ERYTHROPOIESIS STIMULATING AGENTS

Generic	Brand	HICL	GCN	Exception/Other
DARBEPOETIN	ARANESP	22890		
EPOETIN ALFA	EPOGEN PROCRIT	04553		
EPOETIN ALFA-EPBX	RETACRIT	44931		
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		

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 Procrit for 12 months by NDC with the following quantity limits:**
   - **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
   - **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
   - **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
   - **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
   - **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
   - **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
   - **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**

   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 **ONE** of the following criteria?
   - 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 Procrit for 12 months by NDC with the following quantity limits:**
   (See initial Procrit approval directions on next page)

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INITIAL CRITERIA FOR PROCRIT (CONTINUED)

If yes, **approve Procrit for 12 months by NDC with the following quantity limits:**
- **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
- **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
- **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
- **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
- **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
- **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
- **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #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 Procrit for 12 months by NDC with the following quantity limits:**
   - **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
   - **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
   - **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
   - **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
   - **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
   - **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
   - **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**

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

   If yes, **approve Procrit for 6 months by NDC with the following quantity limits:**
   (See initial Procrit approval directions on next page)

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INITIAL CRITERIA FOR PROCRIT (CONTINUED)

If yes, **approve Procrit for 6 months by NDC with the following quantity limits:**
- **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
- **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
- **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
- **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
- **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
- **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
- **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**
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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 Procrit for 1 month by NDC with the following quantity limits:**
   - **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
   - **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
   - **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
   - **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
   - **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
   - **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
   - **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (PROCRIT)** requires that the following criteria are met:
   For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires:
   - The patient has a hemoglobin level of less than 10g/dL

   For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires one of the following:
   - 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.

   (Initial Procrit denial text continued on next page)

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INITIAL CRITERIA FOR PROCRIT (CONTINUED)

For a diagnosis of anemia related to zidovudine therapy, approval requires:
- The patient has a hemoglobin level of less than 10g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:
- The patient has had a trial of or contraindication to ribavirin dose reduction
- The patient has a hemoglobin level of less than 10g/dL

For patients undergoing elective, noncardiac, or nonvascular surgery, approval requires:
- The patient has a hemoglobin level of less than 13g/dL

Please discuss the information needed to get the drug approved with your physician.

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 Aranesp for 12 months by HICL 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 Aranesp for 12 months by HICL 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.

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 Aranesp for 6 months by HICL with the following quantity limits:**
   (See initial Aranesp approval directions on next page)

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INITIAL CRITERIA FOR ARANESP (CONTINUED)

If yes, **approve Aranesp for 6 months by HICL 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.
INITIAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (ARANESP)** requires that the following criteria are met:
For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires:

- The patient has had a trial of Procrit
- The patient has a hemoglobin level of less than 10g/dL

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:

- 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

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:

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

Please discuss the information needed to get the drug approved with your physician.

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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 Epogen for 12 months by HICL 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.**
   - **20,000U/2mL: 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 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 Epogen for 12 months by HICL 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.**
   - **20,000U/2mL: 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 Epogen for 12 months by HICL 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.**
   - **20,000U/2mL: 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 Epogen for 6 months by HICL 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.**
   - **20,000U/2mL: no quantity limit.**

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

   If no, continue to #5.

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ERYTHROPOIESIS STIMULATING AGENTS

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 Epogen for 1 month by HICL 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.**
   - **20,000U/2mL: no quantity limit.**

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

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (EPOGEN)** requires that the following criteria are met:
   For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires:
   - The patient has had a trial of Procrit
   - The patient's hemoglobin level of less than 10g/dL if not on dialysis.

   For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin has decreased at least 2g/dL below their baseline level

   For a diagnosis of anemia related to zidovudine therapy, approval requires:
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:
   - The patient has had a trial of Procrit
   - The patient has had a trial of or contraindication to ribavirin dose reduction
   - The patient has a hemoglobin level of less than 10g/dL

   For patients undergoing elective, noncardiac, or nonvascular surgery, approval requires:
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 13g/dL

   Please discuss the information needed to get the drug approved with your physician.

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

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 Retacrit for 12 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days.**
   - **3000U/mL GPID 44765: #12mL in 28 days.**
   - **4000U/mL GPID 44766: #12mL in 28 days.**
   - **10000U/mL GPID 44767: #12mL in 28 days.**
   - **40000U/mL GPID 44768: #6mL in 28 days.**

   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 Retacrit for 12 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days.**
   - **3000U/mL GPID 44765: #12mL in 28 days.**
   - **4000U/mL GPID 44766: #12mL in 28 days.**
   - **10000U/mL GPID 44767: #12mL in 28 days.**
   - **40000U/mL GPID 44768: #6mL in 28 days.**

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

   If no, continue to #3.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR RETACRIT (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 Retacrit for 12 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days.**
   - **3000U/mL GPID 44765: #12mL in 28 days.**
   - **4000U/mL GPID 44766: #12mL in 28 days.**
   - **10000U/mL GPID 44767: #12mL in 28 days.**
   - **40000U/mL GPID 44768: #6mL in 28 days.**

   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 Retacrit for 6 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days.**
   - **3000U/mL GPID 44765: #12mL in 28 days.**
   - **4000U/mL GPID 44766: #12mL in 28 days.**
   - **10000U/mL GPID 44767: #12mL in 28 days.**
   - **40000U/mL GPID 44768: #6mL in 28 days.**

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

   If no, continue to #5.

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INITIAL CRITERIA FOR RETACRIT (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 Retacrit for 1 month by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days.**
   - **3000U/mL GPID 44765: #12mL in 28 days.**
   - **4000U/mL GPID 44766: #12mL in 28 days.**
   - **10000U/mL GPID 44767: #12mL in 28 days.**
   - **40000U/mL GPID 44768: #6mL in 28 days.**

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

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (RETACRIT)** requires that the following criteria are met:
   For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires:
   - The patient has had a trial of Procrit
   - The patient's hemoglobin level of less than 10g/dL if not on dialysis

   For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin has decreased at least 2g/dL below their baseline level

   For a diagnosis of anemia related to zidovudine therapy, approval requires:
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 10g/dL

   For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:
   - The patient has had a trial of Procrit
   - The patient has had a trial of or contraindication to ribavirin dose reduction
   - The patient has a hemoglobin level of less than 10g/dL

   For patients undergoing elective, noncardiac, or nonvascular surgery, approval requires:
   - The patient has had a trial of Procrit
   - The patient has a hemoglobin level of less than 13g/dL

   Please discuss the information needed to get the drug approved with your physician.

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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 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 Mircera for 12 months by HICL 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** meet the following criterion?
   - The patient is on hemodialysis and 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 with a quantity limit of #0.6mL per 28 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (MIRCERA)** requires a diagnosis of anemia associated with chronic kidney disease (CKD). In addition, the following criteria must be met:
   For a patient 18 years of age or older, approval requires:
   - The patient has had a trial of Procrit
     - The patient has a hemoglobin level of less than 10g/dL

   For a patient between 5 and 17 years of age, approval requires:
   - The patient is on hemodialysis and is converting from another erythropoiesis-stimulating agent (ESA) (i.e., epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   Please discuss the information needed to get the drug approved with your physician.

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

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 **OR**
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
   - 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 **OR**
   - 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 Procrit for 12 months by NDC with the following quantity limits:**
   - **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
   - **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
   - **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
   - **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
   - **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
   - **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
   - **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**

   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 the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve Procrit for 12 months by NDC with the following quantity limits:**
   - **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
   - **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
   - **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
   - **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
   - **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
   - **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
   - **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**

   If no, continue to #3.

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RENEWAL CRITERIA FOR PROCRIT (CONTINUED)

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 Procrit for 12 months by NDC with the following quantity limits:**
   - **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
   - **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
   - **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
   - **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
   - **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
   - **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
   - **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**

   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 the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve Procrit for 6 months by NDC with the following limits**:
   - **2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.**
   - **3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.**
   - **4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.**
   - **10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.**
   - **20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.**
   - **40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.**
   - **20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.**

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

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR PROCRIT (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (PROCRIT)** renewal requires that the following criteria are met:
For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires ONE of the following:
- o The patient has a hemoglobin level of less than 10g/dL if not on dialysis **OR**
- o The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
- o The patient has a hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is require to reduce the need for blood transfusions **OR**
- o The patient has a hemoglobin level has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:
- o The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia related to zidovudine therapy, approval requires:
- o The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:
- o The patient has a hemoglobin level between 10g/dL and 12g/dL

Please discuss the information needed to get the drug approved with your physician.

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 **OR**
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
   - 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 **OR**
   - 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 Aranesp for 12 months by HICL with the following quantity limits:**
   (See renewal Aranesp approval directions on next page)

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RENEWAL CRITERIA FOR ARANESP (CONTINUED)

If yes, **approve Aranesp for 12 months by HICL 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.

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 Aranesp for 12 months by HICL with the following quantity limits:**
   (See renewal Aranesp approval directions on next page)

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RENEWAL CRITERIA FOR ARANESP (CONTINUED)

If yes, **approve Aranesp for 12 months by HICL 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.

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 Aranesp for 6 months by HICL with the following quantity limits:**
   (See renewal Aranesp approval directions on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR ARANESP (CONTINUED)

If yes, **approve Aranesp for 6 months by HICL 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: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (ARANESP)** renewal requires that the following criteria are met:
For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires ONE of the following:

- The patient has a hemoglobin level of less than 10g/dL if not on dialysis, **OR**
- The patient has a hemoglobin level of less than 11g/dL if on dialysis, **OR**
- The patient has a hemoglobin has reached 10g/dL (if not on dialysis) or 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:
The patient has a hemoglobin level between 10g/dL and 12g/dL
For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

Please discuss the information needed to get the drug approved with your physician.

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

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 **OR**
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
   - 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 **OR**
   - 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 Epogen for 12 months by HICL 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.**
   - **20,000U/2mL: no quantity limit.**

   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 the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve Epogen for 12 months by HICL 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.**
   - **20,000U/2mL: no quantity limit.**

   If no, continue to #3.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR EPOGEN (CONTINUED)

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 Epogen for 12 months by HICL 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.**
   - **20,000U/2mL: no quantity limit.**

   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 the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve Epogen for 6 months by HICL 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.**
   - **20,000U/2mL: no quantity limit.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (EPOGEN)** renewal requires that the following criteria are met:
   For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires ONE of the following:
   - o The patient has a hemoglobin level of less than 10g/dL if not on dialysis **OR**
   - o The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
   - o The patient has a hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is require to reduce the need for blood transfusions **OR**
   - o The patient has a hemoglobin level has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

   (Renewal Epogen denial text continued on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR EPOGEN (CONTINUED)

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:
- o The patient has a hemoglobin level between 10g/dL and 12 g/dL

For a diagnosis of anemia related to zidovudine therapy, approval requires:
- o The patient has a hemoglobin level between 10g/dL and 12 g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:
- o The patient has a hemoglobin level between 10g/dL and 12 g/dL

Please discuss the information needed to get the drug approved with your physician.

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 **OR**
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
   - 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 **OR**
   - 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 Retacrit for 12 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days.**
   - **3000U/mL GPID 44765: #12mL in 28 days.**
   - **4000U/mL GPID 44766: #12mL in 28 days.**
   - **10000U/mL GPID 44767: #12mL in 28 days.**
   - **40000U/mL GPID 44768: #6mL 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 Retacrit for 12 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days**
   - **3000U/mL GPID 44765: #12mL in 28 days**
   - **4000U/mL GPID 44766: #12mL in 28 days**
   - **10000U/mL GPID 44767: #12mL in 28 days**
   - **40000U/mL GPID 44768: #6mL 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 Retacrit for 12 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days.**
   - **3000U/mL GPID 44765: #12mL in 28 days.**
   - **4000U/mL GPID 44766: #12mL in 28 days.**
   - **10000U/mL GPID 44767: #12mL in 28 days.**
   - **40000U/mL GPID 44768: #6mL in 28 days.**

   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 the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve Retacrit for 6 months by GPID with the following quantity limits:**
   - **2000U/mL GPID 44764: #12mL in 28 days**
   - **3000U/mL GPID 44765: #12mL in 28 days**
   - **4000U/mL GPID 44766: #12mL in 28 days**
   - **10000U/mL GPID 44767: #12mL in 28 days**
   - **40000U/mL GPID 44768: #6mL in 28 days**

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

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RENEWAL CRITERIA FOR RETACRIT (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (RETACRIT)** renewal requires that the following criteria are met:
For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires ONE of the following:

- The patient has a hemoglobin level of less than 10g/dL if not on dialysis **OR**
- The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
- The patient has a hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is require to reduce the need for blood transfusions **OR**
- The patient has a hemoglobin level has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia related to zidovudine therapy, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

Please discuss the information needed to get the drug approved with your physician.

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.

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RENEWAL CRITERIA FOR MIRCERA (CONTINUED)

2. Is the patient 18 years of age or older **AND** meet **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 with a quantity limit of #0.6mL per 28 days.**
   If no, continue to #3.

3. Is the patient between 5 and 17 years of age **AND** meet **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 yes, **approve Mircera for 12 months by HICL with a quantity limit of #0.6mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (MIRCERA)** requires a diagnosis of anemia associated with chronic kidney disease (CKD). In addition, the following criteria must be met:
   For a patient 18 years of age or older, approval requires ONE of the following:
   - **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

   For a patient between 5 and 17 years of age and on dialysis, approval requires ONE of the following:
   - 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

   Please discuss the information needed to get the drug approved with your physician.

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ERYTHROPOIESIS STIMULATING AGENTS

RATIONALE

To ensure appropriate utilization and promote use of preferred ESA treatment.

Anemia due to hepatitis C therapy is not an FDA approved indication for any ESA. AASLD does not recommend the use of ESAs, NIH/DHHS/NIDDKD state that the proper role and dose of ESAs has yet to be defined, and the AGA consider either ribavirin dose reduction or ESA use as viable options for managing treatment-related anemia. None of these guidelines provide specific hemoglobin levels at which to initiate or maintain hemoglobin levels for this patient population, therefore the hemoglobin levels selected for this diagnosis are based off of the recommendations for zidovudine therapy.

FDA APPROVED INDICATIONS

- CHRONIC KIDNEY DISEASE: The prescribing information (PI) of the ESAs and an FDA safety update recommend initiation of therapy only for patients with Hgb of <10g/dL. They recommend reducing or interrupting the dose of ESA and using the lowest dose of an ESA sufficient to reduce the need for blood transfusions at Hgb of 11g/dL for patients on dialysis or Hgb of 10g/dL for patients not on dialysis.
- ANEMIA RELATED TO CANCER CHEMOTHERAPY: ASCO recommends initiating ESA therapy at Hgb levels at less than 10g/dL while NCCN recommends initiation at or below Hgb levels of 11g/dL. ASCO recommends maintaining Hgb levels between 10 and 12g/dL, while NCCN does not comment on a maintenance Hgb range.
- ANEMIA RELATED TO ZIDOVUDINE THERAPY: The clinical trials contained within the prescribing information (PI) of the ESAs recommend initiating therapy at an Hgb of < 10g/dL and maintaining between 10 and 12g/dL.
- PATIENTS SCHEDULED FOR ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY: The prescribing information (PI) of the ESAs recommends therapy only for those patients with Hgb ≤13g/dL.

Aranesp

For the treatment of anemia due to:

- Chronic Kidney Disease (CKD) in patients on dialysis and patients not on dialysis
- The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy

Recommended starting dose:

- CKD on dialysis: 0.45mcg/kg IV/SC as a weekly injection or 0.75mcg/kg once every 2 weeks as appropriate
- CKD not on dialysis: 0.45mcg/kg IV/SC given once at 4-week intervals as appropriate
- Cancer chemotherapy:
  - 2.25mcg/kg SC every week until completion of a chemotherapy course
  - 500mcg every 3 weeks SC until completion of a chemotherapy course

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ERYTHROPOIESIS STIMULATING AGENTS

FDA APPROVED INDICATIONS (CONTINUED)

Epogen Procrit & Retacrit

- Treatment of anemia due to:
  - Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis
  - Zidovudine in HIV-infected patients
  - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
- Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery

Recommended starting dose:

- CKD on dialysis:
  - Adults: 50-100 units/kg 3 times weekly
  - Pediatrics: 50 units/kg 3 times weekly
- CKD not on dialysis:
  - Adult patients: 50-100 units/kg 3 times weekly
- Zidovudine-treated HIV-infected patients
  - Adults: 100 units/kg 3 times per week
- Cancer chemotherapy:
  - Adults: 150 units/kg SC 3 times per week until completion of a chemotherapy course, or 40,000 units SC weekly until completion of a chemotherapy course
  - Pediatrics: 600 units/kg IV until completion of a chemotherapy course
- Surgery:
  - 300 units/kg per day SC for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery
  - 600 units/kg SC in 4 does administered 21, 14, and 7 days before surgery and on the day of surgery

Mircera

Treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis.

Recommended dose:

- Initial treatment: 0.6mcg/kg body weight administered once every 2 weeks
- Conversion from another ESA: dosed once monthly or every 2 weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion

Treatment of anemia associated with chronic kidney disease (CKD) in pediatric patients, 5 to 17 years of age, on hemodialysis whose hemoglobin level has been stabilized by treatment with an ESA. Available as 30 mcg, 50 mcg, 75 mcg, 100 mcg, 120 mcg, 150 mcg, 200 mcg, or 250 mcg in 0.3mL; and 360 mcg in 0.6mL solution of Mircera in single-use prefilled syringes.

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ERYTHROPOIESIS STIMULATING AGENTS

REFERENCES

- Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc. May 2018.
- 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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