Aranesp® (Darbepoetin alfa)

**EPOGEN IS PREFERRED AND WILL BE REIMBURSED THROUGH AN AUTO-PRIOR AUTHORIZATION VIA DIAGNOSIS**

**LENGTH OF AUTHORIZATION: UP TO SIX MONTHS**

**REVIEW CRITERIA:**

- **Anemia associated with chronic kidney disease if patient is not on dialysis:**
  - **Initial Therapy** – Patient must meet all requirements below:
    1. Hemoglobin < 10 g/dL.
    2. Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
    3. Lab data within 2 months of PA submission.
  - **Continuation of Therapy** - Patient must meet all requirements below:
    1. Hemoglobin ≤ 10 g/dL.
    2. Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
    3. Lab data within 2 months of PA submission.

- **Anemia associated with chronic kidney disease if patient is receiving home dialysis:**
  - **Initial Therapy** – Patient must meet all requirements below:
    1. Hemoglobin < 10 g/dL.
    2. Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
    3. Lab data within 2 months of PA submission.
  - **Continuation of Therapy** - Patient must meet all requirements below:
    1. Hemoglobin ≤ 11 g/dL.
    2. Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
    3. Lab data within 2 months of PA submission.

- **Anemia associated with chemotherapy:**
  - **Initial Therapy** - Patient must meet all requirements below:
    1. No existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.
    2. Hemoglobin < 10 g/dL.
    3. Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
    4. Providers must submit documentation of enrollment in the ESA APPRISE Oncology Program.
    5. Must be on or initiating chemotherapy.
  - **Continuation of Therapy** - Patient must meet all requirements below:
    1. No existing history of iron or folate deficiency, hemolysis, or gastrointestinal bleeding.
    2. Hemoglobin < 10 or lowest level sufficient to avoid transfusion.
    3. Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.

Supplemental iron therapy is recommended for all patients whose serum ferritin is below 100 mcg/L or whose serum transferrin saturation is below 20%.
**DOSING INFORMATION:**

**Chronic Kidney Disease Patients**

**Starting Dose:**
- **For patients not on dialysis** the recommended starting dose is 0.45 mcg/kg body weight intravenously or subcutaneously given once at four week intervals as appropriate.
- **For patients on dialysis** the recommended starting dose is 0.45 mcg/kg intravenously or subcutaneously as a weekly injection or 0.75 mcg/kg once every 2 weeks as appropriate. The intravenous route is recommended for patients on hemodialysis.

**Dose Adjustment:** When initiating or adjusting therapy, monitor hemoglobin levels at least weekly until stable, then monitor at least monthly. When adjusting therapy consider hemoglobin rate of rise, rate of decline, ESA responsiveness and hemoglobin variability. A single hemoglobin excursion may not require a dosing change. Do not increase the dose more frequently than once every 4 weeks. Decreases in dose can occur more frequently. Avoid frequent dose adjustments. If the hemoglobin rises rapidly (e.g., more than 1 g/dL in any 2-week period), reduce the dose of Aranesp by 25% or more as needed to reduce rapid responses. For patients who do not respond adequately, if the hemoglobin has not increased by more than 1 g/dL after 4 weeks of therapy, increase the dose by 25%. For patients who do not respond adequately over a 12-week escalation period, increasing the Aranesp dose further is unlikely to improve response and may increase risks. Use the lowest dose that will maintain a hemoglobin level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue Aranesp if responsiveness does not improve.

**Cancer Patients Receiving Chemotherapy**

**Starting Dose:** The recommended starting dose and schedules are:
- 2.25 mcg/kg every week subcutaneously until completion of a chemotherapy course
- 500 mcg every 3 weeks subcutaneously until completion of a chemotherapy course

**Dose Adjustment:**

<table>
<thead>
<tr>
<th>Dose Adjustment</th>
<th>Weekly Schedule</th>
<th>Every 3 Week Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>If hemoglobin increases greater than 1 g/dL in any 2-week period or If hemoglobin reaches a level needed to avoid RBC transfusion</td>
<td>Reduce dose by 40%</td>
<td>Reduce dose by 40%</td>
</tr>
<tr>
<td>If hemoglobin exceeds a level needed to avoid RBC transfusion</td>
<td>Withhold dose until hemoglobin approaches a level where RBC transfusions may be required. Reinitiate at a dose 40% below the previous dose</td>
<td>Withhold dose until hemoglobin approaches a level where RBC transfusions may be required. Reinitiate at a dose 40% below the previous dose</td>
</tr>
<tr>
<td>If hemoglobin increases by less than 1 g/dL and remains below 10 g/dL after 6 weeks of therapy</td>
<td>Increase dose to 4.5 mcg/kg/week</td>
<td>No dose adjustment</td>
</tr>
<tr>
<td>If there is no response as measured by hemoglobin levels or if RBC transfusions are still required after 8 weeks of therapy</td>
<td>Discontinue Aranesp</td>
<td>Discontinue Aranesp</td>
</tr>
</tbody>
</table>
Following completion of a chemotherapy course

**Conversion From Procrit (Epoetin alfa) to Aranesp**
The starting weekly dose of Aranesp for adults and pediatric patients should be estimated on the basis of the weekly Epoetin alfa dose at the time of substitution (see Table). For pediatric patients receiving a weekly Epoetin alfa dose of < 1,500 units/week, the available data are insufficient to determine an Aranesp conversion dose. Due to the longer serum half-life, Aranesp should be administered less frequently than Epoetin alfa. Aranesp should be administered once a week if a patient was receiving Epoetin alfa 2 to 3 times weekly. Aranesp should be administered once every 2 weeks if a patient was receiving Epoetin alfa once per week. The route of administration (intravenous or subcutaneous) should be maintained.

**Estimated Aranesp Starting Doses (mcg/week) for Patients with Chronic Kidney Disease on Dialysis Based on Previous Epoetin alfa Dose (Units/week)**

<table>
<thead>
<tr>
<th>Previous Weekly Epoetin alfa Dose (Units/week)</th>
<th>Aranesp Dose (mcg/week)</th>
<th>Adult</th>
<th>Pediatric</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1,500</td>
<td>6.25</td>
<td>6.25</td>
<td>See text*</td>
</tr>
<tr>
<td>1,500 to 2,499</td>
<td>6.25</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>2,500 to 4,999</td>
<td>12.5</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>5,000 to 10,999</td>
<td>25</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>11,000 to 17,999</td>
<td>40</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>18,000 to 33,999</td>
<td>60</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>34,000 to 89,999</td>
<td>100</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>≥ 90,000</td>
<td>200</td>
<td>200</td>
<td></td>
</tr>
</tbody>
</table>

The dose conversion depicted in the Table does not accurately estimate the once monthly dose of Aranesp in patients with chronic kidney disease not on dialysis.