



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 this request for initial therapy or for continuation of therapy? | | |
| | ☐ Initial (If checked, go to 7) | | |
| | ☐ Continuation (If checked, go to 2) | | |
| 2 | Is the patient currently receiving Fabhalta? | Yes | No |
| | [If no, skip to question 7.] | | |

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Version 06.2026

PRIOR AUTHORIZATION REQUEST

3	Has the patient been receiving medication samples for Fabhalta? [If yes, skip to question 7.]	Yes	No
4	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 requested medication with the current plan, the renewal request will be considered under initial therapy.] [If no, skip to question 7.]	Yes	No
5	Has the patient been established on therapy for at least 3 months? [If no, skip to question 7.]	Yes	No
6	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. [No further questions.]	Yes	No
7	What is the indication or diagnosis? ☐ Paroxysmal Nocturnal Hemoglobinuria (PNH) (If checked, go to 8) ☐ Immunoglobulin A Nephropathy (IgAN) (If checked, go to 19) ☐ Complement 3 Glomerulopathy (C3G) (If checked, go to 29) ☐ Other (If checked, no further questions)		
8	Is the patient 18 years of age or older? [If no, no further questions.]	Yes	No
9	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
10	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
11	Has the patient had at least one blood transfusion within the last 12 months and 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?	Yes	No

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Version 06.2026

PRIOR AUTHORIZATION REQUEST

ACTION REQUIRED: Submit supporting documentation.

[If no, no further questions.]

12	Has documentation been submitted to show a 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
13	Will Fabhalta be prescribed concurrently with Soliris, Empaveli or Ultomiris? [If yes, no further questions.]	Yes	No
14	Has documentation been submitted to show that a meningococcal, pneumoniae, and haemophilus 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
15	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
16	Are the prescriber and patient enrolled in the Fabhalta REMS program? [If no, no further questions.]	Yes	No
17	Is the medication prescribed by or in consultation with a hematologist, oncologist, immunologist, or genetic specialist? [If no, no further questions.]	Yes	No
18	Does the requested dose exceed the Food and Drug Administration (FDA) approved label dosing for the requested indication? [Note: Dosing: 200 mg twice daily.] [No further questions.]	Yes	No
19	Is the patient 18 years of age or older? [If no, no further questions.]	Yes	No
20	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
21	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 of request)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No

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Version 06.2026

PRIOR AUTHORIZATION REQUEST

22	Has documentation been submitted to show that a meningococcal, pneumoniae, and haemophilus 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
23	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
24	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
25	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
26	Are the prescriber and patient enrolled in the Fabhalta REMS program? [If no, no further questions.]	Yes	No
27	Is Fabhalta prescribed by or in consultation with a nephrologist? [If no, no further questions.]	Yes	No
28	Does the requested dose exceed the Food and Drug Administration (FDA) approved label dosing for the requested indication? [Note: Dosing: 200 mg twice daily.] [No further questions.]	Yes	No
29	Is the patient 18 years of age or older? [If no, no further questions.]	Yes	No
30	Does the patient have a documented diagnosis of C3 glomerulopathy confirmed by kidney biopsy? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
31	Has documentation been submitted to show that the urine protein to creatinine ratio (UPCR) is greater than or equal to 1 g/g (within 60 days of the request)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
32	Has documentation been submitted to show that eGFR is at least 30 ml/min/1.73m ² or greater? ACTION REQUIRED: Submit supporting documentation.	Yes	No

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Version 06.2026

PRIOR AUTHORIZATION REQUEST

[If no, no further questions.]

- | | | | |
|----|---|-----|----|
| 33 | Has documentation been submitted to show a trial and failure (at least 3 months) to an angiotensin converting enzyme inhibitor, angiotensin receptor blocker, or a sodium glucose cotransporter-2 inhibitor, unless intolerant or contraindicated to all 3 classes? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 34 | Will Fabhalta be prescribed concurrently with Empaveli or another complement inhibitor?
[If yes, no further questions.] | Yes | No |
| 35 | Has documentation been submitted to show that a meningococcal, pneumoniae, and haemophilus 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 |
| 36 | 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 |
| 37 | Are the prescriber and patient enrolled in the Fabhalta REMS program?
[If no, no further questions.] | Yes | No |
| 38 | Is Fabhalta prescribed by or in consultation with a nephrologist?
[If no, no further questions.] | Yes | No |
| 39 | Does the requested dose exceed the Food and Drug Administration (FDA) approved label dosing for the requested indication?
[Note: Dosing: 200 mg twice daily.] | Yes | No |

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

SECTION B: Physician Signature

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questions, call:
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Version 06.2026



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PHYSICIAN SIGNATURE

DATE

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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