HIGHMARK HEALTH OPTIONS

Updated: 02/2025
Approved: 02/2025

Request for Prior Authorization for Myasthenia Gravis Medications
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

All requests for Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), and Rystiggo (rozanolixizumab-noli) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Myasthenia Gravis Medications Prior Authorization Criteria:

Coverage may be provided with a diagnosis of **generalized Myasthenia Gravis (gMG)** and the following criteria is met:

- Medication is prescribed by, or in consultation with, a neurologist
- Documentation of a positive serologic test for one of the following:
  - anti-acetylcholine antibodies
  - anti-muscle specific tyrosine kinase (MUSK) – Rystiggo only
- Documentation the member meets the following Masthenia Gravis Foundation of America Clinical Classification Class
  - Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Zilbrysq (zilucoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz)
    - II to IV
  - Rystiggo (rozanolixizumab-noli)
    - II to IVa
- Documentation the member has a Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - Zilbrysa (zilucoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz)
    - ≥6
  - Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
    - ≥5
  - Rystiggo (rozanolixizumab-noli)
    - ≥ 3 (with at least 3 points from non-ocular symptoms)
- Documentation of a baseline Quantitative Myasthenia Gravis (QMG) scale score
- Laboratory testing demonstrating IgG levels of the following:
  - Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
    - at least 6g/L
  - Rystiggo (rozanolixizumab-noli)
    - at least 5.5 g/L
- Documentation of at least one of the following:

  - Failed treatment over 1 year or more with 2 or more immunosuppressive therapies either in combination or as monotherapy (e.g. azathioprine, cyclophosphamide, methotrexate)
  - Failed treatment over 1 year or more with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange (PE)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelinesIf requesting Soliris, must have documentation of inadequate response, contraindication, or intolerance to Ultomiris
- The requested agent must not be used in combination with another Myasthenia Gravis medication listed in this policy [e.g. Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), and Rystiggo (rozanolixizumab-noli)]
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - First reauthorization criteria (member on therapy for 0 to 6 months)
    - Documentation from the provider that the member had a positive clinical response and tolerates therapy supported by at least one of the following:
      - A 2 point improvement in the member's total MG-ADL score
      - A 3 or more point improvement in QMG total score
  - Subsequent reauthorization criteria (member on therapy ≥ 6 months)
    - Documentation from the prescriber indicating stabilization or improvement in condition.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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MYASTHENIA GRAVIS MEDICATIONS PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: 1-844-325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient?
☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE: _____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

REFERENCE VALUES

Lab	Initial (Pre-Treatment) Value	Reference Range	Date	Post-Therapy Value (Reauthorization only)	Reference Range	Date
Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score		**N/A**			**N/A**	
Quantitative Myasthenia Gravis (QMG) total score		**N/A**			**N/A**	
IgG levels						

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Does the patient have anti-acetylcholine antibodies? ☐ Yes ☐ No
What is the member's Myasthenia Gravis Foundation of America Clinical Classification? _____
Is there documentation of the member's baseline MG-ADL and QMG scores? ☐ Yes , please document above ☐ No
Is the member currently taking another medication indicated for Myasthenia Gravis? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a positive clinical response and tolerates therapy supported by an improvement in the MG-ADL or QMG score? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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This page is only to be used if the form extends to a second page.

DRUG NAME

PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: 1-844-325-6251 Mon – Fri 8 am to 7 pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

*****Fill in questions as needed****** If you add content to this section that increases the request form to two pages, please have a section on page two that identifies which member the request is being submitted.

☐

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Add questions as needed

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date