IPTACOPAN

Included Products: Fabhalta (iptacopan)

Created: 07/11/2024 *Revised:* 11/14/2024 *Reviewed*: 11/14/2024 *Updated*: 11/14/2024

All Diagnoses			
Initial Criteria: All Diagnoses		**If yes**	**If no**
1.	Is the drug prescribed by or in consultation with one of the following specialists? a. Paroxysmal Nocturnal Hemoglobinuria: hematologist b. Immunoglobulin A Nephropathy: nephrologist	Continue to #2	Continue to #3.
2.	Is the drug supported for the submitted indication?	Proceed to indication specific criteria below.	Continue to #3
3.	Has the case's medical necessity been confirmed with external specialist and medical director review?	Continue to #4	Do not approve.
4.	Approve for 6 months.		
Renewal Criteria		**If yes**	**If no**
1.	Is the request for the treatment of IgA nephropathy?	Continue to IgA nephropathy renewal criteria.	Continue to #2.
2.	Is there documentation which demonstrates a clinically significant and meaningful response to therapy?	Continue to #3.	Do not approve.
3.	Has the case's medical necessity been confirmed with medical director?	Continue to #4	Do not approve.
4.	Approve for 6 months.		

Paroxysmal Nocturnal Hemoglobinuria			
Initial Criteria		**If yes**	**If no**
1.	Does the member have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and using the drug to reduce hemolysis?	Continue to #2	Do not approve.
2.	Has the cases medical necessity been confirmed with external specialist and medical director review?	Continue to #3	Do not approve.
3.	Approve for 6 months.		

Immunoglobulin A Nephropathy (IgAN)			
Initial Criteria		**If yes**	**If no**
1.	Does the member have biopsy confirmed IgA nephropathy?	Continue to #2.	Do not approve.
2.	Does the member meet the following laboratory criteria? a. Urine protein-to-creatinine ratio (UPCR) $\geq$ 1.5 g/g b. eGFR $\geq$ 20 mL/min/1.73 m^2	Continue to #3.	Do not approve.
3.	Is the member's UPCR $\geq$ 1.5 g/g despite trial of a maximally tolerated dose of all of the following? a. ACE inhibitor or ARB b. SGLT2 inhibitor (like Farxiga) c. Systemic steroid or mycophenolate d. Filspari (with prior authorization)	Continue to #4.	Do not approve.
4.	Has the case's medical necessity been confirmed with an external specialist and/or medical director review?	Continue to #5.	Do not approve.
5.	Approve for 6 months.		
Renewal Criteria		**If yes**	**If no**
1.	Has the member's UPCR decreased significantly ($\geq$30%) compared to baseline?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		