

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Iptacopan (Fabhalta)

#### Notes:

- Quantity Limits: Yes

**Initiation (new start) criteria:** Non-formulary **iptacopan (Fabhalta)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by Oncologist or Hematologist enrolled in the FABHLTA REMS
- Completion of vaccination against *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae type B* according to ACIP recommendations at least two weeks before starting Fabhalta, unless the risks of delaying therapy with iptacopan outweigh the risk of developing a serious infection
- Patient is greater than or equal to 18 years of age
  - -AND-
- Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria
  - -AND-
  - Patient has failed an adequate trial or contraindications or intolerance to at least TWO lines of treatment, including (eculizumab, ravulizumab)
  - -AND-
  - Lack of response to ravulizumab OR eculizumab defined as hemoglobin <10.5 and continued need for transfusion after 3 months of treatment

**Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously:** Non-formulary **iptacopan (Fabhalta)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by Oncologist or Hematologist enrolled in the FABHLTA REMS
- Completion of vaccination against *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae type B* according to ACIP recommendations at least two weeks before starting Fabhalta, , unless the risks of delaying therapy with iptacopan outweigh the risk of developing a serious infection
- Patient is greater than or equal to 18 years of age
  - -AND-
- Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary **iptacopan (Fabhalta)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by Oncologist or Hematologist enrolled in the FABHLTA REMS

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Revised: xx/xx/xx  
Effective: xx/xx/xx

All plans offered and underwritten by  
Kaiser Foundation Health Plan of the Northwest

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