



# Fabhalta Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-15-2025

**Date of Origin**  
02-15-2024

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Fabhalta	iptacopan hcl cap	200 MG	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Fabhalta	iptacopan 200 mg capsules	200 MG	60	Capsules	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Fabhalta	iptacopan hcl cap	200 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Fabhalta	iptacopan 200 mg capsules	200 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following:           <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) <b>OR</b></li> <li>B. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy AND ALL of the following:               <ol style="list-style-type: none"> <li>1. ONE of the following:                   <ol style="list-style-type: none"> <li>A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.44 g/g <b>OR</b></li> <li>B. The patient has proteinuria greater than or equal to 0.5 g/day <b>AND</b></li> </ol> </li> <li>2. The patient’s eGFR is greater than or equal to 30 mL/min/1.73 m<sup>2</sup> <b>AND</b></li> <li>3. The patient has ONE of the following:                   <ol style="list-style-type: none"> <li>A. Tried and had an inadequate response after at least a 3-month duration of therapy with a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB <b>OR</b></li> <li>B. An intolerance or hypersensitivity to an ACEi or ARB, or a combination medication containing an ACEi or ARB <b>OR</b></li> <li>C. An FDA labeled contraindication to ALL ACEi or ARB agents <b>OR</b></li> </ol> </li> </ol> </li> <li>C. The patient has a diagnosis of complement 3 glomerulopathy (C3G) confirmed by kidney biopsy AND ALL of the following:               <ol style="list-style-type: none"> <li>1. ONE of the following:                   <ol style="list-style-type: none"> <li>A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than 0.88 g/g <b>OR</b></li> <li>B. The patient has a proteinuria greater than 1.0 g/day <b>AND</b></li> </ol> </li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p>2. The patient has an eGFR is greater than or equal to 30 mL/min/1.73 m<sup>2</sup> <b>AND</b></p> <p>3. ONE of the following:</p> <p style="padding-left: 20px;">A. BOTH of the following:</p> <p style="padding-left: 40px;">1. The patient is currently treated with a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB for at least a 90-day duration of therapy <b>AND</b></p> <p style="padding-left: 40px;">2. The patient will continue maximally tolerated ACEi, or ARB, or a combination medication containing an ACEi or ARB therapy in combination with the requested agent <b>OR</b></p> <p style="padding-left: 20px;">B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL ACEi, ARB, and combination medications containing an ACEi or ARB <b>OR</b></p> <p style="padding-left: 20px;">D. The patient has another FDA labeled indication for the requested agent and route of administration <b>AND</b></p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p style="padding-left: 20px;">A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></p> <p style="padding-left: 20px;">B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></p> <p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></p> <p>4. The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Soliris (eculizumab), Bkempv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), or Piasy (crovalimab-akkz) <b>AND</b></p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months  BCBSIL, BCBSMT, and BCBSTX members: 12 months  ALL other plans: 6 months for PNH AND C3G, 9 months for IgAN, 12 months for all other indications</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>The requested agent will also be approved when the following are met:</b></p> <p>1. The member resides in Ohio <b>AND</b></p> <p>2. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p>4. ONE of the following:</p> <p style="padding-left: 20px;">A. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></p> <p style="padding-left: 20px;">B. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></p> <p style="padding-left: 20px;">C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p>

Module	Clinical Criteria for Approval
	<p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) AND has had improvements or stabilization with the requested agent as indicated by ONE of the following: <ol style="list-style-type: none"> <li>1. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio <b>OR</b></li> <li>2. Decrease from baseline (prior to treatment with the requested agent) in proteinuria <b>OR</b></li> </ol> </li> <li>B. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) AND has had improvements or stabilization with the requested agent (e.g., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization/improvement of symptoms) (medical records required) <b>OR</b></li> <li>C. The patient has a diagnosis of complement 3 glomerulopathy (C3G) AND BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: <ol style="list-style-type: none"> <li>A. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio <b>OR</b></li> <li>B. Decrease from baseline (prior to treatment with the requested agent) in proteinuria <b>AND</b></li> </ol> </li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient is currently treated with a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB within the past 90 days <b>AND</b></li> <li>2. The patient will continue maximally tolerated ACEi, or ARB, or a combination medication containing an ACEi or ARB therapy in combination with the requested agent <b>OR</b></li> </ol> </li> <li>B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL ACEi, ARB, and combination medications containing an ACEi or ARB <b>OR</b></li> </ol> </li> </ol> </li> </ol> </li></ol>

Module	Clinical Criteria for Approval
	<p>D. The patient has a diagnosis other than IgAN, PNH, or C3G AND has had clinical benefit with the requested agent <b>AND</b></p> <p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></p> <p>4. The patient will NOT be using the requested agent in combination with Empaveli (pegcetacoplan), Soliris (eculizumab), Bkemv (eculizumab-aeab), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), or Piasky (crovalimab-akkz) <b>AND</b></p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

### QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity Limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <p>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></p> <p>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:</p> <p>A. BOTH of the following:</p> <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> <p>B. BOTH of the following:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSIL: 12 months</p> <p>All other plans: Initial approval 6 months; Renewal approval 12 months</p>