Updated: 05/2019
PARP Approved: 06/2019

Prior Authorization Criteria

Erythropoiesis Stimulating Agents

All requests for Erythropoiesis Stimulating Agents require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Erythropoiesis Stimulating Agents include Aranesp (darbepoetin alfa), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx), Mircera (methoxy polyethylene glycol-epoetin beta). New products with this classification will require the same documentation.

For all requests for Erythropoiesis Stimulating Agents all of the following criteria must be met:

- Medication is prescribed by, or in consultation with, a hematologist, oncologist, nephrologist, or infectious disease specialist.
- Member has been evaluated for other causes of anemia (e.g., vitamin deficiency, bleeding, metabolic or chronic inflammatory conditions, etc.).
- Must have adequately controlled blood pressure
- Member's iron status has been evaluated prior to and during erythropoietin therapy. Transferrin saturation (TSAT) should be ≥20% and serum ferritin ≥100 ng/mL or the member should be on concurrent iron therapy.
- If hemoglobin exceeds a threshold listed below, prescriber must indicate erythropoietin will be held or titrated downward.
- Lab results (e.g., hemoglobin) must be from within 30 days of the request.
- For non-formulary agents, the member has had a trial and failure of a formulary agent or a clinically submitted reason for not having a trial of a formulary agent
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Examples of products and corresponding FDA-approved indications:

Indication	Product
Anemia of chronic renal disease	Aranesp, Epogen, Mircera, Procrit, Retacrit
Anemia due to myelosuppressive chemotherapy	Aranesp, Epogen, Procrit, Retacrit
Anemia due to treatment with zidovudine in HIV	Epogen, Procrit, Retacrit
Therapy to reduce the need for allogeneic blood transfusions in surgery	Epogen, Procrit, Retacrit

Coverage may be provided for anemia of chronic renal disease when the following criteria is met:

- Hemoglobin < 10 g/dL
- **Initial Duration of Approval**: 3 months
- **Reauthorization Criteria**:
  - Hemoglobin ≤ 10 g/dL for members not on dialysis OR Hemoglobin ≤ 11 g/dL for members on dialysis
  - Must be on concurrent iron therapy unless both the transferrin saturation (TSAT) ≥20% and serum ferritin ≥100 ng/mL
- **Reauthorization Duration of Approval**: 6 months

Coverage may be provided for anemia due to myelosuppressive chemotherapy when the following criteria is met:

- Member will be receiving myelosuppressive chemotherapy for ≥ 2 months
- Hemoglobin < 10 g/dL
- **Initial Duration of Approval**: 3 months
- **Reauthorization Criteria**:
  - Documentation of a minimum of 2 more months of chemotherapy is planned
  - Hemoglobin ≤ 12 g/dL
  - Must be on concurrent iron therapy unless both the transferrin saturation (TSAT) ≥20% and serum ferritin ≥100 ng/mL
- **Reauthorization Duration of Approval**: 6 months

Coverage may be provided for anemia due to treatment with zidovudine in HIV when the following criteria is met:

- Hemoglobin < 10 g/dL
- Member has a serum erythropoietin level ≤ 500 mUnits/mL
- Member is receiving a dose of zidovudine ≤ 4200 mg/week
- **Initial Duration of Approval**: 3 months
- **Reauthorization Criteria**:
  - Hemoglobin ≤ 12 g/dL
  - Must be on concurrent iron therapy unless both the transferrin saturation (TSAT) ≥20% and serum ferritin ≥100 ng/mL
- **Reauthorization Duration of Approval**: 6 months

Coverage may be provided to reduce the need for allogeneic blood transfusions in surgery patients when the following criteria is met:

- Member is scheduled to undergo elective, noncardiac, nonvascular surgery
- Hemoglobin must be >10 g/dL and ≤ 13 g/dL
- **Initial Duration of Approval**: 1 month
- **Reauthorization Criteria**:
  - Provided on a case by case basis, refer to initial criteria for reauthorization
- **Reauthorization Duration of Approval**: 1 month

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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ERYTHROPOETIN STIMULATING AGENTS
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE: _____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:

☐ Anemia of chronic renal disease
- Is the member currently on dialysis? ☐ Yes ☐ No

☐ Anemia due to myelosuppressive chemotherapy
- Will the member be receiving myelosuppressive chemotherapy for ≥ 2 months? ☐ Yes ☐ No

☐ Anemia due to treatment with zidovudine in HIV
- Erythropoietin Level: _____ mUnits/mL Date drawn: _____
- Weekly zidovudine dose: _____ mg/week

☐ Therapy to reduce the need for allogeneic blood transfusions
- Is the member scheduled to undergo elective, noncardiac, nonvascular surgery? ☐ Yes, date: _____ ☐ No

Is the member currently receiving iron supplementation? ☐ Yes ☐ No
Have the member's iron stores been evaluated through an iron study? ☐ Yes ☐ No If **yes**, date of test: _____
Specify serum ferritin (ng/mL) level: _____ Specify transferrin saturation (TSAT) %: _____

Has the member been evaluated for other causes of anemia? ☐ Yes ☐ No

Is blood pressure adequately controlled? ☐ Yes ☐ No

What is the member's current hemoglobin level (lab results must be from within 30 days of the request)?
Hemoglobin level (g/dL): _____ Date: _____

Will erythropoietin be held or titrated downward if hemoglobin exceeds the recommended goal? ☐ Yes ☐ No

Has the member required RBC transfusions? ☐ Yes, please describe: _____ ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date