Pharmacy Drug Policy & Procedure

Policy Name:	Fabhalta (iptacopan)	Policy#:	3228P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Fabhalta (iptacopan).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Fabhalta (iptacopan) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry

1.2 Documentation of lab results, signs, and/or symptoms attributed to PNH (e.g. stomach pain, abnormal blood counts, shortness of breath, extreme tiredness, smooth muscle dystonia, kidney disease, pulmonary hypertension)

1.3 Prescribed by a hematologist (blood doctor) or oncologist (cancer doctor) in the Fabhalta REMS program

1.4 Age 18 years or older

1.5 Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)

1.6 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment by both a pharmacist and medical director

2. Exclusion Criteria

2.1 Patients with unresolved, active infections or patients who are not vaccinated against *Neisseria meningitidis*

- Fabhalta carries a boxed warning related to increased risk of serious, life-threatening infections

2.2 Fabhalta will not be approved in combination with another complement inhibitor, such as Soliris, Ultomiris, or Empaveli

2.3 Fabhalta for the treatment of primary immunoglobulin A nephropathy (IgAN) is not a covered indication

- This indication is approved under accelerated approval based on reduction of proteinuria and it has not been established whether Fabhalta slows kidney function decline in patients with IgAN. Continued approval for this indication is contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

3. Managed Dose Limit

3.1 Fabhalta is limited to a quantity of 60 capsules per 30 days in alignment with approved dosing guidelines

4. Approval Period

4.1 Initial: 12 months

4.2 Reauthorization: 12 months with documented benefit from therapy such as increased or stabilization of

hemoglobin levels, reduction in transfusions, improvement in hemolysis

CPT Codes	
HCPCS Codes	

References

1. Fabhalta (iptacopan) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
2. Risitano AM, Kulasekararaj A, Roeth A, et al. Factor B inhibition with oral iptacopan monotherapy demonstrates sustained long-term efficacy and safety in anti-C5-treated patients (pts) with paroxysmal nocturnal hemoglobinuria (PNH) and persistent anemia: final 48-week results from the multicenter, phase III APPLY-PNH trial. Blood. 2023;142(suppl 1):571.
3. Risitano AM, Han B, Ueda Y, et al. A Multicenter, Single-Arm, Open-Label Trial to Evaluate Efficacy and Safety of Oral, Twice Daily Iptacopan in Adult PNH Patients Who Are Naive to Complement Inhibitor Therapy: Phase III APPOINT-PNH Trial. Presented at: 49th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT); April 23-36, 2023; Paris, France.
4. Perkovic V, Barratt J, Rovin B, et al. Alternative Complement Pathway Inhibition with Iptacopan in IgA Nephropathy. N Engl J Med. 2024 Oct 25.

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