

<b>Clinical Policy Title:</b>	iptacopan
<b>Policy Number:</b>	RxA.832
<b>Drug(s) Applied:</b>	Fabhalta
<b>Original Policy Date:</b>	12/16/2024
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Paroxysmal Nocturnal Hemoglobinuria (must meet all):

1. Diagnosis of paroxysmal nocturnal hemoglobinuria;
2. Member meets one of the following (a or b):
  - a. Documented LDH level >1.5 times the upper limit of normal;
  - b. Documented glycosylphosphatidylinositol-anchored proteins (GPI-AP) absence or deficiency.

#### B. Primary Immunoglobulin A Nephropathy (must meet all):

1. Diagnosis of primary immunoglobulin A nephropathy;
2. Disease is at risk of rapid progression;
3. UPCr  $\geq 1.5$  g/g;
4. eGFR  $\geq 30$  mL/min/1.73 m<sup>2</sup>;
5. Member has been receiving both of the following for at least 3 months, unless contraindicated or clinically significant adverse effects are experienced (a and b):
  - a. ACE inhibitor (e.g., lisinopril) or ARB (e.g., losartan);
  - b. SGLT2 inhibitor (e.g., empagliflozin).

#### C. Complement 3 Glomerulopathy (must meet all):

1. Diagnosis of complement 3 glomerulopathy;
2. Diagnosis confirmed by kidney biopsy;
3. Member meets one of the following (a or b):
  - a. UPCr  $\geq 1$  g/g;
  - b. Proteinuria  $\geq 1$  g/day;
4. eGFR  $\geq 30$  mL/min/1.73 m<sup>2</sup>;
5. Member has received a stable dose of an ACEI or ARB for at least 3 months prior to initiation of therapy, unless contraindicated or clinically significant adverse effects are experienced;
6. Trial and failure of an immunosuppressant and glucocorticoid for at least 6 months.

#### Approval Duration

**All Lines of Business (except Medicare): 12 months**

### II. Continued Therapy Approval

#### A. All Indications in Section I (must meet all):

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met been initial approval criteria.
2. **Approval Duration**  
**All Lines of Business (except Medicare): 12 months**

**Reference**

1. Fabhalta. Package Insert. Novartis Pharmaceuticals Corporation; 2024. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a76b5845-6e21-4d3b-ad07-cd8df1b60bee&type=display>. Accessed March 31, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/16/2024	12/05/2024
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Added new indications.</li> <li>2. Updated continuation of therapy language.</li> <li>3. Reference reviewed.</li> </ol>	03/31/2025	04/10/2025
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Removed the criteria requiring kidney biopsy.</li> </ol>	09/10/2025	09/10/2025
Policy reviewed.	12/11/2025	12/11/2025