HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	**Fabhalta (iptacopan)**
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Fabhalta, approved by the FDA in 2023, is a first-in-class, oral complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH). Like Empaveli, Fabhalta controls both intravascular (IVH) and extravascular hemolysis (EVH), unlike Soliris and Ultomiris, which only impact IVH. PNH is a hematopoietic stem cell disorder in which activation of the complement system destroys red blood cells because of an acquired mutation in the *PIGA* gene. Common manifestations can include hemolytic anemia and fatigue. Thrombosis and bone marrow suppression may also occur.
Fabhalta is also approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.
IgAN is the most common primary glomerular disease. It is an autoimmune condition caused by deposits of immunoglobulin A (IgA) in the kidney, leading to hematuria, proteinuria, and nephropathy (kidney disease) as the kidneys become unable to filter, and can progress to end stage renal disease (ESRD). ACE inhibitors (ACEi) or angiotensin receptor blockers (ARBs) are used to slow the progression of kidney disease.
Fabhalta is also indicated for the treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria. C3G is a rare glomerular disease caused by uncontrolled activation of the alternative complement cascade resulting in C3 deposits in the glomeruli.

Fabhalta (iptacopan) will be considered for coverage when the following criteria are met:

Paroxysmal Nocturnal Hemoglobinuria (PNH)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of PNH as confirmed by high-sensitivity flow cytometry with clone size ≥ 10%; AND
4. Member has a lactate dehydrogenase (LDH) level >1.5x upper limit of normal (ULN); AND
5. Member has at least one PNH-related sign/symptom e.g., fatigue, hemoglobin <10 g/dL, thrombosis, pRBC transfusion, shortness of breath; AND
6. Member has been vaccinated against encapsulated bacteria (Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae type B).
7. **Dosage allowed/Quantity limit:** 200 mg orally twice daily. QL: 60 capsules per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

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For **reauthorization**:
1. Chart notes must show clinical evidence of positive response to therapy such as increased hemoglobin level, decreased need for transfusions, normalized LDH levels, improved fatigue.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Primary Immunoglobulin A Nephropathy (IgAN)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of primary IgA nephropathy confirmed by renal biopsy; AND
4. Chart notes must indicate risk of rapid disease progression per documentation of UPCR 1.5 g/g or greater despite max tolerated dose of an ACEi or ARB for at least 3 months; AND
5. Member's eGFR is at least 20 mL/min/1.73m^2; AND
6. Member has had a trial and failure of Filspari or Tarpeyo; AND
7. Member has been vaccinated against encapsulated bacteria (Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae type B).
8. **Dosage allowed/Quantity limit:** 200 mg orally twice daily. QL: 60 capsules per 30 days.

If all the above requirements are met, the medication will be approved for 9 months.

For **reauthorization**:
1. Chart notes must show reduced proteinuria compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Complement 3 Glomerulopathy (C3G)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of C3G confirmed by renal biopsy; AND
4. Member's UPCR is 1 g/g or greater; AND
5. Member has been on max tolerated dose of an ACEi or ARB for at least 3 months; AND
6. Member's eGFR is at least 30 mL/min/1.73m^2; AND
7. Member has been vaccinated against encapsulated bacteria (Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae type B).
8. **Dosage allowed/Quantity limit:** 200 mg orally twice daily. QL: 60 capsules per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

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For **reauthorization**:
1. Chart notes must show reduced proteinuria compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Fabhalta (iptacopan) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/11/2023	New policy for Fabhalta created.
09/09/2024	Added criteria for new indication of IgAN.
3/28/2025	Added criteria for new indication of C3G.

References:

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