

Applicable Drugs: Fabhalta (iptacopan)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/25/2024

Date Last Reviewed / Revised: 12/8/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

- I. Documented diagnosis of one of the following conditions A OR B and must meet criteria under each applicable diagnosis:
 - A. Paroxysmal nocturnal hemoglobinuria (PNH) diagnosis with flow cytometry analysis confirming presence of PNH clones $\geq 10\%$
 - i. Must meet all four of the following:
 1. Trial of C5 inhibitor for at least 6 months
 2. Hemoglobin < 10 g/dL
 3. Lactate dehydrogenase > 1.5 times the upper limit of normal
 4. Absolute reticulocyte count of at least $100 \times 10^9/L$
 - B. Documented diagnosis of primary immunoglobulin A nephropathy by kidney biopsy
 - i. Documented rapid kidney function loss with proteinuria with urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g
 - ii. Documented blood pressure to target of $< 140/90$ mmHg
 - iii. Documented eGFR ≥ 30 ml/min
 - iv. Documented treatment failure or contraindication to one or more drugs from ALL of the following drug classes in the prior 12 weeks
 1. Max or maximally tolerated ACE inhibitor or ARB
 2. Sodium-glucose co-transporter-2 inhibitor
 3. Glucocorticoids
- C. Documented diagnosis of complement 3 glomerulopathy (C3G) by kidney biopsy
 - i. Documentation monoclonal gammopathy has been excluded
 - ii. Measurement of serum complement proteins/autoantibodies have been obtained with one of the following:

1. Reduced serum C3 (defined as less than 0.85 x lower limit of the central laboratory normal range)
 2. Abnormalities noted (soluble C5b-9, serum factor H, serum factor B, factor I, membrane cofactor protein (MCP, CD46), C3 nephritic factor (C3NeF), C5 nephritic factor (C5NeF), C4 nephritic factor (C4NeF) concerning for C3G
- iii. Documented treatment failure or contraindication to one or more drugs from ALL of the following drug categories in the prior 12 weeks
 1. Max or maximally tolerated ACE inhibitor or ARB
 2. Sodium-glucose co-transporter-2 inhibitor
 3. Mycophenolate with/without glucocorticoid
- iv. UPCr ≥ 1.0 g/g with abnormal renal function felt due to active C3G
 1. Documented eGFR ≥ 30 ml/min
- II. Minimum age requirement: 18 years of age
- III. Must have received meningococcal vaccine and pneumonia vaccine at least 2 weeks before starting treatment. If unable to obtain, administer as soon as possible and provide antibacterial prophylaxis
- IV. Prescriber is enrolled in the Fabhalta REMS program
- V. Medication has been prescribed by or in consultation with a hematologist, oncologist, or nephrologist
- VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment naïve
- Hematopoietic stem cell transplant, or known or suspected hereditary complement deficiency
- Not to be utilized in combination with complement inhibitors (ravulizumab, eculizumab, or pegcetacoplan or crovalimab)

- Solid organ renal transplant
- For C3G exclusions
 - Renal biopsy showing interstitial fibrosis/tubular atrophy of more than 50%
 - Rapidly progressive crescentic glomerulonephritis

OTHER CRITERIA

NA

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 60 capsules per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication. Documentation of positive clinical response to Fabhalta therapy
 - **PNH:** increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc..
 - **IGAN and C3G:** Reduction in proteinuria demonstrated

APPENDIX

- N/A

REFERENCES

1. Fabhalta Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2025. Accessed November 21, 2025. https://www.novartis.com/us-en/sites/novartis_us/files/fabhalta.pdf
2. Peffault de Latour R, Röth A, Kulasekararaj AG, et al. Oral Iptacopan Monotherapy in Paroxysmal Nocturnal Hemoglobinuria. N Engl J Med. 2024;390(11):994-1008.
3. Perkovic V, Barratt J, Rovin B, Kashihara N, Maes B, Zhang H, Trimarchi H, Kollins D, Papachristofi O, Jacinto-Sanders S, Merkel T, Guerard N, Renfurm R, Hach T, Rizk DV; APPLAUSE-IgAN Investigators. Alternative Complement Pathway Inhibition with Iptacopan in IgA Nephropathy. N Engl J Med. 2025;392(6):531-543. doi: 10.1056/NEJMoA2410316.
4. Kavanagh D, Bomback AS, Vivarelli M, Nester CM, Remuzzi G, Zhao MH, Wong EKS, Wang Y, Krishnan I, Schuhmann I, Trapani AJ, Webb NJA, Meier M, Israni RK, Smith RJH; APPEAR-C3G investigators. Oral iptacopan therapy in patients with C3 glomerulopathy: a randomised, double-blind, parallel group, multicentre, placebo-controlled, phase 3 study. Lancet. 2025;406(10512):1587-1598. doi: 10.1016/S0140-6736(25)01148-1.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.