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Policy Number: C15389-A

Erythropoiesis-stimulating agents (ESAs)

PRODUCTS AFFECTED

Aranesp (darbepoetin alfa), Epogen (epoetin alfa), Procrit (epoetin alfa), RETACRIT™ (epoetin alfa- epbx), Mircera'" (methoxy polyethylene glycol-epoetin beta)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Anemia associated with chronic kidney disease (CKD), including members on dialysis and members not on dialysis, Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy
EPOGEN AND PROCRIT ONLY: Anemia in HIV-infected members receiving zidovudine treatment
Reduction of allogeneic blood transfusion in surgery members

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

FOR ALL INDICATIONS:
1. (a) Iron levels (dated within the last 60 days) with the following: Transferrin saturation equal to or greater than 20% AND serum ferritin equal to or greater than 100 ng/mL

OR

(b) Prescriber attestation that member is receiving iron appropriate supplementation

AND

2. (a) Documentation of ONE (1) of the following applies: Member does NOT have hypertension

   OR

   (b) If member has hypertension, blood pressure is adequately controlled before initiation of therapy and will be closely monitored and controlled during therapy

   AND

3. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

   OR

   IF THIS IS FOR A MEDICAL BENEFIT REQUEST: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug and/or pharmacy formulary product per applicable state regulations and there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:

   1. Treatment with at least two (2) associated biosimilar drug(s) has been ineffective, not tolerated, or is contraindicated (i.e. an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes) [DOCUMENTATION REQUIRED-Document when the preferred biologic product or biosimilar was tried and the length of the trial period, Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache)]

   AND

4. CRITERIA BY INDICATION BELOW:

A. ANEMIA IN CHRONIC KIDNEY DISEASE (CKD) INCLUDING MEMBERS ON DIALYSIS AND MEMBERS NOT ON DIALYSIS:

1. Hemoglobin (Hgb) level measured within last two (2) weeks which meets ONE of the following [DOCUMENTATION REQUIRED]:

   (a) Treatment naïve- Hemoglobin <10 g/dL adults and < 11.0 g/dL for children

   OR

   (b) Currently receiving therapy: Hemoglobin < 11.5 g/dL for adults and <12 g/dL for children

   AND

2. Prescriber attests or clinical review has found that any other causes of anemia [i.e., Iron deficiency, underlying infection, or inflammatory process, underlying hematological disease, hemolysis, vitamin deficiencies, blood loss, aluminum intoxication, drug exposure history, gastrointestinal bleeding] have been considered, documented, and corrected (when possible)

B. ANEMIA DUE TO MYELOSUPPRESIVE CHEMOTHERAPY FOR A NON- MYELOID MALIGNANCY:

1. Prescriber attests the member has a diagnosis of non-myeloid malignancy defined as any malignancy that is not a myeloid leukemia AND member is currently receiving chemotherapy

   AND

2. Prescriber attests member has minimum of two (2) additional months of planned chemotherapy or is NOT within 8 weeks of the final chemotherapy dose

   AND

3. Hemoglobin (Hgb) level measured within last two (2) weeks < 10 g/dL [DOCUMENTATION

REQUIRED]
AND

4. Prescriber attests or clinical review has found that other causes of anemia [i.e., Iron deficiency, underlying infection, or inflammatory process, underlying hematological disease, hemolysis, vitamin deficiencies, blood loss, aluminum intoxication, drug exposure history, gastrointestinal bleeding] have been considered, documented, and corrected (when possible)

C. REDUCTION OF ALLOGENIC BLOOD TRANSFUSION IN SURGERY MEMBERS:

1. Documentation member undergoing elective, non-cardiac, non-vascular surgery
   AND
2. Hemoglobin level within 30 days prior to scheduled surgery ≤ 13.0 g/dL [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to all of the following: Member is at high risk for perioperative transfusions with significant, anticipated blood loss AND Member is unable or unwilling to donate autologous blood AND Antithrombotic prophylaxis has been considered
   AND
4. Member has NOT received OR request is NOT for more than a 21-day supply or 15 doses for the surgery

D. ANEMIA IN HIV-INFECTED MEMBER RECEIVING ZIDOVUDINE TREATMENT:

1. Prescriber attests member has been receiving zidovudine with a dose less than or equal to 4200mg per week
   AND
2. Hemoglobin (Hgb) level measured within last two (2) weeks which meets ONE of the following [DOCUMENTATION REQUIRED]:
   (a) Treatment naïve-Hemoglobin < 10g/dL
   OR
   (b) Currently receiving therapy: Hemoglobin < 12 g/dL
   AND
3. Prescriber attests or clinical review has found that other causes of anemia [i.e., Iron deficiency, underlying infection, or inflammatory process, underlying hematological disease, hemolysis, vitamin deficiencies, blood loss, aluminum intoxication, drug exposure history, gastrointestinal bleeding] have been considered, documented and corrected (when possible)
   AND
4. Baseline endogenous erythropoietin lab shows level is less than or equal to 500mUnits/Ml

E. ANEMIA ASSOCAITED WITH MYELODYSPLASTIC SYNDROME:

1. Laboratory values meets ONE of the following [DOCUMENTATION REQUIRED]:
   (a) Hb is ≤ 10 g/dL for initial therapy
   OR
   (b) Serum erythropoietin level is ≤ 500 mU/mL for initial therapy
   OR
   (c) Hb is ≤ 12.0 g/dL for members currently receiving Aranesp or epoetin alfa;
2. Prescriber attests or clinical review has found that other causes of anemia [i.e., Iron deficiency, underlying infection or inflammatory process, underlying hematological disease, hemolysis, vitamin deficiencies, blood loss, aluminum intoxication, drug exposure history, gastrointestinal bleeding] have been considered, documented and corrected (when possible)

F. ANEMIA OF PREMATURITY

1. Documentation member's Gestational age at birth of 28 weeks or less [DOCUMENTATION REQUIRED]
   AND
2. Documentation member's Birth weight of 1500 grams or less [DOCUMENTATION REQUIRED]

AND

3. Prescriber attests to concurrent iron and protein supplementation as required.

CONTINUATION OF THERAPY:

A. ALL INDICATIONS [ANEMIA IN CHRONIC KIDNEY DISEASE (CKD) INCLUDING MEMBERS ON DIALYSIS AND MEMBERS NOT ON DIALYSIS, ANEMIA DUE TO MYELOSUPPRESIVE CHEMOTHERAPY FOR A NON- MYELOIDMALIGNANCY, ANEMIA IN HIV-INFECTED MEMBER RECEIVING ZIDOVUDINE TREATMENT, ANEMIA ASSOCAITED WITH MYELODYSPLASTIC SYNDROME]:
   1. Recent hemoglobin is < 12g/dL [DOCUMENTATION REQUIRED]
      OR
      NONMYELOID MALIGNANCY: Recent hemoglobin (Hgb) level is less than 10 g/dL OR hematocrit is < 30% [DOCUMENTATION REQUIRED]
      AND
   2. Recent serum ferritin is > 100 ng/mL or transferrin saturation > 20% OR member is receiving appropriate iron supplementation
      AND
   3. Improvement in the hematocrit and hemoglobin levels have occurred or there is a significant decrease in transfusion requirements
      AND
   4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

For members not responding, despite dose titrations and/or concomitant use of G-CSF (e.g., Neupogen® [filgrastim injection]) during the first 6 months, discontinue epoetin alfa and evaluate and treat for other causes of anemia

DURATION OF APPROVAL:

For Reduction of Allogenic Blood Transfusion in Surgery Members: Initial authorization: Up to 21 days of therapy per surgery, or up to 15 doses. NO CONTINUATION OF THERAPY
Anemia of Prematurity: Initial authorization: 2 months (8 weeks). NO CONTINUATION OF THERAPY

All other indications: Initial authorization: 2 months (8 weeks) Continuation of Therapy: 6 months (24 weeks)

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified hematologist, oncologist, nephrologist, immunologist, surgeon, infectious disease specialist, or neonatologist (for anemia of prematurity). [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Anemia associated with chronic kidney disease CKD in an individual on dialysis:
Epogen/Procrit/Retacrit/Aranesp: 1 month of age and older
Mircera: ≥ 5 years

Anemia associated with chronic kidney disease CKD in an individual not on dialysis:
Epogen/Procrit/Retacrit/Aranesp: 1 month of age
and older
Mircera: 18 years of age and older

Anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy:
Epogen/Procrit/Retacrit: 5 years of age and older
Aranesp: 18 years of age and older

Reduction of allogenic blood transfusion requirements in surgery:
Epogen/Procrit/Retacrit: 18 years of age and older

Anemia due to zidovudine in HIV-infected patients:
Epogen/Procrit/Retacrit: 3 months of age and older

Anemia associated with myelodysplastic syndrome:
Epogen/Procrit/Retacrit: 18 years of age and older
Aranesp: 18 years of age and older

Anemia of prematurity:
Epogen/Procrit/Retacrit/Aranesp: gestational age at birth of 28 weeks or less

QUANTITY:
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

Epoetin alfa and biosimilars: Not to exceed 3 doses weekly Darbepoetin alfa: Not to exceed 4 doses monthly
Mircera: Not to exceed: Adults- one dose every 2 weeks maximum. Pediatric ages 5 to 17 years of age-one dose every 4 weeks

Single-dose vials and syringes are available in many different strengths. The dose should be calculated, and the number of vials/syringes needed assessed. Refer the corresponding package insert for more information

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products be administered in a place of service that is a non-hospital facility-based location.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous or subcutaneous

DRUG CLASS:
Erythropoiesis-stimulating agents (ESAs)

FDA-APPROVED USES:
EPOETIN ALFA:
Treatment of anemia due to chronic kidney disease (CKD), including members on dialysis and members not on dialysis to decrease the need for red blood cell (RBC) transfusion.
For the treatment of anemia due to zidovudine administered at < 4200 mg per week in HIV-infected members with endogenous serum erythropoietin levels of < 500mUnits/mL.
For the treatment of anemia in members with non-myeloid malignancies where anemia is due to the effect of concomitant
myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
To reduce the need for allogeneic RBC transfusions among members with perioperative hemoglobin

> 10 to ≤ 13 g/dl who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. It is not indicated for members who are willing to donate autologous blood pre-operatively.
DARBEPOETIN ALFA:
For the treatment of anemia associated with chronic kidney disease, including members on dialysis and members not on dialysis
For the treatment of anemia in members with nonmyeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of 2 additional months of planned chemotherapy.

METHOXY POLYETHYLENE GLYCOL-EPOETIN-BETA: indicated for the treatment of anemia associated with chronic kidney disease (CKD) in: adult members on dialysis and adult members not on dialysis and pediatric members 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

Limitations of Use: Mircera is not indicated and is not recommended for use: In the treatment of anemia due to cancer chemotherapy (5.2). As a substitute for RBC transfusions in members who require immediate correction of anemia Mircera has not been shown to improve quality of life, fatigue, or member wellbeing.

Limitations of Use: Procrit/Retacrit/Epogen has not been shown to improve quality of life, fatigue, or patient well-being. Procrit/Retacrit is not indicated for use: In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. In patients scheduled for surgery who are willing to donate autologous

blood. In patients undergoing cardiac or vascular surgery. As a substitute for RBC transfusions in patients who require immediate correction of anemia
Limitations of Use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use: In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. As a substitute for RBC transfusions in patients who require immediate correction of anemia.

COMPENDIAL APPROVED OFF-LABELED USES:
Anemia Associated with Myelodysplastic Syndrome (MDS), Anemia of prematurity

APPENDIX

APPENDIX:
CONDITIONS NOT RECOMMENDED FOR APPROVAL Epoetin alfa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Anemia Associated with Cancer in Members not Receiving Myelosuppressive Cancer Chemotherapy**. Epoetin alfa is not indicated in cancer members who are not receiving cancer chemotherapy.1-3 The American Society of Clinical Oncology (ASCO)/American Society of Hematology (ASH) guidelines for the use of epoetin alfa and Aranesp in adult members with cancer recommend that ESAs not be used in treatment of anemia associated with malignancy in those who are not receiving concurrent myelosuppressive

chemotherapy.6

2. **Anemia Associated with Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia(CML) or other Myeloid Cancers**. Epoetin alfa is indicated for use in non-myeloid cancers. AML and CML are examples of myeloid cancers.1-3
3. **Anemia Associated with Radiotherapy in Cancer**. Epoetin alfa is not indicated for use in members with cancer who are only given radiation therapy.1-3
4. **To Enhance Athletic Performance.** Epoetin alfa is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.
5. **Anemia in Members due to Acute Blood Loss**. Use of epoetin alfa is not appropriate in these types of situations.
6. **Non-Anemic Members (Hemoglobin [Hgb] > 13.0 g/dL) prior to Surgery.** Although studies have been done that involved non-anemic members undergoing various surgeries receiving epoetin alfa preoperatively and sometimes postoperatively to prevent transfusions or subsequent anemia, the overall benefit of this therapy in those with relatively normal preoperative Hb level is questionable

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Anemia of prematurity-

The pathogenetic importance of impaired EPO production in AOP provides the rationale for the therapy with erythropoiesis stimulating agents (ESAs) including recombinant EPO. However, the administration of EPO has not been accepted widely because it appears to have limited efficacy in decreasing the number of blood donors to which the infant is exposed via transfusion, whether EPO is administered early (within the first week of life) or late (at or after eight days of life).

Although early administration (within the first eight days of life) of EPO reduces the number of transfusions required in preterm infants, (12) the small reduction may be of limited clinical importance, because EPO does not decrease the number of donor exposures due to the use of satellite packs.

These findings were best illustrated in a systematic review and meta-analysis of trials in preterm infants that evaluated the effect of early administration of EPO (given before eight days of age) compared with placebo or no intervention [38]. Many of these infants had received blood transfusions prior to enrollment in the trials. The following findings were noted: EPO reduced the risk of receiving one or more red blood cell transfusions (RR 0.79, 95% CI 0.74-0.85), the number of donors to whom transfused infants were exposed to was not reduced, mortality was similar for the EPO and placebo groups, similar risk of developing ROP stage ≥3 for both the EPO and placebo groups (relative risk [RR] 1.24, 95% CI 0.81-1.90). Infants in the EPO group had a lower risk of developing necrotizing enterocolitis (RR 0.69, 95% CI 0.52-91), neurodevelopmental impairment at 18 to 22 months postmenstrual age (PMA), intraventricular hemorrhage, and periventricular leukomalacia. (10) However, in a subsequent multicenter trial of 941 EPT infants studying the neuroprotective effects of EPO given within the first 24 hours after delivery, EPO compared with placebo had similar rates of the primary outcome of death or severe neurodevelopmental outcome at 22 to 26 months PMA (26 versus 26 percent; RR 1.03, [95% CI 0.81 to 1.32]). The groups also had similar rates of retinopathy of prematurity, intracranial hemorrhage, BPD, necrotizing enterocolitis, death or frequency of serious adverse effects (13)

Late administration of EPO reduces the number of transfusions, but the limited benefit does not justify its use. This was illustrated in a meta-analysis that evaluated the effects of late EPO administration (between) eight and 28 days after birth) compared with placebo or no intervention [40]. Most of these infants had received blood transfusions prior to enrollment in the trials. The following findings were noted: EPO reduced the risk of receiving one or more red blood cell transfusions (RR 0.72, 95% CI 0.65-0.79), EPO reduced the number of red blood cell transfusions (weighted mean difference of -0.22, 95% CI -0.38 to -0.06), There was no difference in the volume of blood transfused (mean difference -1.6 mL/kg, 95% CI -5.8

to 2.6) and Late EPO use had no effect on the rates for mortality, sepsis and necrotizing enterocolitis (NEC). However, there was a trend towards an increased risk of ROP associated with EPO administration (RR 1.27, 95% CI 0.99-1.64).

Late administration of EPO reduced the mean number of transfusions by a little less than one transfusion per infant. This small benefit of EPO was diminished due to the exposure of previous blood transfusions before eight days of life, and the use of satellite packs that would mitigate against additional donor exposure in the control group.

NOTE: For the purposes of this policy, a conversion factor of 3 should be used to estimate hemoglobin when only the hematocrit (Hct) is measured, e.g., hemoglobin of 10 g/dL is approximately equal to a hematocrit of 30%, a hemoglobin of 11 g/dL is approximately equal to a hematocrit of 33%, and a hemoglobin of 12 g/dL is approximately equal to a hematocrit of 36%

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

Uncontrolled hypertension, Hypersensitivity to epoetin or any component of the formulation; mammalian cell- derived products; to Albumin (Human), Pure red cell aplasia (PRCA) that alcohol and are contraindicated in neonates, infants, pregnant women, and nursing women, All NON-FDA approved
indications are considered experimental/investigational and therefore, will follow Molina's Off-Label policy., Anemia is associated with the treatment of AML (acute myelogenous leukemia), CML (chronic myelogenous leukemia), or erythroid cancers, Anemia is related to the cancer and not chemotherapy-induced or if anemia is only radiotherapy- induced Prescribed for use under the following conditions: Cancer members receiving hormonal therapy, therapeutic biologic products, or radiation therapy unless also receiving concurrent myelosuppressive chemotherapy or Cancer members receiving myelosuppressive chemotherapy when the expected outcome is curative
For Procrit/Epogen (epoetin alfa) only: Surgery members who are willing to donate autologous blood, Surgery members undergoing cardiac or vascular surgery or As a substitute for RBC transfusion in members requiring immediate correction of anemia Prescribed as treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count Concurrent Procrit/Epogen (epoetin alfa) and Aranesp (darbepoetin alfa) therapy
Begins after receipt of epoetin alfa or other erythropoietin protein drugs, Multidose vials contain benzyl alcohol and is contraindicated in pregnant women

OTHER SPECIAL CONSIDERATIONS:

Boxed warning: ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0885	Injection, epoetin alfa, (for non-ersd use), 1000 units
Q4081	Inj, epoetin alfa, 100 units (for esrd on dialysis)
J0881	Inj, darbepoetin alfa, 1microgram (non-esrd use)
J0882	Inj, darbepoetin alfa, 1microgram (for esrd on dialysis)

Q5105	Inj, epoetin alfa,biosimilar, (retacrit)(for esrd on dialysis), 100units
Q5106	Inj, epoetin alfa, biosimilar, (retacrit) (for non-esrd use), 1000 units
J0887	Inj, epoetin beta, 1microgram, (for esrd on dialysis)
J0888	Inj, epoetin beta, 1microgram, (for non esrduse)

AVAILABLE DOSAGE FORMS:

Aranesp (Single dose prefilled syringes) 10mcg/0.4 mL
Aranesp (Single dose prefilled syringes) 100mcg/0.5 mL
Aranesp (Single dose prefilled syringes) 150mcg/0.3 mL
Aranesp (Single dose prefilled syringes) 200mcg/0.4 mL
Aranesp (Single dose prefilled syringes) 25mcg/0.42mL
Aranesp (Single dose prefilled syringes) 300mcg/0.6 mL
Aranesp (Single dose prefilled syringes) 40mcg/0.4mL
Aranesp (Single dose prefilled syringes) 500mcg/mL
Aranesp (Single dose prefilled syringes) 60mcg/0.3 mL
Aranesp (Single dose vials) 100 mcg/mL.
Aranesp (Single dose vials) 200 mcg/mL
Aranesp (Single dose vials) 25 mcg/mL
Aranesp (Single dose vials) 300 mcg/mL
Aranesp (Single dose vials) 40 mcg/mL
Aranesp (Single dose vials) 500 mcg/mL
Aranesp (Single dose vials) 60 mcg/mL
Epogen (multi-dose vials, contains benzyl alcohol) 20,000units/mL
Epogen (multi-dose vials, contains benzyl alcohol) 40,000units/mL
Epogen (multi-dose vials, contains benzyl alcohol) 20,000units/2mL
Epogen (single dose vials) 10,000units/ mL
Epogen (single dose vials) 2000units/mL
Epogen (single dose vials) 3000units/mL
Epogen (single dose vials) 4000units/mL
Mircera SOSY Prefilled Syringe 100MCG/0.3ML
Mircera SOSY Prefilled Syringe 150MCG/0.3ML
Mircera SOSY Prefilled Syringe 200MCG/0.3ML
Mircera SOSY Prefilled Syringe 30MCG/0.3ML
Mircera SOSY Prefilled Syringe 50MCG/0.3ML
Mircera SOSY Prefilled Syringe 75MCG/0.3ML
Procrit (multi-dose vial containing benzyl alcohol) 20,000Units/mL
Procrit (multi-dose vial containing benzyl alcohol) 20,000units/2mL
Procrit (single dose vial) 10,000units/mL
Procrit (single dose vial) 2000units/mL
Procrit (single dose vial) 3000units/mL
Procrit (single dose vial) 40,000units/mL
Procrit (single dose vial) 4000units/mL
Retacrit (Multi-dose vial containing benzyl alcohol) 20,000units/2mL
Retacrit (Multi-dose vial containing benzyl alcohol) 20,000Units/mL
Retacrit (Single-dose vial) 10,000units/Ml
Retacrit (Single-dose vial) 2000units/mL
Retacrit (Single-dose vial) 3000units/mL
Retacrit (Single-dose vial) 40,000units/mL
Retacrit (Single-dose vial) 4000units/mL

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file