

## iptacopan (Fabhalta)

### Commercial Pharmacy Benefit Drug Policy

#### Drug Details

USP Category: UNCATEGORIZED

**Mechanism of Action:** Binds to factor B of the alternative complement pathway and regulates the cleavage of C3, generation of downstream effectors, and the amplification of the terminal pathway

Label Name	Quantity Limit
Fabhalta 200 MG CAP	2 caps/day

#### Condition(s) listed in policy *(see coverage criteria for details)*

- Paroxysmal nocturnal hemoglobinuria (PNH)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

#### Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

#### The following condition(s) require Prior Authorization/Preservice:

##### Paroxysmal nocturnal hemoglobinuria (PNH)

###### Initial authorization

- Dose does not exceed the FDA labeled maximum.

###### Reauthorization

- Patient continues to respond to therapy.

#### Coverage Period:

one year

#### References

- Fabhalta Package Insert, Novartis Pharmaceuticals Corporation. 3/2024

#### Review History

Date of Last Annual Review: 1Q2024

Date of last revision: 02/28/2024

Changes from previous policy version:



- New policy for new drug Fabhalta; a complement factor B inhibitor indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*