Ultomiris (Ravulizumab) / Soliris (Eculizumab) for Paroxysmal Nocturnal Hemoglobinuria (PNH)

EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Fax: (204) 942-2030 or 1-877-208-3588

Prescriber Name:	**Fax Number:**
Prescriber Address:	**Phone Number:**
	Prescriber License Number (NOT Billing Number):

Patient First Name:	**PHIN:**	**MHSC:**
Patient Last Name:	**Patient's Date of Birth:**	

◯ **New Request (please complete section A, B, D)** ◯ **Renewal Request (please complete section B, C, D)**

Medication Requested:	**Dose and Regimen:**
◯ **Ultomiris (Ravulizumab)**	*Note: Ravulizumab should only be prescribed at the Health Canada recommended dosage.*
◯ **Soliris (Eculizumab)**	◯ 600 mg once per week for the first 4 weeks then from week five of treatment, 900 mg once every 2 weeks.

Expected Duration of Therapy:

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the EDS listing. Please provide the following details about how this patient meets the specific criteria for coverage. Manitoba Health may request additional documentation to support this EDS request.

Section A: For INITIAL Requests

Diagnosis and Symptoms

Indication: ◯ Paroxysmal Nocturnal Hemoglobinuria (PNH)

Diagnosis of PNH has been made based on the following confirmatory results:

Flow cytometry/FLAER exam with granulocyte clone size ≥ 10%	◯ YES	◯ NO
Flow cytometry/FLAER exam with monocyte clone size ≥ 10%	◯ YES	◯ NO
Lactate dehydrogenase (LDH) >1.5 x upper limit of normal (ULN)	◯ YES	◯ NO

PRIOR to initiation with a C5 inhibitor, the patient has exhibited at least ONE of the following attributed to PNH *(check all that apply)*:

- ☐ A thrombotic or embolic event which required the initiation of therapeutic anticoagulant therapy.
- ☐ Transfusion requirement of ≥ 4 units of red blood cells in the previous 12 months.
- ☐ Chronic or recurrent anemia where causes other than hemolysis have been excluded, and demonstrated by more than one hemoglobin measure of ≤ 70 g/L, or more than one hemoglobin measure of ≤ 100 g/L with concurrent symptoms of anemia.
- ☐ Pulmonary insufficiency, as defined by debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded.
- ☐ Renal insufficiency, demonstrated by an eGFR ≤ 60 mL/min/1.73m^2, where causes other than PNH have been excluded.
- ☐ Smooth muscle spasm, as defined by recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia where causes other than PNH have been excluded.

Provide a brief description of the patient's current PNH symptoms based on the selection above:

Section B: For BOTH INITIAL and RENEWAL Requests		
Exclusion Criteria		
Please specify whether the patient meets any of the following EXCLUSION/DISCONTINUATION criteria:		
The patient experienced a prior treatment failure with ravulizumab or eculizumab.	○ YES	○ NO
The patient is receiving concurrent treatment with another C5 inhibitor drug.	○ YES	○ NO
Granulocyte clone size below 10%.	○ YES	○ NO
Monocyte clone size below 10%.	○ YES	○ NO
Presence of aplastic anemia with two or more of the following: ☐ Neutrophil count below 0.5 x 10^9/L ☐ Platelet count below 20 x 10^9/L ☐ Reticulocytes below 25 x 10^9/L ☐ Severe bone marrow hypocellularity	○ YES	○ NO
Presence of another life threatening or severe disease where the long-term prognosis is unlikely to be influenced by therapy (e.g., acute myeloid leukemia or high-risk myelodysplastic syndrome).	○ YES	○ NO
Presence of another medical condition that might reasonably be expected to compromise a response to therapy.	○ YES	○ NO
Documentation and Additional Information		
The request for coverage is being made by or in consultation with a nephrologist or hematologist with experience managing PNH.	○ YES	○ NO
A copy of the patient's current blood work is attached **(required).**	○ YES	○ NO
A copy of the patient's current flow cytometry report is attached **(required).**	○ YES	○ NO
Additional Relevant Clinical Information:		

Section C: For RENEWAL Requests		
There has been relief in the PNH symptoms that qualified the patient for initial approval.	○ YES	○ NO
There is a demonstrated clinical improvement in the patient, or stabilization of the patient's condition, while receiving treatment for PNH.	○ YES	○ NO
The patient and treating physician have been adequately adherent to treatment and to measures including monitoring requirements, taken to evaluate the effectiveness of the therapy.	○ YES	○ NO
Provide a description of the clinical improvements seen in the patient's PNH symptoms:		

Section D: Prescriber Signature and Date	
☐ **I have discussed with the patient that the purpose of releasing their information to Manitoba Health, Seniors and Long-Term Care is to obtain Exception Drug Status for prescription coverage.**	
Date:	**Prescriber Signature:**