BlueCross BlueShield
Federal Employee Program

FABHALTA
(iptacopan)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

a. Documented baseline value for hemoglobin (Hgb)
b. Vaccination against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation [unless Fabhalta (iptacopan) treatment cannot be delayed]
c. Prescriber is enrolled in the Fabhalta REMS program
d. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Primary immunoglobulin A nephropathy (IgAN)

AND ALL of the following:

a. Diagnosis has been confirmed by a kidney biopsy
b. Patient is at risk of rapid disease progression indicated by a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g
c. Used in combination with maximum recommended or maximum tolerated dose of ACEI or ARB therapy
d. eGFR ≥ 20 mL/min/1.73 m2
e. Prescribed by or recommended by a nephrologist

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f. Vaccination against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation [unless Fabhalta (iptacopan) treatment cannot be delayed]
g. Prescriber is enrolled in the Fabhalta REMS program

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Complement 3 glomerulopathy (C3G)

AND ALL of the following:

a. Diagnosis has been confirmed by a kidney biopsy
b. Used to reduce proteinuria
c. Documented baseline urine protein-to-creatinine ratio (UPCR)
d. Used in combination with maximum recommended or maximum tolerated dose of ACEI or ARB therapy
e. Vaccination against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation [unless Fabhalta (iptacopan) treatment cannot be delayed]
f. Prescriber is enrolled in the Fabhalta REMS program

Prior - Approval Limits

Quantity 400 mg per day

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

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1. Paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

a. Increase in hemoglobin (Hgb) from pretreatment baseline
b. Absence of unacceptable toxicity from the drug
c. Prescriber is enrolled in the Fabhalta REMS program
d. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Primary immunoglobulin A nephropathy (IgAN)
2. Complement 3 glomerulopathy (C3G)

AND ALL of the following:

a. Decrease in urine protein-to-creatinine ratio (UPCR)
b. Prescriber is enrolled in the Fabhalta REMS program
c. Used in combination with maximum recommended or maximum tolerated dose of ACEI or ARB therapy

Prior - Approval *Renewal* Limits

Same as above

Appendix 1 - List of PA Medications for PNH

Generic Name	Brand Name
eculizumab	Soliris
iptacopan	Fabhalta
pegcetacoplan	Empaveli
ravulizumab-cwvz	Ultomiris