

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

**\*NON-DIALYSIS\***

Document Number: MODA-0243

Last Review Date: 04/03/2019

Date of Origin: 10/17/2008

Dates Reviewed: 11/2008, 06/2009, 12/2009, 09/2010, 12/2010, 02/2011, 03/2011, 06/2011, 08/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 10/2012, 12/2012, 03/2013, 05/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 04/2017, 8/2017, 11/2017, 12/2017, 05/2018, 06/2018, 04/2019

## 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  $\geq 100$  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**
- Patient does not have uncontrolled hypertension; **AND**

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

**Anemia secondary to myelodysplastic syndrome (MDS) ‡**

- Endogenous serum erythropoietin level of  $\leq 500$  mUnits/mL; **AND**
- Patient has lower risk disease (*i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]*); **AND**
  - Used for treatment of symptomatic anemia, as an alternative to lenalidomide, in patients with del(5q); **OR**
  - Used for treatment of symptomatic anemia in patients without del(5q); **AND**
    - Patient has ring sideroblasts  $< 15\%$  and used as a single agent or in combination with lenalidomide in patients who have failed single agent therapy; **OR**
    - Patient has ring sideroblasts  $\geq 15\%$  and used in combination with a granulocyte-colony stimulating factor (G-CSF)

**Anemia secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis ‡**

- Endogenous serum erythropoietin level of  $< 500$  mUnits/mL

**Anemia secondary to rheumatoid arthritis ‡**

**Anemia secondary to chemotherapy treatment †**

- Patient is 5 years of age or older; **AND**
- Patient is receiving concomitant 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) †**

- Patient age is 1 month or older

**Anemia secondary to zidovudine treated, HIV-infected patients †**

- Endogenous serum erythropoietin level of  $\leq 500$  mUnits/mL; **AND**
- Patient is receiving zidovudine administered at  $\leq 4200$  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**

- Patient is at high-risk of blood-loss from surgery that is elective, non-cardiac and non-vascular; **AND**
- Patient is unwilling or unable to participate in an autologous blood donation program prior to surgery

† 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  $\geq 100$  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  $\leq 4200$  mg/week

**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"> <li>• Adults: 50-100 units/kg intravenously or subcutaneously three times weekly</li> <li>• Pediatric patients: 50 units/kg intravenously or subcutaneously three times weekly</li> </ul>  |
| Anemia due to HIV on zidovudine    | <ul style="list-style-type: none"> <li>• 100 units/kg three times weekly</li> <li>• May titrate up to 300 units/kg</li> </ul>   |
| Anemia due to chemotherapy§        | <ul style="list-style-type: none"> <li>• Adults: 150 units/kg intravenously or subcutaneously three times weekly or 40,000 units once weekly <ul style="list-style-type: none"> <li>○ May titrate up to 300 units/kg three times weekly or 60,000 units once weekly</li> </ul> </li> <li>• Pediatric patients (5-18 years): 600 units/kg intravenously or subcutaneously once weekly <ul style="list-style-type: none"> <li>○ May titrate up to 900 units/kg once weekly</li> </ul> </li> </ul> |
| Perioperative use                  | <ul style="list-style-type: none"> <li>• 300 units/kg/day subcutaneously for 10 days before surgery, on the day of surgery, and for 4 days after surgery (15 days total)</li> <li>• 600 units/kg/dose subcutaneously on days 21, 14, and 7 before surgery plus 1 dose on the day of surgery (4 total doses)</li> </ul>  |
| Anemia due to MDS/MPN              | <ul style="list-style-type: none"> <li>• 150-300 units/kg intravenously or subcutaneously three times weekly</li> <li>• 40,000 to 60,000 units once to twice weekly</li> </ul>  |
| 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, LP; July 2018. Accessed March 2019.
2. Epogen [package insert]. Thousand Oaks, CA; Amgen, Inc; July 2018. Accessed March 2019.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin alfa. National Comprehensive Cancer Network, 2019. 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 2019.

4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cancer-and Chemotherapy-Induced Anemia Version 3.2018. National Comprehensive Cancer Network, 2019. 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 2019.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myelodysplastic Syndrome Version 2.2019. National Comprehensive Cancer Network, 2019. 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 2019.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloproliferative Neoplasms Version 2.2019. National Comprehensive Cancer Network, 2019. 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 2019.
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. 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
12. 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.

13. Reiter PD, Rosenberg AA, Valuck RJ. Factors associated with successful epoetin alfa therapy in premature infants. *Ann Pharmacother* 2000; 34:433-439.
14. 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 12/18/2018 with effective dates 1/1/2019. Accessed March 2019.
15. CGS Administrators, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L34356). Centers for Medicare & Medicare Services. Updated on 09/26/2018 with effective dates 10/01/2018. Accessed March 2019.
16. First Coast Service Options, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L36276). Centers for Medicare & Medicare Services. Updated on 10/03/2018 with effective dates 10/01/2018. Accessed March 2019.
17. 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 2019.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description  |
|--------|---|
| B20    | Human immunodeficiency virus [HIV] disease                                |
| 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   |
| 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 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):

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

|   |                                     |
|---|-------------------------------------|
| <b>Jurisdiction(s):</b> 5, 8  | <b>NCD/LCD Document (s):</b> L34633 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34633&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34633&amp;bc=gAAAAAAAAAAAAAA==</a> |                                     |

|   |                                     |
|---|-------------------------------------|
| <b>Jurisdiction(s):</b> 15  | <b>NCD/LCD Document (s):</b> L34356 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34356&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34356&amp;bc=gAAAAAAAAAAAAAA==</a> |                                     |

|   |                                     |
|---|-------------------------------------|
| <b>Jurisdiction(s):</b> N   | <b>NCD/LCD Document (s):</b> L36276 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L36276&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L36276&amp;bc=gAAAAAAAAAAAAAA==</a> |                                     |

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

| <b>Jurisdiction</b> | <b>Applicable State/US Territory</b> | <b>Contractor</b> |
|---------------------|--------------------------------------|-------------------|
|---------------------|--------------------------------------|-------------------|

|             |   |   |
|-------------|---|---|
| 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                           |