UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1432-3
Program	Prior Authorization/Notification
Medication	Fabhalta® (iptacopan)
P&T Approval Date	2/2024, 4/2024, 10/2024
Effective Date	1/1/2025

1. Background:

Fabhalta (iptacopan) a complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) and 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.[1]

2. Coverage Criteria[a]:

A. Paroxysmal nocturnal hemoglobinuria (PNH)

1. **Initial Authorization**

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

(1) Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

-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, Soliris, Ultomiris)

-OR-

(b) Patient is currently receiving another complement inhibitor (e.g., Empaveli, PiaSky, Soliris, Ultomiris) which will be discontinued and Fabhalta will be initiated in accordance with the United States Food and Drug Administration approved labeling

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Fabhalta therapy

-AND-

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

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)

-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]

-AND-

(3) Used to reduce proteinuria

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

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 also be in place.

4. References:

1. Fabhalta [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; August 2024.

Program	Prior Authorization/Notification - 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 added coverage criteria with additional indication for primary immunoglobulin A nephropathy (IgAN). Updated list of examples for combination use requirement for PNH. Updated reference.