**Request for Prior Authorization for Myasthenia Gravis Medications**

**Website Form –** [**www.wv.highmarkhealthoptions.com**](http://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)** | |
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| **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** | | | | | | | | |
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| **Prescribing Provider Signature** | | | Date | | | | | |
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This page is only to be used if the form extends to a second page.

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| **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)** | |
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| **REAUTHORIZATION** | | | | | | |
| Add questions as needed | | | | | | |
| Has the member experienced a significant improvement with treatment? Yes  No | | | | | | |
| **SUPPORTING INFORMATION or CLINICAL RATIONALE** | | | | | | |
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| **Prescribing Provider Signature** | | | Date | | | |
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