FORM-0116060 Version 7.0

UK – Certificate of vaccination and/or prophylactic antibiotics (CoV)

IMPORTANT INFORMATION

Soliris® (eculizumab) and Ultomiris ® (ravulizumab) are authorised under controlled distribution. Drug distribution will only be possible after written confirmation that the patient received or will receive meningococcal vaccination and/or antibiotic prophylaxis is submitted by the prescriber to Alexion Pharma UK. Therefore, it is mandatory that this certificate of vaccination is completed for each patient and returned to CustomerOperationsUK@alexion.com
You will also be sent an annual vaccination status reminder during December of each year to check each patient's vaccination status. It is also a requirement that all healthcare professionals ensure that they have read and understood the Physician guide before prescribing eculizumab or ravulizumab for any patient. The physician should also discuss the Patient/parent information with the patient or parent/guardian during consultation and provide it to the patient or parent/guardian along with the safety card.

To: ALEXION **Email: CustomerOperationsUK@alexion.com**

*Managing physician (Prescriber)	
First name	
Surname	
Email address	
Phone Number	
***Treating Hospital**	
Name	
Hospital address	
Postal Code	

*Mandatory information required – Missing information may lead to delays in processing

Information on Patient: Birth Date _____
(dd/mmm/yyyy)

Please indicate by ticking the respective box below, whether the CoV is for:
☐ a **new patient** to begin treatment with ravulizumab or eculizumab
☐ a **patient switching therapy** from eculizumab to ravulizumab (or vice versa)

ULTOMIRIS® *(ravulizumab)*	
Tick indication ☐ PNH ☐ aHUS ☐ gMG ☐ NMOSD	Other: (optional)
SOLIRIS® *(eculizumab)*	
Tick indication ☐ PNH ☐ aHUS ☐ refractory gMG ☐ NMOSD	Other: (optional)

HCP Commitment

I, the undersigned, _____ hereby undertake to ensure or confirm that:

I have explained the complement inhibitor treatment to the patient/parent(s)/legal guardian(s), provided the Data Privacy Notice (see link below) and obtained patient/parent(s)/legal guardian(s) consent for processing and transferring their personal data to Alexion along with the COV.
I must deliver to the patient/parent(s)/legal guardian(s) all necessary information, including the "Patient Safety Card" and relevant educational materials before initiating the complement inhibitor treatment.

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Risk of Serious meningococcal infection

Due to its mechanism of action, the use of eculizumab/ravulizumab increases the patient's susceptibility to meningococcal infection/sepsis (Neisseria meningitidis). Meningococcal disease due to any serogroup may occur.

- To reduce this risk of infection, all patients must be vaccinated against meningococcal infections at least two weeks prior to receiving/initiating treatment with eculizumab or ravulizumab unless the risk of delaying eculizumab/ravulizumab therapy outweighs the risk of developing a meningococcal infection.
- Patients who initiate eculizumab or ravulizumab treatment less than 2 weeks after receiving a meningococcal vaccine, must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.
- Vaccines against serogroups A, C, Y, W135 and B where available, are recommended in preventing the commonly pathogenic meningococcal serogroups.
- Patients must be vaccinated or revaccinated according to current national guidelines for vaccination use. If the patient is being switched from eculizumab to ravulizumab treatment (or vice versa), physicians should verify that meningococcal vaccination is current according to national guidelines for vaccination use.
- Vaccination may not be sufficient to prevent meningococcal infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

☐ I confirm that I have read and understood the risk of serious meningococcal infection associated with treatment and that the patient has adequate meningococcal cover in line with the above and in line with the PNH/aHUS National Service recommendations (where appropriate according to indication).

Healthcare professionals are asked to report any suspected adverse reactions to: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Sincerely,

Signature: Date: _____ (dd/mmm/yyyy)

Alexion's Data Privacy Notice

Alexion Pharmaceuticals, Inc., USA, and its local affiliates (collectively, "Alexion", "we", "us") as data controllers, processes personal data relating to patients receiving eculizumab/ravulizumab and to healthcare professionals involved in their therapeutic management, for the purposes of managing and reducing the risk linked to the use of eculizumab/ravulizumab as legally required. Such personal data will refer to the patient's date of birth, treatment type, and prescribed medication linked to the certificate of vaccination, while for healthcare professionals, we process personal data such as name, hospital when providing the patient's COV or when identified as the treating physicians, and email address when submitting the E-COV. You may contact us at any time to ask what Personal Data we process about you, request that we correct inaccurate Personal Data, opt out of or suppress certain Personal Data processing, request deletion of your Personal Data, impose restrictions on our processing of your Personal Data, you have a right to object on grounds relating to your particular situation, at any time to the processing of your personal data by us, and withdraw your consent to certain processing of your Personal Data. If such a request places Alexion or its affiliates in breach of its obligations under applicable laws, regulations or codes of practice, then Alexion may not be able to comply with your request.

To exercise your rights: Privacy@alexion.com.

To learn more about the processing of your data, please visit our website: https://alexion.com/Documents/UK/COV/DPN.pdf or use the QR Code below

FOR ALEXION USE ONLY

SAP Reference Code: _____ will be completed by Alexion.

After the patient is validated by Alexion, an SAP reference code will be allocated by Alexion. The SAP reference code and patient birth date will need to be provided for any further orders.

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REVISION HISTORY

Version No.	Change Type *(New, Revise, or Admin)*	Revision Summary	Justification
6.0	Revise	• To remove the date on section 1 of the form • To revise indication table to make it clearer for HCPs to make the appropriate selection. • Removal of educational material request statement • To change the form reference number from ALXN-FRM-0008110 to FORM-0116060	To simplify CoV form Changes due to AZALEA (AZ - Alexion Alliance) Patient Safety Integration
7.0	Revise	• To Remove the black Triangle	MHRA approved the safety updates - (consolidation of all PNH final clinical studies (CSRs)) and the removal of the black triangle.

Document Approvals

Business Approval	Ayat Sherif Ayat.Sherif@astrazeneca.com 06-Aug-2024 09:27:50 GMT+0000