SmartPA Criteria

Proposal

Drug/Drug Class:	Erythropoiesis Stimulating Agents PDL Edit
First Implementation Date:	July 3, 2008
Revised Date:	January 12, 2203
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐ Existing Criteria ☒ Revision of Existing Criteria ☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Erythropoietin is a glycoprotein hormone produced by the kidneys that stimulate the formation of red blood cells (erythropoiesis). A recombinant human erythropoietin, epoetin alfa (Epogen®, Procrit®, Retacrit®), has FDA approved indications for the treatment of anemia associated with several conditions: chronic renal failure (with and without dialysis), zidovudine treatment in HIV infected patients, and chemotherapy for non-myeloid cancers. It is also indicated for use prior to elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions. Studies have shown epoetin alfa to improve hematologic indices, reduce the need for transfusions, and improve quality of life. Illicit use of epoetin alfa has been reported in athletes wishing to increase their endurance. Darbepoetin alfa (Aranesp®) is another erythropoiesis-stimulating agent available on the market and is approved for the treatment of anemia associated with both chronic renal failure (with and without dialysis) and chemotherapy for non-myeloid malignancies. It differs from epoetin alfa by containing two additional N-glycosylation sites which serve to lengthen the duration of action of the drug, thereby reducing the dosing frequency required with epoetin alfa. Methoxy polyethylene glycol-epoetin beta (Mircera®), an erythropoietin receptor activator, is indicated for the treatment of anemia associated with chronic kidney disease (with and without dialysis).

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Aranesp® • Epogen® • Procrit®	• Mircera® • Retacrit®

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **Clinical Edit**

Data Sources:

☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Erythropoiesis Stimulating Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented diagnosis of anemia due to chronic kidney disease or cancer (excluding myeloid leukemia) in the past year **OR**
- Documented diagnosis of anemia due to HIV treatment with zidovudine in the past 30 days **OR**
- Clinical consultant review required for documented diagnosis of reduction of allogenic red blood cell transfusion in participants undergoing elective, noncardiac, nonvascular surgery **AND**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Mircera:
  - Participants aged 5 years or older **AND**
  - Documented diagnosis of chronic kidney disease in the past 30 days

Denial Criteria

- Lack of adequate trial on required preferred agents
- Participants not responding to usual doses of therapy, prescriber to rule out causes for delayed/ diminished response before continuing therapy, including:
  - Iron deficiency
  - Underlying infectious, inflammatory, or malignant processes
  - Occult blood loss
  - Underlying hematologic diseases
  - Folic acid or vitamin B12 deficiency
  - Hemolysis
  - Aluminum intoxication
  - Osteitis fibrosa cystica
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: “Erythropoiesis-Stimulating Agents (ESAs)”, UMKC-DIC; April 2022.
- Leung, L., (2020). Approach to the adult with anemia. In J.S. Tirnauer & L. Kunins (Eds.), *UpToDate.*
- Evidence-Based Medicine and Fiscal Analysis: “Erythropoiesis Stimulating Agents – Therapeutic Class Review – Therapeutic Drug Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc; January 2019.
- Epogen [package insert]. Thousand Oaks, CA: Amgen; July 2018.
- Mircera [package insert]. South San Francisco, CA: Hoffmann-La Roche Inc; June 2018.
- Procrit [package insert]. Horsham, PA: Janssen Products LP; July 2018.
- Retacrit [package insert]. Lake Forest, IL: Hospira, Inc; August 2020.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.