NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS

Request for Insured Coverage of Ravulizumab (Ultomiris) or Pegcetacoplan (Empaveli) for PNH

PATIENT INFORMATION

PATIENT SURNAME	PATIENT GIVEN NAME	HEALTH CARD NUMBER	DATE OF BIRTH

PATIENT ADDRESS	PATIENT WEIGHT (KG)

REQUESTED DRUG

☐ **Ravulizumab (Ultomiris)** ☐ **Pegcetacoplan (Empaveli)**

INITIAL AND RENEWAL EXCLUSION CRITERIA

☐ Yes ☐ No **1.)** Small granulocyte or monocyte clone size - the treatment of patients with a granulocyte and monocyte clone size below 10% will not be eligible for treatment; **OR**

☐ Yes ☐ No **2.)** 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, or severe bone marrow hypocellularity; **OR**

☐ Yes ☐ No **3.)** Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); **OR**

☐ Yes ☐ No **4.)** The presence of another medical condition that might reasonably be expected to compromise a response to therapy.

☐ Yes ☐ No **5.)** **Ravulizumab Requests Only**: Insufficient initial response or failed treatment with eculizumab at the Health Canada–recommended dosage (not eligible for reimbursement of ravulizumab)

INITIAL REQUEST

For the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet the following criteria:

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

1.) ☐ Flow cytometry/FLAER exam with granulocytes or monocyte clone ≥ 10%; **AND**

2.) ☐ LDH > 1.5 ULN; **AND**

3.) **At least one** of the following:

- ☐ A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,
- ☐ Minimum 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 measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100g/L with concurrent symptoms of anemia,
- ☐ Pulmonary insufficiency: 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: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded,
- ☐ Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.

Pegcetacoplan Requests Only: The patient has experienced the following:

☐ Persistent anemia with hemoglobin levels < 105 g/L, despite an adequate trial of C5 inhibitor treatment and where causes other than extravascular hemolysis have been excluded. **Please specify**:_____ **OR**

☐ Intolerable adverse events from C5 inhibitor treatment. **Please specify:** _____

RENEWAL REQUEST

☐ Yes ☐ No **1.)** Has confirmation of granulocyte clone size (by flow cytometry) been completed?

☐ Yes ☐ No **2.)** Does the patient demonstrate clinical improvement while on therapy? **OR**
Please specify: _____

☐ Yes ☐ No **3.)** Has therapy been shown to stabilize the patient's condition?
Please specify: _____

Additional 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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NOVA SCOTIA