Mass General Brigham
Health Plan

Fabhalta (iptacopan)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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.

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. The 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 had intolerance, adverse effect or contraindication to maximally tolerated renin-angiotensin system (RAS) inhibitor (e.g., angiotensin converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB]) for at least 3 months

Continuation of Therapy

Reauthorization will be granted when the following 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

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; August 2024.

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.