MEDICARE PART D COVERAGE CRITERIA

ARANESP (darbepoetin)

Plan Limitations:
- Applies to all Blue Shield of California Medicare Part D plans

Diagnoses Considered for Coverage:
- All FDA-approved indications not otherwise excluded from Part D
- Anemia due to Multiple Myeloma
- Anemia due to Myelodysplastic Syndrome (MDS)

Coverage Criteria:

1) Anemia due to Chronic Renal Failure (CRF) or End Stage Renal Disease (ESRD):
   Initial authorization:
   - Dose does not exceed FDA label maximum for the diagnosis, AND
   - One of the following:
     - Hgb does not meet target or is not maintained at a stable level at the maximum dose of Procrit for 8 weeks, OR
     - Patient has a contraindication to Procrit that is not a contraindication to Aranesp, OR
     - Patient has a side effect to Procrit that would not be expected with Aranesp, OR
     - Patient has a religious belief objecting to treatment with a drug containing human albumin.
   Reauthorization:
   - Hgb ≤ 12 g/dl or Hct ≤ 36%, AND
   - Dose does not exceed FDA label maximum for the diagnosis.

2) Anemia due to cancer/myelosuppressive chemotherapy:
   Initial authorization:
   - Patient is using Aranesp concurrently with chemotherapy OR final dose of myelosuppressive chemotherapy was given within the last 8 weeks, AND
   - Diagnosis is a solid organ tumor, lymphoma or lymphocytic leukemia, AND
   - Hgb < 10g/dl or Hct < 30%, AND
   - Patient does not have uncontrolled HTN, AND
   - Dose does not exceed FDA label maximum for the diagnosis, AND
   - One of the following:
     - Hgb does not meet target or is not maintained at a stable level at the maximum dose of Procrit for 8 weeks, OR
     - Patient has a contraindication to Procrit that is not a contraindication to Aranesp, OR
     - Patient has a side effect to Procrit that would not be expected with Aranesp, OR
     - Patient has a religious belief objecting to treatment with a drug containing human albumin.

Reauthorization:
• Patient is using Aranesp concurrently with chemotherapy OR final dose of myelosuppressive chemotherapy was given within the last 8 weeks, AND
• Current Hgb ≤ 12g/dl or Hct ≤ 36% within the last 21 days, AND
• Dose does not exceed FDA label maximum for the diagnosis.

3) Anemia due to Multiple Myeloma:

Initial authorization:
• Patient is using Aranesp concurrently with chemotherapy OR final dose of myelosuppressive chemotherapy was given within the last 8 weeks OR patient is currently on Revlimid therapy, AND
• Hgb < 10g/dl or Hct < 30%, AND
• Patient does not have uncontrolled HTN, AND
• Dose does not exceed FDA label maximum for the diagnosis, AND
• One of the following:
  o Hgb does not meet target or is not maintained at a stable level at the maximum dose of Procrit for 8 weeks, OR
  o Patient has a contraindication to Procrit that is not a contraindication to Aranesp, OR
  o Patient has a side effect to Procrit that would not be expected with Aranesp, OR
  o Patient has a religious belief objecting to treatment with a drug containing human albumin.

Reauthorization:
• Patient is using Aranesp concurrently with chemotherapy OR final dose of myelosuppressive chemotherapy was given within the last 8 weeks OR patient is scheduled for upcoming myelosuppressive chemotherapy OR patient is currently on Revlimid therapy, AND
• Current Hgb ≤ 12g/dl or Hct ≤ 36% within the last 21 days, AND
• Dose does not exceed FDA label maximum for the diagnosis.

4) Anemia due to Myelodysplastic Syndrome (MDS):

Initial authorization:
• Patient has symptomatic anemia, AND
• EPO level ≤ 500U/ml, AND
• Dose does not exceed FDA label maximum for the diagnosis, AND
• One of the following:
  o Hgb does not meet target or is not maintained at a stable level at the maximum dose of Procrit for 8 weeks, OR
  o Patient has a contraindication to Procrit that is not a contraindication to Aranesp, OR
  o Patient has a side effect to Procrit that would not be expected with Aranesp, OR
  o Patient has a religious belief objecting to treatment with a drug containing human albumin.

Reauthorization after 3 months:
• Current Hgb ≤ 12 g/dl or Hct ≤ 36%, AND
• There is a ≥ 1.5 g/dl increase in Hgb OR there is a reduction in frequency of blood transfusions compared to baseline, AND
• Dose does not exceed FDA label maximum for the diagnosis.

**Reauthorization after 6 months:**
• Current Hgb ≤ 12 g/dl or Hct ≤ 36%, AND
• Patient maintains a stable Hgb OR there is a reduction in the frequency of blood transfusions compared to baseline, AND
• Dose does not exceed FDA label maximum for the diagnosis.

**Coverage Duration:** Up to 6 months

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