**STANDARD COMMERCIAL DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**DARBEPOETIN ALFA**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| DARBEPOETIN ALFA IN POLYSORBAT | ARANESP | 22890 | | GPI-10 (8240101510) | |

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #2.

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## DARBEPOETIN ALFA

**INITIAL CRITERIA (CONTINUED)**

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit
   - The patient has a hemoglobin level of less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #3.

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## DARBEPOETIN ALFA

**INITIAL CRITERIA (CONTINUED)**

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

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## DARBEPOETIN ALFA

**INITIAL CRITERIA (CONTINUED)**

**INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried the preferred medication: Retacrit
   2. You have a hemoglobin level (type of blood test) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried the preferred medication: Retacrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried the preferred medication: Retacrit
   2. You have tried or have a contraindication (harmful for) to a lower ribavirin dose
   3. You have a hemoglobin level of less than 10g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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## DARBEPOETIN ALFA

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (if on dialysis) and the dose is being reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #2.

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## DARBEPOETIN ALFA

**RENEWAL CRITERIA (CONTINUED)**

2. Does the patient have a diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy **AND** meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
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   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #3.

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## DARBEPOETIN ALFA

**RENEWAL CRITERIA (CONTINUED)**

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa **AND** meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
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   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   **RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
      2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

   ***(Renewal denial text continued on next page)***

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## DARBEPOETIN ALFA

### RENEWAL CRITERIA (CONTINUED)

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (type of blood test) of less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions
   4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and your dose is being reduced/interrupted to decrease the need for blood transfusions.

C. **If you have anemia due to the effects of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/Dl and 12g/Dl

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aranesp.

### REFERENCES


- Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen, January 2019.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 04/17/23
Created: 02/11
Client Approval: 03/23
P&T Approval: 01/21