RX.PA.065.MPC Erythropoiesis-Stimulating Agent (ESA) Products

PURPOSE

The purpose of this policy is to define the prior authorization process for Aranesp (darbepoetin alfa), Epogen (epoetin alfa), Mircera (epoetin beta), Procrit (epoetin alfa), and Retacrit (epoetin alfa-epbx).

	Products
Preferred	• **Aranesp® (darbepoetin alfa)** • **Retacrit® (epoetin alfa-epbx)**
Non-preferred	• **Epogen, Procrit® (epoetin alfa)** • **Mircera® (epoetin beta)**

Note: Requests for non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

1. Darbepoetin alfa (Aranesp)

- Must be prescribed by or in consultation with a nephrologist, hematologist/oncologist, gastroenterologist, hepatologist, transplant physician, or an infectious disease physician
- Must have ONE of the following diagnoses and hemoglobin levels: (labs must be within 30 days)
  - Anemia of chronic renal failure and on renal dialysis when Hgb <10g/dL
  - Anemia of chronic renal failure not requiring dialysis when Hgb <10g/dL
  - Anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy (Hgb <10g/dL) and there is a minimum of two additional months of planned chemotherapy

    - Anemia associated with the use of ribavirin when Hgb <10g/dL OR a 3g/dL decrease from baseline Hgb with symptoms. If ribavirin is being prescribed as part of a triple-therapy regimen (including a protease inhibitor), documentation that an attempt at ribavirin dose reduction was not able to resolve the anemia must be provided
- Must be on supplemental iron therapy if serum ferritin saturation (TSAT) is below 20%
- Must not have uncontrolled hypertension (Systolic >140 mmHg or diastolic >90 mmHg). Blood pressure should be controlled prior to start of therapy and monitored closely throughout treatment.
- Must not have a known hypersensitivity to the active substance or any of the excipients of the product
- Member must have been evaluated for other causes of anemia (e.g. vitamin deficiency, bleeding, metabolic or chronic inflammatory conditions)

2. Epoetin alfa (Epogen, Retacrit, or Procrit)

- Must be prescribed by or in consultation with a nephrologist, hematologist/oncologist, gastroenterologist, hepatologist, transplant physician, or an infectious disease physician
- Must have ONE of the following diagnoses and hemoglobin levels: (labs must be within 30 days)
    - Anemia of chronic renal failure and on renal dialysis when Hgb <10g/dL
    - Anemia of chronic renal failure not requiring dialysis when Hgb <10g/dL
    - Zidovudine treatment-induced anemia in HIV members when lab value showing Hgb <10g/dL
    - Anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy when Hgb <10g/dL and there is a minimum of two additional months of planned chemotherapy
    - Anemic members with lab value showing Hgb >10 and < 13g/dL, who are at high risk for perioperative transfusions secondary to significant, and anticipated blood loss and are scheduled to undergo elective, non-cardiac, or nonvascular surgery to reduce the risk for allogeneic blood transfusions
    - Anemia associated with the use of ribavirin when Hgb <10g/dL OR a 3g/dL decrease from baseline Hgb with symptoms. If ribavirin is being prescribed as part of a triple-therapy regimen (including a protease inhibitor), documentation that an attempt at ribavirin dose reduction was not able to resolve the anemia must be provided
- Must be on supplemental iron therapy if serum ferritin saturation (TSAT) is below 20%
- Must not have uncontrolled hypertension (Systolic >140 mmHg or diastolic >90 mmHg). Blood pressure should be controlled prior to start of therapy and monitored closely throughout treatment.



- Must not have a known hypersensitivity to the active substance or any of the

excipients of the product
- Member must have been evaluated for other causes of anemia (e.g. vitamin deficiency, bleeding, metabolic or chronic inflammatory conditions)

3. Methoxy polyethylene glycol-epoetin beta (Mircera)
- Must be prescribed by or in consultation with a nephrologist or hematologist
- Must be age 5 years or older
- Must have anemia due to chronic kidney disease and Hgb <10g/dL (labs must be within 30 days)
- Must be on supplemental iron therapy if serum transferrin saturation (TSAT) is <20%
- Must not have uncontrolled hypertension (Systolic >140 mmHg or diastolic >90 mmHg). Blood pressure should be controlled prior to start of therapy and monitored closely throughout treatment.
- Must not have a known hypersensitivity to the active substance or any of the excipients of the product
- Member must have been evaluated for other causes of anemia (e.g. vitamin deficiency, bleeding, metabolic or chronic inflammatory conditions)

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. ESA Products will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

	Products
Preferred	• **Aranesp® (darbepoetin alfa)** • **Retacrit® (epoetin alfa-epbx)**
Non-preferred	• **Epogen, Procrit® (epoetin alfa)** • **Mircera® (epoetin beta)**

<u>Note: Requests for reauthorization of non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products</u>

1. Darbepoetin alfa (Aranesp) and epoetin alfa (Epogen, Retracrit, or Procrit)
MPC Renewal:
- Must have the following supporting laboratory documentation based on diagnosis (labs must be within the past 3 months):

  - Anemia of chronic renal failure and on renal dialysis and Hgb <11g/dL
  - Anemia of chronic renal failure not requiring dialysis and Hgb <10g/dL
  - Anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy and Hgb <12g/dL
  - Anemia associated with myelodysplastic syndrome and Hgb <12g/dL
  - Zidovudine treatment-induced anemia in HIV members when lab value showing <12g/dL [Epogen, Procrit, or Retacrit only]
  - Anemia associated with the use of ribavirin and Hgb <12g/dL
- Must be on supplemental iron therapy if serum ferritin saturation (TSAT) is below 20%
- Member has a documented clinical improvement while on therapy as determined by the prescriber
- Member's hemoglobin must have increased greater than or equal to 1 g/dL from pre-treatment level after at least 12 weeks of therapy
- Must be prescribed by or in consultation with a nephrologist, hematologist/oncologist, gastroenterologist, hepatologist, transplant physician, or an infectious disease physician

Renewal from Previous Insurer:
- Members who have received prior approval (from insurer other than MPC) and have been taking Darbepoetin alfa (Aranesp) and epoetin alfa (Epogen, Retracrit, or Procrit) or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria). Provider has a documented clinical response of the member's condition which has stabilized improved compared to baseline

2. Methoxy polyethylene glycol-epoetin beta (Mircera)
MPC Renewal:
- Must have the following supporting laboratory documentation based on diagnosis (labs must be within the past 3 months):
  - Anemia due to chronic kidney disease and on dialysis and Hgb <11g/dL
  - Anemia due to chronic kidney disease not requiring dialysis and Hgb <10g/dL
- Must be on supplemental iron therapy if serum ferritin saturation (TSAT) is below 20%
- Member has a documented clinical improvement while on therapy as determined by the prescriber
- Member's hemoglobin must have increased greater than or equal to 1 g/dL from pre-treatment level after at least 12 weeks of therapy
- Must be prescribed by or in consultation with a nephrologist or hematologist

Renewal from Previous Insurer:
- Members who have received prior approval (from insurer other than MPC) and have been taking Mircera, or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).

- Provider has a documented clinical response of the member's condition which has stabilized or improved compared to baseline

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	3 months
Reauthorization	Anemia associated with Ribavirin: 2 months All other indications: 6 months

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J0881	Injection, darbepoetin alfa, 1 microgram (non-esrd use)
J0882	Injection, darbepoetin alfa, 1 microgram (for esrd on dialysis)
J0885	Injection, epoetin alfa, (for non-esrd use), 1000 units
J0886	Injection, epoetin alfa, 1000 units (for esrd on dialysis)
J0888	Injection, epoetin beta, 1 microgram, (for non-esrd use)
Q4081	Injection, epoetin alfa, 100 units (for esrd on dialysis)
Q5105	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for esrd on dialysis), 100 units
Q5106	Injection, epoetin alfa-epbx, biosimilar, (for non-esrd use), 1000 units

REFERENCES

1. Epogen [package insert]. Thousand Oaks, CA: Amgen; July 2018.
2. Procrit [package insert]. Horsham, PA: Janssen; July 2018.
3. Mircera [package insert]. South San Francisco, CA: Hoffmann-La Roche Inc; June 2018.
4. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc; February 2019.
5. Retacrit [package insert]. Lake Forest, IL: Hospira, Inc; September 2020.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Update to reauthorization criteria to add preferred vs non-preferred medication table	*07/2026*
Annual Review	*02/2026*
Removal of Eviti review for oncology related indications	*07/2025*

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2025*
Annual policy review. Update to reauthorization criteria for non-MPC renewals	*02/2024*
Annual Review	*02/2023*
New Policy	*11/2022*