Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 28, 2024

Fabhalta® (iptacopan)*

LENGTH OF AUTHORIZATION: Up to 1 year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH).
- The prescribing physician must be or in consultation with a hematologist.
- Patient must have been vaccinated against encapsulated bacteria (*Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B). If patient has not been previously vaccinated, then the patient must be vaccinated at least 2 weeks prior to first dose of Fabhalta according to the Advisory Committee on Immunization Practices (ACIP) guidelines.
- Documented baseline values including:
  - Serum lactate dehydrogenase (LDH)
  - Hemoglobin
  - Serum lipid parameters

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 200 mg oral capsule.

* Fabhalta is available only through a restricted program under a REMS called FABHALTA REMS. Further information is available by telephone: 1-833-99FABHA or online at www.FABHALTA-REMS.com.