

Erythropoiesis Stimulating Agents (ESAs): Epogen/Procrit® (epoetin alfa) (Subcutaneous/Intravenous)

NON-DIALYSIS

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I. Length of Authorization

- Coverage will be provided for 45 days and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 2,000 U/mL single-dose vial: 3 vials per week
- 3,000 U/mL single-dose vial: 3 vials per week
- 4,000 U/ml single-dose vial: 3 vials per week
- 10,000 U/mL single-dose vial: 3 vials per week
- 10,000 U/mL 2 mL multi-dose vial: 3 vials per week
- 20,000 U/mL multi-dose vial: 3 vials per week
- 40,000 U/mL single-dose vial: 1 vial per week

B. Max Units (per dose and over time) [Medical Benefit]:

- MDS and MPN: 120 billable units every 7 days
- Surgery patients: 600 billable units every 15 days
- All other indications: 60 billable units every 7 days

III. Initial Approval Criteria

Retacrit is the preferred erythropoiesis stimulating agent (ESA) product.

- Patients must have a contraindication or intolerance to Retacrit prior to consideration of any other erythropoietin product.
- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**

- Prior to initiation of therapy, patient should have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) $\geq 20\%^*$; **AND**
- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) $< 30\%$ (unless otherwise specified); **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**

Procrit/Epogen is covered for the following indication(s):

Anemia secondary to myelodysplastic syndrome (MDS) ‡

- Treatment of lower risk disease associated with symptomatic anemia; **AND**
- Endogenous serum erythropoietin level of ≤ 500 mUnits/mL

Anemia secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis ‡

- Endogenous serum erythropoietin level of < 500 mUnits/mL

Anemia secondary to Hepatitis C treatment ‡

- Patient is receiving interferon AND ribavirin

Anemia secondary to rheumatoid arthritis ‡

Anemia secondary to chemotherapy treatment †

- Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
- Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
- There are a minimum of two additional months of planned chemotherapy

Anemia secondary to chronic kidney disease (non-dialysis patients) †

Anemia secondary to zidovudine treated, HIV-infected patients †

- Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
- Patient is receiving zidovudine administered at ≤ 4200 mg/week

Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery †

- Hemoglobin (Hb) between 10 g/dL and 13 g/dL and/or Hematocrit (Hct) between 30% and 39%; **AND**
- Surgery must be elective, non-cardiac and non-vascular

Anemia of Prematurity ‡

- Used in combination with iron supplementation

† FDA approved indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Last dose less than 60 days ago; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe cardiovascular events (stroke, myocardial infarction, thromboembolism, uncontrolled hypertension), tumor progression or recurrence in patients with cancer, seizures, pure red cell aplasia, severe cutaneous reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis), “gaspings syndrome” (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.; **AND**
- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) $\geq 20\%$ measured within the previous 3 months*; **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**

Anemia secondary to myelodysplastic syndrome (MDS):

- Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) $< 36\%$

Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis)

- Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) $< 30\%$

Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery

- Hemoglobin(Hb) between 10 g/dL and 13 g/dL and/or Hematocrit(Hct) between 30% and 39%

Anemia secondary to chemotherapy treatment

- Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) $< 30\%$; **AND**
- Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
- There are a minimum of two additional months of planned chemotherapy

Anemia secondary to zidovudine treated, HIV-infected patients:

- Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) $< 36\%$; **AND**
- Patient is receiving zidovudine administered at ≤ 4200 mg/week

Anemia secondary to Hepatitis C treatment:

- Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) $< 33\%$; **AND**
- Patient must be receiving interferon AND ribavirin

Anemia secondary to chronic kidney disease:

- **Pediatric patients:** Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) $< 36\%$
- **Adults:** Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) $< 33\%$

All other indications:

- Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

* Intravenous iron supplementation may be taken into account when evaluating iron status

V. Dosage/Administration

Indication	Dose
Anemia due to CKD – non-dialysis §	<ul style="list-style-type: none"> • Adults: 50-100 units/kg intravenously or subcutaneously three times weekly • Pediatric patients: 50 units/kg intravenously or subcutaneously three times weekly
Anemia due to HIV on zidovudine	<ul style="list-style-type: none"> • 100 units/kg three times weekly • May titrate up to 300 units/kg
Anemia due to chemotherapy§	<ul style="list-style-type: none"> • Adults: 150 units/kg intravenously or subcutaneously three times weekly or 40,000 units once weekly <ul style="list-style-type: none"> ○ May titrate up to 300 units/kg three times weekly or 60,000 units once weekly • Pediatric patients (5-18 years): 600 units/kg intravenously or subcutaneously once weekly <ul style="list-style-type: none"> ○ May titrate up to 900 units/kg once weekly
Perioperative use	<ul style="list-style-type: none"> • 300 units/kg/day subcutaneously for 10 days before surgery, on the day of surgery, and for 4 days after surgery (15 days total) • 600 units/kg/dose subcutaneously on days 21, 14, and 7 before surgery plus 1 dose on the day of surgery (4 total doses)
Anemia due to HCV	<ul style="list-style-type: none"> • 40,000 units intravenously or subcutaneously once weekly • May titrate up to 60,000 units weekly
Anemia due to MDS/MPN	<ul style="list-style-type: none"> • 150-300 units/kg intravenously or subcutaneously three times weekly • 40,000 to 60,000 units once to twice weekly
All other indications	Dosing varies; generally up to 150 units/kg intravenously or subcutaneously three times weekly
Most commonly initiated dose	40,000 units weekly

§

- Dose increases of 25% can be considered if after 4 weeks of initial therapy the hemoglobin has increased less than 1 g/dL and the current hemoglobin level is less than the indication specific level noted above
- Dose decreases of 25% or more can be considered if the hemoglobin rises rapidly by more than 1 g/dL in any 2-week period
- Dose and frequency requested are the minimum necessary for the patient to avoid RBC transfusions.
- For patients with CKD,
 - Avoid frequent dose adjustments. Do not increase the dose more frequently than once every 4 weeks; decreases can occur more frequently.
 - If patients fail to respond over a 12-week dose escalation period, further doses increases are unlikely to improve response and discontinuation of therapy should be considered.
- For patients on Cancer Chemotherapy
 - After 8 weeks of therapy, if there is no response as measured by hemoglobin levels or if RBC transfusions are still required, discontinue therapy
- For zidovudine treated HIV infected patients
 - If the patient fails to respond after 8 weeks of therapy, increase dose by approximately 50-100 U/kg at 4- to 8- week until the hemoglobin reaches levels need to avoid transfusion or max dosing reached.
 - If the hemoglobin exceeds the indication specific level noted above, withhold therapy and resume therapy once level declines to <11 g/dL, at a dose 25% below the previous dose.

VI. Billing Code/Availability Information

Jcode:

- J0885 – Injection, epoetin alfa, (for non-esrd use), 1000 units: 1 billable unit = 1,000 Units

NDC:

- Epogen 2,000 U/mL single-dose vial solution for injection: 55513-0126
- Epogen 3,000 U/mL single-dose vial solution for injection: 55513-0267
- Epogen 4,000 U/ml single-dose vial solution for injection: 55513-0148
- Epogen 10,000 U/mL single-dose vial solution for injection: 55513-0144
- Epogen 10,000 U/mL 2 mL multi-dose vial solution for injection: 55513-0283
- Epogen 20,000 U/mL 1 mL multi-dose vial solution for injection: 55513-0478
- Procrit 2,000 U/mL single-dose vial solution for injection 59676-0302
- Procrit 3,000 U/mL single-dose vial solution for injection 59676-0303)
- Procrit 4,000 U/mL single-dose vial solution for injection 59676-0304
- Procrit 10,000 U/mL single-dose vial solution for injection 59676-0310
- Procrit 10,000 U/mL 2 mL multi-dose vial solution for injection: 59676-0312
- Procrit 20,000 U/mL 1 mL multi-dose vial solution for injection: 59676-0320
- Procrit 40,000 U/mL single-dose vial solution for injection: 59676-0340

VII. References

1. Procrit [package insert]. Horsham, PA; Janssen Products, LP; September 2017. Accessed March 2018.
2. Epogen [package insert]. Thousand Oaks, CA; Amgen, Inc; September 2017. Accessed March 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin alfa. National Comprehensive Cancer Network, 2018. The NCCN

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5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) Myelodysplastic Syndrome Version 2.2018. National Comprehensive Cancer Network, 2017. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) Myeloproliferative Neoplasms Version 2.2018. National Comprehensive Cancer Network, 2017. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
7. Peeters, HR, Jongen-Lavrencic, M, Vreugdenhil, G, Swaak, AJ. Effect of recombinant human erythropoietin on anaemia and disease activity in patients with rheumatoid arthritis and anaemia of chronic disease: a randomized placebo controlled double blind 52 weeks clinical trial. *Ann Rheum Dis* 1996; 55:739.
8. Pincus T, Olsen NJ, Russell IJ, et al. Multicenter study of recombinant human erythropoietin in correction of anemia in rheumatoid arthritis. *Am J Med* 1990; 89:161-8.
9. Saag, MS, Bowers, P, Leitz, GJ, Levine, AM. Once-weekly epoetin alfa improves quality of life and increases hemoglobin in anemic HIV+ patients. *AIDS Res Hum Retroviruses* 2004; 20:1037.
10. Grossman, HA, Goon, B, Bowers, P, Leitz, G. Once-weekly epoetin alfa dosing is as effective as three times-weekly dosing in increasing hemoglobin levels and is associated with improved quality of life in anemic HIV-infected patients. *J Acquir Immune Defic Syndr* 2003; 34:368.
11. Afdhal, NH, Dieterich, DT, Pockros, PJ, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: a prospective, double-blind, randomized controlled study. *Gastroenterology* 2004; 126:1302.
12. Cervantes F, Alvarez-Laran A, Hernandez-Boluda JC, et al. Erythropoietin treatment of the anaemia of myelofibrosis with myeloid metaplasia: results in 20 patients and review of the

literature. British Journal of Haematology, 127: 399–403. doi:10.1111/j.1365-2141.2004.05229.x

13. Shaffer CL, Ransom JL. Current and theoretical considerations of erythropoietin use in anemia of bronchopulmonary dysplasia. J of Pediatric Pharmacy Practice 1996; 1:23-29.
14. Reiter PD, Rosenberg AA, Valuck RJ. Factors associated with successful epoetin alfa therapy in premature infants. Ann Pharmacother 2000; 34:433-439.
15. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents - Epoetin alfa, Epoetin beta, Darbepoetin alfa, Peginesatide (L34633). Centers for Medicare & Medicaid Services, Inc. Updated on 09/20/2017 with effective dates 10/1/2017. Accessed March 2018.
16. CGS Administrators, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L34356). Centers for Medicare & Medicare Services. Updated on 02/26/2018 with effective dates 10/01/2017. Accessed March 2018.
17. First Coast Service Options, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L36276). Centers for Medicare & Medicare Services. Updated on 02/22/2018 with effective dates 02/08/2018. Accessed March 2018.
18. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Centers for Medicare & Medicare Services, Inc. Updated 12/3/2015 with an effective date 10/1/2015. Accessed March 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
B18.2	Chronic viral hepatitis C
B19.20	Unspecified viral hepatitis C without hepatic coma
B20	Human immunodeficiency virus [HIV] disease
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia, in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.21	Extramedullary plasmacytoma in remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.31	Solitary plasmacytoma in remission
C90.32	Solitary plasmacytoma in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C93.10	Chronic myelomonocytic leukemia, not having achieved remission
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis in remission
C94.42	Acute panmyelosis with myelofibrosis in relapse

C94.6	Myelodysplastic disease, not classified
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.Z	Other myelodysplastic syndromes
D47.1	Malignant neoplasm of peripheral nerves of upper limb, including shoulder
D47.4	Malignant neoplasm of peripheral nerves of abdomen
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agent
D61.3	Idiopathic aplastic anemia
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D63.0	Anemia in neoplastic disease
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic diseases classified elsewhere
D64.81	Anemia due to antineoplastic chemotherapy
D64.9	Anemia unspecified
D75.81	Secondary polycythemia
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
M05.10	Rheumatoid lung disease with rheumatoid arthritis of unspecified site
M05.111	Rheumatoid lung disease with rheumatoid arthritis of right shoulder
M05.112	Rheumatoid lung disease with rheumatoid arthritis of left shoulder
M05.119	Rheumatoid lung disease with rheumatoid arthritis of unspecified shoulder
M05.121	Rheumatoid lung disease with rheumatoid arthritis of right elbow
M05.122	Rheumatoid lung disease with rheumatoid arthritis of left elbow
M05.129	Rheumatoid lung disease with rheumatoid arthritis of unspecified elbow
M05.131	Rheumatoid lung disease with rheumatoid arthritis of right wrist
M05.132	Rheumatoid lung disease with rheumatoid arthritis of left wrist
M05.139	Rheumatoid lung disease with rheumatoid arthritis of unspecified wrist
M05.141	Rheumatoid lung disease with rheumatoid arthritis of right hand

M05.142	Rheumatoid lung disease with rheumatoid arthritis of left hand
M05.149	Rheumatoid lung disease with rheumatoid arthritis of unspecified hand
M05.151	Rheumatoid lung disease with rheumatoid arthritis of right hip
M05.152	Rheumatoid lung disease with rheumatoid arthritis of left hip
M05.159	Rheumatoid lung disease with rheumatoid arthritis of unspecified hip
M05.161	Rheumatoid lung disease with rheumatoid arthritis of right knee
M05.162	Rheumatoid lung disease with rheumatoid arthritis of left knee
M05.169	Rheumatoid lung disease with rheumatoid arthritis of unspecified knee
M05.171	Rheumatoid lung disease with rheumatoid arthritis of right ankle and foot
M05.172	Rheumatoid lung disease with rheumatoid arthritis of left ankle and foot
M05.179	Rheumatoid lung disease with rheumatoid arthritis of unspecified ankle and foot
M05.19	Rheumatoid lung disease with rheumatoid arthritis of multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist

M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow

M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement

M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip

M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.80	Other specified rheumatoid arthritis, unspecified site
M06.811	Other specified rheumatoid arthritis, right shoulder
M06.812	Other specified rheumatoid arthritis, left shoulder
M06.819	Other specified rheumatoid arthritis, unspecified shoulder
M06.821	Other specified rheumatoid arthritis, right elbow
M06.822	Other specified rheumatoid arthritis, left elbow
M06.829	Other specified rheumatoid arthritis, unspecified elbow
M06.831	Other specified rheumatoid arthritis, right wrist
M06.832	Other specified rheumatoid arthritis, left wrist

M06.839	Other specified rheumatoid arthritis, unspecified wrist
M06.841	Other specified rheumatoid arthritis, right hand
M06.842	Other specified rheumatoid arthritis, left hand
M06.849	Other specified rheumatoid arthritis, unspecified hand
M06.851	Other specified rheumatoid arthritis, right hip
M06.852	Other specified rheumatoid arthritis, left hip
M06.859	Other specified rheumatoid arthritis, unspecified hip
M06.861	Other specified rheumatoid arthritis, right knee
M06.862	Other specified rheumatoid arthritis, left knee
M06.869	Other specified rheumatoid arthritis, unspecified knee
M06.871	Other specified rheumatoid arthritis, right ankle and foot
M06.872	Other specified rheumatoid arthritis, left ankle and foot
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot
M06.88	Other specified rheumatoid arthritis, vertebrae
M06.89	Other specified rheumatoid arthritis, multiple sites
M06.9	Rheumatoid arthritis, unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified
P07.20	Extreme immaturity of newborn unspecified weeks of gestation
P07.21	Extreme immaturity of newborn gestational age less than 23 completed weeks
P07.22	Extreme immaturity of newborn gestational age 23 completed weeks
P07.23	Extreme immaturity of newborn gestational age 24 completed weeks
P07.24	Extreme immaturity of newborn gestational age 25 completed weeks
P07.25	Extreme immaturity of newborn gestational age 26 completed weeks
P07.26	Extreme immaturity of newborn gestational age 27 completed weeks
P07.30	Preterm newborn, unspecified weeks of gestation
P07.31	Preterm newborn, gestational age 28 completed weeks
P07.32	Preterm newborn, gestational age 29 completed weeks
P07.33	Preterm newborn, gestational age 30 completed weeks
P07.34	Preterm newborn, gestational age 31 completed weeks
P07.35	Preterm newborn, gestational age 32 completed weeks
P07.36	Preterm newborn, gestational age 33 completed weeks
P07.37	Preterm newborn, gestational age 34 completed weeks
P07.38	Preterm newborn, gestational age 35 completed weeks
P07.39	Preterm newborn, gestational age 36 completed weeks
T37.5X5A	Adverse effect of antiviral drugs, initial encounter
T37.5X5D	Adverse effect of antiviral drugs subsequent encounter
T37.5X5S	Adverse effect of antiviral drugs sequela

Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z51.11	Encounter for antineoplastic chemotherapy
Z51.89	Encounter for other specified aftercare

Dual coding requirements:

- J0885 must be billed in conjunction with BOTH D63.8 or D64.9 AND Z41.8 for preoperative use.
- J0885 must be billed in conjunction with BOTH D63.1 AND one of the I or N series of codes for CKD not on dialysis
- J0885 must be billed in conjunction with BOTH D61.1-D61.3, D61.89, or D64.9 AND B20 for anemia due to HIV
- J0885 must be billed in conjunction with BOTH D63.8 or D64.9 AND either B18.2 or B19.20 for anemia due to HCV
- J0885 must be billed in conjunction with BOTH D63.8 or D64.9 AND a code from the M series for anemia due to RA

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): ALL	NCD/LCD Document (s): NCD110.21
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=110.21&bc=gAAAAAAAAAAAAAA%3d%3d&	

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L34633
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34633&bc=gAAAAAAAAAAAAAA==	

Jurisdiction(s): 15	NCD/LCD Document (s): L34356
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34356&bc=gAAAAAAAAAAAAAA==	

Jurisdiction(s): N	NCD/LCD Document (s): L36276
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L36276&bc=gAAAAAAAAAAAAAA==	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC