

Medical Drug Clinical Criteria

Subject:	Erythropoiesis Stimulating Agents		
Document #:	CC-0001	Publish Date:	03/27/2023
Status:	Revised	Last Review Date:	11/19/2021

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Overview

This document addresses recombinant erythropoietin products, also known as erythropoiesis stimulating agents (ESAs):

- Aranesp (darbepoetin alfa)
- Epogen (epoetin alfa)
- Mircera (methoxy polyethylene glycol-epoetin beta)
- Procrit (epoetin alfa)
- Retacrit (epoetin alfa-epbx)

Erythropoietin (EPO) is a hormone naturally produced in the body, primarily by the kidneys, which stimulates the bone marrow to produce red blood cells. ESAs are approved for the treatment of severe anemia in chronic kidney disease (CKD), HIV, cancer, surgery and other indications as applicable.

ESAs have black box warnings for an increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence.

For CKD: In controlled trials, individuals experienced greater risks for death, serious adverse cardiovascular reactions and stroke when ESAs were administered to target a hemoglobin (Hgb) level greater than 11 g/dL. Use the lowest dose needed to reduce the need for red blood cell (RBC) transfusions.

For Cancer: In controlled trials, ESAs shortened overall survival and/or increased the risk for tumor progression or recurrence in individuals with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. Use the lowest dose needed to avoid RBC transfusions. Use ESAs only for anemia from myelosuppressive chemotherapy when the anticipated outcome is not cure and discontinue ESAs following completion of a chemotherapy course. Per specialty committee consensus opinion in 4Q21, ongoing treatment with Aranesp or epoetin alfa agents may be used to maintain a hemoglobin level of no greater than 11g/dL in individuals using for myelosuppressive chemotherapy related anemia or myelodysplastic syndrome due to the risk vs. benefit ratio with higher hemoglobin targets.

For Perisurgery: Deep venous thrombosis (DVT) prophylaxis is recommended due to increased risk for DVTs.

ESAs are contraindicated in individuals with uncontrolled hypertension. Blood pressure should be adequately controlled prior to initiation and during treatment with ESAs.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Aranesp (darbepoetin alfa)

Initial requests for Aranesp (darbepoetin alfa) may be approved if the following criteria are met:

- I. Individual has a baseline hemoglobin (Hgb) level less than 10 g/dL; **AND**
- II. Baseline iron status is adequate as defined by one of the following:
 - A. Transferrin saturation 20% or greater; **OR**
 - B. Ferritin 80 ng/mL or greater; **OR**

- C. Bone marrow demonstrates adequate iron stores;

AND

- III. Individual is using for one of the following:
 - A. Anemia associated with chronic kidney disease (CKD), for individuals on dialysis, to achieve and maintain Hgb levels within the range of 10 to 11 g/dL; **OR**
 - B. Anemia associated with CKD, for individuals not on dialysis, to achieve and maintain Hgb levels of 10 g/dL; **OR**
 - C. Myelosuppressive chemotherapy when the following are met:
 - 1. Chemotherapy is planned for a minimum of 2 months; **AND**
 - 2. Individual has a diagnosis of non-myeloid cancer and the anticipated outcome is not cure;
- OR**
- D. Myelodysplastic syndrome with an endogenous erythropoietin level less than or equal to 500 mU/mL (NCCN 2A).

Continuation requests for Aranesp (darbepoetin alfa) may be approved if the following criteria are met:

- I. Individual demonstrates continued need for ESA treatment and has confirmation of response to treatment as evidenced by an increase in hemoglobin levels from baseline (i.e., increase of approximately 1 g/dL or greater from baseline); **AND**
- II. Individual is using the lowest ESA dose necessary to avoid transfusions; **AND**
- III. Individual meets one of the following criteria:
 - A. Hemoglobin level is not greater than 11 g/dL for CKD individuals on dialysis, or greater than 10 g/dL for CKD non-dialysis, unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels is within the range of 10 to 12 g/dL); **OR**
 - B. Hemoglobin level is not greater than 11 g/dL for individuals using for myelosuppressive chemotherapy related anemia or myelodysplastic syndrome; **AND**
- IV. If using for myelosuppressive chemotherapy-related anemia, individual is not using beyond 6 weeks after chemotherapy has completed.

Aranesp (darbepoetin alfa) may not be approved for the following:

- I. Continued use when the hemoglobin level exceeds 11 g/dL unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels within the range of 10 to 12 g/dL);
- II. Individuals with uncontrolled hypertension;
- III. Use beyond 12 weeks of continuous treatment at therapeutic doses in the absence of response in individuals with chronic kidney disease;
- IV. Use beyond 8 weeks of continuous treatment at therapeutic doses in the absence of response in individuals with myelodysplastic syndrome (MDS);
- V. Use beyond 8 weeks of continuous treatment at therapeutic doses in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia;
- VI. As treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count;
- VII. To treat anemia in individuals with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion;
- VIII. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed.

Epogen, Procrit (epoetin alfa); Procrit (epoetin alfa); Retacrit (epoetin alfa-epbx)

Initial requests for Epogen (epoetin alfa), Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx) may be approved if the following criteria are met:

- I. Individual has a baseline hemoglobin (Hgb) level less than 10 g/dL; **AND**
- II. Baseline iron status is adequate as defined by one of the following:
 - A. Transferrin saturation 20% or greater; **OR**
 - B. Ferritin 80 ng/mL or greater; **OR**
 - C. Bone marrow demonstrates adequate iron stores;

AND

- III. Individual is using for one of the following:
 - A. Anemia associated with chronic kidney disease (CKD), for individuals on dialysis, to achieve and maintain Hgb levels within the range of 10 to 11 g/dL; **OR**
 - B. Anemia associated with CKD, for individuals not on dialysis, to achieve and maintain Hgb levels of 10 g/dL; **OR**
 - C. Myelosuppressive chemotherapy when the following are met:
 - 1. Chemotherapy is planned for a minimum of 2 months; **AND**
 - 2. Individual has a diagnosis of non-myeloid cancer and the anticipated outcome is not cure;
- OR**
- D. Myelodysplastic syndrome with an endogenous erythropoietin level less than or equal to 500 mU/mL (NCCN 2A); **OR**

- E. HIV infection, receiving zidovudine at a dose less than or equal to 4200 mg/week, with an endogenous erythropoietin level less than or equal to 500 mU/mL.

Continuation requests for Epogen (epoetin alfa), Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx) may be approved if the following criteria are met:

- I. Individual demonstrates continued need for ESA treatment and has confirmation of response to treatment as evidenced by an increase in hemoglobin levels from baseline (i.e., increase of approximately 1 g/dL or greater from baseline); **AND**
- II. Individual is using the lowest ESA dose necessary to avoid transfusions; **AND**
- III. Individual meets one of the following criteria:
 - A. Hemoglobin level is not greater than 11 g/dL for CKD individuals on dialysis, or greater than 10 g/dL for CKD non-dialysis, unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels is within the range of 10 to 12 g/dL); **OR**
 - B. Hemoglobin level is not greater than 11 g/dL for individuals using for myelosuppressive chemotherapy related anemia or myelodysplastic syndrome; **OR**
 - C. Hemoglobin level is not greater than 12 g/dL for zidovudine-related anemia in patients with HIV (Label); **AND**
- IV. If using for myelosuppressive chemotherapy-related anemia, individual is not using beyond 6 weeks after chemotherapy has completed.

Initial and continuation requests for Epogen (epoetin alfa), Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx) may also be approved if the following criteria are met:

- I. Individual is undergoing elective, non-cardiac, non-vascular surgery and requires Epogen, Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx) to reduce the need for allogenic blood transfusions; **AND**
 - A. Baseline Hgb level is greater than 10 g/dL and less than or equal to 13 g/dL; **AND**
 - B. Individual is at high risk for perioperative transfusions with significant, anticipated blood loss; **AND**
 - C. Baseline iron status is adequate as defined by one of the following:
 - 1. Transferrin saturation 20% or greater; **OR**
 - 2. Ferritin 80 ng/mL or greater; **OR**
 - 3. Bone marrow demonstrates adequate iron stores.

Epogen (epoetin alfa), Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx) may not be approved for the following:

- I. Continued use when the hemoglobin level exceeds 11 g/dL unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels within the range of 10 to 12 g/dL);
- II. Individuals with uncontrolled hypertension;
- III. Use beyond 12 weeks of continuous treatment at therapeutic doses in the absence of response in individuals with chronic kidney disease;
- IV. Use beyond 8 weeks of continuous treatment at therapeutic doses in the absence of response in individuals with myelodysplastic syndrome (MDS);
- V. Use beyond 8 weeks of continuous treatment at therapeutic doses in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia;
- VI. As treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count;
- VII. To treat anemia in individuals with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion;
- VIII. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed

Mircera (methoxy polyethylene glycol-epoetin beta)

Initial requests for Mircera (methoxy polyethylene glycol-epoetin beta) may be approved if the following criteria are met:

- I. Individual has a baseline hemoglobin (Hgb) level less than 10 g/dL; **AND**
- II. Baseline iron status is adequate as defined by one of the following:
 - A. Transferrin saturation 20% or greater; **OR**
 - B. Ferritin 80 ng/mL or greater; **OR**
 - C. Bone marrow demonstrates adequate iron stores;

AND

- III. Individual is using for one of the following:
 - A. Anemia associated with chronic kidney disease (CKD), for individuals on dialysis, to achieve and maintain Hgb levels within the range of 10 to 11 g/dL; **OR**
 - B. Anemia associated with CKD, for individuals not on dialysis, to achieve and maintain Hgb levels of 10 g/dL.

Continuation requests for Mircera (methoxy polyethylene glycol-epoetin beta) may be approved if the following criteria are met:

- I. Individual demonstrates continued need for ESA treatment and has confirmation of response to treatment as evidenced by an increase in hemoglobin levels from baseline (i.e., increase of approximately 1 g/dL or greater from baseline); **AND**
- II. Individual is using the lowest ESA dose necessary to avoid transfusions; **AND**
- III. Hemoglobin level is not greater than 11 g/dL for CKD individuals on dialysis, or greater than 10 g/dL for CKD non-dialysis, unless otherwise specified.

Mircera (methoxy polyethylene glycol-epoetin beta) may not be approved for the following:

- I. Continued use when the hemoglobin level exceeds 11 g/dL unless otherwise specified;
- II. Individuals with uncontrolled hypertension;
- III. Use beyond 12 weeks of continuous treatment at therapeutic doses in the absence of response in individuals with chronic kidney disease;
- IV. As treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count.

Approval Duration for Erythropoiesis Stimulating Agents (dialysis-dependent use excluded)

Initial Requests: 6 months
 Continuation Requests: 6 months

Step Therapy

Summary of FDA-Approved Indications or Indications Meeting Off-Label Use Policy for Erythropoiesis Stimulating Agents (ESAs):

Agent	Aranesp	Epogen	Mircera	Procrit	Retacrit
Anemia due to CKD	X	X	X	X	X
Anemia due to zidovudine in HIV infection		X		X	X
Anemia due to myelosuppressive chemotherapy	X	X		X	X
Reduction of allogenic RBC transfusions in individuals undergoing elective, non-cardiac, non-vascular surgery		X		X	X
Myelodysplastic syndrome [†]	X	X		X	X

[†] Off-label use

Note: When an erythropoiesis stimulating agent (ESA) is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferred¹ agent or agents.

Non-Preferred Erythropoiesis Stimulating Agents (ESAs) Step Therapy

A list of the preferred erythropoiesis stimulating agents is available [here](#).

In the presence of a drug shortage of the preferred product, the non-preferred product may be approved.

Requests for a non-preferred erythropoiesis stimulating agent (ESA) may be approved if the following criteria are met:

- I. If designated, individual has had a trial and inadequate response or intolerance to one preferred ESA;
- OR**
- II. The preferred agent is not FDA-approved and does not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does;
- OR**
- III. If Epogen (epoetin alfa), Procrit (epoetin alfa), or Retacrit (epoetin alfa-epbx) are designated as non-preferred agents, either may be approved if individual is requesting for anemia associated with one of the following:
 - A. Chronic kidney disease and between 1 month and less than 12 months of age; **OR**
 - B. Myelosuppressive chemotherapy and between 5 years and less than 18 years of age;
- OR**
- IV. Individual is dialysis-dependent and using in conjunction with dialysis.

¹Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Erythropoiesis Stimulating Agents Quantity Limits

Drug	Limit
Aranesp (darbepoetin alfa) 10 mcg/0.4 mL, 40 mcg/0.4 mL, 200 mcg/0.4 mL Syringe	4 syringes (1.6 mL) per 28 days
Aranesp (darbepoetin alfa) 25 mcg/0.42 mL Syringe	4 syringes (1.68 mL) per 28 days
Aranesp (darbepoetin alfa) 60 mcg/0.3 mL, 150 mcg/0.3 mL Syringe	4 syringes (1.2 mL) per 28 days
Aranesp (darbepoetin alfa) 100 mcg/0.5 mL Syringe	4 syringes (2 mL) per 28 days
Aranesp (darbepoetin alfa) 300 mcg/0.6 mL Syringe	4 syringes (2.4 mL) per 28 days
Aranesp (darbepoetin alfa) 500 mcg/mL Syringe	4 syringes (4 mL) per 28 days
Aranesp (darbepoetin alfa) 25 mcg/mL, 40 mcg/mL, 60 mcg/mL, 100 mcg/mL, 200 mcg/mL, 300 mcg/mL Vial	4 vials (4 mL) per 28 days
Epogen (epoetin alfa) 2,000 Units/mL; 3,000 Units/mL; 4,000 Units/mL; 10,000 Units/mL Vial; 20,000 Units/mL Vial *	12 vials (12 mL) per 28 days
Epogen (epoetin alfa) 20,000 Units/2 mL Multi-Dose Vial*	6 vials (12 mL) per 28 days
Mircera (methoxy polyethylene glycol-epoetin beta) 30 mcg/0.3mL, 50 mcg/0.3 mL, 75 mcg/0.3 mL, 100 mcg/0.3 mL, 150 mcg/0.3 mL, 200 mcg/0.3 mL Syringe	2 syringes (0.6 mL) per 28 days
Procrit (epoetin alfa) 2,000 Units/mL; 3,000 Units/mL; 4,000 Units/mL; 10,000 Units/mL; 20,000 Units/mL; 40,000 Units/mL Vial**	12 vials (12 mL) per 28 days
Procrit (epoetin alfa) 20,000 Units/2 mL Multi-Dose Vial**	6 vials (12 mL) per 28 days
Retacrit (epoetin alfa-epbx) 2,000 Units/mL; 3,000 Units/mL; 4,000 Units/mL; 10,000 Units/mL; 20,000 Units/mL, 40,000 Units/mL Vial†	12 vials (12 mL) per 28 days
Retacrit (epoetin alfa-epbx) 20,000 Units/2 mL Multi-Dose Vial†	6 vials (12 mL) per 28 days
Override Criteria	
*When Epogen (epoetin alfa) is being used to reduce the need for allogeneic red blood cell transfusions in elective, noncardiac, nonvascular surgery, may allow up to an additional 3 vials (2,000 Units/mL; 3,000 Units/mL; 4,000 Units/mL; 10,000 Units/mL; 20,000 Units/mL; 20,000 Units/2 mL) in a rolling 28 days for completion of therapy.	
**When Procrit (epoetin alfa) is being used to reduce the need for allogeneic red blood cell transfusions in elective, noncardiac, nonvascular surgery, may allow up to an additional 3 vials (2,000 Units/mL; 3,000 Units/mL; 4,000 Units/mL; 10,000 Units/mL; 20,000 Units/mL; 20,000 Units/2 mL; 40,000 Units/mL) in a rolling 28 days for completion of therapy.	
†When Retacrit (epoetin alfa-epbx) is being used to reduce the need for allogeneic red blood cell transfusions in elective, noncardiac, nonvascular surgery, may allow up to an additional 3 vials (2,000 Units/mL; 3,000 Units/mL; 4,000 Units/mL; 10,000 Units/mL; 40,000 Units/mL) in a rolling 28 days for completion of therapy.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J0881	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)
J0885	Injection, epoetin alfa (for non-ESRD use), 1000 units [Epogen, Procrit]
J0887	Injection, epoetin beta, 1 microgram, (for ESRD on dialysis) [Mircera]
J0888	Injection, epoetin beta, 1 microgram, (for non-ESRD use) [Mircera]
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis) [Epogen, Procrit]
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units

EA	Erythropoetic stimulating agent (ESA) administered to treat anemia due to anti-cancer chemotherapy
EB	Erythropoetic stimulating agent (ESA) administered to treat anemia due to anti-cancer radiotherapy
EC	Erythropoetic stimulating agent (ESA) administered to treat anemia not due to anti-cancer radiotherapy or anti-cancer chemotherapy

ICD-10 Diagnosis

D63.1	Anemia in chronic kidney disease
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
N18.1-N18.5	Chronic kidney disease (CKD) Stages I-V
N18.6	End state renal disease

Document History

Revised: 08/19/2022

Document History:

- 03/27/2023 – Step therapy table updates.
- 01/25/2023 – Step therapy table updates.
- 08/19/2022 – Annual Review: wording and formatting change, remove Aranesp vial. Coding Reviewed: No changes.
- 02/01/2022 – Administrative update for drug shortage.
- 11/19/2021 – Select Review: Update Aranesp and epoetin alfa agents criteria to change maximum hemoglobin level in MDS and myelosuppressive chemotherapy-related anemia for continuation of therapy. Add notation regarding maximum hemoglobin levels per committee specialist consensus. Update continuation criteria for Aranesp to align with continuation criteria for epoetin alfa products. Update continuation criteria for epoetin alfa agents in zidovudine-related anemia in HIV patients. Clarify initiation and continuation criteria for epoetin alfa in elective surgeries. Step therapy table updates. Coding reviewed: No changes.
- 08/20/2021 – Annual Review: Update criteria to add continuation criteria for all ESA agents. Update criteria to remove requirement for autologous blood donations in peri-operative use. Update non-approvable criteria to clarify response to treatment after 8 and 12 weeks of therapy. Update Epogen QL and override for consistency. Wording and formatting changes. Coding reviewed: No changes.
- 11/20/2020 – Select Review: Update criteria to clarify response to treatment after 8 and 12 weeks of therapy. Coding Reviewed: Added HCPCS code Q4081, Removed HCPCS S9537. Added ICD-0-CM D63.1, I12.0, N18.1-N18.5, N18.6.
- 08/21/2020 – Annual Review: Update criteria to add approval duration. Clarify use in MDS per NCCN. Clarify step therapy to exclude patients with ESRD on dialysis. Update quantity limits to add new strengths for Retacrit. Coding reviewed: No changes.
- 08/16/2019 – Annual Review: Update criteria to change timeframe for response from 8-9 weeks to 8 weeks with use in myelosuppressive chemotherapy. Update quantity limit for all agents to clarify day supply limits. Coding Review: No changes.
- 08/17/2018 – Annual Review: Initial review of CG-DRUG-05. Update epoetin alfa PA to add new biosimilar agent Retacrit and delete off-label indications for hepatitis C, chronic inflammatory disease receiving myelosuppressive drugs, and bone marrow transplant as they do not meet off-label use policy requirements. Update Non-Preferred Erythropoiesis Stimulating Agents step edit to add Retacrit as a potential preferred agent. Move uncontrolled hypertension from approval criteria to not approved section in PAs for clarity. Modify not approved sections in darbepoetin and epoetin alfa PAs to allow for higher Hgb threshold in pediatric individuals with CKD per label updates. Add new QLs for Retacrit per label. Wording and formatting changes for consistency.
- 11/08/2018 – Reviewed HCPCS and ICD-10 coding. No change. HCPCS coding up to date. Kept ICD-10 at all diagnosis. Criteria to designate medical necessity.

References

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Inter*. 2012; Suppl 2: 279–335. Available from: https://www.kidney.org/professionals/guidelines/guidelines_commentaries/anemia. Accessed on June 22, 2022.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 22, 2022.
 - a. Hematopoietic Growth Factors. Version 1.2022. Revised December 22, 2021.
 - b. Myelodysplastic Syndromes. Version 3.2022. Revised January 13, 2022.
 - c. Myeloproliferative Neoplasms. Version 2.2022. Revised April 13, 2022.

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CC-0001 Erythropoiesis Stimulating Agents

Commercial Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
N/A	N/A	N/A
01/01/2022 CalPERS For members 18 years and older, step therapy criteria applies to new starts only (defined as no use of the requested Epogen/Procrit product in the last 12 months)	Retacrit	Epogen Procrit

Medicaid Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
03/01/2020: MD, NY, NJ, NV, SC, DC, WNY 03/15/2020: GA, IN 04/01/2020: KY 06/01/2020: CA 02/01/2023: OH 04/01/2023: DC	Retacrit	Procrit <i>(only applies to non-ESRD use – J0885)</i>

Medicare Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
N/A	N/A	N/A