UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1432-1
Program	Prior Authorization/Notification
Medication	Fabhalta® (iptacopan)
P&T Approval Date	2/2024
Effective Date	5/1/2024

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. Initial Authorization

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

   a. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

   -AND-

   b. **Both** 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)

      -AND-

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

         (a) Patient is not currently receiving a complement inhibitor medication used for the treatment of PNH (e.g., Empaveli, Soliris, Ultomiris)

         -OR-

         (b) Patient is currently receiving Soliris (eculizumab) which will be stopped and Fabhalta will be initiated no more than 1 week after the last dose of Soliris

         -OR-

         (c) Patient is currently receiving Ultomiris (ravulizumab-cwvz) which will be stopped and Fabhalta will be initiated no more than 6 weeks after the last dose of Ultomiris

Authorization will be issued for 12 months.

B. Reauthorization

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

   a. Documentation of positive clinical response to Fabhalta therapy

   -AND-

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

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; December 2023.

Program	Prior Authorization/Notification - Fabhalta® (iptacopan)
Change Control	
2/2024	New program