# Ultomiris

## Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4**.**

**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*

**Drug Information:**

*Strength/Measure*_____ *Units* ❑ ml ❑ Gm ❑ mg ❑ ea ❑ Un

*Directions(sig)*_____ *Route of administration*_____

*Dosing frequency*_____

What is the ICD-10 code? _____

**Site of Service Questions:**

A. Indicate the site of service requested:
- ❑ *Ambulatory Surgical (POS Code 24)*
- ❑ *Home (POS Code 12)*
- ❑ *Off Campus Outpatient Hospital (POS Code 19)*
- ❑ *On Campus Outpatient Hospital (POS Code 22)*
- ❑ *Office (POS Code 11)*

B. Is the patient less than 18 years of age?
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No

C. 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 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

**Send completed form to: Priority Partners Fax: 1-866-212-4756**

D. 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

E. 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

F. 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

G. Has the patient's home been deemed not eligible or appropriate for home infusion services by a home infusion provider? ***ACTION REQUIRED: If 'Yes', please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. 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 ❑ No

**Criteria Questions:**

1. What is the diagnosis?

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

❒ Atypical hemolytic uremic syndrome (aHUS), *Continue to 10*

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

❒ Other, please specify. _____, *No further questions*

2. Is this a request for continuation of therapy with the requested medication?
❒ Yes, *Continue to 3*
❒ No, *Continue to 5*

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., 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. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 24*
❒ No, *Continue to 24*

5. Was the diagnosis of PNH confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs)?
❒ Yes, *Continue to 6*
❒ No, *Continue to 6*

6. How was the diagnosis established?

❒ Quantification of PNH cells, *Continue to 7*

❒ Quantification of GPI-anchored protein deficient poly-morphonuclear cells, *Continue to 8*

❒ None of the above, *Continue to 9*

7. What was the percentage of PNH cells?

_____%, *Continue to 9*

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

_____%, *Continue to 9*

9. Was flow cytometry used to demonstrate the deficiency of GPI-anchored proteins? ***ACTION REQUIRED***: If Yes, attach flow cytometry report.
❒ Yes, *Continue to 41*
❒ No, *Continue to 41*

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 24*
❒ No, *Continue to 24*

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 41*

16. Is this a request for continuation of therapy with the requested medication?
❒ Yes, *Continue to 17*
❒ No, *Continue to 19*

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

18. 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 71*
❒ No, *Continue to 71*

19. 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 20*
❒ No, *Continue to 20*

20. 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 21*

❒ Class II ***ACTION REQUIRED****: Submit supporting documentation, Continue to 21*

❒ Class III ***ACTION REQUIRED****: Submit supporting documentation, Continue to 21*

❒ Class IV ***ACTION REQUIRED****: Submit supporting documentation, Continue to 21*

❒ Class V ***ACTION REQUIRED****: Submit supporting documentation, Continue to 21*

❒ Unknown, *Continue to 21*

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

_____MG-ADL Score, ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

22. Has the patient had an inadequate response to at least two 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 23*
❒ No, *Continue to 23*

23. 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 64*
❒ No, *Continue to 64*

24. What is the requested formulation?

❒ Ultomiris subcutaneous (SQ), *Continue to 25*

❒ Ultomiris intravenous (IV), *Continue to 31*

25. Is this for a pediatric patient?
❒ Yes, *Continue to 26*
❒ No, *Continue to 26*

26. What is the patient' s weight?

_____kg, *Continue to 27*

27. Is the patient switching from the intravenous formulation to subcutaneous formulation?
❒ Yes, *Continue to 28*
❒ No, *Continue to 29*

28. Will the treatment with the subcutaneous formulation be given 8 weeks after the last Ultomiris intravenous maintenance dose?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

29. Does the prescribed dose exceed a maintenance dose of 490 mg?
❒ Yes, *Continue to 30*
❒ No, *Continue to 30*

30. Is the prescribed frequency for the maintenance dose more frequent than one dose weekly?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ Less than 5 kg, *No further questions*

❒ 5 kg to less than 10 kg, *Continue to 32*

❒ 10 kg to less than 20 kg, *Continue to 33*

❒ 20 kg to less than 30 kg, *Continue to 35*

❒ 30 kg to less than 40 kg, *Continue to 36*

❒ 40 kg to less than 60 kg, *Continue to 37*

❒ 60 kg to less than 100 kg, *Continue to 38*

❒ 100 kg or greater, *Continue to 39*

32. Does the prescribed dose exceed a maintenance dose of 300 mg?
❒ Yes, *Continue to 34*
❒ No, *Continue to 34*

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

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

35. Does the prescribed dose exceed a maintenance dose of 2,100 mg?
❒ Yes, *Continue to 40*
❒ No, *Continue to 40*

36. Does the prescribed dose exceed a maintenance dose of 2,700 mg?
❒ Yes, *Continue to 40*
❒ No, *Continue to 40*

37. Does the prescribed dose exceed a maintenance dose of 3,000 mg?
❒ Yes, *Continue to 40*
❒ No, *Continue to 40*

38. Does the prescribed dose exceed a maintenance dose of 3,300 mg?
❒ Yes, *Continue to 40*
❒ No, *Continue to 40*

39. Does the prescribed dose exceed a maintenance dose of 3,600 mg?
❒ Yes, *Continue to 40*
❒ No, *Continue to 40*

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

41. What is the requested formulation?

❒ Ultomiris subcutaneous (SQ), *Continue to 42*

❒ Ultomiris intravenous (IV), *Continue to 50*

42. Is this for a pediatric patient?
❒ Yes, *Continue to 43*
❒ No, *Continue to 43*

43. Which of the following applies to the patient?

❒ Currently treated with eculizumab, *Continue to 44*

❒ New to treatment with ravulizumab, *Continue to 45*

44. Will the intravenous loading dose of the requested medication be administered 2 weeks after the last eculizumab infusion?
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

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

❒ Less than 40 kg, *No further questions*

❒ 40 kg to less than 60 kg, *Continue to 46*

❒ 60 kg to less than 100 kg, *Continue to 47*

❒ 100 kg or greater, *Continue to 48*

46. Does the prescribed dose exceed an intravenous loading dose of 2,400 mg and a subcutaneous maintenance dose of 490 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 49*
❒ No, *Continue to 49*

47. Does the prescribed dose exceed an intravenous loading dose of 2,700 mg and a subcutaneous maintenance dose of 490 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 49*
❒ No, *Continue to 49*

. Does the prescribed dose exceed an intravenous loading dose of 3,000 mg and a subcutaneous maintenance dose of 490 mg thereafter beginning 2 weeks after the loading dose?
❒ Yes, *Continue to 49*
❒ No, *Continue to 49*

49. Is the prescribed frequency for the maintenance dose more frequent than one dose weekly?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

50. Which of the following treatments is being requested?

❒ Initiation of therapy with IV loading dose, *Continue to 51*

❒ Initiation of therapy with IV after SQ use, *Continue to 53*

51. Is the patient switching from eculizumab to the requested medication?
❒ Yes, *Continue to 52*
❒ No, *Continue to 54*

52. Will the loading dose of the requested medication be administered 2 weeks after the last eculizumab infusion?
❒ Yes, *Continue to 54*
❒ No, *Continue to 54*

53. Will the maintenance dose of the requested medication be administered 1 week after the last subcutaneous maintenance dose?
❒ Yes, *Continue to 54*
❒ No, *Continue to 54*

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

❒ Less than 5 kg, *No further questions*

❒ 5 kg to less than 10 kg, *Continue to 55*

❒ 10 kg to less than 20 kg, *Continue to 56*

❒ 20 kg to less than 30 kg, *Continue to 58*

❒ 30 kg to less than 40 kg, *Continue to 59*

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

❒ 60 kg to less than 100 kg, *Continue to 61*

❒ 100 kg or greater, *Continue to 62*

55. 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 57*
❒ No, *Continue to 57*

56. 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 57*
❒ No, *Continue to 57*

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

58. 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 63*
❒ No, *Continue to 63*

59. 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 63*
❒ No, *Continue to 63*

60. 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 63*
❒ No, *Continue to 63*

61. 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 63*
❒ No, *Continue to 63*

62. 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 63*
❒ No, *Continue to 63*

63. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks?

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

64. Is the patient switching from eculizumab to the requested medication?
❒ Yes, *Continue to 65*
❒ No, *Continue to 66*

65. Will the loading dose of the requested medication be administered 2 weeks after the last eculizumab infusion?
❒ Yes, *Continue to 66*
❒ No, *Continue to 66*

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

❒ Less than 40 kg, *No further questions*

❒ 40 kg to less than 60 kg, *Continue to 67*

❒ 60 kg to less than 100 kg, *Continue to 68*

❒ 100kg or greater, *Continue to 69*

67. 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 70*
❒ No, *Continue to 70*

68. 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 70*
❒ No, *Continue to 70*

69. 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 70*
❒ No, *Continue to 70*

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

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

❒ Less than 40 kg, *No further questions*

❒ 40 kg to less than 60 kg, *Continue to 72*

❒ 60 kg to less than 100 kg, *Continue to 73*

❒ 100 kg or greater, *Continue to 74*

72. Does the prescribed dose exceed a maintenance dose of 3000 mg?
❒ Yes, *Continue to 75*
❒ No, *Continue to 75*

73. Does the prescribed dose exceed a maintenance dose of 3300 mg?
❒ Yes, *Continue to 75*
❒ No, *Continue to 75*

74. Does the prescribed dose exceed a maintenance dose of 3600 mg?
❒ Yes, *Continue to 75*
❒ No, *Continue to 75*

75. 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)**

**Send completed form to: Priority Partners Fax: 1-866-212-4756**



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