ALBERTA BLUE CROSS®

ECULIZUMAB/ PEGCETACOPLAN/ RAVULIZUMAB
For Paroxysmal Nocturnal Hemoglobinuria
SPECIAL AUTHORIZATION REQUEST FORM

Patients may or may not meet eligibility requirements as established by Alberta Government sponsored drug programs.

PATIENT INFORMATION

Patient last name	First name	Middle initial	Gender M / F	Birth date (YYYY-MM-DD)	Alberta Personal Health Number

Street address	City	Province	Postal code

ID/client/coverage number	Coverage type
	☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other

SPECIALIST IN HEMATOLOGY INFORMATION

Last name	First name	Middle initial

Street address	City	Province	Postal code

Telephone number	Fax number	College of Physicians and Surgeons registration number

Date form completed (YYYY-MM-DD)	Last consult date (YYYY-DD-MM)	Specialist in Hematology signature

PHARMACY INFORMATION

Pharmacy name	Telephone number	Fax number

INFORMATION REQUIRED

For **INITIAL COVERAGE (new to drug)** please complete the first two pages, and submit laboratory data and consent form as attachments

For **CONTINUED COVERAGE (on drug now or prior use of drug)** please complete applicable sections of all pages, and submit laboratory data as an attachment

Note: Additional pages may be attached as required; please submit all required pages and attachments together

TREATMENT REQUESTED

Drug requested ☐ Eculizimab (e.g. Soliris) ☐ Pegcetacoplan (e.g. Empaveli) ☐ Ravulizumab (e.g. Ultomiris)	Current weight (kg) – for ravulizumab
Dosage and frequency requested	

Diagnosis ☐ Paroxysmal Nocturnal Hemoglobinuria (PNH) ☐ Other, specify _____

CONFIRMATION OF DIAGNOSIS	Yes	No	Date (YYYY-MM-DD)	Lab result
Does the patient have a PNH granulocyte or monocyte clone size (by flow cytometry and/or FLAER test) equal to or greater than 10%?	☐granulocyte ☐monocyte	☐		
Does the patient have a Lactate Dehydrogenase (LDH) level at least 1.5 times the upper limit of normal (ULN)?	☐	☐		

FOR PEGCETACOPLAN REQUESTS ONLY	Yes	No	Date (YYYY-MM-DD)	Lab result
Does the patient have persistent anemia with hemoglobin levels <10.5 g/dL despite an adequate trial (i.e., 6 months) of C5 inhibitor treatment and causes other than extravascular hemolysis have been excluded?	☐	☐		
If the patient has intolerable adverse effects from C5 inhibitor treatment, please specify				
For requests to change to 1080 mg every third day: Does the patient have a LDH level at least 2 times the ULN on twice weekly dosing?	☐	☐		

Please mail this request to	Or fax to	Case number
▪ **Alberta Blue Cross, Clinical Drug Services** **10009 108 Street NW, Edmonton, Alberta T5J 3C5**	▪ **780-401-1150** in Edmonton ▪ **1-888-401-1150** toll free all other areas	

ALBERTA BLUE CROSS®

ECULIZUMAB/ PEGCETACOPLAN/ RAVULIZUMAB SPECIAL AUTHORIZATION REQUEST FORM

Patient's Alberta Personal Health Number (only)

ADDITIONAL CLINICAL CRITERIA

Does the patient have any of the following?	Yes	No	Comment
Thrombosis: Evidence that the patient has had a thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy	☐	☐	
Transfusions: Evidence that the patient has been transfused with at least four units of red blood cells in the last 12 months	☐	☐	
Anemia: Evidence that the patient has 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 100 g/L with concurrent symptoms of anemia	☐	☐	
Pulmonary insufficiency: Evidence that the patient has 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: Evidence that the patient has a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60mL/min/1.73m^2, where causes other than PNH have been excluded	☐	☐	
Smooth muscle spasm: Evidence that the patient has recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded	☐	☐	

CONTRAINDICATIONS TO COVERAGE

Does the patient have any of the following?	Yes	No
Small clone size - granulocyte and monocyte clone sizes below 10%	☐	☐
Aplastic anaemia 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	☐	☐
Presence of another life threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukaemia or high-risk myelodysplastic syndrome)	☐	☐
Presence of another medical condition that might reasonably be expected to compromise a response to therapy	☐	☐

IMMUNIZATION

		Yes	No	Date (YYYY-MM-DD)
All patients must receive meningococcal immunization with a quadravalent vaccine (A, C, Y and W135) at least two weeks prior to receiving the first dose of eculizumab. Treating physicians will be required to submit confirmation of meningococcal immunizations in order for their patients to continue to be eligible for treatment with eculizumab. Pneumococcal immunization with a 23-valent polysaccharide vaccine and a 13-valent conjugate vaccine, and a Haemophilus influenza type b (Hib) vaccine must be given according to current clinical guidelines. All patients must be monitored and reimmunized according to current clinical guidelines for vaccine use.	Meningococcal (A,C,Y and W135)	☐	☐	
	Pneumococcal 23-valent	☐	☐	
	Pneumococcal 13-valent	☐	☐	
	Hib	☐	☐	

TRANSFUSION HISTORY

Transfusion date (YYYY-MM-DD)	RBC units	Comments

Case number

ALBERTA BLUE CROSS®

ECULIZUMAB/ PEGCETACOPLAN/ RAVULIZUMAB SPECIAL AUTHORIZATION REQUEST FORM

Patient's Alberta Personal Health Number (only)

MONITORING REQUIREMENTS (please attach the following laboratory results with each request)

- Lactate dehydrogenase (LDH)
- Full blood count and reticulocytes
- Iron studies
- Urea, electrolytes and eGFR
- PNH Granulocyte or Monocyte clone size (Initial coverage and every 12 months)

Recent clinical history (update for each request, attach additional pages as required. For requests to switch agents, please include reason for switch and monitoring information taken just prior to the intended switch.)

Case number

ALBERTA BLUE CROSS®

ECULIZUMAB/ PEGCETACOPLAN/ RAVULIZUMAB SPECIAL AUTHORIZATION REQUEST FORM

Patient's Alberta Personal Health Number (only)

Progress report on the clinical symptoms that formed the basis of initial eligibility (update annually, attach additional pages as required)

☐ Thrombosis ☐ Transfusions ☐ Anemia ☐ Pulmonary insufficiency ☐ Renal insufficiency ☐ Smooth muscle spasm

Quality of life, through clinical narrative (update annually, attach additional pages as required)

Case number