

# Remicade® (infliximab)

## (Intravenous)

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### I. Length of Authorization

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

Therapy for the management of Immune-Checkpoint Inhibitor related toxicity may not be renewed.

### II. Dosing Limits

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

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|---|
| <p><b><u>Loading Dose:</u></b><br/>Remicade 100 mg single-use vial: 6 vials at weeks 0, 2, 6 (18 vials total)</p> |
| <p><b><u>Maintenance Dose:</u></b><br/>Remicade 100 mg single-use vial: 10 vials every 4 weeks</p>                |

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

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|--|
| <p><b><u>Loading Dose:</u></b><br/> <b>Rheumatoid Arthritis (RA)</b> <ul style="list-style-type: none"> <li>40 billable units at weeks 0, 2, 6</li> </ul> <b>All other indications (except management of immune checkpoint inhibitor toxicity)</b> <ul style="list-style-type: none"> <li>60 billable units at weeks 0, 2, 6</li> </ul> <b>Management of immune checkpoint inhibitor toxicity</b> <ul style="list-style-type: none"> <li>60 billable units at weeks 0,2</li> </ul> </p>  |
| <p><b><u>Maintenance Dose:</u></b><br/> <b>Rheumatoid Arthritis (RA)</b> <ul style="list-style-type: none"> <li>100 billable units every 4 weeks</li> </ul> <b>Crohn's Disease/Ulcerative Colitis</b> <ul style="list-style-type: none"> <li>100 billable units every 8 weeks</li> </ul> <b>Ankylosing spondylitis</b> <ul style="list-style-type: none"> <li>60 billable units every 6 weeks</li> </ul> <b>All other indications (except management of immune checkpoint inhibitor toxicity)</b> <ul style="list-style-type: none"> <li>60 billable units every 8 weeks</li> </ul> </p> |

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; AND
- Patient does not have an active infection, including clinically important localized infections; AND
- Must not be administered concurrently with live vaccines; AND
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast tofacitinib, baricitinib); AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND

Crohn's Disease †

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Adult patient (18 years or older); AND
- Documented moderate to severe 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)

Pediatric Crohn's Disease †

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Patient is at least 6 years of age; AND
- Documented moderate to severe 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, etc.)

Ulcerative Colitis †

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Adult patient (18 years or older); AND
- Documented moderate to severe 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)

Pediatric Ulcerative Colitis †

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND

- Patient is at least 6 years of age; AND
- Documented moderate to severe 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, etc.)

#### Fistulizing Crohn's Disease †

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Adult patient (18 years or older); 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)

#### Rheumatoid Arthritis (RA) †

- Must be prescribed by, or in consultation with, a specialist in rheumatology; AND
- Adult patient (18 years or older); AND
- Documented moderate to severe 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, or leflunomide; AND
- Used in combination with methotrexate (MTX) unless contraindicated

#### Psoriatic Arthritis †

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- Adult patient (18 years or older); AND
- Documented moderate to severe active disease; AND
  - For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; OR
  - For patients with peripheral arthritis, 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, or hydroxychloroquine

#### Ankylosing Spondylitis †

- Must be prescribed by, or in consultation with, a specialist in rheumatology; AND
- Adult patient (18 years or older); AND
- Documented active disease; AND

- Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated

#### Plaque Psoriasis †

- Must be prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- Adult patient (18 years or older); AND
- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Involvement of at least 10% of body surface area (BSA); OR
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR
  - Incapacitation due to plaque location (i.e. head and neck, palms, soles or genitalia); AND
- Patient did not respond adequately (or is not a candidate) to a 3 month 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 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)

#### Uveitis Associated with Behçet's Syndrome ‡

- Must be prescribed by, or in consultation with, a specialist in rheumatology or ophthalmology; AND
- Patient's disease is refractory to immunosuppressive therapy (e.g., corticosteroids, etc.); AND
- Patient had an inadequate response to a self-administered biologic therapy (e.g., adalimumab)

#### Management of Immune Checkpoint Inhibitor related Toxicity ‡

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, etc.); AND
- Patient has one of the following toxicities related to their immunotherapy:
  - Moderate (grade 2) to severe (grade 3-4) diarrhea or colitis
  - Severe (grade 3-4) pneumonitis refractory to methylprednisolone after 48 hours of therapy
  - Severe (grade 3) or life-threatening (grade 4) renal failure or elevated serum creatinine that is refractory to at least 1 week of therapy with corticosteroids
  - Uveitis (grade 3-4) that is refractory to high-dose systemic corticosteroids

- Life-threatening (grade 4) myocarditis, pericarditis, arrhythmias or impaired ventricular function if no improvement within 24 hours of starting pulse-dose methylprednisolone
- Severe inflammatory arthritis as additional disease-modifying therapy refractory to high-dose corticosteroids after 14 days of treatment

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, malignancy, significant hematologic abnormalities, serious infections, cerebrovascular accidents, cardiotoxicity/heart failure, neurotoxicity, hepatotoxicity, lupus-like syndrome, demyelinating disease, etc.; AND
- Patient is receiving ongoing monitoring for presence of TB or other active infections; AND

##### Crohn's Disease

- 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, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, 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.]

##### Pediatric Crohn's Disease

- 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, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Pediatric Crohn's Disease Activity Index (PCDAI) score or the Harvey-Bradshaw Index score.]

##### Ulcerative Colitis

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

##### Pediatric Ulcerative Colitis

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity

scoring tool [e.g. an improvement on the Pediatric Ulcerative Colitis Activity Index (PUCAI) score or the Mayo Score].

#### Fistulizing Crohn's Disease

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as a reduction in number of enterocutaneous fistulas draining upon gentle compression, 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

- 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.]

#### Rheumatoid Arthritis

- 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].

#### Ankylosing Spondylitis

- 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.  $\geq 1.1$  improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of  $\geq 2$  on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)].

#### Plaque Psoriasis

- 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.]

#### Uveitis Associated with Behçet's Syndrome

- Disease response as indicated by an improvement in signs and symptoms compared to baseline [e.g. reduction in inflammation and/or lesions, dose reduction of oral glucocorticoids and/or immunosuppressive agents, improvement in vitreous haze, improvement in best corrected visual acuity (BCVA), disease stability and/or reduced rate of decline]

#### Management of Immune Checkpoint Inhibitor related Toxicity ‡

- May not be renewed.

## V. Dosage/Administration

| Indication   | Loading Doses              | Maintenance Dosing               | Maximum Dose & Frequency     |
|--|----------------------------|----------------------------------|------------------------------|
| Rheumatoid Arthritis                                       | 3 mg/kg at weeks 0, 2, & 6 | 3 mg/kg every 8 weeks thereafter | Up to 10 mg/kg every 4 weeks |
| Ankylosing Spondylitis                                     | 5 mg/kg at weeks 0, 2, & 6 | 5 mg/kg every 6 weeks thereafter | 5 mg/kg every 6 weeks        |
| Crohn's Disease & Ulcerative Colitis                       | 5 mg/kg at weeks 0, 2, & 6 | 5 mg/kg every 8 weeks thereafter | Up to 10 mg/kg every 8 weeks |
| Psoriatic Arthritis, Plaque Psoriasis, Behçet's Uveitis    | 5 mg/kg at weeks 0, 2, & 6 | 5 mg/kg every 8 weeks thereafter | 5 mg/kg every 8 weeks        |
| Management of Immune Checkpoint Inhibitor Related Toxicity | 5 mg/kg at weeks 0,2       | N/A                              | N/A                          |

- Dose escalation (up to the maximum dose and frequency specified above) 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 above; AND
  - Received a minimum of one maintenance dose at the dose AND interval specified above; AND
  - Responded to therapy (by treatment week 16) with subsequent loss of response; AND
  - Dose escalation may either increase the dose OR decrease the interval provided it does not exceed the following limits:
    - Dose increase by no more than 2.5 mg/kg; OR
    - Interval decrease by no more than 2 weeks

### Note:

- Prior to escalating doses a patient's neutralizing IFX-antibodies should be assessed and addition of a DMARD (e.g, thiopurine or MTX), if not already on such therapy, should be considered.
- Criteria for disease-specific response to therapy are noted in section IV. Patients with moderate to severe heart failure (NYHA Functional Class III/IV; LVEF  $\leq$ 35%) should not receive doses in excess of 5 mg/kg.

## VI. Billing Code/Availability Information

### JCode:

- J1745 – Injection, infliximab, excludes biosimilar, 10 mg; 1 billable unit = 10 mg

### NDC:

- Remicade 100 mg single-use vial for injection: 57894-0030-xx

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## Appendix 1 – Covered Diagnosis Codes

| ICD-10  | ICD-10 Description  |
|---------|---|
| H30.891 | Other chorioretinal inflammations, right eye                      |
| H30.892 | Other chorioretinal inflammations, left eye                       |
| H30.893 | Other chorioretinal inflammations, bilateral                      |
| H30.899 | Other chorioretinal inflammations, unspecified eye                |
| H30.90  | Unspecified chorioretinal inflammation, unspecified eye           |
| H30.91  | Unspecified chorioretinal inflammation, right eye                 |
| H30.92  | Unspecified chorioretinal inflammation, left eye                  |
| H30.93  | Unspecified chorioretinal inflammation, bilateral                 |
| I30.8   | Other forms of acute pericarditis                                 |
| I30.9   | Acute pericarditis, unspecified                                   |
| I40.8   | Other acute myocarditis   |
| I40.9   | Acute myocarditis, unspecified                                    |
| I50.9   | Heart failure, unspecified  |
| J70.2   | Acute drug-induced interstitial lung disorders                    |
| J70.4   | Drug-induced interstitial lung disorders, unspecified             |
| 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        |
| 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           |

### REMICADE® (infliximab) Prior Auth Criteria

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| ICD-10  | ICD-10 Description   |
|---------|--|
| 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                     |
| K51.00  | Ulcerative (chronic) pancolitis without complications                            |
| K51.011 | Ulcerative (chronic) pancolitis with rectal bleeding                             |
| K51.012 | Ulcerative (chronic) pancolitis with intestinal obstruction                      |
| K51.013 | Ulcerative (chronic) pancolitis with fistula                                     |
| K51.014 | Ulcerative (chronic) pancolitis with abscess                                     |
| K51.018 | Ulcerative (chronic) pancolitis with other complication                          |
| K51.019 | Ulcerative (chronic) pancolitis with unspecified complications                   |
| K51.20  | Ulcerative (chronic) proctitis without complications                             |
| K51.211 | Ulcerative (chronic) proctitis with rectal bleeding                              |
| K51.212 | Ulcerative (chronic) proctitis with intestinal obstruction                       |
| K51.213 | Ulcerative (chronic) proctitis with fistula                                      |
| K51.214 | Ulcerative (chronic) proctitis with abscess                                      |
| K51.218 | Ulcerative (chronic) proctitis with other complication                           |
| K51.219 | Ulcerative (chronic) proctitis with unspecified complications                    |
| K51.30  | Ulcerative (chronic) rectosigmoiditis without complications                      |

| ICD-10  | ICD-10 Description   |
|---------|--|
| K51.311 | Ulcerative (chronic) rectosigmoiditis with rectal bleeding           |
| K51.312 | Ulcerative (chronic) rectosigmoiditis with intestinal obstruction    |
| K51.313 | Ulcerative (chronic) rectosigmoiditis with fistula                   |
| K51.314 | Ulcerative (chronic) rectosigmoiditis with abscess                   |
| K51.318 | Ulcerative (chronic) rectosigmoiditis with other complication        |
| K51.319 | Ulcerative (chronic) rectosigmoiditis with unspecified complications |
| K51.50  | Left sided colitis without complications                             |
| K51.511 | Left sided colitis with rectal bleeding                              |
| K51.512 | Left sided colitis with intestinal obstruction                       |
| K51.513 | Left sided colitis with fistula                                      |
| K51.514 | Left sided colitis with abscess                                      |
| K51.518 | Left sided colitis with other complication                           |
| K51.519 | Left sided colitis with unspecified complications                    |
| K51.80  | Other ulcerative colitis without complications                       |
| K51.811 | Other ulcerative colitis with rectal bleeding                        |
| K51.812 | Other ulcerative colitis with intestinal obstruction                 |
| K51.813 | Other ulcerative colitis with fistula                                |
| K51.814 | Other ulcerative colitis with abscess                                |
| K51.818 | Other ulcerative colitis with other complication                     |
| K51.819 | Other ulcerative colitis with unspecified complications              |
| K51.90  | Ulcerative colitis, unspecified, without complications               |
| K51.911 | Ulcerative colitis, unspecified with rectal bleeding                 |
| K51.912 | Ulcerative colitis, unspecified with intestinal obstruction          |
| K51.913 | Ulcerative colitis, unspecified with fistula                         |
| K51.914 | Ulcerative colitis, unspecified with abscess                         |
| K51.918 | Ulcerative colitis, unspecified with other complication              |
| K51.919 | Ulcerative colitis, unspecified with unspecified complications       |
| K52.1   | Toxic gastroenteritis and colitis                                    |
| 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  |

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

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

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



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

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

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

| ICD-10  | ICD-10 Description   |
|---------|--|
| 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             |
| M06.4   | Inflammatory polyarthropathy   |
| 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                            |

| ICD-10  | ICD-10 Description   |
|---------|--|
| 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                                |
| M35.2   | Behçet's disease   |
| M45.0   | Ankylosing spondylitis of multiple sites in spine                |
| M45.1   | Ankylosing spondylitis of occipito-atlanto-axial region          |
| M45.2   | Ankylosing spondylitis of cervical region                        |
| M45.3   | Ankylosing spondylitis of cervicothoracic region                 |
| M45.4   | Ankylosing spondylitis of thoracic region                        |
| M45.5   | Ankylosing spondylitis of thoracolumbar region                   |
| M45.6   | Ankylosing spondylitis lumbar region                             |
| M45.7   | Ankylosing spondylitis of lumbosacral region                     |
| M45.8   | Ankylosing spondylitis sacral and sacrococcygeal region          |
| M45.9   | Ankylosing spondylitis of unspecified sites in spine             |
| N17.8   | Other acute kidney failure                                       |
| N17.9   | Acute kidney failure, unspecified                                |
| R19.7   | Diarrhea, unspecified  |

## 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): 5, 8  | NCD/LCD Document (s): L34741 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34741&amp;bc=gAAAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34741&amp;bc=gAAAAAAAAAAAAAA</a> == |                              |

|  |                              |
|--|------------------------------|
| Jurisdiction(s): N, 9  | NCD/LCD Document (s): L33704 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33704&amp;bc=gAAAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33704&amp;bc=gAAAAAAAAAAAAAA</a> == |                              |

|  |                              |
|--|------------------------------|
| Jurisdiction(s): M, 11   | NCD/LCD Document (s): L35677 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35677&amp;bc=gAAAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35677&amp;bc=gAAAAAAAAAAAAAA</a> == |                              |

|  |                              |
|--|------------------------------|
| Jurisdiction(s): 6, K  | NCD/LCD Document (s): A52423 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52423&amp;bc=gAAAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52423&amp;bc=gAAAAAAAAAAAAAA</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                                 |
| 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                           |