Soliris

Prior Authorization Request

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 **1-888-877-0518.** 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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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*

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

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)
   - ❑ Paroxysmal nocturnal hemoglobinuria (PNH)
   - ❑ Generalized myasthenia gravis (gMG)
   - ❑ Neuromyelitis optica spectrum disorder (NMOSD)
   - ❑ Other _____
2. What is the ICD-10 code? _____
3. Is this a request for continuation of therapy? ❑ Yes ❑ No *If No, skip to diagnosis section.*
4. Is there evidence of unacceptable toxicity or disease progression while on the current regimen? ❑ Yes ❑ No
5. Has the patient experienced a positive response to therapy by any of the following?
   - ❑ normalization of lactate dehydrogenase (LDH) levels, platelet counts
   - ❑ improvement in hemoglobin levels, normalization of lactate dehydrogenase (LDH) levels
   - ❑ improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score
   - ❑ reduction in number of relapses
   - ❑ None of the above

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

Section A: Atypical Hemolytic Uremic Syndrome (aHUS)

6. Is the disease caused by Shiga toxin? ❑ Yes ❑ No
7. Do tests confirm the absence of Shiga toxin? ❑ Yes ❑ No
8. What is the ADAMTS13 level? ***ACTION REQUIRED: Please attach documentation of ADAMTS13 level.*** _____***%***

Section B: Paroxysmal Nocturnal Hemoglobinuria (PNH)

9. Was the diagnosis of PNH confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs)? ❑ Yes ❑ No
10. Was flow cytometry used to demonstrate the deficiency of GPI-anchored proteins? ***ACTION REQUIRED: Please attach flow cytometry report.*** ❑ Yes ❑ No
11. How was the diagnosis established?
    - ❑ Quantification of PNH cells
    - ❑ Quantification of GPI-anchored protein deficient poly-morphonuclear cells, *skip to #13*
    - ❑ No
12. What was the percentage of PNH cells? _____***%*** *No further questions*
13. What was the percentage of GPI-anchored protein deficient poly-morphonuclear cells? _____***%***

Section C: Generalized Myasthenia Gravis (gMG)

14. Is Soliris being used to treat a patient who is anti-acetylcholine receptor (AchR) antibody positive? ***ACTION REQUIRED: Please attach documentation of AchR antibody testing.*** ❑ Yes ❑ No
15. What is the patient's Myasthenia Gravis Foundation of America (MGFA) clinical classification? ***ACTION REQUIRED: Please attach documentation of MGFA clinical classification.***
    ❑ Class I ❑ Class II ❑ Class III ❑ Class IV ❑ Class V ❑ Unknown
16. What is the patient's score on the MG activities of daily living? ***ACTION REQUIRED: Please attach documentation of MG-ADL score.*** _____

17. Has the patient had an inadequate response to at ANY immunosuppressive therapies listed below? ***ACTION REQUIRED: Please attach documentation of inadequate response to the immunosuppressive therapies.*** *Indicate ALL that apply.*
    - ❑ Azathioprine
    - ❑ Cyclosporine
    - ❑ Methotrexate
    - ❑ Mycophenolate mofetil
    - ❑ Cyclophosphamide
    - ❑ Tacrolimus
    - ❑ None of the above

18. Has the patient experienced an inadequate response to chronic intravenous immunoglobulins (IVIG) AND rituximab? ***ACTION REQUIRED: Please attach documentation of inadequate response to both IVIG and rituximab*.** ❑ Yes ❑ No

Section D: Neuromyelitis Optica Spectrum Disorder (NMOSD)

19. Is the patient anti-aquaporin-4 (AQP4) antibody positive? ***ACTION REQUIRED: Please attach immunoassay confirming presence of anti-AQP4 antibody.*** ❑ Yes ❑ No

20. Does the patient exhibit at least one of the core clinical characteristics of NMOSD?
    - ❑ Optic neuritis
    - ❑ Acute myelitis
    - ❑ Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
    - ❑ Acute brainstem syndrome
    - ❑ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
    - ❑ Symptomatic narcolepsy or acute diencephalatic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - ❑ None of the above

21. Will the patient receive the requested drug concomitantly with other biologics for the treatment of neuromyelitis optica spectrum disorder (NMOSD)? ❑ 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)**

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