PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Erythropoiesis-Stimulating Agents Preferred Specialty Management Policy

- Aranesp® (darbepoetin alfa intravenous or subcutaneous injection Amgen)
- Epogen® (epoetin alfa intravenous or subcutaneous injection Amgen)
- Mircera® (methoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection Vifor Pharma)
- Procrit[®] (epoetin alfa intravenous or subcutaneous injection Janssen)
- Retacrit® (epoetin alfa-epbx intravenous or subcutaneous injection Pfizer)

REVIEW DATE: 09/21/2022

OVERVIEW

The erythropoiesis-stimulating agents (ESAs) are indicated for **anemia** in certain patient populations.¹⁻⁵ More specifically, all ESAs are indicated for the treatment of anemia due to chronic kidney disease. Additionally, epoetin alfa (Epogen, Procrit, Retacrit) and Aranesp are indicated for the treatment of anemia due to myelosuppressive chemotherapy in patients with cancer. Epoetin alfa is also indicated for the treatment of anemia due to zidovudine in human immunodeficiency virus-infected patients and the reduction of allogeneic red blood cell transfusions in elective, noncardiac, nonvascular surgery. All ESAs stimulate erythropoiesis by the same mechanism as endogenous erythropoietin. Retacrit is the biosimilar to Epogen/Procrit.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Erythropoiesis-Stimulating Agents Prior Authorization Policy* criteria. The program also directs the patient to try at least one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). For patients with chronic kidney disease who are on dialysis, prior authorization and step management are not required for medical benefit coverage. If the patient meets the corresponding standard *Erythropoiesis-Stimulating Agents Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Products will be authorized. Approval duration for patients with chronic kidney disease who are on dialysis is for 3 years. For Other Conditions, approval durations are as noted in the respective standard *Erythropoiesis-Stimulating Agents Prior Authorization Policy*.

Automation: None.

Preferred Products: Procrit, Retacrit

Non-Preferred Products: Aranesp, Epogen, Mircera

RECOMMENDED EXCEPTION CRITERIA

| Non-Preferred | Exception Criteria | | | |
|---------------|--|--|--|--|
| Product(s) | | | | |
| Aranesp | 1. Anemia in Patients with Chronic Kidney Disease who are on Dialysis. | | | |
| 1 | Approve. | | | |
| | 2. Other Conditions. Approve if the patient meets the following criteria (A and | | | |
| | B): | | | |
| | A) Patient meets the standard Erythropoiesis-Stimulating Agents – Aranesp | | | |
| | Prior Authorization Policy criteria; AND | | | |
| | B) Patient has tried one of Procrit or Retacrit. | | | |
| | 3. If the patient has met criterion 2A (the standard Erythropoiesis-Stimulating | | | |
| | Agents – Aranesp Prior Authorization Policy criteria), but criterion 2B is not met | | | |
| | and the requested agent is not approved: approve the Preferred Products. | | | |
| Epogen | 1. Anemia in Patients with Chronic Kidney Disease who are on Dialysis. | | | |
| | Approve. | | | |
| | 2. Other Conditions. Approve if the patient meets the following criteria (A and | | | |
| | B): | | | |
| | A) Patient meets the standard <i>Erythropoiesis-Stimulating Agents – Epoetin Alfa</i> | | | |
| | Prior Authorization Policy criteria; AND | | | |
| | B) Patient meets both of the following (i and ii): | | | |
| | i. Patient has tried one of Procrit or Retacrit; AND | | | |
| | ii. 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. | | | |
| | If the patient has met criterion 2A (the standard <i>Erythropoiesis-Stimulatin</i> , | | | |
| | Agents – Epoetin Alfa Prior Authorization Policy criteria), but criterion 2B is not | | | |
| Minara | met and the requested agent is not approved: approve the Preferred Products. | | | |
| Mircera | 1. Anemia in Patients with Chronic Kidney Disease who are on Dialysis. | | | |
| | Approve. 2. Other Conditions. Approve if the nations mosts the following criteria (A and | | | |
| | 2. Other Conditions. Approve if the patient meets the following criteria (A and B): | | | |
| | A) Patient meets the standard Erythropoiesis-Stimulating Agents – Mircera | | | |
| | Prior Authorization Policy criteria; AND | | | |
| | B) Patient has tried one of Procrit or Retacrit. | | | |
| | 3. If the patient has met criterion 2A (the standard Erythropoiesis-Stimulating | | | |
| | Agents – Mircera Prior Authorization Policy criteria), but criterion 2B is not met | | | |
| | and the requested agent is not approved: approve the Preferred Products. | | | |

REFERENCES

- 1. Procrit® intravenous or subcutaneous injection [prescribing information]. Horsham, PA: Janssen; May 2020.
- 2. Epogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; July 2018.
- 3. Retacrit[™] intravenous or subcutaneous injection [prescribing information]. New York, NY: Pfizer; July 2022.
- 4. Mircera® intravenous or subcutaneous injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; August 2019.
- 5. Aranesp® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2019.

| Erythropoiesis-Stimulating | Agents | PSM | Policy |
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