# Commercial PA Criteria
***Effective: February 8, 2024***

***Prior Authorization:*** Fabhalta (iptacopan)

***Products Affected:*** Fabhalta (iptacopan) oral capsules

***Medication Description:*** Fabhalta is indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH). Iptacopan 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. In paroxysmal nocturnal hemoglobinuria, intravascular hemolysis (IVH) is mediated by the downstream membrane attack complex (MAC), while extravascular hemolysis (EVH) is facilitated by C3b opsonization. Iptacopan acts proximally in the alternative pathway of the complement cascade to control both C3b-mediated EVH and terminal complement-mediated IVH

***Covered Uses:*** Paroxysmal nocturnal hemoglobinuria (PNH)

***Exclusion Criteria:*** None

***Required Medical Information:***
1. Diagnosis

***Prescriber Restriction:*** The medication must be prescribed by, or in consultation with, a Hematologist

***Age Restriction***: 18 years and older

***Coverage Duration:***
Initial: 4 months
Continuation: 12 months

***Other Criteria:***

**Initial Approval Criteria**

**1. Paroxysmal Nocturnal Hemoglobinuria.**

A. Paroxysmal nocturnal hemoglobinuria diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins on at least two cell lineages

**Renewal Criteria**

**Paroxysmal Nocturnal Hemoglobinuria**

A. Patient is continuing to derive benefit from Fabhalta according to the prescriber;
*Note: Examples of benefit include increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis*.

***References:***

1. Product Information: FABHALTA® oral capsules, iptacopan oral capsules. Novartis Pharmaceuticals Corp (per FDA), East Hanover, NJ, 2023.

***Policy Revision history***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 02/08/2024 |