Policy Title:	Erythropoiesis stimulating agents: Retacrit (epoetin alfa), Epogen (epoetin alfa), Procrit(epoetin alfa), Aranesp (darbepoetin alfa)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/18/2019		
Revision Date:	09/18/2019		

Purpose: To support safe, effective and appropriate use of Erythropoiesis stimulating agents.

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Erythropoiesis stimulating agents are covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Erythropoiesis stimulating agents will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

Retacrit (epoetin alfa), Epogen (epoetin alfa), Procrit(epoetin alfa):

- Patient must have one of the following indications:
  - Patient has anemia due to myelosuppressive chemotherapy and meet the following criteria:
    - Patients have a non-myeloid malignancy
    - Patient has a minimum of two additional months of planned chemotherapy
    - The intent of chemotherapy is non-curative
    - Pretreatment hemoglobin < 10 g/dL; OR
  - Anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis with pretreatment hemoglobin < 10 g/dL; OR
  - Anemia due to zidovudine in patients with HIV-infection with pretreatment hemoglobin < 10 g/dL; OR
  - Reduction of Allogeneic Red Blood Cell Transfusion in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery and patients are scheduled to have an elective, noncardiac, nonvascular surgery when the pretreatment hemoglobin is > 10 to ≤ 13 g/dL; OR
  - Symptomatic anemia in patients with myelodysplastic syndromes (MDS) with pretreatment hemoglobin < 10 g/dL; OR
  - Anemia in congestive heart failure (CHF) with pretreatment hemoglobin < 9 g/dL; OR

- Anemia in rheumatoid arthritis (RA) with pretreatment hemoglobin < 10 g/dL; OR
- Anemia due to hepatitis C treatment in patients with pretreatment hemoglobin < 10 g/dL who are receiving ribavirin in combination with either interferon alfa or peginterferon alfa; OR
- Anemia in patients whose religious beliefs forbid blood transfusions with pretreatment hemoglobin < 10 g/dL; OR
- Anemia due to cancer in patients who have cancer and are undergoing palliative treatment; OR
- Symptomatic anemia in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis and meet all of the following criteria:
  - Member has symptomatic anemia
  - Pretreatment hemoglobin < 10 g/dL
  - Pretreatment serum erythropoietin level < 500 mU/mL ; AND

- For patients requesting Epogen (epoetin alfa) or Procrit (epoetin alfa) they must have a documented intolerable adverse event to Retacrit (epoetin alfa), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information OR
- For patients that are currently on treatment with Epogen (epoetin alfa) or Procrit (epoetin alfa) they can remain on treatment.

Aranesp (darbepoetin alfa):

- Patient must have one of the following indications:
  - Patient has anemia due to myelosuppressive chemotherapy and meet the following criteria:
    - Patients have a non-myeloid malignancy
    - The intent of chemotherapy is non-curative
    - Patient has a minimum of two additional months of planned chemotherapy
    - Pretreatment hemoglobin < 10 g/dL; OR
  - Anemia in patients with CKD with pretreatment hemoglobin < 10 g/dL; OR
  - Symptomatic anemia in patients with myelodysplastic syndromes (MDS) with pretreatment hemoglobin < 10 g/dL; OR
  - Anemia in patients whose religious beliefs forbid blood transfusions with pretreatment hemoglobin < 10 g/dL; OR
  - Anemia due to cancer in patients who are undergoing palliative treatment; OR
  - Symptomatic anemia in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis and meet all of the following criteria:
    - Member has symptomatic anemia
    - Pretreatment hemoglobin < 10 g/dL
    - Pretreatment serum erythropoietin level < 500 mU/mL

Renewal Coverage (Retacrit (epoetin alfa), Epogen (epoetin alfa), Procrit(epoetin alfa), Aranesp (darbepoetin alfa)):

For all indications below: all members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of ESA treatment must show a response with a rise in hemoglobin of ≥ 1 g/dL. Members who completed less than 12 weeks of ESA treatment and have not yet responded with a rise in hemoglobin of ≥ 1 g/dL may be granted authorization of up to 12 weeks to allow sufficient time to demonstrate a response.

- Anemia due to CKD and the current hemoglobin is ≤ 12 g/dL;
- Patient has anemia due to myelosuppressive chemotherapy and meet the following criteria:
    - Patients have a non-myeloid malignancy
    - Patient has a minimum of two additional months of planned chemotherapy
    - The intent of chemotherapy is non-curative
    - Pretreatment hemoglobin < 11 g/dL
- Anemia due to zidovudine in patients with HIV-infection with current hemoglobin ≤ 12 g/dL;
- Anemia in MDS and the current hemoglobin is ≤ 12 g/dL;
- Anemia in CHF or RA and current hemoglobin is ≤ 12 g/dL;
- Anemia due to Hepatitis C treatment and patient meets all of the following criteria:
    - The member is receiving ribavirin in combination with either interferon alfa or peginterferon alfa
    - The current hemoglobin is ≤ 12 g/dL
- Anemia in patients whose religious beliefs forbid blood transfusions and current hemoglobin is ≤ 12 g/dL
- Anemia in in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis and current hemoglobin is ≤ 12 g/dL;
- Anemia due to cancer in patients who are undergoing palliative treatment;

Dosage and Administration:
Retacrit (epoetin alfa), Epogen (epoetin alfa), Procrit(epoetin alfa)

Indication	Dose
Anemia due to CKD	• Adults: 50-100 units/kg intravenously or subcutaneously three times weekly • Pediatric patients: 50 units/kg intravenously or subcutaneously three times weekly
Anemia due to HIV on zidovudine	• 100 units/kg three times weekly • May titrate up to 300 units/kg
Anemia due to chemotherapy	• Adults: 150 units/kg intravenously or subcutaneously three times weekly or 40,000 units once weekly o May titrate up to 300 units/kg three times weekly or 60,000 units once weekly

	• Pediatric patients (5-18 years): 600 units/kg intravenously or subcutaneously once weekly ○ May titrate up to 900 units/kg once weekly
Perioperative use	• 300 units/kg/day subcutaneously for 10 days before surgery, on the day of surgery, and for 4 days after surgery (15 days total) • 600 units/kg/dose subcutaneously on days 21, 14, and 7 before surgery plus 1 dose on the day of surgery (4 total doses)
Anemia due to MDS/MPN	• 150-300 units/kg intravenously or subcutaneously three times weekly • 40,000 to 60,000 units once to twice weekly
All other indications	Dosing varies; generally up to 150 units/kg intravenously or subcutaneously three times weekly

Dosage and Administration:
Aranesp (darbepoetin alfa)

Indication	**Dose**
Anemia due to myelosuppressive chemotherapy	• Initiate at 2.25 mcg/kg subcutaneously every 7 days; may increase up to 4.5 mcg/kg every 7 days for insufficient response • Initiate at 500 mcg subcutaneously every 21 days
Anemia due to CKD-Not on dialysis	Adults • Initiate at 0.45 mcg/kg intravenously or subcutaneously every 28 days Pediatric patients • Initiate at 0.45 mcg/kg intravenously or subcutaneously every 7 days or 0.75 mcg/kg every 14 days
Anemia due to MDS and myeloproliferative neoplasms	• Up to 300 mcg subcutaneously every 7 days • Initiate at 500 mcg subcutaneously every 21 days
Most common weekly dose	• Up to 200 mcg
Most common every 2 week dose	• Up to 300 mcg
Most common every 3 week dose	• Up to 500 mcg

Billable Units:

Drug	**Billable unit**
Epogen/Procrit (non-ESRD use)	1000 IU = 1 billable unit
Retacrit (non-ESRD use)	1000 IU = 1 billable unit
Aranesp (non-ESRD use)	1mcg = 1 billable unit

Coverage durations: 12 weeks

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
Q5106	Injection, epoetin alfa, biosimilar, (retacrit) (for non-esrd use), 1000 units
J0885	Injection, epoetin alfa, (for non-esrd use), 1000 units
J0881	Injection, darbepoetin alfa, 1 mcg (non-esrd use)

Note: The following HCPCS codes Q5105, Q4081 & J0882 are NOT covered under this policy, but are covered under the dialysis bundle.

References:

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4. Retacrit package insert. New Yok, NY: Hospira, Inc; January 2019.
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15. Cervantes F, Alvarez-Larran A, Hernandez-Boluda JC, et al. Erythropoietin treatment of the anemia of myelofibrosis with myeloid metaplasia: results in 20 patients and review of the literature. Br J Haematol. 2004;127(4):399-403.