Erythropoiesis Stimulating Agents (ESAs):
Aranesp® (darboepoetin alfa)
(Subcutaneous/Intravenous)

*NON-DIALYSIS*

Last Review Date: January 1, 2019  Number: MG.MM.PH.80

Medical Guideline Disclaimer

C All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member’s benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, (“EmblemHealth”) has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Related Medical Guideline

Off-Label Use of FDA-Approved Drugs and Biologicals

LENGTH OF AUTHORIZATION

Coverage will be provided for 60 days and may be renewed.

DOISING LIMITS

Max Units (per dose and over time) [Medical Benefit]:

- MDS or MPN (J0881 only): 900 billable units every 21 days
- All other indications: 600 billable units every 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); AND
- Prior to initiation of therapy, patient should have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%; AND
- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%; AND
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; AND

Aranesp is covered for the following indication(s):
Erythropoiesis Stimulating Agents (ESAs):
Aranesp® (darbepoetin alfa)
Last review: January 1, 2019

Page 2 of 6

Anemia secondary to myelodysplastic syndrome (MDS) ‡
- Treatment of lower risk disease associated with symptomatic anemia; **AND**
- Endogenous serum erythropoietin level of ≤ 500 mUnits/mL

Anemia secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis ‡
- Endogenous serum erythropoietin level of < 500 mUnits/mL

Anemia secondary to Hepatitis C treatment ‡
- Patient must be receiving interferon **AND** ribavirin

Anemia secondary to chemotherapy treatment †
- Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
- Patient’s chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
- There are a minimum of two additional months of planned chemotherapy

Anemia secondary to chronic kidney disease (non-dialysis patients) †
† FDA approved indications; ‡ Compendium approved indications

II. **RENEWAL CRITERIA**

Coverage can be renewed based upon the following criteria:

- Last dose less than 60 days ago; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples include pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, uncontrolled hypertension), seizures, increased risk of tumor progression/recurrence in patients with cancer, etc.; **AND**
- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months*; **AND**
- Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**

Anemia secondary to myelodysplastic syndrome (MDS):
- Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%

Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis)
Erythropoiesis Stimulating Agents (ESAs):
Aranesp® (darbepoetin alfa)

Last review: January 1, 2019

Page 3 of 6

- Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%

**Anemia secondary to chemotherapy treatment**
- Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%; **AND**
- Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
- There are a minimum of two additional months of planned chemotherapy

**Anemia secondary to chronic kidney disease:**
- **Pediatric patients:** Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
- **Adults:** Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

**Anemia secondary to Hepatitis C treatment:**
- Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%; **AND**
- Patient must be receiving interferon **AND** ribavirin

* Intravenous iron supplementation may be taken into account when evaluating iron status

**Limitations/Exclusions**
Aranesp is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

**Applicable Procedure Codes**

| J0881 | Injection, darbepoetin alfa, 1 microgram (non-ESRD use) = 1 billable unit |

**Applicable NDCs**

<table>
<thead>
<tr>
<th>Single-dose Vial</th>
<th>Single-dose Prefilled Syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Vial/Pack, 4 Packs/Case</strong></td>
<td><strong>1 Syringe/Pack, 4 Packs/Case</strong></td>
</tr>
<tr>
<td>200 mcg/1 mL</td>
<td>55513-0006-01</td>
</tr>
<tr>
<td>200 mcg/0.4 mL</td>
<td>55513-0028-01</td>
</tr>
<tr>
<td>300 mcg/1 mL</td>
<td>55513-0110-01</td>
</tr>
<tr>
<td>300 mcg/0.6 mL</td>
<td>55513-0111-01</td>
</tr>
<tr>
<td>500 mcg/1 mL</td>
<td>55513-0032-01</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>4 Vials/Pack, 10 Packs/Case</strong></th>
<th><strong>4 Syringes/Pack, 10 Packs/Case</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mcg/1 mL</td>
<td>55513-0002-04</td>
</tr>
<tr>
<td>10 mcg/0.4 mL</td>
<td>55513-0098-04</td>
</tr>
<tr>
<td>40 mcg/1 mL</td>
<td>55513-0003-04</td>
</tr>
<tr>
<td>25 mcg/0.42 mL</td>
<td>55513-0057-04</td>
</tr>
<tr>
<td>60 mcg/1 mL</td>
<td>55513-0004-04</td>
</tr>
<tr>
<td>40 mcg/0.4 mL</td>
<td>55513-0021-04</td>
</tr>
<tr>
<td>100 mcg/1 mL</td>
<td>55513-0005-04</td>
</tr>
<tr>
<td>60 mcg/0.3 mL</td>
<td>55513-0023-04</td>
</tr>
<tr>
<td>150 mcg/0.75 mL</td>
<td>55513-0053-04</td>
</tr>
<tr>
<td>100 mcg/0.5 mL</td>
<td>55513-0025-04</td>
</tr>
<tr>
<td>150 mcg/0.3 mL</td>
<td>55513-0027-04</td>
</tr>
</tbody>
</table>

**Applicable Diagnosis Codes**

| B18.2 | Chronic viral hepatitis C |
| B19.20 | Unspecified viral hepatitis C without hepatic coma |
### Dual Coding Requirements:
- J0881 must be billed in conjunction with BOTH D63.1 AND one of the I or N series of codes for CKD not on dialysis
- J0881 must be billed in conjunction with BOTH D63.8 OR D64.9 AND one of the B series of codes for anemia due to HCV

### Revision History
Erythropoiesis Stimulating Agents (ESAs):
Aranesp® (darbepoetin alfa)
Last review: January 1, 2019
Page 5 of 6

N/A

References


2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) darbepoetin alfa. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.


