



PRIOR AUTHORIZATION REQUEST

Fabhalta

Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for ALL PA requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

1	Is the patient currently receiving Fabhalta? [If no, skip to question 9.]	Yes	No
2	Has the patient been receiving medication samples for Fabhalta? [If yes, skip to question 9.]	Yes	No
3	Does the patient have a previously approved prior authorization (PA) on file with the current plan? [Note: If the patient does NOT have a previously approved PA on file for the	Yes	No

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requested medication with the current plan, the renewal request will be considered under initial therapy.]

[If no, skip to question 9.]

- | | | | |
|----|---|-----|----|
| 4 | Has the patient been established on therapy for at least 3 months?
[If no, skip to question 9.] | Yes | No |
| 5 | Has documentation been submitted to confirm that the patient has had a clinically significant response to therapy, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 6 | What is the indication or diagnosis?
<input type="checkbox"/> Paroxysmal Nocturnal Hemoglobinuria (PNH) (If checked, go to 7)

<input type="checkbox"/> Immunoglobulin A Nephropathy (IgAN) (If checked, go to 8)

<input type="checkbox"/> Other (If checked, no further questions) | | |
| 7 | Is the requested medication prescribed by or in consultation with a hematologist, oncologist, immunologist, or genetic specialist?
[No further questions.] | Yes | No |
| 8 | Is the requested medication prescribed by or in consultation with a nephrologist?
[No further questions.] | Yes | No |
| 9 | What is the indication or diagnosis?
<input type="checkbox"/> Paroxysmal Nocturnal Hemoglobinuria (PNH) (If checked, go to 10)

<input type="checkbox"/> Immunoglobulin A Nephropathy (IgAN) (If checked, go to 21)

<input type="checkbox"/> Other (If checked, no further questions) | | |
| 10 | Has documentation been submitted to confirm a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as evidenced by having detectable GPI-deficient hematopoietic clones (Type III PNH RBC) via Flow Cytometry? ACTION REQUIRED: Submit supporting documentation.
[Note: Documentation of Flow Cytometry pathology report support must indicate presence of PNH-type RBC (red blood cell).]
[If no, no further questions.] | Yes | No |
| 11 | Has documentation been submitted to confirm that the patient has a LDH level of 1.5 times the upper limit of normal range? ACTION REQUIRED: Submit supporting documentation.
[Note: Laboratory results with reference range must be submitted]
[If no, no further questions.] | Yes | No |
| 12 | Has the patient had at least one blood transfusion within the last 12 months and | Yes | No |

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one of the following: A) Hemoglobin (Hgb) less than or equal to 7 g/dL, or B) Hemoglobin (Hgb) less than or equal to 9 g/dL with symptoms of anemia?

ACTION REQUIRED: Submit supporting documentation.

[If no, no further questions.]

13	Is the patient 18 years of age or older? [If no, no further questions.]	Yes	No
14	Is the medication prescribed by or in consultation with a hematologist, oncologist, immunologist, or genetic specialist? [If no, no further questions.]	Yes	No
15	Has documentation been submitted to show a of trial and failure (at least 3 months), intolerance to, or contraindication to Soliris? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
16	Will Fabhalta be prescribed concurrently with Soliris, Empaveli or Ultomiris? [If yes, no further questions.]	Yes	No
17	Has documentation been submitted to show that a meningococcal, pneumoniae, and haemophilis influenzae type b vaccines have been given or will be given at least two (2) weeks prior to the administration of the first dose of Fabhalta? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
18	Does the patient have an unresolved serious infection caused by encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, or Haemophilus influenzae type b? [If yes, no further questions.]	Yes	No
19	Are the prescriber and patient enrolled in the Fabhalta REMS program? [If no, no further questions.]	Yes	No
20	Is dosing within the FDA approved labeling? [No further questions.]	Yes	No
21	Has documentation been submitted to confirm a diagnosis of proteinuria with primary immunoglobulin A nephropathy confirmed by biopsy? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
22	Has documentation been submitted to confirm that the patient is at risk for rapid disease progression and has a documented lab of urine protein-to-creatinine ratio (UPCR) greater than 1.5 g/g (within 60 days for request)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No

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23	Is the patient 18 years of age or older? [If no, no further questions.]	Yes	No
24	Is Fabhalta prescribed by or in consultation with a nephrologist? [If no, no further questions.]	Yes	No
25	Has documentation been submitted to show that a meningococcal, pneumoniae, and haemophilis influenzae type b vaccines have been given or will be given at least two (2) weeks prior to the administration of the first dose of Fabhalta? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
26	Does the patient have an unresolved serious infection caused by encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, or Haemophilus influenzae type b? [If yes, no further questions.]	Yes	No
27	Has documentation been submitted to show that there has been a trial and failure (for at least 3 months to maximum tolerated dose), intolerance, or contraindication to an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
28	Has documentation been submitted to show that there has been a trial and failure (for at least 2 months with each glucocorticoid), intolerance, or contraindication to TWO glucocorticoids? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
29	Are the prescriber and patient enrolled in the Fabhalta REMS program? [If no, no further questions.]	Yes	No
30	Is dosing within the FDA approved labeling?	Yes	No

Please document the diagnoses, symptoms, and/or any other information important to this review:

SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

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FAX COMPLETED FORM TO: 1-833-896-0656

Disclaimer: An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

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