UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2324-4
Program	Prior Authorization/Medical Necessity
Medication	Fabhalta® (iptacopan)
P&T Approval Date	2/2024, 4/2024, 10/2024, 5/2025
Effective Date	8/1/2025

A. Background

Fabhalta (iptacopan) is a complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH); the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g; and for the treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.[1]

B. Coverage Criteria[a]:

A. Paroxysmal nocturnal hemoglobinuria (PNH)

1. **Initial Authorization**

a. **Fabhalta** will be approved based on **all** of the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by **both** of the following[2,3,4,5]:

(a) Flow cytometry analysis confirming presence of PNH clones

-AND-

(b) Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

-AND-

(2) **One** of the following:

(a) Patient will not be prescribed Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, eculizumab, Ultomiris)

-OR-

(b) Patient is currently receiving another complement inhibitor (e.g., Empaveli, PiaSky, eculizumab, Ultomiris) which will be discontinued and Fabhalta

will be initiated in accordance with the United States Food and Drug Administration approved labeling

-AND-

(3) Prescribed by, or in consultation with **one** of the following:

(a) Hematologist
(b) Oncologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Fabhalta will be approved based on **all** the following criteria:

(1) Documentation of positive clinical response to Fabhalta therapy (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.)

-AND-

(2) Patient is not receiving Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, eculizumab, Ultomiris)

-AND-

(3) Prescribed by, or in consultation with **one** of the following:

(a) Hematologist
(b) Oncologist

Authorization will be issued for 12 months.

B. Primary immunoglobulin A nephropathy (IgAN)

1. **Initial Authorization**

a. **Fabhalta** will be approved based on **all** the following criteria:

(1) Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

-AND-

(2) Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

-AND-

(3) Used to reduce proteinuria

-AND-

(4) Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2

-AND-

(5) **One** of the following:

(a) Patient is on a stabilized dose and receiving concomitant therapy with **one** of the following:

i. Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
ii. Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

-OR-

(b) Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs

-AND-

(6) **One** of the following:

(a) Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin)]

-OR-

(b) Patient has an allergy, contraindication, or intolerance to SGLT2 inhibitors

-AND-

(7) History of failure, contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)

-AND-

(8) Prescribed by or in consultation with a nephrologist

Authorization will be issued for 12 months.

2. **Reauthorization**

(1) **Fabhalta** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Fabhalta therapy demonstrated by a reduction in proteinuria

Authorization will be issued for 12 months.

C. Complement 3 glomerulopathy (C3G)

1. **Initial Authorization**

a. **Fabhalta** will be approved based on **all** the following criteria:

(1) Diagnosis of complement 3 glomerulopathy (C3G) confirmed by **all** of the following:

(a) Documentation of a kidney biopsy demonstrating characteristic findings of C3G

-AND-

(b) Glomerulonephritis has persisted ≥ 3 months in duration

-AND-

(c) **One** of the following:

i. Serum complement 3 (C3) protein < 77 mg/dL (alternatively, less than 0.85 x lower limit of the central laboratory normal range)

ii. Other complement abnormalities are present [e.g., soluble membrane attack complex (sC5b-9), serum factor H, serum factor B, factor I, membrane cofactor protein (MCP, CD46), C3/C4/C5 nephritic factor (NeF)] which are suggestive of a C3 glomerulopathy

-AND-

(d) Presence of monoclonal gammopathy of undetermined significance (MGUS) has been excluded by measurement of serum free light chains or other investigative means based on standards of care

-AND-

(2) Disease is considered to be moderate to severe based on proteinuria ≥ 1.5 g/day and/or abnormal kidney function

-AND-

(3) Used to reduce proteinuria

-AND-

(4) History of failure, contraindication or intolerance to a glucocorticoid (e.g., methylprednisolone, prednisone)

-AND-

(5) **One** of the following:

(a) Patient is on a stabilized dose and receiving concomitant therapy with **one** of the following:

i. Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
ii. Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

-OR-

(b) Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs

-AND-

(6) Patient has not undergone a solid-organ or cell transplant, including kidney transplant

-AND-

(7) Prescribed by or in consultation with a nephrologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Fabhalta** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Fabhalta therapy demonstrated by a reduction in proteinuria

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Fabhalta [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; March 2025.
2. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005 Dec 1; 106(12): 3699–3709.
3. Devalet B, Mullier F, Chatelain B, et al. Pathophysiology, diagnosis, and treatment of paroxysmal nocturnal hemoglobinuria: a review. Eur J Haematol. 2015 Sep;95(3):190-8.
4. Sutherland DR, Keeney M, Illingworth A. Practical guidelines for the high-sensitivity detection and monitoring of paroxysmal nocturnal hemoglobinuria clones by flow cytometry. Cytometry B Clin Cytom. 2012 Jul;82(4):195-208.
5. Röth A, Maciejewski J, Nishimura JI, et al. Screening and diagnostic clinical algorithm for paroxysmal nocturnal hemoglobinuria: Expert consensus. Eur J Haematol. 2018 Jul;101(1):3-11.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1-S276. doi:10.1016/j.kint.2021.05.021
7. Kopel, T. C3 glomerulopathies: Dense deposit disease and C3 glomerulonephritis. In: UpToDate, Lam, A (Ed), UpToDate, Waltham, MA, 2025.

Program	Prior Authorization/Medical Necessity - Fabhalta® (iptacopan)
Change Control	
2/2024	New program.
4/2024	Simplified criteria language for converting to new complement inhibitor therapy.
10/2024	Updated background and included coverage criteria for primary immunoglobulin A nephropathy (IgAN). Updated list of examples for combination use requirement for PNH. Updated references.
5/2025	Added new indication and criteria for C3 glomerulopathy (C3G). Replaced Soliris with eculizumab in list of examples of complement inhibitors. Updated background and references.