Soliris

CareFirst 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*

What is the ICD-10 code? _____

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

 CareFirst MR C26772-A Soliris 3537-A SGM CFT SOC 5979-A – 1/2025.

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Exception Criteria Questions:

A. The preferred products for your patient's health plan are Ultomiris, Vyvgart and Vyvgart Hytrulo. Can the patient's treatment be switched to one of the preferred products?

❒ Yes, Ultomiris, *Please obtain Form for preferred product and submit for corresponding PA.*
❒ Yes, Vyvgart, *Please obtain Form for preferred product and submit for corresponding PA.*
❒ Yes, Vyvgart Hytrulo, *Please obtain Form for preferred product and submit for corresponding PA*
❒ No, *Continue to Question B*

B. What is the patient's diagnosis?

❒ Myasthenia Gravis, *Continue to Question C*

❒ Other, *Skip Question D*

C. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to all of the preferred products (Ultomiris, Vyvgart and Vyvgart Hytrulo)? ***Action Required***: If Yes, attach supporting chart note(s)

❒ Yes, *Continue to Site of Service Questions*
❒ No, *Continue to Site of Service Questions*

D. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to Ultomiris? ***Action Required***: If Yes, attach supporting chart note(s).

❒ Yes, *Continue to Site of Service Questions*

❒ No, *Continue to Site of Service Questions*

Site Of Care Questions:

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

B. Is the patient less than 14 years of age?
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to C*

C. Is this request to continue previously established treatment with the requested medication? ***ACTION REQUIRED: If No please attach supporting clinical documentation.***
- ❑ Yes - This is a continuation of an existing treatment., *Continue to D*
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months)., *skip to Clinical Criteria Questions*

D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) 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 clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to E*

E. 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 clinical documentation.
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to F*

F. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to G*

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

H. Are ***all*** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? ***ACTION REQUIRED: If Yes, please attach supporting documentation.***
- ❑ Yes, *Continue to Clinical Criteria Questions*
- ❑ No, *Continue to Clinical Criteria Questions*

Clinical Criteria Questions:

1. What is the patient's diagnosis?

❒ Atypical hemolytic uremic syndrome (aHUS), *Continue to 2*

❒ Paroxysmal nocturnal hemoglobinuria (PNH), *Continue to 36*

❒ Generalized myasthenia gravis (gMG), *Continue to 49*

❒ Neuromyelitis optica spectrum disorder (NMOSD), *Continue to 62*

❒ Other, please specify. _____, *No Further Questions*

2. Is this a request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 3*
❒ No, *Continue to 16*

3. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 4*
❒ No, *Continue to 4*

4. Did the patient demonstrate a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, platelet counts)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive clinical response to therapy.
❒ Yes, *Continue to 5*
❒ No, *Continue to 5*

5. Is the patient 18 years of age or older?
❒ Yes, *Continue to 14*
❒ No, *Continue to 6*

6. What is the patient's weight?

❒ Less than 5 kg, *No Further Questions*

❒ 5 kg to less than 10 kg, *Continue to 7*

❒ 10 kg to less than 20 kg, *Continue to 9*

❒ 20 kg to less than 30 kg, *Continue to 10*

❒ 30 kg to less than 40 kg, *Continue to 11*

❒ 40 kg or greater, *Continue to 12*

7. Does the prescribed dose exceed a maintenance dose of 300 mg?
❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Is the prescribed frequency for the maintenance dose more frequent than one dose every 3 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

9. Does the prescribed dose exceed a maintenance dose of 300 mg?
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

10. Does the prescribed dose exceed a maintenance dose of 600 mg?

❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

11. Does the prescribed dose exceed a maintenance dose of 900 mg?
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

12. Does the prescribed dose exceed a maintenance dose of 1200 mg?
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

13. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

14. Does the prescribed dose exceed a maintenance dose of 1200 mg?
❒ Yes, *Continue to 15*
❒ No, *Continue to 15*

15. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

16. Is the disease caused by Shiga toxin?
❒ Yes, *Continue to 18*
❒ No, *Continue to 17*

17. Do tests confirm the absence of Shiga toxin?
❒ Yes, *Continue to 18*
❒ No, *Continue to 18*

18. What is the ADAMTS13 level? ***ACTION REQUIRED***: Please attach documentation of ADAMTS13 level.
_____%, ***ACTION REQUIRED****: Submit supporting documentation, Continue to 19*

19. Is the patient 18 years of age or older?
❒ Yes, *Continue to 33*
❒ No, *Continue to 20*

20. What is the patient's weight?

❒ Less than 5 kg, *No Further Questions*

❒ 5 kg to less than 10 kg, *Continue to 21*

❒ 10 kg to less than 20 kg, *Continue to 24*

❒ 20 kg to less than 30 kg, *Continue to 26*

❒ 30 kg to less than 40 kg, *Continue to 28*

❒ 40 kg or greater, *Continue to 30*

21. Does the prescribed dose exceed a loading dose of 300 mg for one dose followed by 300 mg at week 2?

❒ Yes, *Continue to 22*
❒ No, *Continue to 22*

22. Does the prescribed dose exceed a maintenance dose of 300 mg?
❒ Yes, *Continue to 23*
❒ No, *Continue to 23*

23. Is the prescribed frequency for the maintenance dose more frequent than one dose every 3 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

24. Does the prescribed dose exceed a loading dose of 600 mg for one dose followed by 300 mg at week 2?
❒ Yes, *Continue to 25*
❒ No, *Continue to 25*

25. Does the prescribed dose exceed a maintenance dose of 300 mg?
❒ Yes, *Continue to 32*
❒ No, *Continue to 32*

26. Does the prescribed dose exceed a loading dose of 600 mg weekly for two doses followed by 600 mg at week 3?
❒ Yes, *Continue to 27*
❒ No, *Continue to 27*

27. Does the prescribed dose exceed a maintenance dose of 600 mg?
❒ Yes, *Continue to 32*
❒ No, *Continue to 32*

28. Does the prescribed dose exceed a loading dose of 600 mg weekly for two doses followed by 900 mg at week 3?
❒ Yes, *Continue to 29*
❒ No, *Continue to 29*

29. Does the prescribed dose exceed a maintenance dose of 900 mg?
❒ Yes, *Continue to 32*
❒ No, *Continue to 32*

30. Does the prescribed dose exceed a loading dose of 900 mg weekly for four doses followed by 1200 mg at week 5?
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

31. Does the prescribed dose exceed a maintenance dose of 1200 mg?
❒ Yes, *Continue to 32*
❒ No, *Continue to 32*

32. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

33. Does the prescribed dose exceed a loading dose of 900 mg weekly for 4 weeks followed by a fifth dose of 1200 mg one week later?
❒ Yes, *Continue to 34*
❒ No, *Continue to 34*

34. Does the prescribed dose exceed a maintenance dose of 1200 mg?
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

35. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

36. Is this a request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 37*
❒ No, *Continue to 41*

37. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 38*
❒ No, *Continue to 38*

38. Did the patient demonstrate a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive clinical response.
❒ Yes, *Continue to 39*
❒ No, *Continue to 39*

39. Does the prescribed dose exceed a maintenance dose of 900 mg?
❒ Yes, *Continue to 40*
❒ No, *Continue to 40*

40. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

41. Was the diagnosis of PNH confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs)?
❒ Yes, *Continue to 42*
❒ No, *Continue to 42*

42. How was the diagnosis established?

❒ Quantification of PNH cells, *Continue to 43*

❒ Quantification of GPI-anchored protein deficient poly-morphonuclear cells, *Continue to 44*

❒ None of the above, *Continue to 45*

43. What was the percentage of PNH cells?

_____%, *Continue to 45*

44. What was the percentage of GPI-anchored protein deficient poly-morphonuclear cells?

_____%, *Continue to 45*

45. Was flow cytometry used to demonstrate the deficiency of GPI-anchored proteins? ***ACTION REQUIRED***: If Yes, please attach flow cytometry report.
❒ Yes, *Continue to 46*
❒ No, *Continue to 46*

46. Does the prescribed dose exceed a loading dose of 600 mg weekly for 4 weeks followed by a fifth dose of 900 mg one week later?
❒ Yes, *Continue to 47*
❒ No, *Continue to 47*

47. Does the prescribed dose exceed a maintenance dose of 900 mg?
❒ Yes, *Continue to 48*
❒ No, *Continue to 48*

48. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

49. Is this a request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 50*
❒ No, *Continue to 54*

50. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 51*
❒ No, *Continue to 51*

51. Has the patient experienced a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis [QMG] total score)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive response to therapy.
❒ Yes, *Continue to 52*
❒ No, *Continue to 52*

52. Does the prescribed dose exceed a maintenance dose of 1200 mg?
❒ Yes, *Continue to 53*
❒ No, *Continue to 53*

53. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

54. Is the requested medication being used to treat a patient who is anti-acetylcholine receptor (AchR) antibody positive? ***ACTION REQUIRED***: If Yes, please attach documentation of AchR antibody testing.
❒ Yes, *Continue to 55*
❒ No, *Continue to 55*

55. What is the patient's Myasthenia Gravis Foundation of America (MGFA) clinical classification? ***ACTION REQUIRED***: Please attach documentation of MGFA clinical classification.

❒ Class I ***ACTION REQUIRED****: Submit supporting documentation, Continue to 56*

❒ Class II ***ACTION REQUIRED****: Submit supporting documentation, Continue to 56*

❒ Class III ***ACTION REQUIRED****: Submit supporting documentation, Continue to 56*

❒ Class IV ***ACTION REQUIRED****: Submit supporting documentation, Continue to 56*

❒ Class V ***ACTION REQUIRED****: Submit supporting documentation, Continue to 56*

❒ Unknown, *Continue to 56*

56. What is the patient's score on the MG activities of daily living? ***ACTION REQUIRED***: Please attach documentation of MG-ADL score.

_____MG-ADL, ***ACTION REQUIRED****: Submit supporting documentation, Continue to 57*

57. Has the patient had an inadequate response to at least two of the following immunosuppressive therapies: a) Azathioprine, b) Cyclosporine, c) Mycophenolate mofetil, d) Tacrolimus, e) Methotrexate, f) Cyclophosphamide, g) Rituximab? ***ACTION REQUIRED***: If Yes, please attach documentation of inadequate response to the immunosuppressive therapies.
❒ Yes, *Continue to 58*
❒ No, *Continue to 58*

58. Has the patient experienced an inadequate response to chronic intravenous immunoglobulins (IVIG)? ***ACTION REQUIRED***: If Yes, please attach documentation of inadequate response to IVIG.
❒ Yes, *Continue to 59*
❒ No, *Continue to 59*

59. Does the prescribed dose exceed a loading dose of 900 mg weekly for 4 weeks followed by a fifth dose of 1200 mg one week later?
❒ Yes, *Continue to 60*
❒ No, *Continue to 60*

60. Does the prescribed dose exceed a maintenance dose of 1200 mg?
❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

61. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

62. Is this a request for continuation of therapy?
❒ Yes, *Continue to 63*
❒ No, *Continue to 68*

63. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 64*
❒ No, *Continue to 64*

64. Has the patient experienced a positive response to therapy (e.g., reduction in number of relapses)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive response to therapy.
❒ Yes, *Continue to 65*
❒ No, *Continue to 65*

65. Will the patient receive the requested drug concomitantly with other biologics for the treatment of neuromyelitis optica spectrum disorder (NMOSD)?
❒ Yes, *Continue to 66*
❒ No, *Continue to 66*

66. Does the prescribed dose exceed a maintenance dose of 1200 mg?

❒ Yes, *Continue to 67*
❒ No, *Continue to 67*

67. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

68. Is the patient anti-aquaporin-4 (AQP4) antibody positive? ***ACTION REQUIRED***: If Yes, please attach immunoassay confirming presence of anti-AQP4 antibody.
❒ Yes, *Continue to 69*
❒ No, *Continue to 69*

69. Does the patient exhibit at least one of the core clinical characteristics of NMOSD: a) Optic neuritis, b) Acute myelitis, c) Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting), d) Acute brainstem syndrome, e) Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, f) Symptomatic cerebral syndrome with NMOSD-typical brain lesions?
❒ Yes, *Continue to 70*
❒ No, *Continue to 70*

70. Will the patient receive the requested drug concomitantly with other biologics for the treatment of neuromyelitis optica spectrum disorder (NMOSD)?
❒ Yes, *Continue to 71*
❒ No, *Continue to 71*

71. Does the prescribed dose exceed a loading dose of 900 mg weekly for 4 weeks followed by a fifth dose of 1200 mg one week later?
❒ Yes, *Continue to 72*
❒ No, *Continue to 72*

72. Does the prescribed dose exceed a maintenance dose of 1200 mg?
❒ Yes, *Continue to 73*
❒ No, *Continue to 73*

73. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	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