Reference number(s)
5278-D

This document applies to the following:

Product	Applies
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Erythropoiesis Stimulating Agents

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the erythropoiesis stimulating agents specified in this document. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members requesting treatment with a non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Erythropoiesis Stimulating Agents

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Aranesp (darbepoetin alfa) • Retacrit (epoetin alfa-epbx)
Non-preferred	• Epogen (epoetin alfa) • Mircera (methoxy polyethylene glycol-epoetin beta) • Procrit (epoetin alfa)

Step Therapy Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Anemia Due to Chronic Kidney Disease (CKD)

Epogen or Procrit

Coverage for Epogen or Procrit is provided when either of the following criteria is met:

- Member has received treatment with Epogen or Procrit in the past 365 days.
- Member meets both of the following criteria:
  - Member has had a documented intolerable adverse event with Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).
  - Member has a documented inadequate response or intolerable adverse event with the preferred product Aranesp.

Mircera

Coverage for Mircera is provided when either of the following criteria is met:

- Member has received treatment with Mircera in the past 365 days.
- Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Retacrit.

Anemia Due to Myelosuppressive Chemotherapy in Cancer

Coverage for Epogen or Procrit is provided when either of the following criteria is met:

- Member has received treatment with Epogen or Procrit in the past 365 days.
- Member meets both of the following criteria:
  - Member has had a documented intolerable adverse event with Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).
  - Member has a documented inadequate response or intolerable adverse event with the preferred product Aranesp.

Anemia Due to Zidovudine in Patients with Human Immunodeficiency Virus (HIV) Infection and To Reduce Need for Allogeneic Red Blood Cell (RBC) Transfusions

Coverage for Epogen or Procrit is provided when either of the following criteria is met:

- Member has received treatment with Epogen or Procrit in the past 365 days.
- Member has had a documented intolerable adverse event with Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).

References

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
3. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; June 2024.
4. Procrit [package insert]. Horsham, PA: Janssen Products, LP; April 2024.
5. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2024.