Soliris, Bkemv, Epysqli

HMSACOM - 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.

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:** _____
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 ❒ Bkemv ❒ Epysqli

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

Criteria Questions:

1. What is the patient's diagnosis?
❒ Atypical hemolytic uremic syndrome (aHUS), *Continue to #10*
❒ Paroxysmal nocturnal hemoglobinuria (PNH), *Continue to #20*
❒ Generalized myasthenia gravis (gMG), *Continue to #30*
❒ Neuromyelitis optica spectrum disorder (NMOSD), *Continue to #45*
❒ Other, *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 this a request for continuation of therapy with the requested medication?
❒ Yes, *Continue to #12*
❒ No, *Continue to #15*

12. Was Soliris therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #13*
❒ No, *Continue to #15*
❒ Unknown, *Continue to #15*

13. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to #14*
❒ No, *Continue to #14*

14. Did the patient demonstrate a positive response to therapy (e.g., normalization of lactate dehydrogenase (LDH) levels platelet counts)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

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

17. What is the ADAMTS13 level? ***ACTION REQUIRED****: Please attach documentation of ADAMTS13 level*
_____ *ADAMTS13 level*, *No Further Questions*

Paroxysmal nocturnal hemoglobinuria (PNH)

20. Will the patient receive the requested drug concomitantly with another complement inhibitor (e.g., Empaveli, Fabhalta, Piasky, Ultomiris) for the treatment of PNH (concomitant use with Voydeya is allowed)?
❒ Yes, *Continue to #21*
❒ No, *Continue to #21*

21. Is this a request for continuation of therapy with the requested medication?
❒ Yes, *Continue to #22*
❒ No, *Continue to #25*

22. Was Soliris therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #23*
❒ No, *Continue to #25*
❒ Unknown, *Continue to #25*

23. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to #24*
❒ No, *Continue to #24*

24. Did the patient demonstrate a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase (LDH) levels)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

25. 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 #26*
❒ No, *Continue to #26*

26. Was flow cytometry used to demonstrate the deficiency of GPI-AP? ***ACTION REQUIRED****: Please attach flow cytometry report*
❒ Yes, *Continue to #27*
❒ No, *Continue to #27*

27. Does the patient exhibit clinical manifestations of disease (e.g., LDH > 1.5 ULN, thrombosis, renal dysfunction, pulmonary hypertension, dysphagia)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Generalized myasthenia gravis (gMG)

30. Will the patient receive the requested medication concomitantly with another complement inhibitor (e.g., Ultomiris, Zilbrysq) or neonatal Fc receptor blocker (e.g., Vyvgart, Vyvgart Hytrulo, Rystiggo)?
❒ Yes, *Continue to #31*
❒ No, *Continue to #31*

31. Is this a request for continuation of therapy with the requested medication?
❒ Yes, *Continue to #32*
❒ No, *Continue to #35*

32. Was Soliris therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #33*
❒ No, *Continue to #35*
❒ Unknown, *Continue to #35*

33. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to #34*
❒ No, *Continue to #34*

34. Has the patient demonstrated a positive response to therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

35. Is the requested medication being used to treat a patient who is anti-acetylcholine receptor (AchR) antibody positive? ***ACTION REQUIRED****: Please attach documentation of AchR antibody testing*
❒ Yes, *Continue to #36*
❒ No, *Continue to #36*

36. What is the patient's Myasthenia Gravis Foundation of America (MGFA) clinical classification? ***ACTION REQUIRED****: Please attach documentation of MGFA clinical classification*
❒ Class I, *Continue to #37*
❒ Class II, *Continue to #37*
❒ Class III, *Continue to #37*
❒ Class IV, *Continue to #37*
❒ Class V, *Continue to #37*
❒ Unknown, *Continue to #37*

37. What is the patient's score on the MG activities of daily living (MG-ADL)? ***ACTION REQUIRED****: Please attach documentation of MG-ADL score*
_____ *MG-ADL score, Continue to #38*

38. Has the patient had an inadequate response to at least two immunosuppressive therapies over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, tacrolimus)? ***ACTION REQUIRED****: Please attach documentation of inadequate response to the immunosuppressive therapies*
❒ Yes, *No Further Questions*
❒ No, *Continue to #39*

39. 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?
❒ Yes, *No Further Questions*
❒ No, *Continue to #40*

40. Does the patient have a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Neuromyelitis Optica Spectrum Disorder (NMOSD)

45. Is this a request for continuation therapy?
❒ Yes, *Continue to #46*
❒ No, *Continue to #50*

46. Was Soliris therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #47*

❒ No, *Continue to #50*
❒ Unknown, *Continue to #50*

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

48. Will the patient receive the requested drug concomitantly with other biologics for the treatment of NMOSD?
❒ 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)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

50. Is the patient anti-aquaporin-4 (AQP4) antibody positive? ***ACTION REQUIRED****: Please attach immunoassay confirming presence of anti-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?
- 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 #52*
❒ No, *Continue to #52*

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