blue of california

ARANESP (darbepoetin alfa)

Diagnoses Considered for Coverage:

- Anemia due to Chronic Renal Failure (CRF)
- Anemia due to myelosuppressive chemotherapy
- Anemia due to Myelodysplastic Syndrome (MDS)
- Anemia due to myelofibrosis
- Anemia in patient with cancer who are undergoing palliative treatment

Coverage Criteria:

For anemia due to Chronic Renal Failure (CRF):

Initial Authorization

• Patient is NOT on hemodialysis or peritoneal dialysis, **and**
• Hgb ≤ 10 g/dl, **and**
• Dose does not exceed 200 mcg per week, **and**
• One of the following:
  • Hgb does not meet target at the max dose of Retacrit for 8 weeks**, or**
  • Contraindication to Retacrit that is not a contraindication to Aranesp**, or**
  • Side effect to Retacrit that would not be expected with Aranesp**, or**
  • Patient has a religious belief objecting to treatment with a drug containing human albumin.
 	
Coverage Duration: 1 year

Reauthorization
• Patient is NOT on hemodialysis or peritoneal dialysis, **and** • Hgb ≤11 g/dl, **and** • Dose does not exceed 200 mcg per week. ***Coverage Duration:*** 1 year

For anemia in patients with cancer who are undergoing palliative treatment

• Patient is undergoing palliative treatment, **and** • Hgb ≤10 g/dl, **and** • Dose does not exceed 300 mcg per week, **and** • One of the following:

- Contraindication to Retacrit that is not a contraindication to Aranesp, or
- Side effect to Retacrit that would not be expected with Aranesp, or
- Patient has a religious belief objecting to treatment with a drug containing human albumin.

Coverage Duration: 1 year

For anemia due to myelosuppressive cancer chemotherapy:

- Patient is currently on chemotherapy or has completed their last dose of chemotherapy within the past 8 weeks, or is currently on Revlimid (lenalidomide) therapy for multiple myeloma, **and**
- Hgb ≤10 g/dl, **and**
- Dose does not exceed 200 mcg per week or 300 mcg every 2 weeks or 500 mcg every 3 weeks, **and**
- One of the following:
  - Hgb does not meet target or is not maintained at a stable level at the max dose of Retacrit for 8 weeks, or
  - Contraindication to Retacrit that is not a contraindication to Aranesp, or
  - Side effect to Retacrit that would not be expected with Aranesp, or
  - Patient has a religious belief objecting to treatment with a drug containing human albumin.

Coverage Duration: duration of chemotherapy not greater than 8 weeks after the last dose of chemotherapy

For myelodysplastic syndromes (MDS)

- Symptomatic anemia (Hgb of less than 10 g/dL), and
- Either of the following:
  - Patient has isolated 5q chromosome deletion [del (5q)], **or**
  - Baseline serum EPO < 500 mU/ml drawn prior to Aranesp therapy, AND
- Dose does not exceed 500 mcg every other week, **and**
- Patient has an inadequate response, is intolerant to, or is contraindicated to Retacrit as defined by one of the following:
  - Hgb does not meet target or is not maintained at a stable level at the max dose of Retacrit for 8 weeks, **or**
  - Contraindication to Retacrit that is not a contraindication to Aranesp, **or**

- Side effect to Retacrit that would not be expected with Aranesp, **or**
- Patient has a religious belief objecting to treatment with a drug containing human albumin.

Coverage Duration: 1 year

For myelofibrosis-associated anemia

- Baseline serum EPO < 500 mU/ml drawn prior to Aranesp therapy, AND
- Symptomatic anemia (Hgb of less than 10 g/dL)
- Dose does not exceed 300 mcg every week, **and**
- One of the following:
  - Hgb does not meet target or is not maintained at a stable level at the max dose of Retacrit for 8 weeks, **or**
  - Contraindication to Retacrit that is not a contraindication to Aranesp, **or**
  - Side effect to Retacrit that would not be expected with Aranesp, **or**
  - Patient has a religious belief objecting to treatment with a drug containing human albumin.

Coverage Duration: 1 year

References:

1. Aranesp® (darbepoetin alfa) Prescribing Information. Thousand Oaks, CA: Amgen, Inc. 1/2019.
2. Erythropoiesis-Stimulating Agents (ESAs) in Chronic Kidney Disease: FDA Drug Safety Communication – Modified Dosing Recommendations. 6-24-11.
3. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Volume 1.2022).
4. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Volume 3.2022).
5. National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Volume 2.2022).
6. Rizzo JD, Brouwers M, Hurley P et al. American Society of Clinical Oncology/American Society of Hematology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. J Clin Oncol. 2010;28(33):4996-5010.
7. Tsiara SN, Chaidos A, Bourantas LK et al. Recombinant human erythropoietin for the treatment of anemia in patients with chronic myelofibrosis. Acta Haematol 2007; 117(3): 156-61.

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