



Empaveli

CareFirst 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 1-855-330-1720.** 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.

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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*

Please indicate the place of service for the requested drug:

- | | | |
|--|---------------------------------|---|
| <input type="checkbox"/> Ambulatory Surgical | <input type="checkbox"/> Home | <input type="checkbox"/> Off Campus Outpatient Hospital |
| <input type="checkbox"/> On Campus Outpatient Hospital | <input type="checkbox"/> Office | <input type="checkbox"/> Pharmacy |

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. CareFirst MR Empaveli SGM 4738-A – 01/2024.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

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Exception Criteria Questions:

- A. The preferred products for your patient's health plan are Ultomiris and Soliris.
Can the patient's treatment be switched to Ultomiris or Soliris?
☐ Yes, *Please obtain Form for preferred product and submit for corresponding PA*
☐ No
- B. Is this request for continuation of therapy with the requested product? ☐ Yes ☐ No, *If No, skip to Question D*
- C. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes. ☐ Yes ☐ No *If No, Skip to Clinical Criteria Questions*
- D. Does the patient have a documented inadequate response or intolerable adverse event to one of the preferred products (Ultomiris, Soliris)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** ☐ Yes ☐ No

Clinical Criteria Questions:

1. What is the patient's diagnosis?
☐ Paroxysmal nocturnal hemoglobinuria (PNH), *Continue to 2*
☐ Other, please specify. _____, *Continue to 2*
2. Is this a request for continuation of therapy with the requested drug?
☐ Yes, *Continue to 3*
☐ No, *Continue to 9*
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.***
☐ Yes, *Continue to 5*
☐ No, *Continue to 5*
5. Does the prescribed dose exceed 1,080 mg by subcutaneous infusion?
☐ Yes, *Continue to 6*
☐ No, *Continue to 6*
6. Is the prescribed frequency more frequent than one dose twice weekly?
☐ Yes, *Continue to 7*
☐ No, *No Further Questions*
7. Does the patient have a lactate dehydrogenase (LDH) level greater than two times the upper limit of normal (ULN)?
☐ Yes, *Continue to 8*
☐ No, *Continue to 8*

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8. Is the prescribed frequency more frequent than one dose every three days?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

9. Was the diagnosis of PNH confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs)?

☐ Yes, *Continue to 10*

☐ No, *Continue to 10*

10. How was the diagnosis established?

☐ Quantification of PNH cells, *Continue to 11*

☐ Quantification of GPI-anchored protein deficient poly-morphonuclear cells, *Continue to 12*

☐ None of the above, *No Further Questions*

11. What was the percentage of PNH cells?

_____, *Continue to 13*

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

_____, *Continue to 13*

13. Was flow cytometry used to demonstrate the deficiency of GPI-anchored proteins? **ACTION REQUIRED:** If Yes, please attach flow cytometry report.

☐ Yes, *Continue to 14*

☐ No, *Continue to 14*

14. Does the prescribed dose exceed 1,080 mg by subcutaneous infusion?

☐ Yes, *Continue to 15*

☐ No, *Continue to 15*

15. Is the prescribed frequency more frequent than one dose twice weekly?

☐ Yes, *Continue to 16*

☐ No, *No Further Questions*

16. Does the patient have a lactate dehydrogenase (LDH) level greater than two times the upper limit of normal (ULN)?

☐ Yes, *Continue to 17*

☐ No, *Continue to 17*

17. Is the prescribed frequency more frequent than one dose every three days?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

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Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

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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