



Soliris, Bkempv, Epysqli

HMSA Medicare Advantage - 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 1-866-237-5512.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414**. 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.

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Patient's Name: _____ **Date:** _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: _____ kg
Patient Height: _____ ft _____ inches

Indicate where the drug is being dispensed:

- Office Outpatient Hospital Ambulatory Surgical Inpatient Hospital
- Off Campus Outpatient Hospital Urgent Care Emergency Room Birthing Center
- Military Facility Skilled Nursing Facility Nursing Facility Hospice
- Inpatient Psychiatric Psychiatric Residential Treatment End Stage Renal Facility
- Psychiatric Facility Pharmacy Other

Indicate where the drug is being administered:

- Ambulatory surgical Home Inpatient Hospital
- Office Outpatient Hospital Pharmacy

What is the ICD-10 code? _____

What product is being requested? Soliris Bkempv Epysqli

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

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Criteria Questions:

1. What is the patient's diagnosis?

- Atypical hemolytic uremic syndrome (aHUS), *Continue to #10*
- Antibody mediated heart transplant rejection, *Continue to #5*
- Antibody mediated renal transplant rejection, *Continue to #5*
- Complement C3 glomerulopathy post-kidney transplant, *Continue to #5*
- Generalized myasthenia gravis (gMG), *Continue to #200*
- Neuromyelitis optica spectrum disorder (NMOSD), *Continue to #300*
- Paroxysmal nocturnal hemoglobinuria (PNH), *Continue to #100*
- Other, *No Further Questions*

Antibody mediated renal transplant rejection/ Antibody mediated heart transplant rejection/C3G post-kidney transplant

5. Is the patient currently receiving treatment with the requested drug?

- Yes, *Continue to #6*
- No, *No Further Questions*

6. Is the patient receiving benefit from therapy? ***If 'Yes', chart notes or medical record documentation supporting benefit from therapy must be available upon request***

- Yes, *No Further Questions*
- No, *No Further Questions*

Atypical hemolytic uremic syndrome (aHUS)

10. Will the patient receive the requested medication concomitantly with another complement inhibitor (e.g., Ultomiris)?

- Yes, *Continue to #11*
- No, *Continue to #11*

11. Is the patient currently receiving treatment with the requested drug?

- Yes, *Continue to #12*
- No, *Continue to #50*

Continuation of Therapy

12. Is the patient receiving benefit from therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, platelet counts)? ***If 'Yes', chart notes or medical record documentation supporting benefit from therapy must be available upon request***

- Yes, *Continue to #13*
- No, *Continue to #13*

13. Is the patient 18 years of age or older?

- Yes, *Continue to #22*
- No, *Continue to #14*

14. What is the patient's weight?

- Less than 5 kg, *No Further Questions*
- 5 kg to less than 10 kg, *Continue to #15*
- 10 kg to less than 20 kg, *Continue to #17*
- 20 kg to less than 30 kg, *Continue to #18*

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- 30 kg to less than 40 kg, *Continue to #19*
- 40 kg or greater, *Continue to #20*

15. Does the prescribed dose exceed a maintenance dose of 300 mg?

- Yes, *Continue to #16*
- No, *Continue to #16*

16. Is the prescribed frequency for the maintenance dose more frequent than one dose every 3 weeks?

- Yes, *No Further Questions*
- No, *No Further Questions*

17. Does the prescribed dose exceed a maintenance dose of 300 mg?

- Yes, *Continue to #21*
- No, *Continue to #21*

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

- Yes, *Continue to #21*
- No, *Continue to #21*

19. Does the prescribed dose exceed a maintenance dose of 900 mg?

- Yes, *Continue to #21*
- No, *Continue to #21*

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

- Yes, *Continue to #21*
- No, *Continue to #21*

21. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

- Yes, *No Further Questions*
- No, *No Further Questions*

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

- Yes, *Continue to #23*
- No, *Continue to #23*

23. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

- Yes, *No Further Questions*
- No, *No Further Questions*

Initial Therapy

50. Is the disease caused by Shiga toxin?

- Yes, *Continue to #51*
- No, *Continue to #51*

51. Is the patient 18 years of age or older?

- Yes, *Continue to #65*
- No, *Continue to #52*

52. What is the patient's weight?

- Less than 5 kg, *No Further Questions*

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- 5 kg to less than 10 kg, *Continue to #53*
- 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 #60*
- 40 kg or greater, *Continue to #62*

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

- Yes, *Continue to #54*
- No, *Continue to #54*

54. Does the prescribed dose exceed a maintenance dose of 300 mg?

- Yes, *Continue to #55*
- No, *Continue to #55*

55. Is the prescribed frequency for the maintenance dose more frequent than one dose every 3 weeks?

- Yes, *No Further Questions*
- No, *No Further Questions*

56. Does the prescribed dose exceed a loading dose of 600 mg for one dose followed by 300 mg at week 2?

- Yes, *Continue to #57*
- No, *Continue to #57*

57. Does the prescribed dose exceed a maintenance dose of 300 mg?

- Yes, *Continue to #64*
- No, *Continue to #64*

58. 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 #59*
- No, *Continue to #59*

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

- Yes, *Continue to #64*
- No, *Continue to #64*

60. 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 #61*
- No, *Continue to #61*

61. Does the prescribed dose exceed a maintenance dose of 900 mg?

- Yes, *Continue to #64*
- No, *Continue to #64*

62. 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 #63*
- No, *Continue to #63*

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

- Yes, *Continue to #64*
- No, *Continue to #64*

64. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

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- Yes, *No Further Questions*
- No, *No Further Questions*

65. 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 #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*

Paroxysmal nocturnal hemoglobinuria (PNH)

100. Will the requested medication be used in combination with another complement inhibitor (e.g., Empaveli, Fabhalta, Piasky, Ultomiris) for the treatment of PNH (concomitant use with Voydeya is allowed)?

- Yes, *Continue to #101*
- No, *Continue to #101*

101. Is the patient currently receiving treatment with the requested drug?

- Yes, *Continue to #102*
- No, *Continue to #150*

Continuation of Therapy

102. Is the patient receiving benefit from therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels)? ***If 'Yes', chart notes or medical record documentation supporting benefit from therapy must be available upon request***

- Yes, *Continue to #103*
- No, *Continue to #103*

103. Does the prescribed dose exceed a maintenance dose of 900 mg?

- Yes, *Continue to #104*
- No, *Continue to #104*

104. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

- Yes, *No Further Questions*
- No, *No Further Questions*

Initial Therapy

150. 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 #151*
- No, *Continue to #151*

151. Was flow cytometry used to demonstrate the deficiency of GPI-anchored proteins? ***If 'Yes', flow cytometry report***

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used to show results of GPI-APs deficiency must be available upon request

Yes, *Continue to #152*

No, *Continue to #152*

152. Does the patient exhibit clinical manifestations of disease (e.g., lactate dehydrogenase [LDH], > 1.5 upper limit of normal [ULN], thrombosis, renal dysfunction, pulmonary hypertension, dysphagia)?

Yes, *Continue to #153*

No, *Continue to #153*

153. 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 #154*

No, *Continue to #154*

154. Does the prescribed dose exceed a maintenance dose of 900 mg?

Yes, *Continue to #155*

No, *Continue to #155*

155. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

Yes, *No Further Questions*

No, *No Further Questions*

Generalized myasthenia gravis (gMG)

200. Will the requested medication be used in combination with another complement inhibitor (e.g., Ultomiris, Zilbrysq) or neonatal Fc receptor blocker (e.g., Vyvgart, Vyvgart Hytrulo, Rystiggo)?

Yes, *Continue to #201*

No, *Continue to #201*

Continuation of Therapy

201. Is the patient currently receiving treatment with the requested drug?

Yes, *Continue to #202*

No, *Continue to #250*

202. Is the patient receiving benefit from therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite)? ***If 'Yes', chart notes or medical record documentation supporting benefit from therapy must be available upon request***

Yes, *Continue to #203*

No, *Continue to #203*

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

Yes, *Continue to #204*

No, *Continue to #204*

204. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

Yes, *No Further Questions*

No, *No Further Questions*

Initial Therapy

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250. Is the requested drug being used to treat a patient who is anti-acetylcholine receptor (AChR) antibody positive? **If 'Yes', documentation of anti-acetylcholine receptor (AChR) antibody testing must be available upon request**

Yes, Continue to #251

No, Continue to #251

251. What is the patient's Myasthenia Gravis Foundation of America (MGFA) clinical classification? **ACTION REQUIRED: Chart notes, medical records, or claims history documenting MGFA clinical classification must be available upon request**

Class I, Continue to #252

Class II, Continue to #252

Class III, Continue to #252

Class IV, Continue to #252

Class V, Continue to #252

Unknown, Continue to #252

252. What is the patient's score on the MG activities of daily living (MG-ADL)? **ACTION REQUIRED: Documentation of MG-ADL score must be submitted upon request**

_____ MG-ADL score, Continue to #253

253. 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', chart notes, medical records or claims history documenting previous medications tried, including response to therapy must be submitted upon request**

Yes, Continue to #256

No, Continue to #254

254. 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', chart notes, medical records or claims history documenting previous medications tried, including response to therapy must be submitted upon request**

Yes, Continue to #256

No, Continue to #255

255. Does the patient have a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG? **ACTION REQUIRED: If 'Yes', chart notes or medical record documentation of clinical reasons to avoid therapy must be submitted upon request**

Yes, Continue to #256

No, Continue to #256

256. 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 #257

No, Continue to #257

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

Yes, Continue to #258

No, Continue to #258

258. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

Yes, No Further Questions

No, No Further Questions

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Neuromyelitis Optica Spectrum Disorder (NMOSD)

300. Will the requested medication be used concomitantly with other biologics for the treatment of neuromyelitis optica spectrum disorder (NMOSD)?

- Yes, *Continue to #301*
 No, *Continue to #301*

Continuation of Therapy

301. Is the patient currently receiving treatment with the requested drug?

- Yes, *Continue to #302*
 No, *Continue to #350*

302. Is the patient receiving benefit from therapy (e.g., reduction in number of relapses as compared to baseline)? ***If 'Yes', chart notes or medical record documentation supporting benefit from therapy must be available upon request***

- Yes, *Continue to #303*
 No, *Continue to #303*

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

- Yes, *Continue to #304*
 No, *Continue to #304*

304. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

- Yes, *No Further Questions*
 No, *No Further Questions*

Initial Therapy

350. Is the patient anti-aquaporin-4 (AQP4) antibody positive? ***If 'Yes', immunoassay used to confirm presence of anti-AQP4 antibody must be available upon request***

- Yes, *Continue to #351*
 No, *Continue to #351*

351. Does the patient exhibit at least one of the following core clinical characteristics of neuromyelitis optica spectrum disorder?

- Optic neuritis
- Acute myelitis
- Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
- Acute brainstem syndrome
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

- Yes, *Continue to #352*
 No, *Continue to #352*

352. 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 #353*
 No, *Continue to #353*

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

Yes, *Continue to #354*

No, *Continue to #354*

354. 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)

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