UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2324-2
Program	Prior Authorization/Medical Necessity
Medication	Fabhalta® (iptacopan)
P&T Approval Date	2/2024, 4/2024
Effective Date	7/1/2024

1. Background

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

2. Coverage Criteria[a]:

A. <u>Initial Authorization</u>

1. **Fabhalta** will be approved based on **<u>all</u>** of the following criteria:

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

      (1) Flow cytometry analysis confirming presence of PNH clones

      -AND-

      (2) 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-

   b. **<u>One</u>** of the following:

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

      -OR-

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

      -AND-

   c. Prescribed by, or in consultation with one of the following:

(1) Hematologist
(2) Oncologist

Authorization will be issued for 12 months.

B. Reauthorization

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

   a. 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-

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

   -AND-

   c. Prescribed by, or in consultation with one of the following:

   (1) Hematologist
   (2) Oncologist

   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; December 2023.
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.

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.