Erythropoiesis-stimulating agents

Epogen (epoetin alfa) J0885, and Procrit (epoetin alfa) J0886, Retacrit (epoetin alpha-epbx) Q5105/Q5106 are non-preferred. The preferred product is Aranesp (darbepoetin alfa) J0881/J0882, Mircera (epoetin beta) J0887/J0888, Epogen (biosimilar-epoetin alfa) Q4081

Prior Authorization Step Therapy

Medicare Part B Request Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Erythropoiesis-Stimulating Agents PA

Drug Name(s):

ARANESP **EPOGEN**
MIRCERA
PROCRIT **RETACRIT**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: **Mircera, Aransep, Epoetin (biosimilar)** OR
   - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Aranesp - Prescribed for ONE of the following diagnoses:

- Anemia due to and following chemotherapy - Neoplastic disease, Non-myeloid
- Anemia of chronic renal failure

Epogen/Procrit - Prescribed for ONE of the following diagnoses:

- Anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.
- Anemia due to zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL.
- 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.
- To reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively.

Mircera

- Anemia of chronic renal failure

Off-Label Uses:

Aranesp

- The American Society of Clinical Oncology/American Society of Hematology Clinical Practice Guidelines titled "Use of Epoetin and Darbepoetin in Patients With Cancer" state that some evidence supports the use of darbepoetin alfa in patients with anemia associated with low-risk myelodysplasia

Epogen/Procrit

- Anemia: due to:
  - Congestive heart failure
  - Radiation
  - During the puerperium
  - Hepatitis C, In patients being treated with a combination of ribavirin and interferon alfa or ribavirin and peginterferon alfa
  - Multiple myeloma
  - Myelodysplastic syndrome
  - Myelofibrosis
  - Prematurity
  - Rheumatoid arthritis
- Beta thalassemia
- Blood unit collection for autotransfusion
- Iron overload – transfusion

Step Therapy Drug(s) and FDA Indications:

Epoetin alpha-epbx (Retacrit)

FDA Indications:

- Anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.
- Anemia due to zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL.
- 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.
- To reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively.

Off-Label Uses:

- Symptomatic anemia in patients with myelodysplastic syndromes (MDS)
- Anemia in congestive heart failure
- Anemia in rheumatoid arthritis
- Anemia due to hepatitis C treatment with ribavirin in combination with either interferon alfa or peginterferon alfa
- Anemia in patients whose religious beliefs forbid blood transfusions
- Symptomatic anemia in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
- Anemia in patients with malignancy.

Age Restrictions:
N/A

Other Clinical Consideration:
N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout

https://careweb.careguidelines.com/ed24/ac/ac04_021.htm