

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	Medicare Part B	Reference # 5278-D
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)	Medical: Advanced Biosimilars First	Medicare Part B: Advanced Biosimilars First	
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)	Medical Benefit: Managed Medicaid		
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)	Medical Benefit: Add-on		
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

EXCEPTIONS CRITERIA ERYTHROPOIESIS STIMULATING AGENTS

PREFERRED PRODUCTS: ARANESP AND RETACRIT

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the erythropoiesis stimulating agents specified in this policy. Coverage for targeted 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 who are new to treatment with a targeted product for the first time.

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

Table. Erythropoiesis Stimulating Agents

	Product(s)
Preferred*	<ul style="list-style-type: none"> • Aranesp (darbepoetin alfa) • Retacrit (epoetin alfa-epbx)
Targeted	<ul style="list-style-type: none"> • Epogen (epoetin alfa) • Mircera (methoxy polyethylene glycol-epoetin beta) • Procrit (epoetin alfa)

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

II. EXCEPTION CRITERIA

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

A. Mircera

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

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

B. Epogen or Procrit

This policy applies to the following:

	Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	Medicare Part B	Reference #
	Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)	Medical: Advanced Biosimilars First	✓ Medicare Part B: Advanced Biosimilars First	5278-D
	Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)	Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)	Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

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

1. Member has received treatment with Epogen or Procrit in the past 365 days.
2. Member meets both of the following criteria:
 - a. Member has a documented inadequate response or intolerable adverse event with the preferred product, Aranesp, when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.
 - b. Member has had a documented intolerable adverse event to the preferred product, 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 products).

REFERENCES

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2019.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2018.
3. Procrit [package insert]. Horsham, PA: Janssen Products, LP; July 2018.
4. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; March 2023.
5. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; April 2023.