

Fabhalta (iptacopan)
Effective 05/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with requested drug, 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 m²
4. Requested medication is being used to reduce proteinuria
5. 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 currently being treated with a maximally tolerated dose of one of the following for at least 12 weeks prior to initiating treatment:
 - a. Angiotensin-converting enzyme inhibitor (e.g., benazepril, lisinopril)
 - b. Angiotensin receptor blocker ((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. Submission of medical records (e.g., chart notes) documenting a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, hemoglobin stabilization, decreased number of red blood cell transfusions)

IgAN:

1. Submission of medical records (e.g., chart notes) documenting 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. Submission of medical records (e.g., chart notes) documenting 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 continues to be treated with a maximally tolerated dose of one of the following:
 - a. Angiotensin-converting enzyme inhibitor (e.g., benazepril, lisinopril)
 - b. Angiotensin receptor blocker (losartan, valsartan)
3. Member has not had a kidney transplant

Limitations

1. Initial and reauthorization approvals will be granted for 12 months.
2. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Fabhalta capsule	2 capsules per day

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.

02/11/2026 – Reviewed and updated at February P&T. Updated criteria for IgAN to require that the requested medication is being used to reduce proteinuria. Updated initial criteria for C3G to specify that member needs to have been on a maximally tolerated ACEi or ARB for at least three months. Added quantity limitation. Effective 05/01/2026.

