Mass General Brigham
Health Plan

# Fabhalta (iptacopan)
# Effective 01/01/2026

| | | | |
|---|---|---|---|
| **Plan** | ☐ MassHealth UPPL<br>☒ Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Medical Benefit**<br>**Pharmacy Benefit** | Phone: 833-895-2611<br>Phone: 800-711-4555 | Fax: 888-656-6671<br>Fax: 844-403-1029 |
| **Exceptions** | N/A | | |

**Overview**

Fabhalta (iptacopan) is a complement factor B inhibitor indicated for:

- Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)
- Reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g
- Treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.

**Coverage Guidelines**

Authorization may be granted for members new to the plan within the previous 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

**OR**

Authorization may be granted if the member meets all of the following diagnosis-specific criteria:

**Paroxysmal Nocturnal Hemoglobinuria (PNH)**

1. Member has a diagnosis of paroxysmal nocturnal hemoglobinuria confirmed by flow cytometry

**Primary Immunoglobulin A Nephropathy (IgAN)**

1. Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy
2. Member is at risk of rapid disease progression (e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool)
3. Member has an estimated glomerular filtration rate (eGFR) greater than or equal to 20 mL/min/1.73 $m^2$
4. Member has received at least a 3-month trial with a renin-angiotensin system (RAS) inhibitor (e.g., angiotensin converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB]) at a maximally tolerated dose, unless the member has had an intolerance, adverse effect, or contraindication

**Complement 3 Glomerulopathy (C3G)**

1. Diagnosis of complement 3 glomerulopathy (C3G)
2. Requested medication is being used to reduce proteinuria
3. Member is on a maximally tolerated rein-angiotensin system (RAS) inhibitor (e.g., benazepril, lisinopril, losartan, valsartan)

4. Member has not had a kidney transplant
5. Requested medication is prescribed by or in consultation with a nephrologist

**Continuation of Therapy**

Requests for reauthorization will be approved when the following diagnosis-specific criteria are met:

**PNH:**

1. Prescriber submits documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, hemoglobin stabilization, decreased number of red blood cell transfusions)

**IgAN:**

1. Documentation is submitted demonstrating member has had a positive clinical response to therapy as evidenced by ONE of the following:
    a. Decreased levels of proteinuria from baseline on a 24-hour urine collection
    b. Decrease in UPCR from baseline based on 24-hour urine collection

**C3G:**

1. Documentation member has had a positive clinical response to therapy (e.g., reduction in 24-hour UPCR, stable or improved eGFR compared to baseline)
2. Member is on a maximally tolerated renin-angiotensin system (RAS) inhibitor (e.g., benazepril, lisinopril, losartan, valsartan)
3. Member has not had a kidney transplant

**Limitations**

1. Initial and reauthorization approvals will be granted for 12 months.

**References**

1. Fabhalta (iptacopan) capsules [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2025.

**Review History**

08/14/2024 – Reviewed at August P&T. Effective 10/1/2024.
12/11/2024 – Reviewed and updated for December P&T. Added criteria for supplemental indication of IgAN. Effective 3/1/2025.
07/09/2025 – Reviewed and updated for July P&T. Added supplemental indication of C3G. Effective 10/01/2025.
10/08/2025 – Reviewed and updated for October P&T. Updated the ACEI/ARB trial verbiage for the diagnosis IgAN. Effective 01/01/2026.