Pharmacy Drug Policy Checklist

POLICY NAME	Fabhalta (iptacopan)	POLICY #	

Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Patients with unresolved, active infections or patients who are not vaccinated against Neisseria meningitidis
  - Fabhalta carries a boxed warning related to increased risk of serious, life-threatening infections
- ☐ **2.2** Fabhalta will not be approved in combination with another complement inhibitor, such as Soliris, Ultomiris, or Empaveli
- ☐ **2.3** Fabhalta for the treatment of primary immunoglobulin A nephropathy (IgAN) is not a covered indication
  - This indication is approved under accelerated approval based on reduction of proteinuria and it has not been established whether Fabhalta slows kidney function decline in patients with IgAN. Continued approval for this indication is contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Coverage Criteria

- ☐ **1.1** Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry
- ☐ **1.2** Documentation of lab results, signs, and/or symptoms attributed to PNH (e.g. stomach pain, abnormal blood counts, shortness of breath, extreme tiredness, smooth muscle dystonia, kidney disease, pulmonary hypertension)
- ☐ **1.3** Prescribed by a hematologist (blood doctor) or oncologist (cancer doctor) in the Fabhalta REMS program
- ☐ **1.4** Age 18 years or older
- ☐ **1.5** Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)
- ☐ **1.6** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment by both a pharmacist and medical director