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 renal failure and meet the following criteria?
   • 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)

CONTINUED ON NEXT PAGE
ERYTHROPOIESIS STIMULATING AGENTS

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 criteria?
   - 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 treatment and meet ALL of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL AND
   - The patient has had a trial or contraindication to ribavirin dose reduction

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

INITIAL CRITERIA FOR PROCRIT (CONTINUED)

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

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 criteria?
- 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.

DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (PROCRIT) requires the following criteria are met:
- Approval for the diagnosis of anemia associated with chronic renal failure requires a hemoglobin level of less than 10g/dL.
- Approval for the diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy requires one of the following:
  - Hemoglobin level of less than 11g/dL OR
  - The patient's hemoglobin level has decreased at least 2g/dL below their baseline level.
- Approval for the diagnosis of anemia related to zidovudine therapy requires a hemoglobin level of less than 10g/dL.

(Initial Procrit denial text continued on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR PROCRIT (CONTINUED)

- Approval for the diagnosis of anemia due to concurrent hepatitis C treatment requires all of the following:
  - A lower dose of ribavirin (ribavirin dose reduction) AND
  - Hemoglobin level of less than 10g/dL.
- Approval for patients undergoing elective, noncardiac, or nonvascular surgery requires 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 renal failure and meet ALL of the following criteria?
   - The patient has tried Procrit AND
   - 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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ERYTHROPOIESIS STIMULATING AGENTS

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 the following criteria?
   - The patient has tried Procrit AND
   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

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 treatment and meet the following criteria?
   - The patient has tried Procrit AND
   All of the following:
   - The patient has a hemoglobin level of less than 10g/dL AND
   - 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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ERYTHROPOIESIS STIMULATING AGENTS

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.

DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (ARANESP) requires the following criteria are met:
- Approval for the diagnosis of anemia associated with chronic renal failure requires:
  - A trial of Procrit AND
  - A hemoglobin level of less than 10g/dL
- Approval for the diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy requires:
  - The patient has tried Procrit AND
  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.
- Approval for the diagnosis of anemia due to concurrent hepatitis C treatment requires:
  - The patient has tried Procrit, AND
  All of the following:
    - A lower dose of ribavirin (ribavirin dose reduction) AND
    - 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 renal failure and meet ALL of the following criteria?
   - The patient has tried Procrit AND
   - 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 tried Procrit AND
   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

   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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ERYTHROPOIESIS STIMULATING AGENTS

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 tried Procrit AND
   • 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 treatment and meet the following criteria?
   • The patient has tried Procrit AND
   • The patient has a hemoglobin level of less than 10g/dL AND
   • 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.

CONTINUED ON NEXT PAGE
ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR EPOGEN (CONTINUED)

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet the following criteria?
   - The patient has tried Procrit AND
   - 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.

DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (EPOGEN) requires the following criteria are met:
   - Approval for the diagnosis of anemia associated with chronic renal failure requires:
     - The patient has tried Procrit AND
     - The patient's hemoglobin level of less than 10g/dL if not on dialysis.
   - Approval for the diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy requires:
     - The patient has tried Procrit AND
   One of the following:
     - Hemoglobin level of less than 11g/dL, OR
     - The patient’s hemoglobin has decreased at least 2g/dL below their baseline level
   - Approval for the diagnosis of anemia related to zidovudine therapy requires:
     - The patient has tried Procrit AND
     - Hemoglobin level of less than 10g/dL.
   - Approval for the diagnosis of anemia due to concurrent hepatitis C treatment requires all of the following:
     - The patient has tried Procrit
     - A lower dose of ribavirin (ribavirin dose reduction)
     - Hemoglobin level of less than 10g/dL.

(Initial Epogen denial text continued on next page)
ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR EPOGEN (CONTINUED)

- Approval for patients undergoing elective, noncardiac, or nonvascular surgery requires:
  - The patient has tried Procrit AND
  - Hemoglobin level of less than 13g/dL.
  Please discuss the information needed to get the drug approved with your physician.

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

1. Does the patient have a diagnosis of anemia associated with chronic renal failure and meet ALL of the following criteria?
   - The patient has tried Procrit AND
   - 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, do not approve.

   DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (MIRCERA) requires a diagnosis of anemia associated with chronic renal failure. The following criteria must also be met:
   - The patient has tried Procrit AND
   - Hemoglobin level of less than 10g/dL

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

CONTINUED ON NEXT PAGE
ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA FOR PROCRIT

1. Does the patient have a diagnosis of anemia associated with chronic renal failure and meet ONE of the following criteria?
   - Hemoglobin level of less than 10g/dL if not on dialysis OR
   - Hemoglobin level of less than 11g/dL if on dialysis OR
   - 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
   - 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 criteria?
   - The patient has a hemoglobin level of between 10 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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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR PROCRIT (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criteria?
   • The patient has a hemoglobin level between 10 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 treatment and meet the following criteria?
   • The patient has a hemoglobin level between 10 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 Procrit renewal denial text at the end of Procrit renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR PROCRIT (CONTINUED)

DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (PROCRIT) renewal requires the following criteria are met:

- Approval for the diagnosis of anemia associated with chronic renal failure requires:
  - Hemoglobin level of less than 10g/dL if not on dialysis OR
  - Hemoglobin level of less than 11g/dL if on dialysis OR
  - Hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions OR
  - Hemoglobin level has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

- Approval for the diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy requires a hemoglobin level between 10 and 12 g/dL.

- Approval for the diagnosis of anemia related to zidovudine therapy requires a hemoglobin level between 10 and 12 g/dL.

- Approval for the diagnosis of anemia due to concurrent hepatitis C treatment requires a hemoglobin level between 10 and 12 g/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 renal failure and meet ONE of the following criteria?
   - Hemoglobin level of less than 10g/dL if not on dialysis OR
   - Hemoglobin level of less than 11g/dL if on dialysis OR
   - 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
   - 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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ERYTHROPOIESIS STIMULATING AGENTS

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 criteria?
   - The patient has a hemoglobin level between 10 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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ERYTHROPOIESIS STIMULATING AGENTS

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 treatment and meet the following criteria?
- The patient has a hemoglobin level between 10 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)

CONTINUED ON NEXT PAGE
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.

DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (ARANESP) renewal requires the following criteria are met:

- Approval for the diagnosis of anemia associated with chronic renal failure requires one of the following:
  - Hemoglobin level of less than 10g/dL if not on dialysis, OR
  - Hemoglobin level of less than 11g/dL if on dialysis, OR
  - 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.
- Approval for the diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy requires a hemoglobin level between 10 and 12 g/dL.
- Approval for the diagnosis of anemia due to concurrent hepatitis C treatment requires a hemoglobin level between 10 and 12 g/dL.

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

CONTINUED ON NEXT PAGE
ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR EPOGEN

1. Does the patient have a diagnosis of anemia associated with chronic renal failure and meet ONE of the following criteria?
   - Hemoglobin level of less than 10g/dL if not on dialysis OR
   - Hemoglobin level of less than 11g/dL if on dialysis OR
   - 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
   - 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 criteria?
   - The patient has a hemoglobin level of between 10 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.

CONTINUED ON NEXT PAGE
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 criteria?
   • The patient has a hemoglobin level between 10 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 treatment and meet the following criteria?
   • The patient has a hemoglobin level between 10 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.

DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (EPOGEN) renewal requires the following criteria are met:
   o Approval for the **diagnosis of anemia associated with chronic renal failure** requires one of the following:
     o Hemoglobin level of less than 10g/dL if not on dialysis **OR**
     o Hemoglobin level of less than 11g/dL if on dialysis **OR**
     o Hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions **OR**
     o 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)

- Approval for the **diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy** requires a hemoglobin level between 10 and 12 g/dL.
- Approval for the **diagnosis of anemia related to zidovudine therapy** requires a hemoglobin level between 10 and 12 g/dL.
- Approval for the **diagnosis of anemia due to hepatitis C treatment** requires a hemoglobin level between 10 and 12 g/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 renal failure and meet ONE of the following criteria?
   - Hemoglobin level of less than 10g/dL if not on dialysis OR
   - Hemoglobin level of less than 11g/dL if on dialysis OR
   - Hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions OR
   - Hemoglobin level has reached 11g/dL (on dialysis) 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.

DENIAL TEXT: Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (MIRCERA) renewal requires the following criteria are met:

- Approval for the **diagnosis of anemia associated with chronic renal failure** requires:
  - Hemoglobin level of less than 10g/dL if not on dialysis, OR
  - Hemoglobin level of less than 11g/dL if on dialysis, OR
  - Hemoglobin has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions OR
  - Hemoglobin level has reached 11g/dL (on dialysis) 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.

RATIONALE
Ensure appropriate utilization and promote use of preferred ESA treatment.

CONTINUED ON NEXT PAGE
ERYTHROPOIESIS STIMULATING AGENTS

RATIONALE (CONTINUED)

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 12d/L, 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
- 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

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


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