Field Name	Field Description
Prior Authorization Group Description	Myasthenia Gravis Agents
Drugs	Rystiggo (rozanolixizumab), Soliris (eculizumab), Ultomiris (ravulizumab),Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Zilbrysq (zilucoplan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or rheumatologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

Other Criteria	**Drug is being requested through the member's medical benefit**
	
	Initial Authorization:
	• Diagnosis of generalized myasthenia gravis (gMG)
	• Patient has a positive serological test for one of the following:
	  ○ Anti-AChR antibodies
	  ○ Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Rystiggo only)
	• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV
	• Patient has tried and failed, or has contraindication, to one of the following:
	  ○ Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  ○ Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin
	• Medication is prescribed at an FDA approved dose
	• Patient is not using agents covered by this policy concurrently (i.e. no concurrent use of Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, Ultomiris, or Zilbrysq)

Revision/Review Date: 4/2024	• **For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart**
	• **Requests for Soliris (eculizumab) Ultomiris (ravulizumab), and Zilbrysq (zilucoplan) will also require all of the following:**
	  ○ **Patient has tried and failed, or has contraindication, to Vyvgart, Vyvgart Hytrulo, or Rystiggo.**
	  ○ **Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor.**
	
	Re-Authorization:
	• **Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality-of-life scores, MG-ADL scores, etc).**
	• **Medication is prescribed at an FDA approved dose.**
	
	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.