SOP
Discharge and Post-discharge Workflow for Patients Treated with Ravulizumab in TACTIC-R

Day 1
Patient randomized to Ravulizumab arm

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Nurse/ doctor to to take responsibility for Ravulizumab list
(Use TACTIC-R RAV Flowsheet; share on local, secure network if team use required)

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TACTIC-R ravulizumab arm letter to be sent to GP; copy stored in patient notes

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Team member to review the Ravulizumab list DAILY to check:
discharge status
continuity of antibiotics

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Discharge day

NURSE to make sure that:	**TACTIC-R DOCTOR to make sure that:**
- the patient has received the Ravulizumab Patient Alert Card and is aware of the plan (vaccination and antibiotic prophylaxis) - the discharge summary was sent to GP	- RAV extra letter has been sent - patient has been prescribed antibiotic in TTO to cover the period until vaccination is done

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2-3 days post discharge:
- TACTIC-R doctor to call surgery to make sure GP has received the discharge summary + RAV extra letter and they have understood the instructions

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Day 28 follow-up (Day 21-35)
Clinician conducting the study visit to call/see patient to complete TACTIC-R RAV Flowsheet and complete Day 28 CRF.
Complete Vaccination Certificate via DocuSign link, if patient has received the first set of vaccines.

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Day 90 follow-up (Day 83-97)
Clinician conducting the study visit to call/see patient to complete TACTIC-R RAV Flowsheet and complete Day 90 CRF.
If not done at Day 28 Visit:
Complete Vaccination Certificate via DocuSign link, if patient has received the first set of vaccines.

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8 Month follow up
- Clinican to call patient either to complete Vaccination Certificate, if not previously done, OR to advise patient to stop prophylactic antibiotics, if the patient had not been vaccinated.

Screenshot of Headers from Excel Worksheet for Managing Discharge and Post-discharge Monitoring of Patients Treated with Ravulizumab

The excel worksheet is supplied as a separate document and is for local use only. It is for guidance only and can be modified according to local workflows.

	INPATIENT			DISCHARGE				
TACTIC Patient ID	Randomised to RAV	Clinician responsible for discharge/post-discharged monitoring	GP letter indicating randomisation to RAV arm sent	Discharge Date	GP letter sent (with RAV information)	RAV alert card given to patient	Antibiotics prescribed on discharge	2-3 days post discharge: GP called

28 DAY FU		90 DAY FU			8 month (only patients who have not received vaccine at 90 day FU)	
Men ACWY' and first MenB given (Y/N)	**Antibiotics continued** (Ongoing/Given until 2 weeks post vaccination/Other	**Men ACWY' and first MenB given** (Y/N/Patient not receiving vaccine)	**Second Men B given** (Y/N/Patient not receiving vaccine)	**Antibiotics continued** (Ongoing/Given until 2 weeks post MenACWY and 1st Men B vaccination/Other (explain)	**Vaccines given** (Y/N)	**Antibiotics continued for 8 months** (Y/N/NA)

Instructions for GP Letter Sent on Discharge of Patients Treated with Ravulizumab

Vaccination:

- should occur between 28 – 90 days post treatment (when patient is stable/recovered)
- vaccine to be administered: tetravalent ACWY + serotype B vaccine (MenB), then after a another one month a booster of MenB only

Antibiotic prophylaxis:

- penicillin V 500mg BD or an alternative if the patient has a penicillin allergy (erythromycin 500mg BD/ fluoroquinolones)
- antibiotic prophylaxis should be administered until 2 weeks after Men ACWY and first Men B vaccine is given and for 8 months post-ravulizumab if vaccinations not administered

Completion of Vaccination Certificate for Ravulizumab by Docusign

For use of Ravulizumab in TACTIC-R, this form can be completed by a Research Nurse or Doctor on the trial delegation log

Click the link below and follow the instructions to add your name and email.
Then complete the areas of the form highlighted in red

https://na2.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=2fc5f4d1-8a15-4bd0-a680-382acc6e28ff&env=na2&acct=4a620ad0-6f8c-4976-93a4-1dea02316bb5.

Certificate – UK: vaccination and/or prophylactic antibiotics

Must be completed and provided to Alexion before initiation of therapy with

Ultomiris® (Ravulizumab) or SOLIRIS® (Eculizumab) , Concentrate for Solution for Infusion (as requested by European Medicines Agency)

This is mandatory before any shipment can be made
TO BE IMMEDIATELY TRANSMITTED as scanned PDF by email

To: ALEXION Page: 1 / 2
Email: CustomerOperationsUK@alexion.com Date: 11-Aug-2020 | 03:32 PDT

IMPORTANT INFORMATION

Completion of this certificate is mandatory in order to allow Alexion to comply with the requirements of the marketing authorization of this medicine. This includes the confirmation of adequate vaccination and/or antibiotic cover of the intended patient as set out below, and the provision of Risk Management Materials and regular reminders to check the patient's vaccination status.

PLEASE COMPLETE IN FULL IN CAPITAL LETTERS

Name of Prescriber: Frances Hall
Hospital: -- select --
Address:
City:
Phone N°:
Email: fch22@medschl.cam.ac.uk

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

✓ **Ultomiris®** *(Ravulizumab)*	**Indication**	☐ PNH	Other: COVID-19 (optional)
☐ **Soliris®** *(Eculizumab)*	**Indication**	☐ PNH ☐ aHUS ☐ refractory gMG ☐ NMOSD	Other: (optional)

Commitment

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

I must explain *Soliris or Ultomiris* treatment to the patient/parent(s)/legal guardian(s) and I must deliver to the patient/parent(s)/legal guardian(s) all necessary information, including the "Patient Alert Card" and relevant educational materials before initiating SOLIRIS or ULTOMIRIS.

☐ -- select -- m requesting specified educational materials and commit to provide these materials to this patient.

The patient (tick as appropriate):

Received a vaccination against meningococcal infection, preferably against serotypes A, B, C, Y, W135:

☐ At least 2 weeks prior to administration of the 1st dose of SOLIRIS or ULTOMIRIS.
☐ Less than 2 weeks prior to administration of the 1st dose of SOLIRIS or ULTOMIRIS.

The patient receives therefore prophylactic antibiotics from at least the 1st day of SOLIRIS or ULTOMIRIS treatment and until 2 weeks after the vaccination against meningococcal infection.

Vaccination date is (dd/mmm/yyyy) _____ **Vaccine(s) /** _____

☐ Receives/will receive prophylactic antibiotics from at least the 1st day of SOLIRIS or ULTOMIRIS treatment and during the entire treatment period because the vaccine is contra-indicated for the patient.

☐ Receives/will receive prophylactic antibiotics from at least the 1st day of SOLIRIS or ULTOMIRIS treatment until 2 weeks after the patient can be vaccinated (e.g., young children or when vaccination may further activate complement and may increase the signs and symptoms of the underlying complement-mediated disease).

Sincerely,

Signature : Sign Date: 11-Aug-2020 | 03:32 PDT (dd/mmm/yyyy)