Fabhalta (iptacopan)
Prior Authorization Request Form

Caterpillar Prescription Drug Benefit
Phone: 877-228-7909 Fax: 800-424-7640

MEMBER'S LAST NAME: _____ **MEMBER'S FIRST NAME:** _____

Instructions: Please fill out all applicable sections completely and legibly. Attach any additional documentation that is important for the review (e.g., chart notes or lab data, to support the authorization request). Information contained in this form is Protected Health Information under HIPAA.

☐ **URGENT**

MEMBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PHONE NUMBER:	**DATE OF BIRTH:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
PATIENT INSURANCE ID NUMBER:	

☐ **MALE** ☐ **FEMALE** **HEIGHT (IN/CM):** _____ **WEIGHT (LB/KG):** _____ **ALLERGIES:** _____

IF YOU ARE NOT THE PATIENT OR THE PRESCRIBER, YOU WILL NEED TO SUBMIT A PHI DISCLOSURE AUTHORIZATION FORM WITH THIS REQUEST WHICH CAN BE FOUND AT THE FOLLOWING LINK: PRIMETHERAPEUTICS.COM/NOPP

PATIENT'S AUTHORIZED REPRESENTATIVE (IF APPLICABLE): _____
AUTHORIZED REPRESENTATIVE'S PHONE NUMBER: _____

PRESCRIBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PRESCRIBER SPECIALTY:	**EMAIL ADDRESS:**
NPI NUMBER:	**DEA NUMBER:**
PHONE NUMBER:	**FAX NUMBER:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
REQUESTER (if different than prescriber):	**OFFICE CONTACT PERSON:**

MEDICATION OR MEDICAL DISPENSING INFORMATION			
MEDICATION NAME:			
DOSE/STRENGTH:	**FREQUENCY:**	**LENGTH OF THERAPY/REFILLS:**	**QUANTITY:**
☐ **NEW THERAPY** ☐ **RENEWAL** **IF RENEWAL:** DATE THERAPY INITIATED: DURATION OF THERAPY (SPECIFIC DATES):			

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1. HAS THE PATIENT TRIED ANY OTHER MEDICATIONS FOR THIS CONDITION? ☐ **YES** (if yes, complete below) ☐ **NO**		
MEDICATION/THERAPY (SPECIFY DRUG NAME AND DOSAGE)**:**	**DURATION OF THERAPY** (SPECIFY DATES)**:**	**RESPONSE/REASON FOR FAILURE/ALLERGY:**

2. LIST DIAGNOSES:	**ICD-10:**
☐ **Paroxysmal nocturnal hemoglobinuria (PNH)** ☐ **Immunoglobulin A nephropathy(IgNA)** ☐ Other diagnosis: _____ ICD-10 Code(s):	

3. REQUIRED CLINICAL INFORMATION: PLEASE PROVIDE ALL RELEVANT CLINICAL INFORMATION TO SUPPORT A PRIOR AUTHORIZATION.

Will the requested agent be used as part of a clinical trial? □ Yes □ No

Is the requested agent being prescribed by, or in consultation with one of the below? □ Yes □ No
□ Hematologist
□ Oncologist
□ Urologist
□ Nephrologist

Will Fabhalta (iptacopan) be used in combination with Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan) or Voydeya (danicopan)? □ Yes □ No

<u>For PNH, answer the following</u>:
Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)? □ Yes □ No

Was the patient's diagnosis confirmed by peripheral blood flow cytometry diagnostic testing showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins? □ Yes □ No ***Please provide documentation***

Is the requested agent being prescribe by, or in consultation with a hematologist or oncologist? □ Yes □ No

Has the patient been on a stable regimen of an anti-C5 (Soliris(eculizumab) or Ultomiris (ravulizumab)) antibody treatment for at least 6-months? □ Yes □ No ***Please provide documentation***

Is patient's hemglobin level less than 10g/dL? □ Yes □ No ***Please provide documentation***

Does the patient have have a known aplastic anemia or other bone marrow failure that requires HSCT or other therapies including anti-thymocyte globulin and/or immunosuppressants?
□ Yes □ No ***Please provide documentation***

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Does the patient have a known or suspected complement deficiency? □ Yes □ No *Please provide documentation*

Does the patient have a history of major organ transplant? □ Yes □ No *Please provide documentation*

Does the patient have a history of hematopoietic stem cell transplantation (HSCT)? □ Yes □ No *Please provide documentation*

For IgNA, answer the following:

Does patient require a reduction of proteinuria? □ Yes □ No *Please submit documentation*

Is patient at risk of rapid disease progression? □ Yes □ No *Please submit documentation*

Does patient have a urine protein-to-creatinine ratio (UPCR) ≥1 g/g (113mg.mmol)? □ Yes □ No *Please submit documentation*

For patients with an eGFR ≥ 45ml/min/1.73m2, does patient have a qualifying biopsy within the last 5 years? □ Yes □ No *Please submit documentation*

For patients with an eGFR 30 to <45ml/min/1.73m2, does patient have a qualifying biopsy within 2 years with < 50% tubulointerstitial fibrosis? □ Yes □ No *Please submit documentation*

For patients with an eGFR 20 to <30ml/min/1.73m2, does patient have a qualifying biopsy? □ Yes □ No *Please submit documentation*

Is patient on stable dose regimens of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB)? □ Yes □ No *Please submit documentation*

Does patient have IgAN secondary to or associated with cirrhosis, celiac disease, Human Immunodeficiency Virus (HIV) infection, dermatitis herpetiformis, seronegative arthritis, small-cell carcinoma, lymphoma, disseminated tuberculosis, bronchiolitis obliterans, and inflammatory bowel disease, familial mediterranean fever? □ Yes □ No *Please submit documentation*

Does patient have any other glomerulopathies? □ Yes □ No *Please submit documentation*

For Complement 3 Glomerulopathy (C3G):

Does patient have diagnosis of complement 3 glomerulopathy (C3G)? □ Yes □ No *Please provide renal biopsy*.

Has patient had any cell or organ transplant, including kidney transplant? □ Yes □ No

Does patient have a protein-to-creatinine ratio (UPCR) greater than or equal to 1g/g? □ Yes □ No *Please submit documentation*

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Does patient have an eGRF greater than or equal to 30mL/min/1.73m^2 ? □ **Yes** □ **No** ***Please submit documentation***

Is patient on the maximally tolerated renin-angiotensin system (RAS) inhibitor (ACE or ARB)?
□ **Yes** □ **No** ***Please submit documentation***

Does patient have a reduced serum C3 of less than 77mg/dl? □ **Yes** □ **No** ***Please submit documentation***

Does patient have progressive crescentic glomerulonephritis (GN), monoclonal gammopathy of undetermined significance? □ **Yes** □ **No**

Upon renal biopsy, does patient have interstitial fibrosis/tubular atrophy (IF/TA) of more than 50%?
□ **Yes** □ **No**

Renewal Request
Is the requested agent being prescribed by, or in consultation with a hematologist or oncologist?
□ **Yes** □ **No**

Is the requested agent being prescribed by, or in consultation with a nephrologist or urologist?
□ **Yes** □ **No**

Will Fabhalta (iptacopan) be used in combination with Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan) or Voydeya (danicopan)? □ **Yes** □ **No**

Has the patient had positive clinical response to therapy? □ **Yes** □ **No** ***Please submit documentation***

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

Please note: Not all drugs/diagnosis are covered on all plans. This request may be denied unless all required information is received.

ATTESTATION: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification: _____ **Date:** _____

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FAX THIS FORM TO: 800-424-7640
MAIL REQUESTS TO: Prime Therapeutics Management Prior Authorization Program
Attn: CP-4201
P.O. Box 64811
St. Paul, MN 55164-0811
Phone: 877-228-7909