

Last review date: 7/1/2025

Applicable Products:	
Bkemv (eculizumab-aeeb)	Uplizna (Inebilizumab)
Epysqli (eculizumab-aagh)	Vyvgart (efgartigimod alfa)
Rystiggo (rozanolixizumab)	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Soliris (eculizumab)	
Ultomiris (ravulizumab)	

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Disease-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Atypical Hemolytic Uremic Syndrome (aHUS) (Bkemv, Epysqli, Soliris, Ultomiris)

- Patient is 1 month of age or older (Ultomiris only); **AND**
- Agent will not be used for the treatment of Shiga toxin E. coli related to hemolytic uremic syndrome (STEC-HUS); **AND**
- Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (i.e., ADAMTS-13 activity level $\geq 10\%$); **AND**
- Patient shows signs of thrombotic microangiopathy (TMA)

Generalized Myasthenia Gravis (gMG) (Bkemv, Epysqli, Rystiggo, Soliris, Ultomiris, Vyvgart, Vyvgart Hytrulo)

- Patient is 18 years of age or older; **AND**
- Patient is positive for antiacetylcholine receptor (AChR) (or anti-muscle-specific tyrosine kinase (MuSK) antibodies for Rystiggo only); **AND**
- Patient meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II – IV; **AND**
- Patient meets Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 3; **AND**
- Patient has tried and failed treatment with two (2) or more classes of agents (e.g., acetylcholinesterase inhibitor, steroids and non-steroidal immunosuppressants)

Paroxysmal Nocturnal Hemoglobinuria (PNH) (Bkemv, Epysqli, Soliris, Ultomiris)

- Patient is 1 month of age or older (Ultomiris only); **AND**
- Patient has laboratory evidence of significant intravascular hemolysis (i.e., LDH $\geq 1.5 \times \text{ULN}$) with symptomatic disease; **AND**
- Diagnosis is confirmed by detection of PNH clones of at least 10% by flow cytometry diagnostic testing

Neuromyelitis Optica Spectrum Disorder (NMOSD) (Soliris, Ultomiris, Uplizna)

- Patient is 18 years of age or older; **AND**
- Patient is positive for anti-aquaporin-4 (AQP4) antibody; **AND**
- Patient has at least one of the following clinical signs:
 - Acute optic neuritis
 - Acute myelitis
 - Area postrema syndrome (APS)
 - Acute brainstem syndrome
 - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
 - Acute cerebral syndrome with NMOSD-typical brain lesions

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo)

- Patient is 18 years of age or older

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Patient has shown a clinical response; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

6 months

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.