Effective date: 9/1/2020
Review date: 7/2020 Scope: Medicaid

NON-ONCOLOGY POLICY

ARANESP (darbepoetin alfa)

For oncology indications, please refer to NHPRI Erythropoiesis Stimulating Agents (ESA) and Biosimilar Oncology Policy

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Anemia Due to Chronic Kidney Disease
   Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.

B. Compendial Uses

1. Anemia in patients whose religious beliefs forbid blood transfusions

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores or are receiving iron therapy before starting Aranesp. Members may not use Aranesp concomitantly with other erythropoiesis stimulating agents. **The member must have tried and failed or have a contraindication to Retacrit**

A. Anemia Due to Chronic Kidney Disease (CKD)
Authorization of 12 weeks may be granted for treatment of anemia due to chronic kidney disease in members with pretreatment hemoglobin < 10 g/dL.

B. Anemia in Members Whose Religious Beliefs Forbid Blood Transfusions
Authorization of 12 weeks may be granted for treatment of anemia in members whose religious beliefs forbid blood transfusions with pretreatment hemoglobin < 10 g/dL.

III. CONTINUATION OF THERAPY

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. Members may not use Aranesp concomitantly with other erythropoiesis stimulating agents.

For all indications below: All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of ESA treatment must show a response with a rise in hemoglobin of ≥ 1 g/dL. Members who completed less than 12 weeks of ESA treatment and have not yet responded with a rise in hemoglobin of ≥ 1 g/dL may be granted authorization of up to 12 weeks to allow for sufficient time to demonstrate a response.

A. Anemia due to Chronic Kidney Disease (CKD)
Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin < 12 g/dL.

B. Anemia in members whose religious beliefs forbid blood transfusions
Authorization of 12 weeks may be granted for continued treatment of anemia in members whose religious beliefs forbid blood transfusions with current hemoglobin < 12 g/dL.

IV. REFERENCES

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2019.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 13, 2019.
3. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012; Suppl 2:279-335.
4. National Kidney Foundation. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. http://www2.kidney.org/professionals/KDOQI/guidelines_anemiaUP/. Accessed September 15, 2019.