

PART B STEP THERAPY CRITERIA FOR APPROVAL

Soliris will be approved when ALL of the following are met:

1. The requested medication is being used for ONE of the following:
 - A. An FDA approved indication

OR

 - B. An indication in CMS approved compendia

AND
2. ONE of the following:
 - A. Information has been provided that indicates the patient has been treated with the requested medication in the past 365 days

OR

 - B. There is documentation that the patient has had an ineffective treatment response to the active ingredient(s) of ALL preferred medication(s) supported for the diagnosis

OR

 - C. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to the active ingredient(s) of ALL preferred medication(s) supported for the diagnosis

OR

 - D. The prescriber has submitted documentation indicating ALL preferred medication(s) supported for the diagnosis are likely to be ineffective or are likely to cause an adverse reaction or other harm to the patient

Length of Approval: up to 12 months

See table of preferred medications on next page

NOTES:

- Prerequisite medications may require prior review under Medicare Part D or Medicare Part B. Medicare Part D prerequisites will not be required for Medical Only members.
- Length of approval may be shorter due to provider network participation status.
- LCD/NCD criteria review completed, if applicable, in addition to the Plan's Medicare Part B Step Therapy criteria.

Targeted Part B Medication	Indication*	Preferred Medication(s)†
Soliris (eculizumab)	Paroxysmal nocturnal hemoglobinuria (PNH)	Ultomiris (ravulizumab-cwvz) AND Empaveli (pegcetacoplan)
	Atypical hemolytic uremic syndrome (aHUS)	Ultomiris (ravulizumab-cwvz)
	Refractory generalized myasthenia gravis (gMG)	Ultomiris (ravulizumab-cwvz) AND Vyvgart (efgartigimod)
	Neuromyelitis optica spectrum disorder (NMOSD)	Enspryng (satralizumab-mwge) AND Uplizna (inebilizumab-cdon)

*Preferred medication(s) may vary based upon indication

†Preferred medications may require prior authorization under the member's medical (Part B) benefit