Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

Iptacopan (Fabhalta)

Notes:

- Quantity Limits: Yes
- Lack of response to ravulizumab OR eculizumab defined as hemoglobin <10.5 and continued need for transfusion after 3 months of treatment
- For C3G recommend not to initiate if any apply:
  - Estimated glomerular filtration rate (eGFR) is below 30 mL/min; or
  - C3G secondary to another condition; or
  - Severe infection within 14 days; or
  - Above 50% global glomerulosclerosis, crescentic glomerulonephritis, or interstitial fibrosis; or
  - Solid organ or cell transplant; or
  - History of recurrent invasive infections caused by encapsulated organisms; or
  - Post-infectious glomerulonephritis; or
  - Monoclonal gammopathy; or
  - Use of immunosuppressants (MMF okay), cyclophosphamide, or systemic corticosteroids equivalent to prednisolone above 7.5 mg/day within 90 days

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

- For paroxysmal nocturnal hemoglobinuria (PNH)
  - Prescribed by Oncologist or Hematologist enrolled in the FABHALTA REMS
  - Completion of vaccination against *Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B* according to ACIP recommendations at least two weeks before starting iptacopan, unless the risks of delaying therapy with iptacopan outweigh the risk of developing a serious infection
  - There is no evidence of an active infection caused by encapsulated bacteria (e.g., *Streptococcus pneumonia*, *Neisseria meningitidis*, *Haemophilus type B*)
  - Patient is at least 18 years of age
  - Patient has a diagnosis of PNH
  - Patient has failed an adequate trial or contraindications or intolerance to at least TWO lines of treatment, including either eculizumab or ravulizumab

Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

Iptacopan (Fabhalta)

- For IgA Nephropathy (IgAN)
  - Prescribed by Nephrologist enrolled in the FABHALTA REMS
  - Completion of vaccination against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B according to ACIP recommendations at least two weeks before starting iptacopan, unless the risks of delaying therapy with iptacopan outweigh the risk of developing a serious infection
  - There is no evidence of an active infection caused by encapsulated bacteria (e.g., *Streptococcus pneumonia*, *Neisseria meningitidis*, *Haemophilus type B*)
  - Patient is at least 18 years of age
  - Patient has a diagnosis of IgAN confirmed with kidney biopsy
  - Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g
  - Patient has an estimated Glomerular Filtration Rate (eGFR) greater than or equal to 30 mL/min/1.73 m^2
  - Patient is not currently receiving dialysis and has not undergone a kidney transplant
  - Patient has an inadequate response after a 3-month course of maximally tolerated ACE-Inhibitor (ACEI) or ARB therapy or an intolerance to ACEI or ARB therapy or contraindication to ALL ACEI or ARB agents
  - Patient has an inadequate response after a 6-month course of glucocorticoid therapy (e.g., methylprednisolone, prednisolone, prednisone), an intolerance to glucocorticoid therapy or contraindication or comorbid condition, and therapy with ALL glucocorticoids is not appropriate for the patient
  - The patient will continue on standard of care IgAN therapy (e.g., ACEI, ARB, SGLT2-inhibitor, aliskiren)
  - The patient has an inadequate response to each of the following:
    - Budesonide EC (Entocort EC)
    - Budesonide DR (Tarpeyo)
    - Sparsentan (Filspari)
  - Patient will not receive therapy in combination with budesonide, sparsentan, or an additional complement inhibitor (e.g., crovalimab, danicopan, eculizumab, ravulizumab, or pegcetacoplan)
  - Dose does not exceed 200 mg twice daily

Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Iptacopan (Fabhalta)

- For complement 3 glomerulopathy (C3G)
  - Prescribed by Nephrologist enrolled in the FABHALTA REMS
  - Patient is at least 18 years of age
  - Biopsy-confirmed primary C3G
  - Reduced serum C3 level below 77 mg/dL
  - Ruled out secondary causes of C3 deposits on biopsy and low serum complement level (e.g., active/subclinical infection, paraproteinemia, systemic autoimmune disorders)
  - UPCR greater than or equal to 1 g/g or 24-hour proteinuria greater than 1 g/day
  - Received vaccinations against *Streptococcus pneumoniae*, *Neisseria meningitidis* (types AC, C, W, Y and B), and *Haemophilus influenzae type B*
  - Trialed mycophenolate mofetil (MMF) in combination with corticosteroids; and
  - Optimizing baseline therapies below:
    - Angiotensin-converting enzyme inhibitors (ACEi) or angiotensin II receptor blockers (ARB)
    - Sodium-glucose cotransporter 2 inhibitor (SGLT2i: i.e., empagliflozin)
    - Statin for renal protective measures
    - Blood pressure management target below 130/80 mm Hg

Criteria for *current Kaiser Permanente members* already taking the medication who have not been reviewed previously and 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:

- For PNH
  - Prescribed by Oncologist or Hematologist enrolled in the FABHALTA REMS
  - Patient is at least 18 years of age
  - Patient has a diagnosis of PNH
  - Completion of vaccination against *Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B* according to ACIP recommendations at least two weeks before starting iptacopan, unless the risks of delaying therapy with iptacopan outweigh the risk of developing a serious infection
  - Patient has been revaccinated against encapsulated bacteria (e.g., *Streptococcus pneumoniae*, *Neisseria meningitidis*) at least 2 weeks prior to therapy initiation according to current medical guidelines for vaccination while on iptacopan therapy

Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

Iptacopan (Fabhalta)

- For IgAN
  - Prescribed by Nephrologist enrolled in the FABHALTA REMS
  - Completion of vaccination against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B according to ACIP recommendations at least two weeks before starting iptacopan, unless the risks of delaying therapy with iptacopan outweigh the risk of developing a serious infection
  - Patient has been revaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis) at least 2 weeks prior to therapy initiation according to current medical guidelines for vaccination while on iptacopan therapy
  - Patient is greater than or equal to 18 years of age
  - Patient has a diagnosis of IgAN
  - Patient is not receiving therapy in combination with budesonide, sparsentan, or an additional complement inhibitor (e.g., crovalimab, danicopan, eculizumab, ravulizumab, or pegcetacoplan)

- For complement 3 glomerulopathy (C3G)
  - Prescribed by Nephrologist enrolled in the FABHALTA REMS
  - Patient is greater than or equal to 18 years of age
  - Biopsy-confirmed primary C3G
  - Received vaccinations against *Streptococcus pneumoniae*, *Neisseria meningitidis* (types AC, C, W, Y and B), and *Haemophilus influenzae type B*.
  - Patient has been revaccinated against encapsulated bacteria (e.g., *Streptococcus pneumoniae*, *Neisseria meningitidis*) at least 2 weeks prior to therapy initiation according to current medical guidelines for vaccination while on iptacopan therapy