Soliris

Prior Authorization Request

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Please indicate the place of service for the requested drug:
❑ *Ambulatory Surgical* ❑ *Home* ❑ *Inpatient Hospital* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

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Site Of Care Questions:

A. Where will this drug be administered?
- ❑ On Campus Outpatient Hospital
- ❑ Home infusion, *skip to Clinical Questions*
- ❑ Ambulatory surgical, *skip to Clinical Questions*
- ❑ Off Campus Outpatient Hospital
- ❑ Physician office, *skip to Clinical Questions*
- ❑ Pharmacy, *skip to Clinical Questions*
- ❑ Inpatient hospital, *skip to Clinical Questions*

B. Is the patient less than 21 years old or 65 years of age or older?
- ❑ Yes – less than 21 years old
- ❑ Yes – age 65 years or older, *skip to Clinical Criteria Questions*
- ❑ No, *Skip to Question D.*

C. After tolerance has been established, would this patient be a candidate to receive the requested medication in a setting other than the outpatient facility? *Please indicate and skip to Clinical Criteria Questions.* ❑ Yes ❑ No

D. How many doses of the requested product has the patient received?
- ❑ 2 or more doses → This is a continuation of an existing treatment. *Continue to Question E.*
- ❑ 0 to 1 dose → This is a new request OR the patient has received only 1 dose. S*kip to Clinical Criteria Questions*

E. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? **ACTION REQUIRED: *If yes, please attach supporting documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Does the patient have severe venous access issues that require the use of a special intervention? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND does not have access to a caregiver? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

I. Are alternative infusion sites (pharmacy, physician office, ambulatory care, etc) not within a reasonable distance from the patient's home? **ACTION REQUIRED: *If yes, please attach supporting documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

Clinical Criteria Questions:

1. What is the patient's diagnosis?
   - ❑ Atypical hemolytic uremic syndrome (aHUS)
   - ❑ Generalized myasthenia gravis (gMA)
   - ❑ Paroxysmal nocturnal hemoglobinuria (PNH)
   - ❑ Other _____
2. What is the ICD-10 code? _____
3. Is the patent currently receiving Soliris? ❑ Yes ❑ No

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Atypical Hemolytic Uremic Syndrome (aHUS)

4. Is atypical hemolytic uremic syndrome caused by Shiga toxin? ❑ Yes ❑ No
5. Is the ADAMTS 13 activity level above 5 percent? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No

6. *Continuation Request:* Has the patient demonstrated a positive response to therapy with Soliris (e.g., normalization of LDH levels, platelet counts)? ❑ Yes ❑ No

Section B: Paraxysmal nocturnal hemoglobulinuria (PNH)

7. Does the patient have a deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No
8. Has the patient's diagnosis been confirmed by flow cytometry results? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No
9. *Continuation Request:* Has the patient demonstrated a positive response to therapy with Soliris (e.g., improvement in hemoglobin levels, normalization of LDH levels)? ❑ Yes ❑ No

Section C: Generalized Myasthenia Gravis (gMA)

10. Is Soliris being used to treat patients with generalized myasthenia gravis who are anti-acetylcholine receptor (AchR) antibody positive? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No
11. Has the patient been classified clinically as II-IV according to the Myasthenia Gravis Foundation of America? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No
12. Does the patient have a Myasthenia Gravis activities of daily living total score of greater than or equal to 6? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No
13. Has the patent had an inadequate response to at least two immunosuppressive agents listed below: **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No
    - azathioprine
    - cyclosporine
    - mycophenolate mofetil
    - tacrolimus
    - methotrexate
    - cyclophosphamide
14. Has the patient had an inadequate response to chronic IVIG AND rituximab? **ACTION REQUIRED: *If yes, please attach supporting documentation.*** ❑ Yes ❑ No
15. *Continuation Request:* Has the patient demonstrated a positive response to therapy with Soliris (e.g., improvement in MG-ADL scores, changes in baseline in Quantitative Myasthenia Gravis (QMG) total score)? ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**