Medical Policy:
Myasthenia Gravis

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 ≥ 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 ≥1.5 x 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