Eculizumab: Soliris®; Bkemv™; Epysqli® (Intravenous)

Document Number: MODA-0114

Last Review Date: 08/01/2024
Date of Origin: 06/21/2011
Dates Reviewed: 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 09/2017, 10/2017, 03/2018, 06/2018, 10/2018, 02/2019, 08/2019, 8/2020, 09/2020, 10/2021, 06/2022, 09/2023, 05/2024, 06/2024, 08/2024

I. Length of Authorization

- PNH and aHUS: Coverage will be provided for twelve (12) months and may be renewed.
- gMG and NMOSD: Initial coverage will be provided for six (6) months and may be renewed annually thereafter.

II. Dosing Limits

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

Soliris 300 mg/30 mL single-dose vial:

- Loading Doses: 3 vials days 1, 8, 15, & 22; then 4 vials day 29
- Maintenance Dose: 4 vials every 14 days

Bkemv 300 mg/30 mL single-dose vial:

- Loading Doses: 3 vials days 1, 8, 15, & 22; then 4 vials day 29
- Maintenance Dose: 4 vials every 14 days

Epysqli 300 mg/30 mL single-dose vial:

- Loading Doses: 3 vials days 1, 8, 15, & 22; then 4 vials day 29
- Maintenance Dose: 4 vials every 14 days

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

Indication	Loading Doses	Maintenance Dose
PNH	60 billable units (600 mg) Days 1, 8, 15, & 22; then 90 billable units (900 mg) Day 29	90 billable units (900 mg) every 14 days
aHUS, gMG, NMOSD	90 billable units (900 mg) Days 1, 8, 15, & 22; then 120 billable units (1200 mg) Day 29	120 billable units (1200 mg) every 14 days

III. Initial Approval Criteria [1-3]

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria [1-3]

- Prescriber is enrolled in the applicable Ultomiris and Soliris, Bkemv, OR Epysqli Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient must be vaccinated against meningococcal infection (serogroups A,C,W,Y and B) according to current ACIP recommendations at least two weeks prior to initiation of therapy and will continue to be revaccinated in accordance with ACIP recommendations *(Note: if urgent eculizumab therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer the vaccines as soon as possible)*; **AND**
- Patient does not have an unresolved, serious systemic infection (e.g., *Neisseria meningitidis*, etc.); **AND**
- Will not be used in combination with other immunomodulatory biologic therapies (e.g., efgartigimod, efgartigimod-hyaluronidase, ravulizumab, pegcetacoplan, satralizumab, tocilizumab, inebilizumab, rozanolixizumab, rituximab, zilucoplan, pozelimab, etc.) *[Note: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan]*; **AND**

Paroxysmal Nocturnal Hemoglobinuria (PNH) † Φ [1-8,11,18,25]

- Diagnosis must be confirmed by detection of PNH clones of at least 10% by flow cytometry diagnostic testing; **AND**
- Patient has at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes); **AND**
- Patient has laboratory evidence of significant intravascular hemolysis (i.e., LDH ≥1.5 x ULN) with symptomatic disease and at least one other indication for therapy from the following (regardless of transfusion dependence):
    - Patient has symptomatic anemia (i.e., hemoglobin < 7 g/dL or hemoglobin < 10 g/dL, in at least two independent measurements in a patient with cardiac symptoms)
    - Presence of a thrombotic event related to PNH
    - Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency/hypertension)
    - Patient is pregnant and potential benefit outweighs potential fetal risk
    - Patient has disabling fatigue

    - Patient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; **AND**
- Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, packed RBC transfusion requirement, and history of thrombotic events; **AND**
- Patient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®)

Atypical Hemolytic Uremic Syndrome (aHUS) † Φ [1-3,9,10,12,19,28]

- Patient is at least 2 months of age; **AND**
- Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); **AND**
- Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level (i.e., ADAMTS13 activity level ≥ 10%); **AND**
- Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) has been ruled out; **AND**
- Other causes have been ruled out such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, Streptococcus pneumoniae sepsis, or known genetic defect in cobalamin C metabolism, etc.); **AND**
- Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and plasma exchange/infusion requirement; **AND**
- Patient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®)

Generalized Myasthenia Gravis (gMG) † Φ [1,13,14,20-24]

- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease **§**; **AND**
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
- Patient has had a thymectomy (*Note: Applicable only to patients with thymomas OR non-thymomatous patients who are 50 years of age or younger)*; **AND**
- Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination [e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.]; **AND**
- Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of ≥6; **AND**
    - Patient had an inadequate response after a minimum one-year trial of concurrent use with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); **OR**

- Patient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy; **AND**

- Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); **AND**
- Patient had an inadequate response, contraindication, or intolerance to a trial of ravulizumab (Ultomiris®); **AND**

- Patient had an inadequate response, or has a contraindication or intolerance, to efgartigimod alfa-fcab [Vyvgart™] or fgartigimod alfa and hyaluronidase-qvfc [Vyvgart Hytrulo™] or rozanolixizumab-noli [Rystiggo®]

§ Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification [21]

- **Class I**: Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
- **Class II**: Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
  - **IIa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
  - **IIb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
- **Class III**: Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
  - **IIIa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
  - **IIIb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
- **Class IV**: Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
  - **IVa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
  - **IVb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
- **Class V**: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

Neuromyelitis Optica Spectrum Disorder (NMOSD) † Φ [1,15-17,26,27]

- Patient has a confirmed diagnosis based on the following:
  - Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
  - Patient has at least one core clinical characteristic **§** *(*Note: some core clinical characteristics require both clinical and typical MRI findings)*; **AND**
  - Alternative diagnoses have been excluded [e.g., myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD), multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.]; **AND**
- Patient has a history of at least 2 relapses in the last 12 months OR 3 relapses in the last 24 months, with at least 1 relapse in the last 12 months; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 7.0; **AND**

- Patients who are receiving concurrent corticosteroid therapy are on ≤ 20 mg per day and those receiving immunosuppressive therapy (e.g., azathioprine, glucocorticoids, mycophenolate, etc.) are on a stable dose regimen; **AND**
- Patient has not received therapy with rituximab or mitoxantrone in the last 3 months; **AND**
- Patient has not received intravenous immune globulin (IVIG) in the last 3 weeks; **AND**
- Patient had an inadequate response, or has a contraindication or intolerance, to rituximab OR inebilizumab (Uplizna®)

§ Core Clinical Characteristics of NMOSD [17,26]
▪ Acute optic neuritis ▪ Acute myelitis ▪ Acute area postrema syndrome (APS): episode of otherwise unexplained hiccups and/or nausea and vomiting (lasting for at least 48 hours or with MRI evidence of a dorsal brainstem lesion) ▪ Acute brainstem syndrome other than APS ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesion on MRI **¥** ▪ Acute cerebral syndrome with NMOSD-typical brain lesion on MRI **ψ**
¥ Diencephalic syndrome: Periependymal lesion (3rd ventricle) OR hypothalamic/thalamic lesion **ψ** Cerebral syndrome: Extensive periependymal lesion (lateral ventricle; often with Gd) OR long (> 1⁄2 length), diffuse, heterogeneous or edematous corpus callosum lesion OR long corticospinal tract lesion (unilateral or bilateral, contiguously involving internal capsule and cerebral peduncle) OR large, confluent (unilateral or bilateral) subcortical or deep white matter lesion

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1-8,25]

Coverage may 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: serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, etc.; **AND**

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Patient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) OR experienced a spontaneous disease remission OR received curative allogeneic stem cell transplant; **AND**
- Disease response compared to pretreatment baseline as indicated by one or more of the following:
    - Decrease in serum LDH
    - Stabilization/improvement in hemoglobin level
    - Decrease in packed RBC transfusion requirement (i.e., reduction of at least 30%)

- Reduction in thromboembolic events

Atypical Hemolytic Uremic Syndrome (aHUS)

- Disease response compared to pretreatment baseline as indicated by one or more of the following**:**
  - Decrease in serum LDH
  - Stabilization/improvement in serum creatinine/eGFR
  - Increase in platelet count
  - Decrease in plasma exchange/infusion requirement

Generalized Myasthenia Gravis (gMG)

- Patient has had an improvement (i.e., reduction) of at least 1-point from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score **Δ**; **AND**
- Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline

  *[**Δ** May substitute an improvement of at least 1-point from baseline in the Quantitative Myasthenia Gravis (QMG) total score, if available]*

Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Disease response as indicated by stabilization and/or improvement in one or more of the following:
  - Neurologic symptoms as evidenced by a decrease in acute relapses, improvement of stability, or improvement in EDSS
  - Reduced hospitalizations
  - Reduction/discontinuation in plasma exchange treatments

V. Dosage/Administration [1-3]

Indication	Dose*
Paroxysmal nocturnal hemoglobinuria (PNH)	Loading dose: – 600 mg intravenously every 7 days for the first 4 weeks, followed by 900 mg intravenously for the fifth dose 7 days later Maintenance dose: – 900 mg intravenously every 14 days
Atypical hemolytic uremic syndrome (aHUS)	**Adults** Loading dose: – 900 mg intravenously every 7 days for the first 4 weeks, followed by 1,200 mg intravenously for the fifth dose 7 days later Maintenance dose: – 1200 mg intravenously every 14 days

	Patients < 18 years 5 kg - <10 kg: – 300 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 3 weeks 10 kg - <20 kg: – 600 mg weekly x 1 dose, 300 mg at week 2, then 300 mg every 2 weeks 20 kg - <30 kg: – 600 mg weekly x 2 doses, 600 mg at week 3, then 600 mg every 2 weeks 30 kg - <40 kg: – 600 mg weekly x 2 doses, 900 mg at week 3, then 900 mg every 2 weeks ≥ 40 kg: – 900 mg weekly x 4 doses, 1200 mg at week 5, then 1200 mg every 2 weeks
Generalized Myasthenia Gravis (gMG) and Neuromyelitis Optica Spectrum Disorder (NMOSD)	Loading dose: – 900 mg intravenously every 7 days for the first 4 weeks, followed by 1,200 mg intravenously for the fifth dose 7 days later Maintenance dose: – 1200 mg intravenously every 14 days

**Doses should be administered at the above intervals, or within two days of these time points.*

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1300 – Injection, eculizumab, 10 mg; 1 billable unit = 10 mg *(Soliris ONLY)*
- J3590 – Unclassified biologics *(Epysqli ONLY) (Discontinue use on 01/01/2025 for Bkemv Only)*
- Q5139 – Injection, eculizumab-aeeb (bkemv), biosimilar, 10 mg; 1 billable unit = 10 mg *(Bkemv Only) (Effective 01/01/2025)*

NDC(s):

- Soliris 300 mg/30 mL single-dose vial for injection: 25682-0001-xx
- Bkemv 300 mg/30 mL single dose vial for injection: 55513-0180-xx
- Epysqli 300 mg/30 mL single dose vial for injection: 71202-0010-xx

VII. References

1. Soliris [package insert]. Boston, MA; Alexion Pharmaceuticals, Inc.; March 2024. Accessed April 2024.
2. Bkemv [package insert]. Thousand Oaks, CA; Amgen Inc.; May 2024. Accessed May 2024.
3. Epysqli [package insert]. Yeonsu-gu, Incheon; Samsung Bioepis Co., Ltd.; July 2024. Accessed July 2024.
4. Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. Borowitz MJ, Craig FE, DiGiuseppe JA, Illingworth AJ, Rosse W,

Sutherland DR, Wittwer CT, Richards SJ. Cytometry B Clin Cytom. 2010 Jul;78(4):211-30. doi: 10.1002/cyto.b.20525.

5. Effect of eculizumab on hemolysis and transfusion requirements in patients with paroxysmal nocturnal hemoglobinuria. Hillmen P; Hall C; Marsh JC; Elebute M; Bombara MP; Petro BE; Cullen MJ; Richards SJ; Rollins SA; Mojcik CF; Rother RP. N Engl J Med 2004 Feb 5;350(6):552-9.
6. The complement inhibitor eculizumab in paroxysmal nocturnal hemoglobinuria. Hillmen P; Young NS; Schubert J; Brodsky RA; Socie G; Muus P; Roth A; Szer J; Elebute MO; Nakamura R; Browne P; Risitano AM; Hill A; Schrezenmeier H; Fu CL; Maciejewski J; Rollins SA; Mojcik CF; Rother RP; Luzzatto L. N Engl J Med. 2006 Sep 21;355(12):1233-43.
7. Multicenter phase 3 study of the complement inhibitor eculizumab for the treatment of patients with paroxysmal nocturnal hemoglobinuria. Brodsky RA; Young NS; Antonioli E; Risitano AM; Schrezenmeier H; Schubert J; Gaya A; Coyle L; de Castro C; Fu CL; Maciejewski JP; Bessler M; Kroon HA; Rother RP; Hillmen P. Blood. 2008 Feb 15;111(4):1840-7. Epub 2007 Nov 30.
8. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005 Dec 1. 106(12):3699-709.
9. Loirat C, Fakhouri F, Ariceta G, et al. An international consensus approach to the management of atypical hemolytic uremic syndrome in children. Pediatr Nephrol. 2016 Jan;31(1):15-39.
10. Taylor CM, Machin S, Wigmore SJ, et al. Clinical practice guidelines for the management of atypical haemolytic uraemic syndrome in the United Kingdom. Br J Haematol. 2010 Jan;148(1):37-47.
11. Sahin F, Akay OM, Ayer M, et al. Pesg PNH diagnosis, follow-up and treatment guidelines. Am J Blood Res. 2016;6(2): 19-27.
12. Cheong HI, Kyung Jo S, Yoon SS, et al. Clinical Practice Guidelines for the Management of Atypical Hemolytic Uremic Syndrome in Korea. J Korean Med Sci. 2016 Oct;31(10):1516-1528.
13. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis-Executive Summary. Neurology. 2016 Jul 26; 87(4): 419-25.
14. Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. Lancet Neurol. 2017 Dec;16(12):976-986.
15. Trebst C, Jarius S, Berthele A, et al. Update on the diagnosis and treatment of neuromyelitis optica: recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol 2014; 261:1.
16. Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in Aquaporin-4-Positive Neuromyelitis Optica Spectrum Disorder. N Engl J Med 2019.
17. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015 Jul;85(2):177-89. Epub 2015 Jun 19.
18. Patriquin CJ, Kiss T, Caplan S, et al. How we treat paroxysmal nocturnal hemoglobinuria: A consensus statement of the Canadian PNH Network and review of the national registry. Eur J Haematol. 2019;102(1):36. Epub 2018 Oct 25.

19. Lee H, Kang E, Kang HG, et al. Consensus regarding diagnosis and management of atypical hemolytic uremic syndrome. Korean J Intern Med. 2020;35(1):25-40. doi:10.3904/kjim.2019.388.
20. Narayanaswami P, Sanders D, Wolfe G, Benatar M, et al. International consensus guidance for management of myasthenia gravis, 2020 update. Neurology® 2021;96:114-122. doi:10.1212/WNL.0000000000011124.
21. Jayam-Trouth A, Dabi A, Solieman N, Kurukumbi M, Kalyanam J. Myasthenia gravis: a review. Autoimmune Dis. 2012;2012:874680. doi:10.1155/2012/874680
22. Gronseth GS, Barohn R, Narayanaswami P. Practice advisory: Thymectomy for myasthenia gravis (practice parameter update): Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2020;94(16):705. Epub 2020 Mar 25.
23. Sussman J, Farrugia ME, Maddison P, et al. Myasthenia gravis: Association of British Neurologists' management guidelines. Pract Neurol 2015; 15: 199-206.
24. Institute for Clinical and Economic Review. Eculizumab and Efgartigimod for the Treatment of Myasthenia Gravis: Effectiveness and Value. Draft evidence report. July 22, 2021. https://icer.org/wp-content/uploads/2021/03/ICER_Myasthenia-Gravis_Draft-Evidence-Report_072221.pdf. Accessed August 09, 2023.
25. Cançado RD, Araújo AdS, Sandes AF, et al.Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. Hematology, Transfusion and Cell Therapy, v43, Iss3, 2021, 341-348. ISSN 2531-1379, https://doi.org/10.1016/j.htct.2020.06.006.
26. Jarius, S., Aktas, O., Ayzenberg, I. et al. Update on the diagnosis and treatment of neuromyelits optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part I: Diagnosis and differential diagnosis. J Neurol 270, 3341–3368 (2023). https://doi.org/10.1007/s00415-023-11634-0
27. Kümpfel T, Giglhuber K, Aktas O, et al. Neuromyelitis Optica Study Group (NEMOS). Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) - revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. J Neurol. 2023 Sep 7. doi: 10.1007/s00415-023-11910-z. Epub ahead of print.
28. Scully M, Rayment R, Clark A, et al. A British Society for Haematology Guideline: Diagnosis and management of thrombotic thrombocytopenic purpura and thrombotic microangiopathies. Br J Haematol. 2023 Nov;203(4):546-563. doi: 10.1111/bjh.19026.
29. National Government Services, Inc. Local Coverage Article: Billing and Coding: Eculizumab (A54548). Centers for Medicare & Medicaid Services, Inc. Updated 09/09/2022 with effective date 10/01/2022. Accessed April 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D59.32	Hereditary hemolytic-uremic syndrome

ICD-10	ICD-10 Description
D59.39	Other hemolytic-uremic syndrome
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
G36.0	Neuromyelitis optica [Devic]
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

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		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6, K	A54548	National Government Services, Inc

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
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