MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY: ESA/Anemia of Chronic Disease
CLASS: Renal Disease/Genitourinary Disorders
LOB: MCL

P&T DATE: 2/12/2019
REVIEW HISTORY: 9/17, 12/16, 9/15, 9/11, 2/11

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Table 1: Available Formulary Agents (Current as of 11/2018):

<table>
<thead>
<tr>
<th>Class</th>
<th>Generic Name (Brand Name)</th>
<th>Available Strengths</th>
<th>Formulary Status</th>
<th>Notes</th>
<th>Average Cost per 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron</td>
<td>Carbonyl Iron (Icar Pediatric, Feosol Caplets)</td>
<td>15 mg chewable tablets, 45mg Tablets, 15mg/1.25mL suspension</td>
<td>NF</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Iron Sucrose (Venofer)</td>
<td>200 mg/10 mL, 100mg/5mL, 50mg/2.5mL IV Solution</td>
<td>PA</td>
<td>Documentation of appropriate diagnosis is required.</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Ferric Citrate (Auryxia)</td>
<td>210 mg Tablet</td>
<td>NF</td>
<td>--</td>
<td>$1,294.80</td>
</tr>
<tr>
<td></td>
<td>Ferrous Fumarate (Hemocyte)</td>
<td>324 mg Tablet (106 mg elemental iron)</td>
<td>NF</td>
<td>--</td>
<td>$11.71</td>
</tr>
<tr>
<td></td>
<td>Ferrous Gluconate (Fergon)</td>
<td>324 mg Tablet (38 mg elemental iron)</td>
<td>NF</td>
<td>--</td>
<td>$1.28</td>
</tr>
<tr>
<td></td>
<td>Ferrous Gluconate, preservative free (Ferate)</td>
<td>324 mg Tablet (37.5 mg elemental iron)</td>
<td>NF</td>
<td>--</td>
<td>$1.08</td>
</tr>
<tr>
<td></td>
<td>Ferrous Sulfate (Ferosul, Fer-In-Sol)</td>
<td>325mg IR Tablet, 324mg DR Tablet, 325mg ER Capsule</td>
<td>--</td>
<td>--</td>
<td>$1.74</td>
</tr>
<tr>
<td></td>
<td>Polysaccharide-iron Complex (Ferrex-150)</td>
<td>150 mg</td>
<td>NF</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Erythropoietin Stimulating Agents (ESA)</td>
<td>Epoetin Alfa (Retacrit)</td>
<td>2,000 Unit/mL Injection Solution, 3,000 Unit/mL Injection Solution, 4,000 Unit/mL Injection Solution, 10,000 Unit/mL Injection Solution, 20,000 Unit/mL Injection Solution</td>
<td>PA, SP</td>
<td>Reserved for patients who have Hemoglobin (Hgb) &lt; 9 g/dl, TSAT &gt; 20%, and ferritin &gt; 100 ng/ml.</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Epoetin Alfa (Epogen)</td>
<td>2,000 Unit/mL Injection Solution, 3,000 Unit/mL Injection Solution, 4,000 Unit/mL Injection Solution, 10,000 Unit/mL Injection Solution, 20,000 Unit/mL Injection Solution</td>
<td>PA, SP</td>
<td>Reserved for patients who have Hemoglobin (Hgb) &lt; 9 g/dl, TSAT &gt; 20%, and ferritin &gt; 100 ng/ml. Must have tried Retacrit first.</td>
<td>$724.20</td>
</tr>
<tr>
<td></td>
<td>Epoetin Alfa (Procrit)</td>
<td>2,000 Unit/mL Injection Solution, 3,000 Unit/mL Injection Solution, 4,000 Unit/mL Injection Solution, 10,000 Unit/mL Injection Solution, 20,000 Unit/mL Injection Solution</td>
<td>NF</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Darbepoetin Alfa (Aranesp)</td>
<td>25 mcg/mL Injection Solution, 40 mcg/mL Injection Solution, 60 mcg/mL Injection Solution</td>
<td>NF</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>
**EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION**

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

### Iron Supplements

**Ferrous Sulfate (Ferosul)**
- **Coverage Criteria:** None
- **Limits:** None
- **Required Information for Approval:** N/A

**Iron Sucrose (Venofer)**
- **Coverage Criteria:**
  - Venofer is reserved for patients currently on dialysis with recent labs showing TSAT ≤30% and ferritin 500 ng/mL
  - OR
  - If patient is not on dialysis, documentation that use of less invasive iron supplementation is not sufficient for treatment of the patient's iron deficiency and current labs showing TSAT ≤30% and ferritin ≤500 ng/mL.
- **Limits:** None
- **Required Information for Approval:** Documentation that use of less invasive iron supplementation is not sufficient for treatment of the patient's iron deficiency. Iron sucrose (Venofer) is approved 3 months at a time. Submission of TSAT and Ferritin levels with the prior authorization renewal request is required, which shows that TSAT ≤30% and ferritin ≤500 ng/mL.

### Erythropoietin Stimulating Agents (ESA)

**Epoetin Alfa (Retacrit, Epogen)**
- **Coverage Criteria:**
  - Retacrit is reserved for patients who have Hemoglobin (Hgb) < 9 g/dl with TSAT > 20% and serum ferritin > 100 ng/ml at initiation. Hgb should be checked monthly and is not to exceed 11 g/dl. Authorization is for 3 months at a time. For renewal, Hgb must be below 11 g/dL.
  - Epogen is reserved for patients who have Hemoglobin (Hgb) < 9 g/dl with TSAT > 20% and serum ferritin > 100 ng/ml at initiation AND treatment failure or contraindication to Retacrit. Hgb should be checked monthly and is not to exceed 11 g/dl. Authorization is for 3 months at a time. For renewal, Hgb must be below 11 g/dL.
- **Limits:** Restricted to Diplomat Specialty Pharmacy.
☐ Required Information for Approval: Submit chart notes including the patient’s most recent iron studies and CBC.

☐ Additional Notes:
- Epoetin is approved for 3 months at a time.
- Submission of Hgb levels with the prior authorization renewal request is required and must not exceed 11g/dL.

☐ Non-Formulary: Procrit

**Clinical Justification**

Studies have shown that patients who used Epoetin Alfa to target normal levels of Hgb had poor cardiovascular outcomes. These trials showed increases in mortality, nonfatal MI, and hospitalization for CHF. ESA therapy should target a Hemoglobin of less than 11 g/dL. In essence, patients should be treated only to avoid blood transfusion. Iron supplementation is required for most patients with CKD, especially those taking ESAs. Various dosage forms of ferrous sulfate are available on formulary without restriction. Iron sucrose IV solution is available for members unable to take oral iron supplements; prior authorization is required.

**Triage:**
1. Duration of Membership
2. Appropriate Diagnosis
3. Current Hemoglobin and Iron studies (TSAT, Ferritin, MCV, Serum Iron)
4. Prescribing Physician Specialty

**References**

3. KDIGO Clinical Practice Guidelines for Anemia in Chronic Kidney Disease (2012)
## REVIEW & EDIT HISTORY

<table>
<thead>
<tr>
<th>Document Changes</th>
<th>Reference</th>
<th>Date</th>
<th>P&amp;T Chairman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update to Policy</td>
<td>ESA Criteria Review 9-20-11.docx</td>
<td>9/2011</td>
<td>Allen Shek, PharmD BCPS</td>
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<tr>
<td>Update to Policy</td>
<td>HPSJ Coverage Policy - Renal - Anemia 2015-09.docx</td>
<td>9/2015</td>
<td>Jonathan Szkotak, PharmD, BCPS</td>
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<tr>
<td>Update to Policy</td>
<td>HPSJ Coverage Policy - Renal - Anemia 2016-12.docx</td>
<td>12/2016</td>
<td>Jonathan Yeh, PharmD</td>
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<td>Update to Policy</td>
<td>HPSJ Coverage Policy - Renal - Anemia 2017-09.docx</td>
<td>9/2017</td>
<td>Jonathan Yeh, PharmD</td>
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<tr>
<td>Update to Policy</td>
<td>HPSJ Coverage Policy - Renal - Anemia 2019-02.docx</td>
<td>2/2019</td>
<td>Matthew Garrett, PharmD</td>
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*Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy*