This policy applies to the following:

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

Reference #
5626-D

EXCEPTIONS CRITERIA

ERYTHROPOIESIS STIMULATING AGENTS

PREFERRED PRODUCTS: ARANESP AND PROCRIT

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 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 who are requesting treatment with the targeted products, Epogen and Retacrit. This program also applies to members who are new to treatment with the targeted product, Mircera, 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*	• **Aranesp** (darbepoetin alfa) • **Procrit** (epoetin alfa)
Targeted	• **Epogen** (epoetin alfa) • **Mircera** (methoxy polyethylene glycol-epoetin beta) • **Retacrit** (epoetin alfa-epbx)

*: 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 products.

A. Epogen

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

1. Member has had a documented intolerable adverse event with the preferred product, Procrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
2. Member has experienced 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.

This policy applies to the following:

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

Reference #
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B. Mircera

Coverage for the targeted product is provided when the member meets either of the following criteria:

1. Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
2. Member has a documented inadequate response or intolerable adverse event with all of the preferred products, Aranesp and Procrit.

C. Retacrit

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

1. Member has had a documented intolerable adverse event with the preferred product, Procrit, 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).
2. Member has experienced 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.

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.; August 2020.