MedImpact

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

## ERYTHROPOIESIS STIMULATING AGENTS

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| DARBEPOETIN | ARANESP | 22890 | | GPI-10 (8240101510) | |
| EPOETIN ALFA | EPOGEN PROCRIT | 04553 | | GPI-10 (8240102000) | |
| EPOETIN ALFA-EPBX | RETACRIT | 44931 | | GPI-10 (8240102004) | |
| METHOXY PEG-EPOETIN BETA | MIRCERA | 35005 | | GPI-10 (8240104010) | |

**GUIDELINES FOR USE**

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

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Procrit for 12 months by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

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**INITIAL CRITERIA FOR PROCRIT (CONTINUED)**

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

   If yes, **approve the requested strength of Procrit for 12 months by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Procrit for 12 months by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

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**INITIAL CRITERIA FOR PROCRIT (CONTINUED)**

4. 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 has a hemoglobin level of less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Procrit for 6 months by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve the requested strength of Procrit for 1 month by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

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

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## INITIAL CRITERIA FOR PROCRIT (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 **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

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

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have a hemoglobin level of less than 10g/dL

E. **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 a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   2. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have a hemoglobin level of less than 13g/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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## ERYTHROPOIESIS STIMULATING AGENTS

### INITIAL CRITERIA FOR ARANESP (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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **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**
   - **150mcg/0.75mL vial: #3mL 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**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

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**INITIAL CRITERIA FOR ARANESP (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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **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**
   - **150mcg/0.75mL vial: #3mL 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**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

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**INITIAL CRITERIA FOR ARANESP (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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Aranesp for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **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**
   - **150mcg/0.75mL vial: #3mL 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**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

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

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## INITIAL CRITERIA FOR ARANESP (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 **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for approval:

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.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen containing protein) 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 Procrit
   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 Procrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. You have a hemoglobin 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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## ERYTHROPOIESIS STIMULATING AGENTS

### INITIAL CRITERIA FOR EPOGEN (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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Epogen for 12 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve the requested strength of Epogen for 12 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

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**INITIAL CRITERIA FOR EPOGEN (CONTINUED)**

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet **ALL** of the following criteria?
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Epogen for 12 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

4. 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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Epogen for 6 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

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**INITIAL CRITERIA FOR EPOGEN (CONTINUED)**

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet **ALL** of the following criteria?
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve the requested strength of Epogen for 1 month as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   If no, do not approve.
   **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 **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
      4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
      5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.
   B. **If you have anemia associated with chronic kidney disease, approval also requires:**
      1. You have tried Procrit
      2. You have a hemoglobin level (amount of oxygen-containing protein) 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 Procrit
      2. You have a hemoglobin level of less than 11g/dL **OR** your hemoglobin has decreased at least 2g/dL below your baseline level
   D. **If you have anemia related to zidovudine therapy, approval also requires:**
      1. You have tried Procrit
      2. You have a hemoglobin level of less than 10g/dL

   ***(Initial Epogen denial text continued on next page)***

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**INITIAL CRITERIA FOR EPOGEN (CONTINUED)**

E. **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 Procrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. Your hemoglobin level is less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 13g/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.

**INITIAL CRITERIA FOR RETACRIT (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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

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**INITIAL CRITERIA FOR RETACRIT (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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet **ALL** of the following criteria?
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

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**INITIAL CRITERIA FOR RETACRIT (CONTINUED)**

4. 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 has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Retacrit for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet **ALL** of the following criteria?
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve the requested strength of Retacrit for 1 month by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

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

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## INITIAL CRITERIA FOR RETACRIT (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 **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) 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 Procrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin has decreased at least 2g/dL below your baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 10g/dL

E. **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 Procrit
   2. You have tried a lower ribavirin dose, unless there is a medical reason why you cannot (contraindication)
   3. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 13g/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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## ERYTHROPOIESIS STIMULATING AGENTS

### INITIAL CRITERIA FOR MIRCERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of Mircera initial guideline.

2. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   - The patient had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**
   **APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is on hemodialysis
   - The patient is converting from another erythropoiesis-stimulating agent (ESA) (i.e., epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**
   If no, do not approve
   **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 **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for approval:
   A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   B. **If you are 18 years of age or older, approval also requires**:
      1. You have tried Procrit
      2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
   C. **If you are between 5 and 17 years of age, approval also requires:**
      1. You are on hemodialysis
      2. You are changing from another erythropoiesis-stimulating agent (ESA; epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   ***(Initial Mircera denial text continued on next page)***

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## INITIAL CRITERIA FOR MIRCERA (CONTINUED)

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.

## RENEWAL CRITERIA FOR PROCRIT

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 dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Procrit for 12 months by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

   If no, continue to #2.

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**RENEWAL CRITERIA FOR PROCRIT (CONTINUED)**

2. Does the patient have a diagnosis of anemia due to the effect 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 the requested strength of Procrit for 12 months by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Procrit for 12 months by NDC [FDB & Medi-Span] with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL per 28 days**

   If no, continue to #4.

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**RENEWAL CRITERIA FOR PROCRIT (CONTINUED)**

4. 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 the requested strength of Procrit for 6 months by NDC [FDB & Medi-Span] with the following limits**:
   - **2,000U/mL: #12mL per 28 days**
   - **3,000U/mL: #12mL per 28 days**
   - **4,000U/mL: #12mL per 28 days**
   - **10,000U/mL: #12mL per 28 days**
   - **20,000U/mL: #12mL per 28 days**
   - **40,000U/mL: #6mL per 28 days**
   - **20,000U/2mL: #12mL 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 **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** 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) due to with chronic kidney disease
      2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
      4. 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, renewal also requires ONE of the following:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
      2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
      3. Your hemoglobin level has reached 10g/dL (if you are NOT on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
      4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

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

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**RENEWAL CRITERIA FOR PROCRIT (CONTINUED)**

C. **If you have anemia due to the effect 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 related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL
E. **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.

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR ARANESP

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 dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **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**
   - **150mcg/0.75mL vial: #3mL 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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**RENEWAL CRITERIA FOR ARANESP (CONTINUED)**

2. Does the patient have a diagnosis of anemia due to the effect 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 the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **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**
   - **150mcg/0.75mL vial: #3mL 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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**RENEWAL CRITERIA FOR ARANESP (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 the requested strength of Aranesp for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **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**
   - **150mcg/0.75mL vial: #3mL 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.
   **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 **ERYTHROPOIESIS STIMULATING AGENTS (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 for Aranesp continued on next page)***

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**RENEWAL CRITERIA FOR ARANESP (CONTINUED)**

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level of less than 10g/dL if you are NOT on dialysis
   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 dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

C. **If you have anemia due to the effect 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.

**RENEWAL CRITERIA FOR EPOGEN**

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 dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Epogen for 12 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   If no, continue to #2.

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**RENEWAL CRITERIA FOR EPOGEN (CONTINUED)**

2. Does the patient have a diagnosis of anemia due to the effect 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 the requested strength of Epogen for 12 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Epogen for 12 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   If no, continue to #4.

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**RENEWAL CRITERIA FOR EPOGEN (CONTINUED)**

4. 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 the requested strength of Epogen for 6 months as follows:**
   - **2,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **3,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **4,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **10,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/mL: by GPID or GPI-14 for #12mL per 28 days.**
   - **20,000U/2mL: by NDC with no quantity limit.**

   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 **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** 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) due to chronic kidney disease
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
      4. 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, renewal also requires ONE of the following:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
      2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
      3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
      4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.
   C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
      1. You have a hemoglobin level between 10g/dL and 12 g/dL

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

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**RENEWAL CRITERIA FOR EPOGEN (CONTINUED)**

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL
E. **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 12 g/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.

**RENEWAL CRITERIA FOR RETACRIT**

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 dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   If no, continue to #2.

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**RENEWAL CRITERIA FOR RETACRIT (CONTINUED)**

2. Does the patient have a diagnosis of anemia due to the effect 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 the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 28 days.**

   If no, continue to #4.

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**RENEWAL CRITERIA FOR RETACRIT (CONTINUED)**

4. 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 the requested strength of Retacrit for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10000U/mL: #12mL in 28 days.**
   - **20000U/mL: #12mL in 28 days.**
   - **40000U/mL: #6mL in 28 days.**
   - **20000U/2mL: #12mL in 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 **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** 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) due to chronic kidney disease
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
      4. 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, renewal also requires ONE of the following:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
      2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
      3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
      4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

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

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**RENEWAL CRITERIA FOR RETACRIT (CONTINUED)**

C. **If you have anemia due to the effect 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 related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL
E. **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.

**RENEWAL CRITERIA FOR MIRCERA**

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of Mircera renewal guideline.

2. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - **If the patient is currently receiving dialysis treatment:**
     - The patient has a hemoglobin level of less than 11g/dL **OR**
     - The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
   - **If the patient is NOT receiving dialysis treatment:**
     - The patient has a hemoglobin level of less than 10g/dL **OR**
     - The patient has a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**
   If no, continue to #3.

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**RENEWAL CRITERIA FOR MIRCERA (CONTINUED)**

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is currently receiving dialysis treatment
   - The patient has **ONE** of the following:
     - A hemoglobin level of less than 11g/dL
     - A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL 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 **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for renewal:
   A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   B. **If you are 18 years of age or older and are currently receiving dialysis treatment, renewal also requires ONE of the following:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
      2. The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
   C. **If you are 18 years of age or older and are NOT receiving dialysis treatment, renewal also requires ONE of the following:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
      2. You have a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
   D. **If you are between 5 and 17 years of age, renewal also requires:**
      1. You are currently receiving dialysis treatment
      2. You have ONE of the following:
         a. A hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
         b. A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

   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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## ERYTHROPOIESIS STIMULATING AGENTS

### RATIONALE

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

### REFERENCES


- Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc. August 2020.
- Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor, June 2018.


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| Yes | Yes | No |

Part D Effective: N/A Created: 02/11
Commercial Effective: 01/01/21 Client Approval: 11/20 P&T Approval: 07/18

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