ALBERTA BLUE CROSS®

RAVULIZUMAB
For Atypical Hemolytic Uremic Syndrome
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 OR NEPHROLOGY 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 or Nephrology 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

Dosage and frequency requested	Current weight – for pediatric patients
	☐ less than 20 kg ☐ 20 kg and over

CONFIRMATION OF DIAGNOSIS

Diagnosis

☐ Atypical Hemolytic Uremic Syndrome (aHUS) ☐ Other, specify _____

Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA):	**Yes**	**No**	**N/A**	**Date** (YYYY-MM-DD)	**Lab result**
A disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 (ADAMTS-13) activity >/=10% on blood samples taken prior to plasma exchange or plasma infusion (PE/PI)	☐	☐	☐		
Shiga toxin producing Escherichia coli (STEC) test negative in patients with a history of bloody diarrhea in the preceding two weeks	☐	☐	☐		
TMA is unexplained (not a secondary TMA)	☐	☐			

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	

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ADDITIONAL CLINICAL CRITERIA

Does the patient have evidence of ongoing active TMA and progressing, defined by laboratory test abnormalities despite plasmapheresis, if appropriate?	Yes	No	Comment
1. Unexplained (not a secondary TMA) thrombocytopenia (platelet count <150 x 10^9/L); and hemolysis as indicated by the documentation of two of the following:	☐	☐	
a) schistocytes on the blood film	☐	☐	
b) low or absent haptoglobin	☐	☐	
c) lactate dehydrogenase (LDH) above normal	☐	☐	
2. Tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and hemolysis	☐	☐	
Evidence of at least one of the following documented clinical features of active organ damage or impairment?	**Yes**	**No**	**Comment**
1. Kidney impairment, as demonstrated by one of the following:	☐	☐	
a) A decline in estimated glomerular filtration rate (eGFR) of >20% in a patient with pre-existing renal impairment	☐	☐	
b) Serum creatinine (SCr) >upper limit of normal (ULN) for age or GFR <60 mL/min and renal function deteriorating despite prior PE/PI in patients who have no history of pre-existing renal impairment (i.e., who have no baseline eGFR measurement)	☐	☐	
c) SCr >the age appropriate ULN in pediatric patients (as determined by or in consultation with a pediatric nephrologist)	☐	☐	
2. Onset of neurological impairment related to TMA	☐	☐	
3. Other TMA-related manifestations, such as cardiac ischemia, bowel ischemia, pancreatitis, or retinal vein occlusion (specify)	☐	☐	
For kidney transplant patients, does the following apply?	**Yes**	**No**	**Comment**
1. Documented history of aHUS (i.e., history of TMA [not secondary TMA only] with ADAMTS 13 >10%); and one of the following applies:	☐	☐	
a) Developed TMA immediately (within hours to 1 month) following a kidney transplant	☐	☐	
b) Previously lost a native or transplanted kidney due to the development of TMA	☐	☐	
c) Have a history of proven aHUS and require prophylaxis with ravulizumab at the time of a kidney transplant	☐	☐	

CONTRAINDICATIONS TO COVERAGE

Does the following apply to the patient?	Yes	No
History of ravulizumab treatment failure* (i.e., treated with ravulizumab with a previous aHUS recurrence). *Treatment failure is defined as: -Dialysis-dependent at six months, and failed to demonstrate resolution or stabilization of neurological or extra-renal complications if these were originally present; OR -On dialysis for >/= four of the previous six months while receiving ravulizumab and failed to demonstrate resolution or stabilization of neurological or extra-renal complications if these were originally present; OR -Worsening of kidney function with a reduction in eGFR or increase in SrCr >/=25% from baseline	☐	☐

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 ravulizumab. Treating physicians will be required to submit confirmation of meningococcal immunizations in order for their patients to continue to be eligible for treatment with ravulizumab. 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	☐	☐	

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TREATMENT RESTART			
Did the patient redevelop a TMA related to aHUS and the following applies?	**Yes**	**No**	**Comment**
1. Significant hemolysis as evidenced by one of the following:	☐	☐	
a) presence of schistocytes on the blood film	☐	☐	
b) low or absent haptoglobin	☐	☐	
c) LDH above normal	☐	☐	
2. Platelet consumption as measured by either >/=25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L)	☐	☐	
3. TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin) including on recent biopsy	☐	☐	

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

- Documented treatment response defined as, hematological normalization (e.g., platelet count, LDH), stabilization of end organ damage (such as acute kidney injury and brain ischemia), transplant graft survival in susceptible individuals, and dialysis avoidance in patients who are pre- end-stage kidney disease (ESKD)
  OR
- Limited organ reserve* or high-risk genetic mutation such as Factor H deficiency.
  *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 <30 mL/min).

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

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

Case number