NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS

Renewal Request for Insured Coverage of Ravulizumab (Ultomiris) for aHUS

PATIENT INFORMATION			
PATIENT SURNAME	**PATIENT GIVEN NAME**	**HEALTH CARD NUMBER**	**DATE OF BIRTH**
PATIENT ADDRESS			**PATIENT WEIGHT (KG)**

RENEWAL REQUEST

For initial requests, please refer to the separate initial request form.

Treatment with ravulizumab can be renewed as long as the patient exhibits a response to treatment or as per physician discretion (e.g., long-term funding based on factors like limited organ reserve or high-risk genetic mutation such as Factor H deficiency).

Initial Renewal (after 6 months of therapy): Please complete sections 1 and 2 below.

- **At the 6-month assessment, treatment response and no treatment failure (defined in Initiation Criteria) is required.**

Subsequent Renewal (after ≥ 12 months of therapy): Please complete sections 1, 2, and 3 below.

- **At the 12-month and annual assessments, treatment response, no treatment failure, and the patient has limited organ reserve or high-risk genetic mutation are required.**

1. All renewals: Response to treatment is defined as, but not limited to:		
☐ Yes	☐ No	Hematological normalization (e.g., platelet count, LDH)
☐ Yes	☐ No	Stabilization of end-organ damage (such as acute kidney injury and brain ischemia)
☐ Yes	☐ No	Transplant graft survival in susceptible individuals
☐ Yes	☐ No	Dialysis avoidance in patients who are pre- end-stage kidney disease (ESKD)
2. All renewals: Treatment failure is defined as:		
☐ Yes	☐ No	Dialysis-dependent at 6 months, and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; **OR**
☐ Yes	☐ No	On dialysis for ≥ 4 of the previous 6 months while receiving ravulizumab and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; **OR**
☐ Yes	☐ No	Worsening of kidney function with a reduction in eGFR or increase in SCr ≥ 25% from baseline.
3. Subsequent renewals only: Please indicate if the patient has the following:		
☐ Yes	☐ No	Limited organ reserve. Limited organ reserve is defined as significant cardiomyopathy, neurological, gastrointestinal, or pulmonary impairment related to TMA; or Grade 4 or 5 chronic kidney disease (eGFR < 30mL/min) is required.
☐ Yes	☐ No	High-risk genetic mutation
Restart of therapy: A patient previously diagnosed with aHUS and who responded to treatment with ravulizumab and has not failed ravulizumab is eligible to restart ravulizumab if the patient redevelops a TMA related to aHUS and meets the following clinical conditions:		
☐ Yes	☐ No	Previously diagnosed with aHUS
☐ Yes	☐ No	Responded to treatment with ravulizumab and has not failed ravulizumab
☐ Yes	☐ No	Patient redeveloped a TMA related to aHUS
☐ Yes	☐ No	Significant hemolysis as evidenced by presence of schistocytes on the blood film, or low or absent haptoglobin, or LDH above normal; **AND EITHER:**
☐ Yes	☐ No	Platelet consumption as measured by either ≥ 25% decline from patient baseline or thrombocytopenia (platelet count < 150,000 × 10^9/L); **OR**
☐ Yes	☐ No	TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin) including on recent biopsy.

Comments (if applicable):

PRESCRIBER NAME & ADDRESS:

LICENCE # | **PRESCRIBER SIGNATURE** | **DATE**

If you need assistance, please contact the Pharmacare Office at (902) 496-7001 or 1-800-305-5026

Please Return Form To: Nova Scotia Pharmacare Programs; P.O. Box 500, Halifax, NS B3J 2S1; Fax: (902) 496-4440

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