BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Complement Inhibitors

Policy Number: 9.134
Version Number: 2.1
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan⁺ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Soliris (eculizumab)**
- **Empaveli (pegcetacoplan)**
- **Ultomiris (ravulizumab-cwvz)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	• For use in the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) • Use of combination complement inhibitor therapy
Required Medical Information	<u>Soliris and Ultomiris:</u> 1. Documented diagnosis of generalized myasthenia gravis (gMG); ***AND*** a. Documentation of a positive serologic test for anti-acetylcholine antibodies; ***AND***

⁺ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

b. Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV generalized myasthenia gravis; ***AND***

c. Documentation of a Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥6; ***AND***

d. Documentation of at least one of the following:

i. At least a 12 month previous trial of two or more immunosuppressive therapies (either in combination or as monotherapy) (e.g., azathioprine, cyclophosphamide, methotrexate); ***OR***

ii. Previous trial of one immunosuppressive therapy for at least 12 months with required chronic plasmapheresis, plasma exchange, or intravenous immunoglobulin without symptom control; ***AND***

e. Member has been vaccinated against meningococcal infection at least 2 weeks prior to treatment if not previously vaccinated; ***AND***

f. Dosing is consistent with FDA labeling for requested product.

2. Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD); ***AND***

a. Documentation of a positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies; ***AND***

b. Diagnosis of multiple sclerosis or other diagnoses have been ruled out; ***AND***

c. Trial and failure, contraindication, or intolerance to rituximab therapy; ***AND***

d. One of the following:

i. History of at least 2 relapses during the previous 12 months; **OR**

ii. History of at least 3 relapses during the previous 24 months with 1 of the relapses occurring within the past 12 months; ***AND***

e. Member is not receiving complement inhibitor therapy with any of the following:

i. Disease modifying therapies for the treatment of multiple sclerosis (e.g., fingolimod,dimethyl fumarate, ocrelizumab, etc.) **AND**

ii. Anti-IL6 therapy (e.g., tocilizumab) ***AND***

iii. Member will not be receiving rituximab concurrently ***AND***

e. Member has been vaccinated against meningococcal infection at least 2 weeks prior to treatment if not previously vaccinated; ***AND***

f. Dosing is consistent with FDA labeling for requested product.

3. Documented diagnosis of atypical hemolytic uremic syndrome (aHUS) *AND*

a. Diagnosis of thrombocytopenic purpura (TTP) has been excluded (for example, rule out ADAMTS13 deficiency) OR a trial of plasma exchange did not result in clinical improvement; **AND**

	b. Member has been vaccinated against meningococcal infection at least 2 weeks prior to treatment if not previously vaccinated; ***AND*** c. Dosing is consistent with FDA labeling for requested product. 4. Documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); ***AND*** a. Flow cytometry shows detectable GPI-deficient hematopoietic clones or ≥5% PNH cells; ***AND*** b. Member has been vaccinated against meningococcal infection at least 2 weeks prior to treatment if not previously vaccinated *AND* c. Dosing is consistent with FDA labeling for requested product <u>Empaveli:</u> a. Diagnosis of Paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high sensitivity flow cytometry which shows detectable glycosylphosphatidylinositol (GPI) - deficient hematopoietic clones or ≥5% paroxysmal nocturnal hemoglobinuria (PNH) cells; AND b. Must have received meningococcal vaccine at least 2 weeks before starting Empaveli.
Age Restriction	gMG, NMOSD: 18 years of age and older aHUS: 1 month of age and older PNH: Solirs and Empaveli: 18 years of age and older Ultomiris: 1 month of age and older
Prescriber Restriction	▪ gMG: Prescribed by a neurologist ▪ NMOSD: Prescribed by a neurologist or ophthalmologist ▪ aHUS, PNH: Prescribed by a hematologist or nephrologist
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Quantity Limit	None
Other criteria	Reauthorization: Documentation of all of the following (1&2): 1. Positive clinical response to therapy from baseline as evidenced by any of the following by diagnosis: a) PNH – increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc. b) aHUS – reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis, etc. c) gMG – 2-point reduction in MG-ADL total score d) NMOSD – reduction in the number and/or severity of relapses or signs and symptoms of NMOSD 2. Dosing is consistent with FDA labeling for requested product

Applicable Coding:

Code	Medication
J1300	Injection, eculizumab, 10mg
J1303	Injection, ravulizumab-cwvz, 10mg
J3590	Injection, pegcetacoplan

Clinical Background Information and References

1. Bird SJ. Chronic immunosuppressive therapy for myasthenia gravis. Available at UptoDate®. Last updated: April 21 2020. Accessed May 5 2020.
2. Dhillon S. Eculizumab: A Review in Generalized Myasthenia Gravis. Drugs (2018) 78:367–376
3. Glisson CC. Neuromyelitis optica spectrum disorders. Available at UptoDate. Last updated: July 22 2021. Accessed July 26 2021.
4. Empaveli (pegcetacoplan) [prescribing information]. Waltham, MA: Apellis Pharmaceuticals Inc. Accessed Sept. 2021.
5. Loirat C, Fremeaux-Bacchi V. Atypical hemolytic uremic syndrome. Orphanet J Rare Dis. 2011; 6:60
6. Soliris (eculizumab) [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc. November 2020.
7. Ultomiris (ravulizumab-cwvz) [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc. June 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.206 Complement Inhibitors Policy retired, new policy created.	1/1/2021	P&T Committee
8/12/2021	Annual P&T Review: For NMOSD added criteria for relapses and requirement that member not be receiving rituximab	1/1/2022	P&T Committee

Policy Revisions History			
	concurrently. For aHUS added criteria for diagnosis of TTP to be excluded or a trial of plasma exchange did not result in improvement. Updated age restrictions based on FDA labeling updates (Ultomiris for PNH of 1 month and older)		
11/11/2021	Addition of Empaveli and associated criteria to the policy.	3/1/2022	P&T Committee

Next Review Date

2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.