

Cimzia® (certolizumab pegol) (Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

– Loading Dose

- Cimzia 200 mg single-dose vial powder for injection : 6 vials first 29 days
- Cimzia 200 mg single-dose prefilled syringes: 6 syringes first 29 days

– Maintenance/Flat Dosing

- Cimzia 200 mg single-dose vial powder for injection: 2 vials every 14 days
- Cimzia 200 mg single-dose prefilled syringes: 2 syringes every 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

– Plaque Psoriasis

- 400 billable units every other week

– All Other Indications

- Loading Dose
 - 400 billable units on weeks 0, 2 and 4
- Maintenance Dose
 - 400 billable units every 4 weeks

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; **AND**

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

Universal Criteria ¹

- Patient has been evaluated and screened for the presence of latent TB (tuberculosis) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**

Rheumatoid Arthritis (RA) † ^{1,30,33}

- Documented moderate to severe active disease; **AND**
- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.; **AND**
- Prescribed in combination with methotrexate unless contraindicated; **AND**

- If the medication is being self-injected, patient must have tried and failed treatment with at least two of the following: Enbrel, Adalimumab-adaz (Sandoz), Hadlima, Humira, Rinvoq, Xeljanz/XR or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

Crohn's Disease (CD) † ^{1,8,20,34}

- Documented moderate to severe active disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **AND**

- If the medication is being self-injected, patient must have tried and failed treatment with at least two of the following: Adalimumab-adaz (Sandoz), Hadlima, Humira, Rinvoq, Skyrizi SQ, Stelara SQ or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

Psoriatic Arthritis (PsA) † ^{1,26,31,35}

- Documented moderate to severe active disease; **AND**
 - For patients with predominantly axial disease OR active enthesitis, a trial and failure of at least a 4 week trial of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**

- For patients with peripheral arthritis or dactylitis, a trial and failure of at least a 3 month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, hydroxychloroquine, etc.; **AND**

- If the medication is being self-injected, patient must have tried and failed treatment with at least two of the following: Enbrel, Adalimumab-adaz (Sandoz), Hadlima, Humira, Otezla, Rinvoq, Skyrizi, Stelara SQ, Taltz, Tremfya, Xeljanz/XR or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

Ankylosing Spondylitis †^{1,13,25}

- Documented active disease; **AND**
- Patient had an adequate trial and failure of at least TWO non-steroidal anti-inflammatory agents (NSAIDs) over 4 weeks (in total), unless use is contraindicated; **AND**

- If the medication is being self-injected, patient must have tried and failed treatment with at least two of the following: Enbrel, Adalimumab-adaz (Sandoz), Hadlima, Humira, Rinvoq, Taltz, Xeljanz/XR, or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

Non-radiographic Axial Spondyloarthritis (nr-axSpA) †^{1,9,25}

- Patient has objective signs of inflammation noted by an elevation of C-reactive protein (CRP) above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI); **AND**
- Patient is without definitive radiographic evidence of structural damage on sacroiliac joints; **AND**
- Patient has active disease as defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4 and spinal pain ≥ 4 on a 0 to 10 Numerical Rating Scale (NRS); **AND**
- Patient had an adequate trial and failure of at least TWO non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated

Plaque Psoriasis †^{1,27-29,32,36,37,43}

- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
 - Involvement of at least 3% of body surface area (BSA); **OR**
 - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
 - Incapacitation or serious emotional consequences due to plaque location (i.e. hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
- Patient did not respond adequately (or is not a candidate) to a 4 week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or vitamin D analogues); **AND**

- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least ONE non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
- Patient did not respond adequately (or is not a candidate*) to a 3 month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol): **AND**

- If the medication is being self-injected, patient must have tried and failed treatment with least two of the following: Enbrel, Adalimumab-adaz (Sandoz), Hadlima, Humira, Otezla, Skyrizi, Stelara SQ, Taltz, Tremfya or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

Note: Patients with body weight ≤ 90 kg should initiate therapy at the lower dosing regimen of 200 mg every other week plus loading doses.

***Examples of contraindications to phototherapy (PUVA or UVB) include the following:** ^{28,29}

- Xeroderma pigmentosum
- Pregnancy or lactation (*PUVA only*)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (*PUVA only*), or treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (*UVB only*)
- Photosensitizing medications (*PUVA only*)
- Severe liver, renal, or cardiac disease (*PUVA only*)
- Young age < 12 years old (*PUVA only*)

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, serious infection, cardiotoxicity/heart failure, lupus-like syndrome, demyelinating disease, cytopenias, development of malignancies, Hepatitis B reactivation, etc.; **AND**

Rheumatoid Arthritis ^{1,16-18}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a $\geq 20\%$ improvement on the American College of Rheumatology-20 (ACR20) criteria].

Crohn's Disease ^{1,19}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering of corticosteroids or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

Psoriatic Arthritis ^{1,15}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria.]

Ankylosing Spondylitis ^{1,13,42}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, morning stiffness, and/or an improvement on a disease activity scoring tool [e.g. ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)].

Non-radiographic Axial Spondyloarthritis ^{1,39}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, reduction of C-reactive protein, and/or an improvement on a disease activity scoring tool [e.g. ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS), achievement of an ASDAS-Major Improvement (ASDAS-MI e.g. improvement of ≥ 2.0 is the ASDAS and/or reaching the lowest possible ASDAS), improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), improvement of the Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL) score from baseline, or an ASAS40 response (defined as a $\geq 40\%$ improvement and an absolute improvement from baseline of ≥ 2 units in ≥ 3 of 4 domains without any worsening in the remaining domain)].

Plaque Psoriasis ^{1,22,32,36-38}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement $\leq 1\%$), and/or an improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and a four-point reduction in the DLQI from when treatment started]; **AND**

- Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
 - Shown an initial response to therapy; **AND**
 - Received the three loading doses at the dose and interval specified below; **AND**
 - Received a minimum of one maintenance dose at the dose and interval specified below; **AND**
 - Responded to therapy (by treatment week 6) with subsequent loss of response

V. Dosage/Administration ¹

| Indication | Dose |
|--|---|
| Rheumatoid Arthritis | <u>Loading</u> 400 mg, subcutaneously, at weeks 0, 2 and 4; then <u>Maintenance</u> 200 mg subcutaneously, every other week, thereafter (or 400 mg every 4 weeks) |
| Crohn's Disease | <u>Loading</u> 400 mg, subcutaneously, at weeks 0, 2 and 4; then <u>Maintenance</u> 400 mg, subcutaneously, every 4 weeks, thereafter |
| Psoriatic Arthritis | <u>Loading</u> 400 mg, subcutaneously, at weeks 0, 2 and 4; then <u>Maintenance</u> 200 mg, subcutaneously, every other week, thereafter (or 400 mg every 4 weeks) |
| Plaque Psoriasis | 400 mg, subcutaneously, every other week <u>Optional alternate dosing for patients with body weight < 90 kg</u> – Loading: 400 mg, subcutaneously, at weeks 0, 2 and 4 – Maintenance: 200 mg, subcutaneously, every other week thereafter |
| Ankylosing Spondylitis | <u>Loading</u> 400 mg, subcutaneously, at weeks 0, 2 and 4; then <u>Maintenance</u> 200 mg, subcutaneously, every other week, thereafter (or 400 mg every 4 weeks) |
| Non-radiographic Axial Spondyloarthritis | <u>Loading</u> 400 mg, subcutaneously, at weeks 0, 2 and 4; then <u>Maintenance</u> 200 mg, subcutaneously, every other week, thereafter (or 400 mg every 4 weeks) |
| <i>*Note: 400 mg doses are given as 2 subcutaneous injections of 200 mg each</i> | |

VI. Billing Code/Availability Information

HCPCS Code:

- J0717* – Injection, certolizumab pegol, 1 mg; 1 billable unit = 1mg

** Code may be used for Medicare when drug is administered under the direct supervision of a physician; not to be used when drug is self-administered*

NDC:

- Cimzia 400 mg Kit-powder for injection; single-dose vial: 50474-0700-xx
- Cimzia 200 mg/mL single-dose prefilled syringe and Starter Kit: 50474-0710-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---------|--|
| K50.00 | Crohn's disease of small intestine without complications |
| K50.011 | Crohn's disease of small intestine with rectal bleeding |
| K50.012 | Crohn's disease of small intestine with intestinal obstruction |
| K50.013 | Crohn's disease of small intestine with fistula |
| K50.014 | Crohn's disease of small intestine with abscess |
| K50.018 | Crohn's disease of small intestine with other complication |

CIMZIA® (certolizumab pegol) Prior Auth Criteria

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| ICD-10 | ICD-10 Description |
|---------|--|
| K50.019 | Crohn's disease of small intestine with unspecified complications |
| K50.10 | Crohn's disease of large intestine without complications |
| K50.111 | Crohn's disease of large intestine with rectal bleeding |
| K50.112 | Crohn's disease of large intestine with intestinal obstruction |
| K50.113 | Crohn's disease of large intestine with fistula |
| K50.114 | Crohn's disease of large intestine with abscess |
| K50.118 | Crohn's disease of large intestine with other complication |
| K50.119 | Crohn's disease of large intestine with unspecified complications |
| K50.80 | Crohn's disease of both small and large intestine without complications |
| K50.811 | Crohn's disease of both small and large intestine with rectal bleeding |
| K50.812 | Crohn's disease of both small and large intestine with intestinal obstruction |
| K50.813 | Crohn's disease of both small and large intestine with fistula |
| K50.814 | Crohn's disease of both small and large intestine with abscess |
| K50.818 | Crohn's disease of both small and large intestine with other complication |
| K50.819 | Crohn's disease of both small and large intestine with unspecified complications |
| K50.90 | Crohn's disease, unspecified, without complications |
| K50.911 | Crohn's disease, unspecified, with rectal bleeding |
| K50.912 | Crohn's disease, unspecified, with intestinal obstruction |
| K50.913 | Crohn's disease, unspecified, with fistula |
| K50.914 | Crohn's disease, unspecified, with abscess |
| K50.918 | Crohn's disease, unspecified, with other complication |
| K50.919 | Crohn's disease, unspecified, with unspecified complications |
| L40.0 | Psoriasis vulgaris |
| L40.50 | Arthropathic psoriasis, unspecified |
| L40.51 | Distal interphalangeal psoriatic arthropathy |
| L40.52 | Psoriatic arthritis mutilans |
| L40.53 | Psoriatic spondylitis |
| L40.59 | Other psoriatic arthropathy |
| 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 |

| ICD-10 | ICD-10 Description |
|---------|---|
| 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 |

| ICD-10 | ICD-10 Description |
|---------|--|
| 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 |

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| ICD-10 | ICD-10 Description |
|---------|---|
| 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 |

| ICD-10 | ICD-10 Description |
|---------|--|
| 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 |
| M05.7A | Rheumatoid arthritis with rheumatoid factor of other specified 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 |

| ICD-10 | ICD-10 Description |
|---------|--|
| 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 |
| M05.8A | Other rheumatoid arthritis with rheumatoid factor of other specified 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 |
| M06.0A | Rheumatoid arthritis without rheumatoid factor, other specified 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 |

| ICD-10 | ICD-10 Description |
|---------|--|
| 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 |
| M06.8A | Other specified rheumatoid arthritis, other specified 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 |

| ICD-10 | ICD-10 Description |
|---------|--|
| 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 |
| M45.AB | Non-radiographic axial spondyloarthritis of multiple sites in spine |
| M45.A1 | Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region |
| M45.A2 | Non-radiographic axial spondyloarthritis of cervical region |
| M45.A3 | Non-radiographic axial spondyloarthritis of cervicothoracic region |
| M45.A4 | Non-radiographic axial spondyloarthritis of thoracic region |
| M45.A5 | Non-radiographic axial spondyloarthritis of thoracolumbar region |
| M45.A6 | Non-radiographic axial spondyloarthritis of lumbar region |
| M45.A7 | Non-radiographic axial spondyloarthritis of lumbosacral region |
| M45.A8 | Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region |
| M45.A0 | Non-radiographic axial spondyloarthritis of unspecified sites in spine |

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), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/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/LCA): N/A

| 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 |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|--|---|--|
| Jurisdiction | Applicable State/US Territory | Contractor |
| 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 |