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), BVEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh), **Imaavy (nipocalimab-aahu)**
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	According to package insert
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:
	  o Anti-AChR antibodies
	  o Anti-muscle-specific tyrosine kinase (MuSK) antibodies (**Imaavy and** Rystiggo only)
	• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV
	• For adults: patient has tried and failed, or has contraindication, to one of the following:
	  o Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  o Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin
	• For eculizumab in patients 6-17 years: one of the following:
	  o Trial and failure of at least 1 conventional therapy (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  o Patient requires maintenance plasma exchange or intravenous immunoglobulin to control symptoms
	• Medication is prescribed at an FDA approved dose
	• Patient is not using agents covered by this policy concurrently (i.e. no concurrent use of **Imaavy,** Vyvgart, Vyvgart Hytrulo,

Revision/Review Date: **7**4/2025	Rystiggo, Soliris, Ultomiris, BKEMV, Epysqli or Zilbrysq) • For Vyvgart Hytrulo, patient has tried and failed, or has contraindication, to Vyvgart • Requests for **Imaavy,** Soliris (eculizumab), BKEMV (eculizimab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab), and Zilbrysq (zilucoplan) will also require all of the following: o For adults: patient has tried and failed, or has contraindication, to Vyvgart, Vyvgart Hytrulo, or Rystiggo. ▪ Additionally, if the request is for Soliris or BKEMV, member must also have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used. o All ages: 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.**