THE Great-West Life ASSURANCE COMPANY

Drug Prior Authorization Form
Soliris (eculizumab)

The purpose of this form is to obtain information required to assess your drug claim. Approval for coverage of this drug may be reassessed at any time at Great-West Life's discretion. For additional information regarding Prior Authorization and Health Case Management, please visit our Great-West Life website at www.greatwestlife.com.

IMPORTANT: Please answer all questions. Your claim assessment will be delayed if this form is incomplete or contains errors.

Any costs incurred for the completion of this form are the responsibility of the plan member/patient.

Great-West Life recognizes and respects the importance of privacy. Personal information collected is used for the purposes of assessing eligibility for this drug and for administering the group benefits plan. For a copy of our Privacy Guidelines, or if you have questions about Great-West Life's personal information policies and practices (including with respect to service providers), refer to www.greatwestlife.com or write to Great-West Life's Chief Compliance Officer.

I authorize Great-West Life, any healthcare provider, my plan administrator, any insurance or reinsurance company, administrators of government benefits or patient assistance programs or other benefits programs, other organizations, or service providers working with Great-West Life or any of the above, located inside or outside Canada, to exchange personal information when relevant and necessary for these purposes. I understand that personal information may be subject to disclosure to those authorized under applicable law within or outside Canada.

I acknowledge that the personal information is needed to assess eligibility for this drug and to administer the group benefits plan. I acknowledge that providing consent will help Great-West Life to assess my claim and that refusing to consent may result in delay or denial of my claim. Great-West Life reserves the right to audit the information provided on this form at any time and this consent extends to any audit of my claim. This consent may be revoked by me at any time by sending written instruction to that effect.

If the patient is a person other than myself, I confirm that the patient has given their consent to provide their personal information and for Great-West Life to use and disclose it as set out above.

I certify that the information given below is true, correct, and complete to the best of my knowledge. Failure to provide true, correct and complete information on this form could result in revocation of any approval decision, a requirement to repay paid claims or other appropriate action.

Plan Member's signature: _____ Date: _____

Form Completion Instructions:

1. **Complete "Patient Information" sections.**
2. **Have the prescribing physician complete the "Physician Information" sections.**
3. **Send all pages of the completed form to us by mail, fax or email as noted below.**

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: **The Great-West Life Assurance Company**
Drug Services
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: **The Great-West Life Assurance Company**
Fax 1-204-946-7664
Attention: Drug Services

Email to: **gwldrug.services@gwl.ca**
Attention: Drug Services

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THE Great-West Life ASSURANCE COMPANY

Patient Information
Soliris (eculizumab)

Plan Member Information – Complete all sections of this page (please print)

Plan Member:	Patient Name:	
Plan Name:	Plan Number:	Plan Member ID Number:
Patient Date of Birth (DD/MM/YYYY):	Address (number, street, city, province, postal code):	

Please indicate preferred contact number and if there are any times when telephone contact with you about your claim would be most convenient.

May we contact you by email? (Note that some correspondence may still need to be sent by regular mail).

☐ Yes ☐ No If yes, please provide email address: _____

Tell us if you have been on this drug before

Is the patient currently on, or previously been on this drug? ☐ Yes ☐ No

If Yes, a) indicate start date (DD/MM/YYYY): _____

b) coverage provided by: _____

(if coverage is not provided by Great-West Life please provide pharmacy print-out showing purchase of this drug)

Tell us if you have coverage with any other benefits plan

Does the patient have drug coverage under any other group benefits plan? ☐ Yes ☐ No

If Yes, name of other insurance company: _____

If other plan is with Great-West Life, tell us the plan and ID number: _____

Name of plan member: _____

Relationship to patient: _____

Provide details and attach documentation of acceptance or decline:

_____

_____

Tell us about any Provincial or other coverage you may have

Does the patient have coverage under a provincial program or from any other source? ☐ Yes ☐ No

If Yes, name of program or other source: _____

Provide details and attach documentation of acceptance or decline: _____

Is the patient currently receiving disability benefits for the condition for which this drug has been prescribed? ☐ Yes ☐ No

Tell us about any Patient Assistance Program you might be enrolled in

Has the patient enrolled in the patient assistance program for this drug? ☐ Yes ☐ No

If Yes, please provide the following information:

1. Patient assistance program patient ID Number: _____
2. Patient assistance program contact person name and phone number:

   Contact Name: _____ Phone Number: _____

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THE Great-West Life ASSURANCE COMPANY

Physician Information
Soliris (eculizumab)

Note to Physician: In order to assess a patient's claim for this drug, we require detailed information on the patient's prescription drug history as requested below.

Attach extra information if necessary. *GENETIC TEST RESULTS ARE NOT REQUIRED*

Physician's Information (please print)

Name of prescribing physician:

Specialty:

Address (number, street, city, province, postal code):

Telephone Number (including area code):	Fax Number (including area code):

1. Prescribed dosage and frequency. Include initial loading dose if applicable:
   - ☐ Induction: _____ mg every week for _____ weeks, _____1 week later, 5th dose
   - ☐ Maintenance: _____ mg every 2 weeks
   - ☐ Other (please specify): _____
2. Health Canada Indication (include date of initial diagnosis) (MM/YYYY): _____
   - ☐ atypical Hemolytic Uremic Syndrome (aHUS)
   - ☐ Paroxysmal nocturnal hemoglobinuria (PNH)

   Complete questions 1 - 5 and Physician's information
   - ☐ Other (approved by Health Canada): _____

   Complete questions 1 - 5 and Other Condition (Health Canada approved)
   - ☐ Other (prescribed use is not approved by Health Canada): _____

   Complete questions 1 - 5 and Off-label use
3. What is the anticipated duration of treatment with this drug? _____
4. Where will treatment be administered? ☐ Home ☐ Physician's Office ☐ Private clinic ☐ Hospital in-patient ☐ Hospital out-patient
5. Drug and Treatment History – **must be completed for every request.**

Drug(s) and Treatment(s) past and present	Dosing Regimen	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Clinical Results/Outcome
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:

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Physician's Information *(continued)* (please print)

Atypical Hemolytic Uremic Syndrome (aHUS)

Initial Requests/Recommencement Requests:

☐ Initial request

☐ Recommencement request (patient has previously been diagnosed with aHUS and responded to treatment with Soliris)

Shiga toxin-related HUS has been ruled out ☐ Yes ☐ No Submit report.

Secondary causes of thrombotic microangiopathy, such as pregnancy, HIV, collagen vascular disease, drugs, malignancy, stem cell transplant, or malignant hypertension have been ruled out ☐ Yes ☐ No

Does patient have any extra-renal TMA-related manifestations? ☐ Yes ☐ No

If yes, please provide a description and include any supporting test results or clinic notes to confirm.

_____

_____

_____

For renewals, provide details pertaining to last 12 months.

Does patient have pre-existing kidney dysfunction? ☐ Yes ☐ No

If yes, please include a copy of laboratory results showing baseline levels prior to aHUS presentation in addition to current results

Required laboratory reports for initial requests

Baseline ADAMTS-13 report required with submission. Please check one of the following:

☐ Submitted with initial request

☐ Not available for initial request, will be submitted once available

If ADAMTS-13 sample not collected prior to plasma exchange or infusion, it may be taken 1-2 weeks following the last plasma exchange and must be submitted with the renewal request.

☐ Peripheral blood smear

☐ Direct antiglobulin test

For all requests (initial, recommencement, renewal):

Laboratory reports required for the last 12 months with initial requests and since previous request for renewals

Indicate if attached by checking box below

Serum Creatinine	☐	Platelets	☐
eGFR	☐	LDH	☐
Bilirubin	☐	Haptoglobin	☐

Physician's Information *(continued)* (please print)

Please complete chart below with details regarding patient's aHUS treatments received, such as dialysis or plasma exchange/infusions.

Type Example(s) – Dialysis or Plasma exchange/infusion therapy	Duration (DD/MM/YYYY) to (DD/MM/YYYY)	Frequency	Results

Renewals

Has patient experienced stabilization of their disease? Please provide a description of which TMA complications have stabilized since starting eculizumab. Please provide clinic notes to describe patient's benefit from eculizumab therapy

Physician's Information *(continued)* (please print)

Paroxysmal nocturnal hemoglobinuria

Required laboratory reports (submit documentation with initial request):

Provide all reports for the last **12 months** on intitial request and **indicate if attached below**.

	Yes	No		Yes	No
Serum creatinine	☐	☐	Platelets	☐	☐
eGFR	☐	☐	Serum LDH	☐	☐
BUN	☐	☐	Hemoglobin and/or Haptoglobin	☐	☐

Upon renewal, provide lab data and treatments since previous request.
Note: an assessment cannot be made unless all of the tests above have been performed and reports submitted.

Further clinical documentation - check all that apply and provide details.

Does the patient have any of the following:	Yes	No	Comments/dates (DD/MM/YYYY)
A history of a major adverse vascular event (MAVE)?	☐	☐	
If yes, did the patient require anti-coagulation:	☐	☐	
Anemia	☐	☐	
Pulmonary insufficiency	☐	☐	
Renal insufficiency	☐	☐	
Smooth muscle spasm	☐	☐	
Aplastic anemia	☐	☐	
Myelodysplastic syndrome	☐	☐	
Other myelopathies	☐	☐	

Transfusion History: provide details for the last 12 months on initial requests. Upon renewal, provide details since previous request.

Transfusion date (DD/MM/YYYY)	RBC Units	Platelet Units	Results

Other condition (Health Canada approved)

Please provide any relevant information related to the disease and attach supporting documentation.

Off-label use

Is there clinical evidence supporting the off-label use of this drug? ☐ Yes ☐ No

Provide clinical literature / studies to support the request for off-label use, such as:

- At least two Phase II or two Phase III clinical trials showing consistent results of efficacy; and
- Published recommendations in evidence-based guidelines supporting its use.

Provide medical rational why Soliris has been prescribed off-label instead of an alternate drug with an approved indication for this condition.

Provide any pertinent medical history or information to support this off-label request.

If this is a renewal request, provide documentation showing treatment efficacy since previous request.

Drug(s) and Treatment(s) past and present	Dosing Regimen	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Clinical Results/Outcome
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:
				☐ Failure ☐ Intolerance ☐ Other Clinical details:

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Physician Information
Soliris (eculizumab)

Note for Physician: To be eligible for reimbursement, Great-West Life may require your patient to purchase a drug requiring prior authorization from a pharmacy designated by Great-West Life. If applicable, a health case manager will contact you with further information.

I certify that the information provided is true, correct, and complete.

Physician's Signature: _____ Date: _____

License Number: _____

It is important to provide the requested information in detail to help avoid delay in assessing claims for the above drug. This form may be subject to audit. The completed form can be returned to Great-West Life by mail, fax, or email.

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: **The Great-West Life Assurance Company**
Drug Services
PO Box 6000
Winnipeg MB R3C 3A5

Email to: **gwldrug.services@gwl.ca**
Attention: Drug Services

Fax to: **The Great-West Life Assurance Company**
Fax 1-204-946-7664
Attention: Drug Services

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