (medical records required) OR
        - The patient has an FDA labeled contraindication to ALL preferred agents that is NOT expected to occur with the requested agent (medical records required) AND

Preferred Epoetin Alfa Containing Agent(s)

Retacrit (epoetin alfa-epbx)

- If the client has preferred agents not addressed previously ONE of the following:
    - The requested agent is a preferred agent (Preferred and Nonpreferred Agents to be determined by client) **OR**
    - The patient has tried and had an inadequate response to ONE preferred agent **OR**
    - The patient has an intolerance or hypersensitivity to ONE preferred agent that is NOT expected to occur with the requested agent **OR**
    - The patient has an FDA labeled contraindication to ALL preferred agent(s) that is NOT expected to occur with the requested agent **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence, NCCN 1 or 2a recommended use

Length of Approval:

- 1 month for allogeneic blood transfusion in a surgery patient;
- 6 months for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy
- 12 months for anemia associated with chronic kidney disease in patients on/not on dialysis, anemia due to myelodysplastic syndrome, anemia resulting from zidovudine treatment of HIV infection

- 6 months for all other diagnoses.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

- All Pharmacy and Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

- Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:		
(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: