COMPLEMENT C5 INHIBITORS

Included Products: PiaSky (crovalimab-akkz), Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan)

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Soliris, PiaSky and Ultomiris: Nonformulary for outpatient benefit, PA required on medical benefit.

All Diagnoses			
Initial Criteria: All Diagnoses		**If yes**	**If no**
1.	Is the drug prescribed by or in consultation with an appropriate specialist? a. Atypical hemolytic uremic syndrome(aHUS) or paroxysmal nocturnal hemoglobinuria (PNH): hematologist. b. Myasthenia gravis (gMG): neurologist c. Neuromyelitis optica (NMOSD): neurologist	Continue to #2	Continue to #4
2.	Is the drug supported for the submitted indication?	Proceed to indication specific criteria below.	Continue to #3
3.	Has the case's medical necessity been confirmed with external specialist and medical director review?	Continue to #4	Do not approve.
4.	Approve for 6 months.		
Renewal Criteria		**If yes**	**If no**
1.	Is there documentation which demonstrates a clinically significant and meaningful response to therapy?	Continue to #2	Do not approve.
2.	Has the case's medical necessity been confirmed with medical director?	Continue to #3	Do not approve.
3.	Approve for 6 months.		

Hemolytic Uremic Syndrome			
Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of atypical hemolytic uremic syndrome (aHUS) and using the drug to inhibit complement-mediated thrombotic microangiopathy?	Continue to #2	Do not approve.
2.	Has the case's medical necessity been confirmed with external specialist and medical director review?	Continue to #3	Do not approve
3.	Approve for 6 months.		

Myasthenia Gravis			
Initial Criteria		If yes	If no
1.	Does the member have generalized myasthenia gravis with clinical classification II to IV?	Continue to #2	Do not approve.
2.	Is there documentation which confirms the diagnosis is anti-acetylcholine receptor antibody positive?	Continue to #3	Pend for this information and if not available do not approve.
3.	Has the member tried and failed ALL the following? a. Pyridostigmine; AND b. Corticosteroids; AND c. At least two immune modulating agents including azathioprine, mycophenolate, cyclosporine and tacrolimus; AND d. IVIG: AND e. A FcRn antagonist (such as Rystiggo or Vyvgart)	Continue to #4	Do not approve.
4.	Has a baseline MG Activities of Daily Living (MG-ADL) score been obtained?	Continue to #5	Pend for this information.
5.	Is this drug to be given in combination with a FcRn antagonist (Rystiggo or Vyvgart)?	Do not approve.	Continue to #6.
6.	Has the cases medical necessity been confirmed with external specialist and medical director review?	Continue to #7	Do not approve.
7.	Approve for 6 months.		

Neuromyelitis Optica			
Initial Criteria		If yes	If no
1.	Does the member have neuromyelitis optica spectrum disorder (NMOSD) and is anti-aquaporin-4 antibody positive?	Continue to #2	Do not approve.
2.	Has the member tried and failed the following? a. Azathioprine or mycophenolate; AND b. Rituximab; AND c. Uplizna	Continue to #3	Do not approve.
3.	Has the cases medical necessity been confirmed with external specialist and medical director review?	Continue to #4	Do not approve.
4.	Approve for 6 months.		

Paroxysmal Nocturnal Hemoglobinuria			
Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and using the drug to reduce hemolysis?	Continue to #2	Do not approve.
2.	Has the member failed Soliris?	Continue to #3	Do not approve.
3.	Has the cases medical necessity been confirmed with external specialist and medical director review?	Continue to #3	Do not approve.
4.	Approve for 6 months.		