MEDICARE PART D COVERAGE CRITERIA

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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:

***Excluded from Part D if meets coverage criteria under Part B***

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 is equal or less than 12 g/dl or Hct is equal or less than 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 is less than 10g/dl or Hct is less than 30%, 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 is equal or less than 12g/dl or Hct is equal or less than 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 is less than 10g/dl or Hct is less than 30%, 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, OR
- Patient is scheduled for upcoming myelosuppressive chemotherapy, OR
- Patient is currently on Revlimid therapy, AND
- Current Hgb is equal or less than 12g/dl or Hct is equal or less than 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 is equal or less than 500U/ml, 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.
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**Reauthorization after 3 months:**
- Current Hgb equal or less than 12 g/dl or Hct is equal or less than 36%, AND
- There is a 1.5 g/dl or higher 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 is equal or less than 12g/dl or Hct is equal or less than 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:** 6 months

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