Ultomiris

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the member 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

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

Site of Service Questions (SOS):

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*

Criteria Questions:

1. What is the diagnosis?

❒ Atypical hemolytic uremic syndrome (aHUS), *Continue to 9*

❒ Generalized myasthenia gravis (gMG), *Continue to 16*

❒ Neuromyelitis optica spectrum disorder (NMOSD), *Continue to 46*

❒ Paroxysmal nocturnal hemoglobinuria (PNH), *Continue to 2*

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

2. Will the patient receive the requested drug concomitantly with another complement inhibitor (e.g., Empaveli, Fabhalta, Piasky, Soliris) for the treatment of PNH (concomitant use with Voydeya is allowed)?
❒ Yes, *Continue to 3*
❒ No, *Continue to 3*

3. Is this a request for continuation of therapy with the requested medication?
❒ Yes, *Continue to 4*
❒ No, *Continue to 6*

4. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 5*
❒ No, *Continue to 5*

5. 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 26*
❒ No, *Continue to 26*

6. Was the diagnosis of PNH confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) (e.g., at least 5% PNH cells, at least 51% of GPI-AP deficient poly-morphonuclear cells)?
❒ Yes, *Continue to 7*
❒ No, *Continue to 7*

7. Was flow cytometry used to demonstrate the deficiency of GPI-anchored proteins? ***ACTION REQUIRED***: If Yes, attach flow cytometry report used to show results of glycosylphosphatidylinositol-anchored proteins (GPI-APs) deficiency.
❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Does the patient exhibit clinical manifestations of disease (e.g., LDH > 1.5 ULN, thrombosis, renal dysfunction, pulmonary hypertension, dysphagia)?
❒ Yes, *Continue to 36*
❒ No, *Continue to 9*

9. Will the patient receive the requested drug concomitantly with another complement inhibitor (e.g., Soliris) for the treatment of atypical hemolytic uremic syndrome (aHUS)?
❒ Yes, *Continue to 10*
❒ No, *Continue to 10*

10. Is the patient currently receiving treatment with the requested medication?
❒ Yes, *Continue to 11*
❒ No, *Continue to 13*

11. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 12*
❒ No, *Continue to 12*

12. 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.
❒ Yes, *Continue to 26*
❒ No, *Continue to 26*

13. Is the disease caused by Shiga toxin?
❒ Yes, *Continue to 15*
❒ No, *Continue to 14*

14. Do tests confirm the absence of Shiga toxin?
❒ Yes, *Continue to 15*
❒ No, *Continue to 15*

15. What is the ADAMTS13 level? ***ACTION REQUIRED***: Please attach documentation of ADAMTS13 level.
_____% ***ACTION REQUIRED****:* Submit supporting documentation, *Continue to 36*

16. Will the patient receive the requested drug concomitantly with another complement inhibitor (e.g., Soliris, Zilbrysq) or neonatal Fc receptor blocker (e.g., Vyvgart, Vyvgart Hytrulo, Rystiggo)?
❒ Yes, *Continue to 17*
❒ No, *Continue to 17*

17. Is this a request for continuation of therapy with the requested medication?
❒ Yes, *Continue to 18*
❒ No, *Continue to 20*

18. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 19*
❒ No, *Continue to 19*

19. Has the patient demonstrated a positive response to therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive response to therapy.
❒ Yes, *Continue to 57*
❒ No, *Continue to 57*

20. 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 positive anti-acetylcholine receptor (AchR) antibody testing.

❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

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

❒ Class I ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

❒ Class II ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

❒ Class III ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

❒ Class IV ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

❒ Class V ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

❒ Unknown, *Continue to 22*

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

_____MG-ADL score, ***ACTION REQUIRED****: Submit supporting documentation*, *Continue to 23*

23. Has the patient had an inadequate response or intolerable adverse event to at least two immunosuppressive therapies over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, tacrolimus)? ***ACTION REQUIRED***: If Yes, please attach documentation of previous medications tried, including response to therapy.
❒ Yes, *Continue to 52*
❒ No, *Continue to 24*

24. Has the patient had an inadequate response or intolerable adverse event to at least one immunosuppressive therapy and intravenous immunoglobulin (IVIG) over the course of at least 12 months? ***ACTION REQUIRED***: If Yes, please attach documentation of previous medications tried, including response to therapy.
❒ Yes, *Continue to 52*
❒ No, *Continue to 25*

25. Does the patient have a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of clinical reasons to avoid therapy.
❒ Yes, *Continue to 52*
❒ No, *Continue to 52*

26. What is the patient's weight (in kilograms)? _____kg

❒ Less than 5 kg, *No Further Questions*

❒ 5 kg to less than 10 kg, *Continue to 27*

❒ 10 kg to less than 20 kg, *Continue to 28*

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

❒ 30 kg to less than 40 kg, *Continue to 31*

❒ 40 kg to less than 60 kg, *Continue to 32*

❒ 60 kg to less than 100 kg, *Continue to 33*

❒ 100 kg or greater, *Continue to 34*

27. Does the prescribed dose exceed a maintenance dose of 300 mg?
❒ Yes, *Continue to 29*
❒ No, *Continue to 29*

28. Does the prescribed dose exceed a maintenance dose of 600 mg?
❒ Yes, *Continue to 29*
❒ No, *Continue to 29*

29. Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

30. Does the prescribed dose exceed a maintenance dose of 2,100 mg?
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

31. Does the prescribed dose exceed a maintenance dose of 2,700 mg?
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

32. Does the prescribed dose exceed a maintenance dose of 3,000 mg?
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

33. Does the prescribed dose exceed a maintenance dose of 3,300 mg?
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

34. Does the prescribed dose exceed a maintenance dose of 3,600 mg?
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

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

36. What is the patient's weight (in kilograms)?_____kg

❒ Less than 5 kg, *No Further Questions*

❒ 5 kg to less than 10 kg, *Continue to 37*

❒ 10 kg to less than 20 kg, *Continue to 38*

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

❒ 30 kg to less than 40 kg, *Continue to 41*

❒ 40 kg to less than 60 kg, *Continue to 42*

❒ 60 kg to less than 100 kg, *Continue to 43*

❒ 100 kg or greater, *Continue to 44*

37. Does the prescribed dose exceed a loading dose of 600 mg and a maintenance dose of 300 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 39*
❒ No, *Continue to 39*

38. Does the prescribed dose exceed a loading dose of 600 mg and a maintenance dose of 600 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 39*
❒ No, *Continue to 39*

39. Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

40. Does the prescribed dose exceed a loading dose of 900 mg and a maintenance dose of 2,100 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

41. Does the prescribed dose exceed a loading dose of 1,200 mg and a maintenance dose of 2,700 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

42. Does the prescribed dose exceed a loading dose of 2,400 mg and a maintenance dose of 3,000 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

43. Does the prescribed dose exceed a loading dose of 2,700 mg and a maintenance dose of 3,300 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

44. Does the prescribed dose exceed a loading dose of 3,000 mg and a maintenance dose of 3,600 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

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

46. Will the patient receive the requested medication concomitantly with other biologics for the treatment of neuromyelitis optica spectrum disorder (NMOSD)?

❒ Yes, *Continue to 47*
❒ No, *Continue to 47*

47. Is the patient currently receiving treatment with the requested medication?
❒ Yes, *Continue to 48*
❒ No, *Continue to 50*

48. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 49*
❒ No, *Continue to 49*

49. 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 57*
❒ No, *Continue to 57*

50. Is the patient anti-aquaporin-4 (AQP4) antibody positive? ***ACTION REQUIRED***: If Yes, please attach immunoassay confirming presence of anti-aquaporin-4 (AQP4) antibody.
❒ Yes, *Continue to 51*
❒ No, *Continue to 51*

51. 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 52*
❒ No, *Continue to 52*

52. What is the patient's weight (in kilograms)? _____kg.

❒ Less than 40 kg, *No Further Questions*

❒ 40 kg to less than 60 kg, *Continue to 53*

❒ 60 kg to less than 100 kg, *Continue to 54*

❒ 100kg or greater, *Continue to 55*

53. Does the prescribed dose exceed a loading dose of 2400 mg and a maintenance dose of 3000 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 56*
❒ No, *Continue to 56*

54. Does the prescribed dose exceed a loading dose of 2700 mg and a maintenance dose of 3300 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 56*
❒ No, *Continue to 56*

55. Does the prescribed dose exceed a loading dose of 3000 mg and a maintenance dose of 3600 mg thereafter beginning 2 weeks after the loading dose?

❒ Yes, *Continue to 56*
❒ No, *Continue to 56*

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

57. What is the patient's weight (in kilograms)?_____kg.
❒ Less than 40 kg, *No Further Questions*
❒ 40 kg to less than 60 kg, *Continue to 58*
❒ 60 kg to less than 100 kg, *Continue to 59*
❒ 100 kg or greater, *Continue to 60*

58. Does the prescribed dose exceed a maintenance dose of 3000 mg?
❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

59. Does the prescribed dose exceed a maintenance dose of 3300 mg?
❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

60. Does the prescribed dose exceed a maintenance dose of 3600 mg?
❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

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

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)**