PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Fabhalta (iptacopan)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Fabhalta, approved by the FDA in 2023, is a first-in-class, oral complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH). Like Empaveli, Fabhalta controls both intravascular and extravascular hemolysis, unlike Soliris and Ultomiris, which only impact intravascular hemolysis. The APPLY-PNH study demonstrated superiority of Fabhalta versus continuation of Soliris or Ultomiris for outcomes including hemoglobin levels and transfusion avoidance.
PNH is a hematopoietic stem cell disorder in which activation of the complement system destroys red blood cells because of an acquired mutation in the *PIGA* gene. Common manifestations can include hemolytic anemia and fatigue. Thrombosis and bone marrow suppression may also occur.

Fabhalta (iptacopan) will be considered for coverage when the following criteria are met:

Paroxysmal Nocturnal H