Rota code: HROTA451	Issue date: April 2025	Written by: Steve Hill	Authorised by: Shankara Paneesha	age: 1 of 3
Version no. 1.0	Valid until: Next Review	Checked by (Pharmacist) Djouerlah Anshur	Clinical Nurse Specialist:	Reference: ECHO trial, SmPC, EAMS Document

University Hospitals Birmingham

Acalabrutinib and Rituximab Maintenance for Mantle Cell Lymphoma (EAMS):

MRN: Ward/Unit:

Name:

DOB: Consultant:

Address:

NHS No:

Hb		Na+		Alb		Height	
WBC		K+		AlKP		Weight	
Plt		Urea		ALT		BSA	
Neuts		Cr		Bili		Date	
		GFR		TSH		Allergies :	
		Ca		T4			
		Mg		Cortisol			

Recorded by Date

Funding status: Bendamustine/Rituximab—Blueteq required
Acalabrutinib—Supplied Free of Charge from Astra Zeneca

Emetogenic potential: Low emetogenicity

Extravasation classification: Neutral

Hepatitis B Status:

Treatment intent: Disease Modification

Cycle frequency and duration: Every 56 days, up to 12 cycles

Cycle number:

Indication: Previously untreated Mantle Cell Lymphoma (consult eligibility/exclusion criteria for further information).

To commence on the next even numbered cycle following completion of HROTA450 (i.e. 56 days after C6 D1 of HROTA450).

To be given every 56 days until disease progression/unacceptable toxicity or max 12 cycles

Day No. Date	DRUG or ELECTRO-LYTE	CALCULATION	DOSE	IV FLUIDS	VOL. MLS.	ROUTE/FLOW RATE	SPECIAL DIRECTIONS/ ADMINISTRATION DE-TAILS	DRUG ADMINISTRATION Sig.		TIME	Pharmacy
1	Dexamethasone		8mg			Oral	1 hour before				
1	Paracetamol		1000 mg			Oral	1 hour before				
1	Chlorphenamine		8mg			Oral	1 hour before rituximab				
1	**RITUXIMAB (Rixathon)**	375mg/m^2		Sodium Chloride 0.9%	500ml	IV Infusion— see below for rate					

Prescriber sig: .....Name..... Date: ..... Pharmacist initial sig: .....Name..... Date: .....

Nurse final auth sig: .....Name..... Date: ..... Pharmacist final sig:.....Name..... Date.....

Acalabrutinib and Rituximab Maintenance for Mantle Cell Lymphoma (EAMS):

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Proceed rules, valid within 96 hours:

Drug	Neuts	Platelets	Renal	Hepatic
Rituximab	< 1.0 x 10^9/L (<0.75 x 10^9/L with marrow involvement) - Contact prescriber	< 50 x 10^9/L – contact prescriber	No dose adjustment required	No dose adjustment required
Acalabrutinib	< 0.5 x 10^9/L – see other information	<25 x 10^9/L (<50 x 10^9/L with concurrent bleeding) – see other information	CrCl > 30ml/min – No dose adjustment recommended. CrCl ≤ 30ml/min or dialysis – No data. Use if benefit outweighs risk	Child Pugh A/B or Bilirubin ≤ 63 µmol/L (≤3 x ULN) – No dose adjustment recommended Child Pugh C or Bilirubin > 63 µmol/L (> 3 x ULN) – Not recommended

Missed dose advice: If a dose of Acalabrutinib is missed by more than 3 hours then skip the dose and take the next dose as planned. Double dose of Acalabrutinib should NOT be taken to make up for a missed dose. **See overleaf for additional information**

Day No. Date	DRUG	DOSE	ROUTE	SPECIAL DIRECTIONS/ ADMINISTRATION DETAILS	QUANTITY	Dispensed by	Checked by
1	**ACALABRUTINIB (CALQUENCE) Tablets (FOC)**	100mg twice daily	ORAL	Take 12 hours apart. Swallow whole with water (with or without food) Do not break, crush or chew. Avoid grapefruit, and grapefruit juice.	C1-5: 28 days □ C6: 56 days □ **(FOC stock)**		

Medications to be prescribed on PICS

Anti-emetics	Supportive medication
Metoclopramide 10mg TDS PRN PO	• Aciclovir 400mg BD PO • Co-trimoxazole 480mg BD M/W/F PO

Prescriber sig: .....Name..... Date: ..... Pharmacist initial sig: .....Name..... Date: .....

Nurse final auth sig: .....Name..... Date: ..... Pharmacist final sig:.....Name..... Date.....

Acalabrutinib and Rituximab Maintenance for Mantle Cell Lymphoma (EAMS):

Other Information—Acalabrutinib

Haematology parameters and dose modifications: In case of grade 3 thrombocytopenia with bleeding, (platelets 25-50 x 10^9/L), grade 4 thrombocytopenia (platelets < 25 x 10^9/L), or grade 4 neutropenia (Neuts < 0.5 x 10^9/L) lasting longer than 7 days. First and second occurrence, interrupt treatment. When toxicity has resolved to grade 1 (Neuts > 1.5 x 10^9/L, platelets > 75 x 10^9/L), or baseline level, resume at 100mg BD. Third occurrence, interrupt treatment. Once toxicity has resolved to Grade 1 or baseline level, resumed at 100mg daily. Fourth occurrence, permanently discontinue treatment.

Toxicities and dose modifications: Acalabrutinib should be interrupted for a grade 3 or greater non-haematological toxicity. Once toxicity has resolved to baseline or grade 1; for the 1st/2nd occurrence restart acalabrutinib at 100mg BD, for the 3rd occurrence restart acalabrutinib at 100mg once daily. If it is the 4th occurrence discontinue acalabrutinib.

Drug interactions: Avoid co-administration with strong CYP3A inhibitors and inducers. Adverse effect monitoring recommended with concomitant moderate CYP3A inhibitors. Caution with anti-thrombotic agents—may require additional monitoring. Warfarin or other vitamin K antagonists should not be given concomitantly with Acalabrutinib.

Undesirable effects: Monitor for bleeding, and manage appropriately. Monitor patients for signs and symptoms of infection, and treat as needed. Other malignancies have occurred in patients, including skin cancers and other carcinomas. Advise patients to use sun protection. Monitor for atrial fibrillation and atrial flutter, and manage as appropriate.

Surgery: Consider the benefit-risk of withholding acalabrutinib for at least 3 days pre and post-surgery.

Rituximab Administration

First Infusion:

Initial rate of 50mg/hr for the first 30 minutes. Can then be escalated in 50mg/hr increments every 30 minutes, to a maximum rate of 400mg/hr.

Subsequent infusions:

If first infusion is well tolerated, the following rapid schedule can be used: give 100ml over 30 minutes. Then give remaining 400ml over 60 minutes.

In patients receiving the rapid infusion schedule, record all infusional toxicity on the appropriate form.

In the event of a slower infusion rate being required, use the following schedule: Initial rate of 100mg/hr for the first 30 minutes. Can then be escalated in 100mg/hr increments every 30 minutes, to a maximum rate of 400mg/hr.

Fast infusion rate for patients who tolerate their first cycle – 20% of total dose given over 30 minutes and 80% of total dose over the following 60 minutes.

- Elderly patients or those with a high tumour burden may require a slower infusion rate.
- If a patient develops severe cytokine release syndrome the infusion should be interrupted immediately. On resolution, the infusion can be resumed at not more than one-half the previous rate. Mild to moderate infusion-related reactions usually respond to a reduction in infusion rate.
- **During infusion, the patient's vital signs (BP, pulse, respiration and temperature) should be monitored every 15 minutes for the first hour, and then if stable, hourly until infusion stops.**