Harvard Pilgrim Health Care

# Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

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| **Guideline Name** | **Hematinic Agents**:<br>Aranesp (darbepoetin alfa), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx), Mircera (methoxy peg-epoetin beta) |

## 1. Criteria

| Product Name: Aranesp | |
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| Approval Length | 12 Week(s) |
| Therapy Stage | Initial Authorization |
| Guideline Type | Prior Authorization |

**Approval Criteria**

**1** - ONE of the following:

**1.1** Prescribed for the treatment of anemia due to ONE of the following conditions:
- Chronic kidney disease (CKD)
- Patient whose religious beliefs forbid blood transfusions
- Cancer and receiving palliative treatment
- Myelosuppressive chemotherapy and the patient has a non-myeloid malignancy

**OR**

**1.2** BOTH of the following:
- Prescribed for the treatment of anemia due to Primary Myelofibrosis (MF), Post-polycythemia Vera MF, Post-Essential Thrombocythemia MF, or Myelodysplastic Syndrome (MDS); AND
- Pre-treatment serum erythropoietin level less than 500mU/mL

**AND**

**2** - Patient has a documented pre-treatment hemoglobin level less than 10g/dL*

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| Notes | *Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion |

| Product Name: Aranesp* | |
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| Therapy Stage | Reauthorization |
| Guideline Type | Prior Authorization |

**Approval Criteria**

**1** - ONE of the following:

**1.1** Patient has not yet completed 12-weeks of treatment

**OR**

**1.2** ALL of the following:

**1.2.1** Anemia due to ONE of the following conditions:
- Chronic kidney disease (CKD)
- Myelodysplastic Syndrome (MDS)
- Patient whose religious beliefs forbid blood transfusions
- Primary Myelofibrosis (MF), Post-polycythemia Vera MF, or Post-Essential Thrombocythemia MF
- Cancer and receiving palliative treatment
- Myelosuppressive chemotherapy and the patient has a non-myeloid malignancy

**AND**

**1.2.2** Current hemoglobin is less than or equal to 12g/dL

**AND**

**1.2.3** Response to therapy is noted with a hemoglobin increase of at least 1g/dL from baseline

| Notes | *Approval Duration: 12 weeks or up to 12 weeks for patients who did not complete the initial 12 weeks of therapy |
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| Product Name: Epogen, Procrit, or Retacrit | |
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| Therapy Stage | Initial Authorization |
| Guideline Type | Prior Authorization |

**Approval Criteria**

**1** - BOTH of the following:

**1.1** Prescribed for the treatment of anemia due to ONE of the following conditions:
- Chronic kidney disease (CKD)

- Myelosuppressive chemotherapy with non-myeloid malignancy
- Myelodysplastic Syndrome (MDS) with a pre-treatment serum erythropoietin level < 500 mU/mL
- Rheumatoid arthritis (RA)
- Hepatitis C treatment and the patient is receiving ribavirin in combination with either interferon alfa or peginterferon alfa
- Zidovudine in HIV-infected patients with a pre-treatment serum erythropoietin level < 500 mU/mL
- Patient whose religious beliefs forbid blood transfusions
- Primary Myelofibrosis (MF), Post-polycythemia Vera MF, or Post-Essential Thrombocythemia MF with symptomatic anemia and a pre-treatment serum erythropoietin level < 500mU/mL
- Cancer and receiving palliative therapy

**AND**

**1.2** Patient has a pre-treatment hemoglobin less than 10gm/dL*

**OR**

**2** - Prescribed for the treatment of anemia due to Congestive Heart Failure (CHF) with a pre-treatment hemoglobin level less than 9g/dL**

**OR**

**3** - Prescribed for the treatment of reduction of allogeneic red blood cell transfusion in a patient undergoing elective, non-cardiac, nonvascular surgery with a pre-treatment hemoglobin less than 13g/dL*

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| Notes | *Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. **Approval Duration: 12 weeks or 30 days for treatment of reduction of allogeneic red blood cell transfusion in a patient undergoing elective, non-cardiac, nonvascular surgery |

| Product Name: Epogen*, Procrit*, or Retacrit* | |
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| Therapy Stage | Reauthorization |
| Guideline Type | Prior Authorization |

**Approval Criteria**

**1** - ONE of the following:

**1.1** Patient has not yet completed 12-weeks of treatment

**OR**

**1.2** ALL of the following:

**1.2.1** Anemia due to ONE of the following conditions:
- Chronic kidney disease (CKD)
- Myelodysplastic Syndrome (MDS)
- Congestive Heart Failure (CHF)
- Rheumatoid arthritis (RA)
- Hepatitis C patient receiving ribavirin in combination with either interferon alfa or peginterferon alfa
- HIV-infected patient receiving Zidovudine
- Religious beliefs forbid blood transfusions
- Primary Myelofibrosis (MF), Post-polycythemia Vera MF, or Post-Essential Thrombocythemia MF
- Cancer and receiving palliative treatment
- Myelosuppressive chemotherapy and the patient has a non-myeloid malignancy

**AND**

**1.2.2** Current hemoglobin is less than or equal to 12g/dL

**AND**

**1.2.3** Response to therapy is noted with a hemoglobin increase of at least 1g/dL from baseline

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| Notes | *Approval Duration: 12 weeks or up to 12 weeks for patients who did not complete the initial 12 weeks of therapy |

| Product Name: Mircera | |
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| Approval Length | 12 Week(s) |
| Therapy Stage | Initial Authorization |
| Guideline Type | Prior Authorization, Non-Formulary |

**Approval Criteria**

**1** - Prescribed for the treatment of anemia due to chronic kidney disease in a patient with a pre-treatment hemoglobin level less than 10g/dL*

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| Notes | *Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion |

| Product Name: Mircera* | |
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| Therapy Stage | Reauthorization |
| Guideline Type | Prior Authorization, Non-Formulary |

**Approval Criteria**

**1** - ONE of the following:

**1.1** Patient has not yet completed 12 weeks of treatment

**OR**

**1.2** ALL of the following:

**1.2.1** Response to therapy is noted with a rise in hemoglobin of at least 1gm/dL from baseline (excludes values due to recent transfusion)

**AND**

**1.2.2** Treatment of anemia due to chronic kidney disease

**AND**

**1.2.3** Current hemoglobin is less than or equal to 12gm/dL from baseline

| Notes | *Approval Duration: 12 weeks or up to 12 weeks for patients who did not complete the initial 12 weeks of therapy |
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## 2. Background

**Benefit/Coverage/Program Information**

**RATIONALE**
To ensure the appropriate use of these agents as indicated and demonstrated by low hemoglobin levels. Safety of these products has been questioned when the hemoglobin is above 11g/dL.

**FDA Approved Indications**
Epoetin alfa (Epogen, Procrit) is indicated for the treatment of:

- Anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.
- Anemia due to zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL.
- Anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Epoetin alfa is indicated to reduce the need for allogeneic red blood cell (RBC) transfusions

among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to willing to donate autologous blood preoperatively.

**Limitations of Use:**
Epoetin alfa is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- In patients scheduled for surgery who are willing to donate autologous blood.
- In patients undergoing cardiac or vascular surgery.
- As a substitute for RBC transfusions in patients who require immediate correction of anemia.

Aranesp (darbepoetin) is indicated for:

- Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.
- Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

**Limitations of Use:**

- Aranesp has not been shown to improve quality of life, fatigue, or patient well-being.
- Aranesp is not indicated for use:
    - In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
    - In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
    - As a substitute for RBC transfusions in patients who require immediate correction of anemia

Mircera (methoxy polyethylene glycol-epoetin beta) is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in:

- adult patients on dialysis and adult patients not on dialysis
- pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

**Limitations of Use:**
Mircera is not indicated and is not recommended for use:

- In the treatment of anemia due to cancer chemotherapy
- As a substitute for RBC transfusions in patients who require immediate correction of anemia

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| Created: 01/01/10 |
| P&T Approval: 12/02/19 |
| Effective: 1/1/20 |