Soliris

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 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?

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Phone: 888-819-1043 ● Fax: 1-866-212-4756 ● www.hopkinshealthplans.org

❒ 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*

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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