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## DRUG POLICY

# Erythropoiesis Stimulating Agents

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

This policy informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization. The intent of the policy is to also provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

This program applies to the erythropoiesis stimulating agents specified in this policy when used for an indication that is FDA-approved for the preferred product. The biosimilar, Retacrit, will be preferred over the reference brands for all indications not just the FDA-approved indications. Coverage for a non-preferred product 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 all members who are requesting treatment with a targeted product.

**Table. Erythropoiesis Stimulating Agents Products**

Medication	Generic Name
<b>Preferred Products:</b>	
Aranesp	darbepoetin alfa
Retacrit	epoetin alfa
<b>Targeted Products:</b>	
Epogen	epoetin alfa
Mircera	methoxy polyethylene glycol-epoetin beta

**EXCEPTION CRITERIA**

- A. Coverage for a non-preferred product, Mircera, is provided when the member has a documented inadequate response or intolerable adverse event with both of the preferred products.
- B. Coverage for either of the targeted products, Epogen or Procrit, is provided when both of the following criteria are met:
- 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.
  - Member has a documented intolerable adverse event with the preferred product, Retacrit, which was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information.

**Approval will be for 12 months.**

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

**Prior approval is required.**

**POLICY (Note: applicable to Mircera only)**

Member must meet BOTH the Exception Criteria for Mircera (methoxy polyethylene glycol-epoetin beta) and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Criteria for Initial Approval

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as serum transferrin saturation [TSAT] level  $\geq 20\%$  within the prior 3 months) or are receiving iron therapy before starting Mircera. Members may not use Mircera concomitantly with other erythropoiesis stimulating agents or with hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHIs).

**Anemia due to Chronic Kidney Disease (CKD)**

Authorization of 12 months may be granted for the treatment of anemia due to chronic kidney disease in adult members with pretreatment hemoglobin  $< 10$  g/dL

Authorization of 12 months may be granted for the treatment of anemia due to chronic kidney disease in pediatric members 3 months to 17 years of age who are converting from another ESA after their hemoglobin level was stabilized (e.g., Hgb level of 10 to 12 g/dL) with an ESA.

Continuation of Therapy

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as serum transferrin saturation [TSAT] level  $\geq 20\%$  within the prior 3 months) or are receiving iron therapy before starting Mircera. Members may not use Mircera concomitantly with other erythropoiesis stimulating agents or with hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHIs)..

**Anemia due to Chronic Kidney Disease (CKD)**

Authorization of 12 months may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin less than 12 g/dL.

Mircera (methoxy polyethylene glycol-epoetin beta) is considered **not medically necessary** for patients who do not meet the criteria set forth above.

#### Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

### PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- J0885 - Injection, epoetin alfa, (for non-esrd use), 1000 units
- Q4081 - Injection, epoetin alfa, 100 units (for esrd on dialysis)
- J0887 - Injection, epoetin beta, 1 microgram, (for esrd on dialysis)
- J0888 - Injection, epoetin beta, 1 microgram, (for non esrd use)

### REFERENCES

- Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2019.
- Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2018.
- Procrit [package insert]. Horsham, PA: Janssen Products, LP; July 2018.
- Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; April 2024.
- Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2020.
- Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int.* 2012;Suppl 2:279-335.

### POLICY HISTORY

**Policy #:** 05.04.25

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