| Prior Authorization | Fundhuan sissis Stimulating Agents (FSAs) |
|------------------------------|---|
| Group Description | Erythropoiesis-Stimulating Agents (ESAs) |
| Drugs | Preferred: Retacrit (epoetin alfa-epbx) Mircera (methoxy peg-epoetin beta): (Available under the medical benefit for requests for anemia of chronic kidney disease (CKD) only) Non-preferred: Aranesp (darbepoetin alfa-polysorbate 80) Procrit (epoetin alfa) Epogen (epoetin alfa) |
| Covered Uses | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria | N/A |
| Required Medical Information | See "Other Criteria" |
| Age Restrictions | According to package insert |
| Prescriber Restrictions | N/A |
| Coverage Duration | If criteria are met, the request will be approved for up to 1 month if the member is deficient in iron, vitamin B12, folate, or in the persurgical setting, and up to 3 months for all other requests. |
| Other Criteria | Existing ESA users who are NEW to the plan: Documentation of current dose Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines The members HgB is within the following indication specific range: Anemia of CKD: ≤ 11 g/dL Anemia related to cancer: ≤ 12 g/dL Zidovudine related anemia in members with HIV: HgB ≤ 12 g/dL Ribavirin-induced anemia: HgB ≤ 12g/dL Initial Authorization for all requests: Drug is being prescribed for an FDA-approved indication at an FDA-approved dose or is otherwise supported by the compendia or standard-of-care guidelines All submitted lab results have been drawn within 30 days of the request The following lab results must be submitted: |

- o Hemoglobin (HgB)
- o Hematocrit (HCT)
- The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
 - o Serum ferritin level (> 100ng/mL)
 - o Transferrin saturation (TSAT) (> 20%)
 - o Vitamin B12 level (> 223pg/mL)
 - o Folate level (> 3.1 ng/mL)
- If the request is for a non-preferred ESA the member has tried and failed a preferred ESA or has a documented medical reason (e.g., intolerance, hypersensitivity, contraindication) why the preferred ESAs cannot be used.

Requests for anemia of CKD:

• HgB < 10 g/dL

Requests for anemia related to chemotherapy in cancer patients:

The member must have a documented cancer diagnosis for which they will be receiving myelosuppressive therapy for palliative treatment for at least two additional months (members receiving myelosuppressive therapy with curative intent should not receive ESAs) AND documented symptomatic anemia with HgB < 10 g/dL

The member has symptomatic anemia related to myelodysplastic syndrome AND documented serum erythropoietin level ≤ 500 mU/mL

Requests for zidovudine-related anemia in HIV:

The member is currently receiving highly active antiretroviral therapy (HAART) **AND** has a documented serum erythropoietin level ≤ 500 mU/mL

Requests for ribavirin-induced anemia:

- Member is currently receiving ribavirin and a documented attempt to reduce dose has been made
- Hgb < 12 g/dL

Requests for members undergoing surgery to reduce the need for allogenic blood transfusion:

- Perioperative HgB < 13g/dL and > 10 g/dL.
- The member is scheduled for an elective, non-cardiac, nonvascular surgery.

Reauthorization:

- All submitted lab results have been drawn within 30 days of the reauthorization request.
- The following lab results must be submitted:
 - o Hemoglobin (HgB)
- The following lab results must be submitted and demonstrate normal values, otherwise, the member <u>MUST</u> be receiving, or is beginning therapy, to correct the deficiency:
 - o Serum ferritin level (> 100ng/mL)
 - o Transferrin saturation (TSAT) (> 20%)
 - o Vitamin B12 level (> 223pg/mL)
 - o Folate level (> 3.1 ng/mL)
- The members HgB is within the following indication specific range:
 - o Anemia of CKD: $\leq 11 \text{ g/dL}$
 - o Anemia related to cancer: $\leq 12 \text{ g/dL}$
 - o Zidovudine related anemia in members with HIV: HgB $\leq 12 \text{ g/dL}$
 - o Ribavirin-induced anemia: $HgB \le 12g/dL$

For requests that fall outside of these parameters, or if the criteria are not met, the request will be referred to a Medical Director/clinical reviewer for medical necessity review.

Revision/Review Date: 10/2023