July 27, 2018

**DARBEPOETIN ALFA (ARANESP®) FOR ESRD WILL REQUIRE PRIOR AUTHORIZATION**

Dear Provider,

Darbepoetin alfa (Aranesp®) for use in patients with end-stage renal disease (ESRD) will be added to the list of non-Medicare medical benefit drugs requiring prior authorization.

**Effective October 1, 2018,** prior authorization review will be required for darbepoetin alfa (Aranesp®) for ESRD (J0882). This letter is a notification of the upcoming change in prior authorization approval required before administering this medication in a physician’s office.

Kaiser Foundation Health Plan of Washington requires prior authorization for a select group of injectable drugs that may be administered under the medical benefit in a physician’s office or by home infusion. These reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Kaiser Permanente Pharmacy & Therapeutics Committee’s evidence-based criteria for coverage.

**Prior Authorization Criteria for darbepoetin alfa (Aranesp®):**

- **Epoetin alpha is the preferred agent.** Darbepoetin will be covered when a clinical rationale is provided describing why epoetin alfa cannot be used.

- **End-stage renal disease (ESRD) or chronic kidney disease of at least stage 3 (eGFR < 60)**
  - Hb ≤ 10g/dL within 7 days (Unless medical documentation showing need, e.g. severe angina, severe pulmonary distress, severe hypertension).
  - TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*.
  - B12 and folate not deficient.
  - Patient does not have ongoing bleeding disorders or hemolysis.

- **Chemotherapy-induced anemia. Patients currently receiving a course of chemotherapy or have received a course within the past 2 months for non-myeloid, non-erythroid cancer (e.g. solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia).**
  - Hb ≤ 10g/dL or Hb 10-11 within 7 days and clinical risk of anemia warrants earlier initiation.
  - TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*.
  - B12 and folate not deficient.
  - Patient does not have ongoing bleeding disorders or hemolysis.
  - Patient does not have metastatic breast cancer or head and neck cancer.
Myelodysplastic syndrome (MDS); chronic hepatitis C (under treatment with ribavirin and either interferon alfa or peginterferon alfa); systemic lupus erythematosus; or patient taking chemotherapeutic medications when medically necessary for non-cancer diagnosis or following stem cell transplantation and associated immunosuppression.

- Hb < 10g/dL within 7 days.
- TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*.
- B12 and folate not deficient.
- Patient does not have ongoing bleeding disorders or hemolysis.
- Symptomatic anemia (fatigue, SOB).

Re-authorization

- Target Hb <12 g/dL within 7 days.
- Absence of ongoing bleeding disorder, hemolysis, and bone marrow fibrosis.

*TSAT (Transferrin saturation) measured as a percentage, is the ratio of serum iron and total iron-binding capacity, multiplied by 100.

*CMS regulations allow for measurement of either hemoglobin or hematocrit using the conversion of hematocrit = 3x hemoglobin (e.g., Hct 30% = Hb 10).

Additional Information

A complete list of office-administered injectable drugs requiring prior authorization is available on Kaiser Permanente for Providers at https://provider.ghc.org under Referrals & Clinical Review.

To request prior authorization review, please use the Referral Request online form on the provider website listed above. You can also fax your request to Review Services toll-free at 1-888-282-2685.

Thank you for the care you provide to our members, your patients. If you have any questions about this process, please call Review Services at 1-800-289-1363.

Sincerely,

Bruce Wilson, MD, Chair
Pharmacy & Therapeutics Committee