MEDICAL MUTUAL®

Drug Policy

Policy:	**201832**	**Initial Effective Date: 04/01/2013**
Code(s):	**HCPCS J0885 and Q5106**	**Annual Review Date: 09/20/2018**
SUBJECT:	**Erythroid Stimulating Agents – Epoetin Alfa Products** - Epogen® (epoetin alfa) - Procrit® (epoetin alfa) - **Retacrit™ (epoetin alfa-epbx)***	**Last Revised Date: 12/28/2018**

*** Retacrit™ (epoetin alfa-epbx) is the preferred epoetin alfa product**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Epoetin alfa is an erythroid stimulating agent (ESA) that is approved for the following indications:[1-3]

- Treatment of anemia of chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis, to decrease the need for red blood cell (RBC) transfusions.
- Treatment of anemia due to zidovudine in human immunodeficiency virus (HIV)-infected patients.
- Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
- Reduction of allogeneic blood transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

Epoetin alfa is given intravenously (IV) or subcutaneously (SC). These agents are supplied as a solution in single-dose and multidose vials, both with preservatives and preservative-free. The products are available in various strengths.

In 2018, the U.S. Food and Drug Administration (FDA) approved Hospira's Retacrit™ (epoetin alfa-epbx), a biosimilar to Epogen® (Amgen) and Procrit® (Janssen). Retacrit is approved for treating anemia caused by chronic kidney disease, chemotherapy, or the use of zidovudine in patients with HIV infection. It is also approved to reduce the chance that a red blood cell transfusion will be needed in patients undergoing elective, noncardiac, nonvascular surgery. These are the same indications as Epogen and Procrit. The dose of Retacrit varies depending on the indication

POLICY STATEMENT

This policy involves the use of epoetin alfa. **This policy does not apply to Medicare or Medicare Advantage members.** Prior authorization is recommended for pharmacy and medical benefit coverage of epoetin alfa. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing (medical benefit requests only), Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis. **Retacrit™ (epoetin alfa-epbx) is the preferred epoetin alfa product. Patient must have a**

documented failure, contraindication, intolerance, or ineffective response to Retacrit for a non-preferred epoetin alfa product to be considered for approval.

Because of the specialized skills required for evaluation and diagnosis of patients treated with epoetin alfa as well as the monitoring required for AEs and long-term efficacy, initial approval requires epoetin alfa be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

The site of care medical necessity criteria applies to initial therapy and reauthorizations under the medical benefit.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of epoetin alfa is recommended in those who meet the following criteria:

1. **Anemia in Patients with Chronic Kidney Disease (CKD) who are on Dialysis. – No prior approval needed for this indication.**

   Criteria. *The patient must meet the following criteria (A, B, C, D, and E)*:
   A. For initial therapy, hemoglobin (Hb) is < 10.0 g/dL for adults and ≤ 11.0 g/dL for children; OR
      For patients currently receiving Aranesp, epoetin alfa, or Mircera (methoxy polyethylene glycol-epoetin beta injection for intravenous or subcutaneous use), Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children; AND
   B. The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%).
   C. Evaluation for other causes of anemia, including nutritional causes, has been performed and condition treated as appropriate; AND
   D. If the request is for an epoetin alfa product other than Retacrit, patient must have a documented failure, contraindication, intolerance or ineffective response to Retacrit; AND
   E. Site of care medical necessity is met*.

   Dosing in Patients with CKD who are on Dialysis. *Dosing must meet ONE the following (A OR B):*
   A) For adults, initiate therapy at 50 to 100 Units/kg three times weekly (TIW) IV or SC;[1-3] OR
   B) For pediatric patients initiate therapy at 50 Units/kg TIW SC or IV.[1-3]

   Initial Approval/Extended Approval.
   A) *Initial Approval*. Initial approval is for 6 months if Hb is < 10.0 g/dL for adults and ≤ 11.0 g/dL for children.
   B) *Extended Approval*. Extended approval is at 6-month intervals if the Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children and the patient responds to therapy. Response is defined as Hb has increased, Hb has stayed the same and not decreased further, RBC transfusions are not required, and/or the number of RBC transfusions has decreased. For patients not responding, discontinue epoetin alfa and evaluate and treat for other causes of anemia.

Duration of Therapy in Patients with CKD who are on Dialysis. Indefinite as long as the patient has CKD and is receiving dialysis.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:
A) Monitor Hb at therapy initiation and at 6-month intervals; AND
B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, percent transferrin saturation [TSAT], bone marrow biopsy) must be evaluated at therapy initiation and at 6-month intervals, unless the patient is currently receiving iron therapy.

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2. Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis.

Criteria. *The patient must meet the following criteria (A, B, C, D and E)*:
A) For initial therapy Hb is < 10.0 g/dL for adults and ≤ 11.0 g/dL for children; OR
For patients currently receiving Aranesp or epoetin alfa, Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children OR for patients currently receiving Mircera, Hb is ≤ 11.5 g/dL for adults; AND
B) The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%).
C) Evaluation for other causes of anemia, including nutritional causes, has been performed and condition treated as appropriate; AND
D) If the request is for an epoetin alfa product other than Retacrit, patient must have a documented failure, contraindication, intolerance or ineffective response to Retacrit; AND
E) Site of care medical necessity is met*.

Dosing in Patients with CKD who are not on Dialysis. *Dosing must meet ONE of the following (A OR B):*[1-3]
A) Initiate therapy in adults at 50 to 100 Units/kg TIW IV or SC; OR
B) Initiate therapy in children at 50 Units/kg TIW IV or SC.

Initial Approval/Extended Approval.
A) *Initial Approval*. Initial approval is for 6 months if Hb is < 10.0 g/dL for adults and ≤ 11.0 g/dL for children.
B) *Extended Approval*. Extended approval is at 6-month intervals if the Hb is ≤ 11.5 g/dL for adults and ≤ 12.0 g/dL for children and the patient responds to therapy. Response is defined as Hb has increased, Hb has stayed the same and not decreased further, RBC transfusions are not required, and/or the number of RBC transfusions has decreased. For patients not responding discontinue epoetin alfa and evaluate and treat for other causes of anemia.

Duration of Therapy in Patients with CKD who are not on Dialysis. Indefinite as long as the patient has CKD.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:
A) Monitor Hb at therapy initiation and at 6-month intervals; AND
B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation and at 6-month intervals, unless the patient is currently receiving iron therapy.

3. Patients with Anemia and Human Immunodeficiency Virus (HIV) who are Receiving Zidovudine.

Criteria. *The patient must meet the following criteria (A, B, C, D AND E)*:[1-3,5]
A) The patient is currently receiving zidovudine therapy; AND
B) Hb is ≤ 10.0 g/dL for initial therapy; OR
endogenous erythropoietin levels are ≤ 500 mUnits/mL for initial therapy; OR
Hb is ≤ 12.0 g/dL for patients currently receiving epoetin alfa; AND
C) The patient is currently receiving iron therapy or iron stores are adequate (e.g., epoetin alfa prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%); AND
D) If the request is for an epoetin alfa product other than Retacrit, patient must have a documented failure, contraindication, intolerance or ineffective response to Retacrit; AND
E) Site of care medical necessity is met*.

Dosing for Patients with Anemia and HIV who are Receiving Zidovudine. *Dosing must meet ONE of the following (A OR B)*:
A) For adults initiate at 100 Units/kg IV or SC TIW for 8 weeks and increase up to 300 Units/kg TIW; OR
B) For pediatric patients, the dose is 50 to 400 Units/kg SC or IV two to three times per week.
Note: Refer to the epoetin alfa prescribing information for titration of the dose.

Initial Approval/Extended Approval.
A) *Initial Approval*. Initial approval is for 4 months.
B) *Extended Approval*. Approval can be given at 4-month intervals if the Hb is ≤ 12.0 g/dL and the patient responds to therapy. Response is defined as Hb has increased, Hb has stayed the same and not decreased further, RBC transfusions are not required, and/or the number of RBC transfusions has decreased. If no response is achieved, discontinue therapy and evaluate for other causes of anemia. If the patient does not have a response, discontinue epoetin alfa. Discontinue epoetin alfa when the patient stops zidovudine therapy.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:
A) Monitor Hb or serum erythropoietin levels at therapy initiation and monitor Hb at 4-month intervals; AND
B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation and at 4-month intervals, unless the patient is currently receiving iron therapy.

4. Anemia in Patients with Cancer due to Cancer Chemotherapy.

Criteria. *The patient must meet the following criteria (A, B, C, D and E)*:
A. Hb is < 10.0 g/dL for initial therapy; OR
Hb is ≤ 12.0 g/dL for patients currently receiving Aranesp or epoetin alfa; AND
B. The patient is currently receiving myelosuppressive chemotherapy; AND

C. The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum tranferrin saturation is < 20%); AND
D. If the request is for an epoetin alfa product other than Retacrit, patient must have a documented failure, contraindication, intolerance or ineffective response to Retacrit; AND
E. Site of care medical necessity is met*.

Dosing in Anemia due to Cancer Chemotherapy. *Dosing must meet ONE of the following (A, B, C, D, OR E)*:
Adults
A) 150 Units/kg TIW SC (increase up to 300 Units/kg TIW SC)[1-3,6] until completion of a chemotherapy course; OR
B) 40,000 Units once every week SC (increase dose to 60,000 Units every week by SC injection)[1-3,7] until completion of a chemotherapy course; OR
C) 80,000 Units once every 2 weeks SC until completion of a chemotherapy course; OR[6]
D) 120,000 Units once every 3 weeks SC until completion of a chemotherapy course; OR[6]
Pediatric patients (aged 5 to 18 years)
E) 600 Units/kg IV weekly[1-3] until completion of a chemotherapy course.

Note: Different doses and intervals between doses have been used for initiating therapy and for adjusting the dose to maintain a response. Examples of some initial and maximum doses of epoetin alfa are listed above. Use the lowest dose needed to avoid RBC transfusions. Dosing modifications are determined by the prescribing physician.

Initial Approval/Extended Approval.
A) *Initial Approval*. Initial approval is for 4 months if Hb is < 10.0 g/dL.
B) *Extended Approval*. Approval can be given at 4-month intervals if the Hb is ≤ 12.0 g/dL and the patient responds to therapy. Response is defined as Hb has increased, Hb has stayed the same and not decreased further, RBC transfusions are not required, and/or the number of RBC transfusions has decreased. If the patient does not have a response, discontinue epoetin alfa. Discontinue epoetin alfa following completion of a chemotherapy course.

During of Therapy in Anemia due to Cancer Chemotherapy. Indefinite as long as the patient is receiving myelosuppressive chemotherapy.

Labs/Diagnostics. *Patients must meet the following criteria (A AND B)*:
A) Monitor Hb at therapy initiation and at 4-month intervals; AND
B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation and at 4-month intervals, unless the patient is currently receiving iron therapy.

5. Reduction of Allogeneic Red Blood Cell (RBC) Transfusions in Patients Undergoing Surgery.

Criteria. *The patient must meet the following criteria (A, B, C, D, E AND F)*:
A) Hb level is ≤ 13.0 g/dL; AND
B) The surgery is elective, nonvascular and noncardiac; AND

C) The patient is not willing or able to donate autologous blood prior to surgery; AND
D) The patient is currently receiving iron therapy or iron stores are adequate (e.g., epoetin alfa prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%); AND
E) If the request is for an epoetin alfa product other than Retacrit, patient must have a documented failure, contraindication, intolerance or ineffective response to Retacrit; AND
F) Site of care medical necessity is met*

Dosing in Patients Undergoing Surgery (to Reduce Allogeneic RBC Transfusions). *Dosing must meet ONE the following (A OR B)*:
A) 300 Units/kg/day SC for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery; OR
B) 600 Units/kg SC in doses administered 21, 14, and 7 days before surgery and on the day or surgery.

Initial Approval/Extended Approval. Approve for 1 month.

During of Therapy in Patients Undergoing Surgery (to Reduce Allogeneic RBC Transfusions). Approve for use before surgery for up to 1 month.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:
A) Monitor Hb at therapy initiation; AND
B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation unless the patient is currently receiving iron therapy.

Other Uses with Supportive Evidence

6. Anemia Associated with Myelodysplastic Syndrome (MDS).

Criteria. *The patient must meet the following criteria (A, B, C, D, E, F AND G)*:
A. Patient is ≥ 18 years of age; AND
B. Hb is ≤ 10 g/dL for initial therapy; OR
serum erythropoietin level is ≤ 500 mU/mL for initial therapy; OR
Hb is ≤ 12.0 g/dL for patients currently receiving Aranesp or epoetin alfa; AND
C. Epoetin alfa is prescribed by, or in consultation with, a hematologist or oncologist; AND
D. The patient is currently receiving iron therapy or iron stores are adequate (e.g., Aranesp prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum tranferrin saturation is < 20%).
E. Evaluation for other causes of anemia, including nutritional causes, has been performed and condition treated as appropriate; AND
F. If the request is for an epoetin alfa product other than Retacrit, patient must have a documented failure, contraindication, intolerance or ineffective response to Retacrit; AND
G. Site of care medical necessity is met*.

Dosing in MDS. *Dosing must meet the following*: 40,000 to 60,000 Units 1 to 2 times per week SC.[16]

Initial Approval/Extended Approval.

A) *Initial Approval*. Initial approval is for 6 months if Hb is ≤ 10 g/dL OR the serum erythropoietin level is ≤ 500 mU/mL.

B) *Extended Approval*. Approve at additional 6-months intervals if a response is achieved (increase in Hb or a decrease in transfusions) and Hb is ≤ 12.0 g/dL. For patients not responding, despite dose titrations and/or concomitant use of G-CSF (e.g., Neupogen® [filgrastim injection]) during the first 6 months, discontinue epoetin alfa and evaluate and treat for other causes of anemia.

Duration of Therapy in Myelodysplastic Syndrome (MDS). Indefinite as long as the patient has MDS.

Labs/Diagnostics. *Patient must meet the following criteria (A AND B)*:

A) Monitor Hb or serum erythropoietin levels at therapy initiation and monitor Hb at 6-month intervals; AND

B) Iron stores (for example, serum iron, total iron binding capacity, serum ferritin, TSAT, bone marrow biopsy) must be evaluated at therapy initiation and at 4-month intervals, unless the patient is currently receiving iron therapy.

Waste Management for All Indications.

Single-dose vials and syringes are available in many different strengths. The dose should be calculated and the number of vials/syringes needed assessed. Refer the corresponding package insert for more information.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Epoetin alfa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Anemia Associated with Cancer in Patients not Receiving Myelosuppressive Cancer Chemotherapy.** Epoetin alfa is not indicated in cancer patients who are not receiving cancer chemotherapy.[1-3] The American Society of Clinical Oncology (ASCO)/American Society of Hematology (ASH) guidelines for the use of epoetin alfa and Aranesp in adult patients with cancer recommend that ESAs not be used in treatment of anemia associated with malignancy in those who are not receiving concurrent myelosuppressive chemotherapy.[6]

2. **Anemia Associated with Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML) or other Myeloid Cancers.** Epoetin alfa is indicated for use in non-myeloid cancers. AML and CML are examples of myeloid cancers.[1-3]

3. **Anemia Associated with Radiotherapy in Cancer.** Epoetin alfa is not indicated for use in patients with cancer who are only given radiation therapy.[1-3]

4. **To Enhance Athletic Performance.** Epoetin alfa is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

5. **Anemia in Patients due to Acute Blood Loss.** Use of epoetin alfa is not appropriate in these types of situations.

6. **Non-Anemic Patients (Hemoglobin [Hb] > 13.0 g/dL) prior to Surgery.** Although studies have been done that involved non-anemic patients undergoing various surgeries receiving epoetin alfa preoperatively and sometimes postoperatively to prevent transfusions or subsequent anemia, the overall benefit of this therapy in those with relatively normal preoperative Hb level is questionable.

7. Coverage is not recommended for circumstances not listed in the Recommended Authorization criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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OTHER REFERENCES UTILIZED

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FOR MEDICAL BENEFIT COVERAGE REQUESTS

*MMO Site of Care Medical Necessity Criteria:

- Medications in this policy will be administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met[†]:

    1. Age is less than 18* years; or
    2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
    3. History of a severe adverse event from previous administration of the prescribed medication; or
    4. Requested medication is being administered as follows:
        - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
        - administered with dialysis; or
    5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
    6. Up to 1 dose of medication or re-initiation after at least 12 months; or
    7. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.

†This criterion does not apply to Medicare or Medicare Advantage members.

Prior approval is required for HCPCS Codes J0885 and Q5106.

HCPCS Code(s):	
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units 60
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units