Nucala® (mepolizumab)
(Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

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

- **Chronic Obstructive Pulmonary Disease (COPD), Chronic Rhinosinusitis with Nasal Polyps (CRSwNP), Severe Eosinophilic Asthma:**
  - 100 billable units every 28 days
- **Eosinophilic Granulomatosis with Polyangiitis (EGPA), Hypereosinophilic Syndrome (HES):**
  - 300 billable units every 28 days

III. Initial Approval Criteria

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

      1. The member has been treated with the requested agent (starting on samples is not approvable) within the past 90 days; **OR**
      2. The prescriber states the member has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed; **OR**

   B. BOTH of the following:
      1. ONE of the following:

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A. The member has a diagnosis of severe eosinophilic asthma and BOTH of the following:
    1. The member's diagnosis has been confirmed by ONE of the following:
        A. Baseline (prior to therapy with the requested agent) blood eosinophil count of 150 cells/microliter or higher; **OR**
        B. Fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids; **OR**
        C. Sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids; **OR**
        D. The member is dependent on systemic corticosteroids; **AND**
    2. ONE of the following:
        A. The member has a history of uncontrolled asthma while on asthma control therapy (e.g., inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA] combination therapy) as demonstrated by ONE of the following:
            1. Two or more severe asthma exacerbations (i.e., required treatment with a systemic corticosteroid [steroid burst]) within the past 12 months; **OR**
            2. One or more serious exacerbation(s) (i.e. required hospitalization, mechanical ventilation, or visit to the emergency room or urgent care) within the past 12 months; **OR**
            3. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered; **OR**
            4. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted; **OR**
        B. The member's medication history (excluding sample use) indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma within the past 12 months; **OR**
B. The member has a diagnosis of chronic obstructive pulmonary disease (COPD) AND ALL of the following:
    1. The member's diagnosis was confirmed by spirometry with a post-bronchodilator FEV1/FVC ratio less than 0.7; **AND**

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2. The member has an eosinophilic phenotype defined by a baseline (prior to therapy with the requested agent) blood eosinophil count of 300 cells/microliter or higher; **AND**
3. ONE of the following:
    A. The member has a history of inadequately controlled COPD while on COPD inhaled maintenance therapy (i.e., ICS/LAMA/LABA triple therapy, LAMA/LABA dual therapy) as demonstrated by ONE of the following:
        1. Two or more moderate COPD exacerbations (e.g.., required treatment with a systemic corticosteroid and/or antibiotic) within the past 12 months; **OR**
        2. One or more severe COPD exacerbation(s) (e.g., required hospitalization or observation for over 24 hours in an emergency department/urgent care facility within the past 12 months; **OR**
    B. The member's medication history (excluding sample use) indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of COPD within the past 12 months; **OR**

C. The member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following:
1. The member has ONE of the following:
    A. Baseline (prior to therapy for the requested indication) blood eosinophil count greater than or equal to 1000 cells/microliter; **OR**
    B. Baseline (prior to therapy for the requested indication) blood eosinophil level greater than or equal to 10% eosinophils on white blood cell differential count; **AND**
2. The member has a history or presence of asthma; **AND**
3. The member does NOT have severe disease with organ- or life-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia); **AND**
4. ONE of the following:
    A. BOTH of the following:
        1. The member is currently treated within the past 90 days with oral corticosteroid (OCS) therapy for at least 4 weeks; **AND**

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2. The member will be using oral corticosteroid (OCS) therapy in combination with the requested agent; **OR**

B. The member has an intolerance or hypersensitivity to ONE oral corticosteroid (OCS) used in the treatment of EGPA; **OR**

C. The member has an FDA labeled contraindication to ALL oral corticosteroids; **AND**

5. The member will be using the requested agent for ONE of the following:

A. Treatment of relapsing or refractory disease; **OR**

B. Treatment for maintenance of disease remission; **OR**

D. The member has a diagnosis of hypereosinophilic syndrome (HES) and ALL of the following:

1. The member has had a diagnosis of HES for at least 6 months; **AND**
2. The member has a baseline (prior to therapy with the requested agent) blood eosinophil count of 1000 cells/microliter or greater; **AND**
3. There has been evaluation of hypereosinophilia-related organ involvement (e.g., heart, skin, lungs, gastrointestinal tract, nervous system); **AND**
4. The member does NOT have an identifiable non-hematologic secondary (reactive) cause of HES (e.g., infection, allergy/atopy, autoimmune disease, drug reaction, metabolic condition, solid tumor/lymphoma); **AND**
5. The member does NOT have FIP1L1-PDGFRA-positive disease; **AND**
6. The member has ONE of the following:

A. History of at least 2 HES flares (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) within the past 12 months; **OR**

B. Active signs or symptoms of HES flare; **AND**

7. The member has ONE of the following:

A. Tried and had an inadequate response to ONE of the following used in the treatment of HES:

1. Oral corticosteroid (OCS); **OR**
2. Hydroxyurea; **OR**
3. Interferon-alfa; **OR**

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4. Immunosuppressive agent (e.g., cyclosporine, methotrexate); **OR**

B. Become corticosteroid-dependent for the treatment of HES; **OR**

C. An intolerance or hypersensitivity to ONE oral corticosteroid, hydroxyurea, interferon-a, or immunosuppressive agent (e.g., cyclosporine, methotrexate) used in the treatment of HES; **OR**

D. An FDA labeled contraindication to hydroxyurea, interferon-a, and ALL oral corticosteroids and immunosuppressive agents (e.g., cyclosporine, methotrexate) used in the treatment of HES; **AND**

8. The member will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-alfa, cyclosporine, methotrexate) in combination with the requested agent; **OR**

E. The member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:

1. The member has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS):

A. Nasal discharge (rhinorrhea or post-nasal drainage)

B. Nasal obstruction or congestion

C. Loss or decreased sense of smell (hyposmia)

D. Facial pressure or pain; **AND**

2. The member has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks; **AND**

3. The member's diagnosis was confirmed by ONE of the following:

A. Anterior rhinoscopy; **OR**

B. Nasal endoscopy; **OR**

C. Computed tomography (CT) of the sinuses; **AND**

4. The member has ONE of the following:

A. Tried and had an inadequate response to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) after at least a 4-week duration of therapy; **OR**

B. An intolerance or hypersensitivity to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva); **OR**

C. An FDA labeled contraindication to ALL intranasal corticosteroids; **OR**

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F. The member has another FDA labeled indication for the requested agent and route of administration; **AND**

2. If the member has an FDA labeled indication, then ONE of the following:
   A. The member's age is within FDA labeling for the requested indication for the requested agent; **OR**
   B. There is support for using the requested agent for the member's age for the requested indication; **OR**

C. The member has an indication that is supported in compendia for the requested agent and route of administration; **AND**

2. If the member has a diagnosis of severe eosinophilic asthma, then ALL of the following:
   A. ONE of the following:
      1. The member is NOT currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days; **OR**
      2. The member is currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND ONE of the following:
         A. The member is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms AND has been adherent for 90 days within the past 120 days; **OR**
         B. The member is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days; **OR**
      3. The member has an intolerance or hypersensitivity to ONE inhaled corticosteroid; **OR**
      4. The member has an FDA labeled contraindication to ALL inhaled corticosteroids; **AND**
   B. ONE of the following:
      1. The member is currently treated for at least 3 months AND has been adherent for 90 days within the past 120 days with ONE of the following:
         A. A long-acting beta-2 agonist (LABA); **OR**
         B. A long-acting muscarinic antagonist (LAMA); **OR**
         C. A leukotriene receptor antagonist (LTRA); **OR**
         D. Theophylline; **OR**
      2. The member has an intolerance or hypersensitivity to ONE long-acting beta-2 agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline; **OR**

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3. The member has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA); **AND**

C. The member will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent; **AND**

3. If the member has a diagnosis of chronic obstructive pulmonary disease (COPD), then ALL of the following:

A. ONE of the following:

1. The member is currently treated with an inhaled corticosteroid (ICS) for at least 3 months AND has been adherent for 90 days within the past 120 days; **OR**
2. The member has an intolerance or hypersensitivity to ONE inhaled corticosteroid; **OR**
3. The member has an FDA labeled contraindication to ALL inhaled corticosteroids; **AND**

B. The member is currently treated with a long-acting muscarinic antagonist (LAMA) AND a long-acting beta-2 agonist (LABA) used in combination (LAMA/LABA dual therapy) for at least 3 months AND has been adherent for 90 days within the past 120 days; **AND**

C. The member will continue COPD inhaled maintenance therapy (i.e., ICS/LAMA/LABA triple therapy, LAMA/LABA dual therapy) in combination with the requested agent; **AND**

4. If the member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), then BOTH of the following:

A. The member is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]); **AND**

B. The member will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent; **AND**

5. The prescriber is a specialist in the area of the member's diagnosis (e.g., asthma or COPD: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; EGPA or HES: allergist, immunologist, pulmonologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**

6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):

A. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**

B. The member will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required); **AND**

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7. The member does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

1. The member has been previously approved for the requested agent through the plan's Prior Authorization process (Note: members not previously approved for the requested agent will require initial evaluation review); **AND**
2. The member has had clinical benefit with the requested agent; **AND**
3. If the member has a diagnosis of severe eosinophilic asthma, then the member is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline); **AND**
4. If the member has a diagnosis of chronic obstructive pulmonary disease (COPD), then the member is currently treated within the past 90 days and is compliant with COPD inhaled maintenance therapy (i.e., inhaled corticosteroid [ICS]/long-acting muscarinic antagonist [LAMA]/long-acting beta-2 agonist [LABA] triple therapy, LAMA/LABA dual therapy); **AND**
5. If the member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), then the member will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent; **AND**
6. The prescriber is a specialist in the area of the member's diagnosis (e.g., asthma or COPD: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; EGPA or HES: allergist, immunologist, pulmonologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
    A. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**
    B. The member will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
        2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required); **AND**
8. The member does NOT have any FDA labeled contraindications to the requested agent

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly

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Contraindicated as Concomitant Therapy
Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Anzupgo (delgocitinib) Arcalyst (rilonacept) Avsola (infliximab-axxq) Avtozma (tocilizumab-anoh) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Exdensur (depemokimab-ulaa) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Icotyde (icotrokinra) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Leqselvi (deuruxolitinib) Litfulo (ritlecitinib) Nemluvio (nemolizumab-ilto) Nucala (mepolizumab) Olumiant (baricitinib) Omlyclo (omalizumab-igec) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept)

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Contraindicated as Concomitant Therapy
Otezla (apremilast) Otezla XR (apremilast extended-release) Otulfi (ustekinumab-aauz) Pyzchiva (ustekinumab-ttwe) Remicade (infliximab) Renflexis (infliximab-abda) Rhapsido (remibrutinib) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Saphnelo (anifrolumab-fnia) Selarsdi (ustekinumab-aekn) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) subcutaneous injection Starjemza (ustekinumab-hmny) Stelara (ustekinumab) Steqeyma (ustekinumab-stba) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofacitinib Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tyruko (natalizumab-sztn) Tysabri (natalizumab) Ustekinumab Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yesintek (ustekinumab-kfce) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

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V. Dosage/Administration

Indication	Dose
Severe Eosinophilic Asthma	Pediatrics Aged 6 to 11 years: 40 mg administered subcutaneously once every 4 weeks Adults and Adolescents Aged 12 years and older: 100 mg administered subcutaneously once every 4 weeks
Eosinophilic Granulomatosis with Polyangiitis (EGPA)	300 mg administered subcutaneously once every 4 weeks as 3 separate 100 mg injections. Administer each injection at least 2 inches apart.
Hypereosinophilic Syndrome (HES)	300 mg administered subcutaneously once every 4 weeks as 3 separate 100 mg injections. Administer each injection at least 2 inches apart.
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	100 mg administered subcutaneously once every 4 weeks.
Chronic Obstructive Pulmonary Disease (COPD)	100 mg administered subcutaneously once every 4 weeks.

VI. Billing Code/Availability Information

HCPCS Code:

- J2182 - Injection, mepolizumab, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Nucala 100 mg/mL lyophilized powder single-dose vial: 00173-0881-xx
- Nucala 100 mg/mL single-dose prefilled autoinjector or syringe (cartons of 1): 00173-0892-xx
- Nucala 40 mg/0.4 mL single-dose prefilled syringe (cartons of 1): 00173-0904-xx

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D72.110	Idiopathic hypereosinophilic syndrome [IHES]
D72.111	Lymphocytic Variant Hypereosinophilic Syndrome [LHES]
D72.119	Hypereosinophilic syndrome [HES], unspecified
J33.0	Polyp of nasal cavity

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ICD-10	ICD-10 Description
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified
J40	Bronchitis, not specified as acute or chronic
J41.0	Simple chronic bronchitis
J41.1	Mucopurulent chronic bronchitis
J41.8	Mixed simple and mucopurulent chronic bronchitis
J42	Unspecified chronic bronchitis
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.89	Other specified chronic obstructive pulmonary disease
J44.9	Chronic obstructive pulmonary disease, unspecified
J45.50	Severe persistent asthma, uncomplicated
J82.81	Chronic eosinophilic pneumonia
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified
M30.1	Polyarteritis with lung involvement [Churg-Strauss]

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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		
Jurisdictio	**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)

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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

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