Washington State Health Care Authority

Hematopoietic Agents :
Erythropoiesis-Stimulating Agents (ESAs)

Medical policy no. 82.40.10 Effective Date: July 1, 2019

Note:

- *For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO* preferred agents.*
  **If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed*
- *If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria*

Background:

Endogenous erythropoietin (EPO) is used to stimulate red blood cell (RBC) production in the bone marrow. Suppression of erythropoietin production or suppression of the bone marrow response to erythropoietin results in anemia in several disease processes, including chronic kidney disease (CKD), many types of cancer treatment, other chronic diseases, and use of certain drugs.

Medical necessity:

Drug	Medical Necessity
Darbepoetin Alfa (ARANESP®) Epoetin Alfa (EPOGEN®) Epoetin Alfa (PROCRIT®) Epoetin Alfa-epbx (RETACRIT®) Methoxy Peg-Epoetin Beta (MIRCERA®)	Erythropoiesis-Stimulating Agents may be considered medically necessary when used for ONE of the following conditions: 1. Treatment of anemia of prematurity for less than 6 months of age; **OR** 2. Treatment of anemia associated with chronic kidney disease (CKD) – (including patients on dialysis and not on dialysis); **OR** 3. Anemia associated with zidovudine-treated HIV-infected patients; **OR** 4. Treatment of anemia of cancer patients on chemotherapy, where the intent of treatment is palliative; **OR** 5. Treatment of anemia associated with myelodysplastic syndrome to reduce transfusion dependency; **OR** 6. Treatment of patients after allogeneic bone marrow transplantation; **OR** 7. Treatment of anemia due to ribavirin in patients who did not experience an improvement in hemoglobin level with ribavirin dose reduction; **OR** 8. To reduce the need for blood transfusions in anemic patients scheduled to undergo high-risk surgery who are at increased risk or intolerant to transfusions; **OR** 9. Special circumstance patients who will not or cannot receive whole blood or components as replacement for traumatic or surgical loss

Clinical policy:

Indication	Clinical Criteria (Initial Approval)
Anemia associated with chronic kidney disease (CKD) – (including patients on dialysis and not on dialysis)	1. Diagnosis of chronic kidney disease (CKD); **AND** 2. Most recent hemoglobin level less than 10 g/dL; **AND** 3. Documentation of adequate iron stores as indicated by current (within the last 3 months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%. If ALL criteria are met, the request will be approved for 6 months
	Criteria (Reauthorization)
	1. Hemoglobin level less than 11 g/dL documented in the previous 3 months; **AND** 2. Documentation of positive clinical response (e.g., as evidenced by decrease in blood transfusions) submitted by the prescriber. If ALL criteria are met, the request will be approved for 12 months
Indication	**Clinical Criteria (Initial Approval)**
Anemia of prematurity	1. Documentation of refusal of transfusion due to religious or cultural reasons; **AND** 2. Patient is less than 6 months of age; **AND** 3. Most recent hemoglobin level less than 10 g/dL. If ALL criteria are met, the request will be approved for 3 months
	Criteria (Reauthorization)
	1. Patient is less than 6 months of age; **AND** 2. Hemoglobin level is less than 11 g/dL; **AND** 3. Documentation of positive clinical response submitted by the prescriber. If ALL criteria are met, the request will be approved for 3 months
Indication	**Clinical Criteria (Initial Approval)**
Other specific anemia indications	1. Patient must have at least ONE of the following conditions: a. anemia associated with zidovudine-treated HIV-infected patients; **OR** b. anemia of cancer patients on chemotherapy, where the intent of treatment is palliative; **OR** c. anemia associated with myelodysplastic syndrome to reduce transfusion dependency; **OR** d. anemia after allogeneic bone marrow transplantation; **OR** e. anemia due to ribavirin in patients who did not experience an improvement in hemoglobin level with ribavirin dose reduction; **OR** f. to reduce the need for blood transfusions in anemic participants scheduled to undergo high-risk surgery who are at increased risk or intolerant to transfusions; **OR**

	g. special circumstance patients who will not or cannot receive whole blood or components as replacement for traumatic or surgical loss; **AND** 2. Most recent hemoglobin level less than 10 g/dL If ALL criteria are met, the request will be approved for 3 months
	Criteria (Reauthorization)
	1. Hemoglobin level less than 11 g/dL documented in the previous 3 months; **AND** 2. Documentation of positive clinical response (e.g., as evidenced by decrease in blood transfusions) submitted by the prescriber. If ALL criteria are met, the request will be approved for 6 months

Preferred therapies:

Drug Name	Preferred For:
Darbepoetin Alfa (ARANESP®) Epoetin Alfa (EPOGEN®)	Preferred for all medically necessary indications when clinical criteria is met

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
J0881	500 units (500 mcg) per DOS
J0882	300 billing units (300 mcg) per DOS
J0885	60 billing units (60,000 unit dose) per DOS
J0886	600 billing units (60,000 unit dose) per week
J0887	360 billing units (360 mcg) per DOS
J0888	360 billing units (360 mcg) per DOS
Q4081	100 billing units (10,000 units) per DOS
Q5105	600 billing units (60,000 units) per week
Q5106	60 billing units (60,000 units) per week

Coding:

HCPCS Code	Description
J0881	Injection, darbepoetin alfa, 1 mcg (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)
J0887	Injection, epoetin beta, 1 microgram, (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, biosimilar (Retacrit), 100 units (for ESRD on dialysis)
Q5106	Injection, epoetin alfa, biosimilar (Retacrit), 1000 units (for non-ESRD use)

References

1. Product Information: ARANESP® intravenous injection, subcutaneous injection, darbepoetin alfa intravenous injection, subcutaneous injection. Amgen Inc (per FDA), Thousand Oaks, CA, 2017.
2. Product Information: Epogen® intravenous injection, subcutaneous injection, epoetin alfa intravenous injection, subcutaneous injection. Amgen Inc (per FDA), Thousand Oaks, CA, 2017
3. Product Information: Procrit® intravenous injection, subcutaneous injection, epoetin alfa intravenous injection, subcutaneous injection. Janssen Products LP (per FDA), Horsham, PA, 2017
4. Product Information: RETACRIT™ intravenous, subcutaneous injection, epoetin alfa-epbx intravenous, subcutaneous injection. Hospira, Inc (per FDA), Lake Forest, IL, 2018
5. Product Information: Mircera® intravenous injection, subcutaneous injection, methoxy polyethylene glycol epoetin beta intravenous injection, subcutaneous injection. Hoffmann-La Roche Inc. (per FDA), South San Francisco, CA, 2015
6. KDIGO Clinical Practice Guidelines for Anemia in Chronic Kidney Disease. Kidney International Supplements. 2012; 2(4): 279-335.
7. National Comprehensive Cancer Network Guidelines Version 3.2018. Cancer- and Chemotherapy-Induced Anemia.

History

Date	Action and Summary of Changes
05.06.2019	New Policy