Reference number(s)
4955-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Anemia

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

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), and Value Formulary (VF).

Plan Design Summary

This program applies to the anemia products specified in this document. Coverage for the targeted products is provided based on clinical circumstances that would exclude the use of the preferred products 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 all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Anemia Products

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

	Product(s)
Preferred	• Aranesp (darbepoetin alfa) • Procrit (epoetin alfa) • Retacrit (epoetin alfa-epbx)
Target	• Epogen (epoetin alfa) • Mircera (methoxy polyethylene glycol-epoetin beta)

Exception Criteria

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

Anemia Due to Chronic Kidney Disease (CKD)

Epogen

Coverage for Epogen is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event with both of the preferred products, Procrit and Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (e.g., 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 the member has a documented inadequate response or intolerable adverse event with all of the preferred products.

Anemia Due to Myelosuppressive Chemotherapy in Cancer

Coverage for Epogen is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event with both of the preferred products, Procrit and Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (e.g., 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 is provided when the member has had a documented intolerable adverse event with both of the preferred products, Procrit and Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (e.g., 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. Procrit [package insert]. Horsham, PA: Janssen Products, LP; July 2018.
4. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; June 2024.
5. Retacrit [package insert]. New York, NY: Pfizer Labs; June 2024.