

**Generic Name:** Iptacopan

**Preferred:** N/A

**Therapeutic Class or Brand Name:** N/A

**Non-preferred:** N/A

**Applicable Drugs:** Fabhalta

**Date of Origin:** 9/25/2024

**Date Last Reviewed / Revised:** N/A

## PRIOR AUTHORIZATION CRITERIA

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

- I. Paroxysmal nocturnal hemoglobinuria (PNH) diagnosis with flow cytometry analysis confirming presence of PNH clones  $\geq 10\%$
- II. Enrolled in REMS program
- III. Age >18 years of age
- IV. Must meet all four of the following:
  - A. Trial of C5 inhibitor for at least 6 months
  - B. Hemoglobin <10 g/dL
  - C. Lactate dehydrogenase > 1.5 times the upper limit of normal
  - D. Absolute reticulocyte count of at least  $100 \times 10^9/L$
- V. 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
- VI. Medication has been prescribed by or in consultation with a hematologist or oncologist
- VII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VIII. 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)

## OTHER CRITERIA

- NA

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- 200 mg – 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

## APPENDIX

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## REFERENCES

1. Fabhalta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2023.
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.

**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.