MOGAMULIZUMAB

INDICATION

- Third line systemic therapy or beyond third line systemic therapy for patients with stage IIB to IVB Mycosis Fungoides (MF) [NICE TA754 / Blueteq required]
- Second line systemic therapy or beyond second line systemic therapy for patients with stage IVA to IVB Sezary Syndrome (SS) [NICE TA754 / Blueteq required]

TREATMENT INTENT

- Disease modification

DRUG REGIMEN

Cycle 1

Day	Drug	Dose	Route	Administration
1, 8, 15, 22	Mogamulizumab	1mg/kg	IV	In 250mL sodium chloride 0.9% over at least 60 minutes. Administer using a 0.22 micron (or equivalent) in-line filter

Cycle 2 onwards

Day	Drug	Dose	Route	Administration
1, 15	Mogamulizumab	1mg/kg	IV	In 250mL sodium chloride 0.9% over at least 60 minutes. Administer using a 0.22 micron (or equivalent) in-line filter

Cycle frequency

- 28 days

Number of cycles

- until disease progression or unacceptable toxicity (12 cycles will be set on aria)

ADDITIONAL DOSE INFORMATION

ADDITIONAL ADMINISTRATION INFORMATION

- Administer using a 0.22 micron (or equivalent) in-line filter

- Mogamulizumab should be administered within 2 days of the scheduled day. If the dose is missed by more than 2 days, the next dose should be administered as soon as possible, after which the dosing schedule should be resumed based on the new scheduled days.

- Pre-medications can be omitted from the 2nd Mogamulizumab dose if no infusion reaction(s) occurred after the 1st dose. If an infusion reactions occurs, administer pre-medication for subsequent infusions.

EXTRAVASATION RISK

Mogamulizumab – neutral

Supportive medications
(*Only include where indicated – delete/add items as required)

CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients listed in the Summary of Product Characteristics (SmPCs).

INVESTIGATIONS PRE-FIRST CYCLE

Investigation	Validity period
FBC	14 days (or at consultant discretion)
U&E, Calcium, Magnesium	14 days (or at consultant discretion)
LFTs	14 days (or at consultant discretion)
LDH, Glucose	14 days (or at consultant discretion)
TFTs	14 days (or at consultant discretion)

Other pre-treatment investigations:

- Hepatitis B and C serology
- Immunoglobulin levels
- ECG +/- ECHO - if clinically indicated.

INVESTIGATIONS PRE-CYCLE 2 ONWARDS

Investigation	Validity period
FBC	96 hours*
U&E	7 days*
LFTs	7 days*

Investigations to be conducted as per consultant request – if these are to be less frequent than stated it must be documented on the e-prescribing system as such.

DOSE MODIFICATIONS

Please discuss all dose reductions / delays with the relevant consultant before prescribing, if appropriate. The approach may be different depending on the clinical circumstances. All dose reductions to be discussed with the Consultant.

In principle any dose reduction due to adverse drug reactions **should not** be re-escalated in subsequent cycles without consultant approval. It is also a general rule for SACT that if a third dose reduction is necessary treatment should be stopped.

Dose modifications listed are for haematological, hepatic function, renal function and limited drug specific toxicities. Adjustments may be necessary for other toxicities as well.

Haematological toxicities on the day of treatment

Consider delaying the cycle if required – clinical decision.

Renal toxicities

No dose adjustment is recommended in patients with mild to severe renal impairment

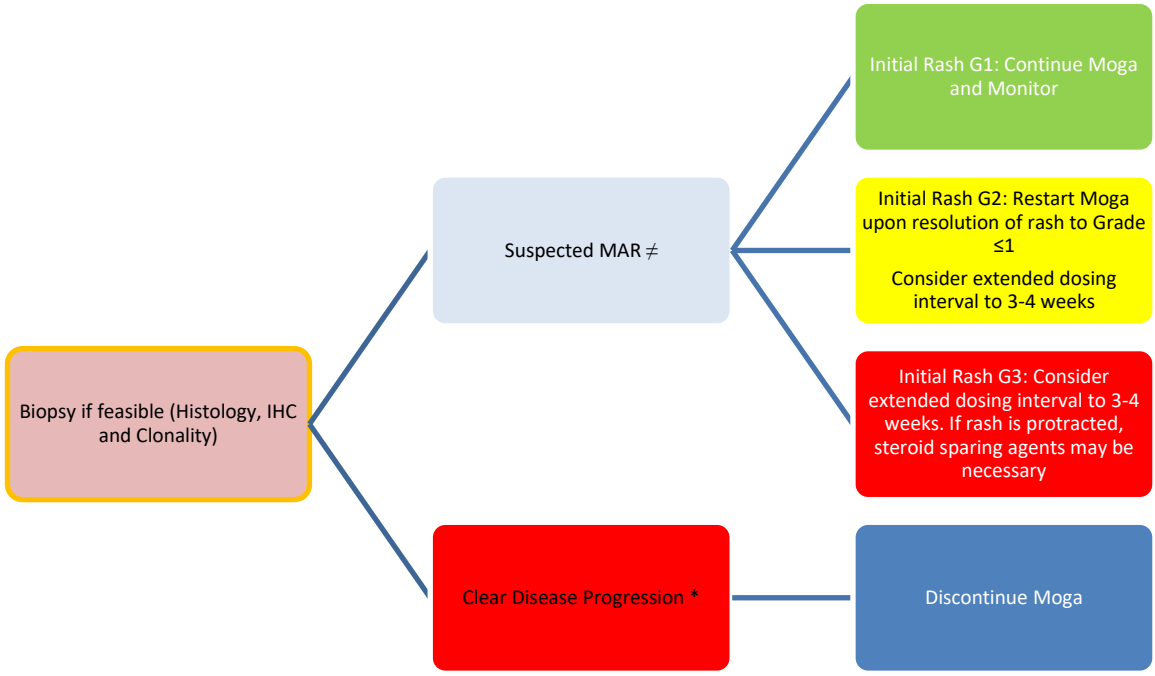
Hepatic Toxicities

No dose adjustment is recommended in patients with mild or moderate hepatic impairment. mogamulizumab has not been studied in patients with severe hepatic impairment

Other drug specific toxicities	
Dermatologic reactions	• In the event of a rash (drug related) with severity of Grade 2 or 3 (moderate or severe), treatment with Mogamulizumab must be interrupted and the rash should be treated appropriately until rash improves to Grade 1 or less (mild severity), at which time Mogamulizumab treatment may be resumed. • Mogamulizumab should be permanently discontinued for a life-threatening (Grade 4) rash.
Infusion related reactions	• The infusion of Mogamulizumab should be temporarily interrupted for mild to severe (Grades 1–3) infusion-related reactions and symptoms treated. The infusion rate should be reduced by at least 50% when re-starting the infusion after symptoms are resolved. If reaction recurs, discontinuing the infusion should be considered. • Mogamulizumab should be permanently discontinued for a life-threatening (Grade 4) infusion-related reaction and symptoms treated.
Autoimmune complications	• Interrupt or permanently discontinue Mogamulizumab as appropriate for suspected immune-mediated adverse reactions.
Tumour Lysis syndrome	• TLS has been observed in patients receiving Mogamulizumab, most frequently during the first month of treatment. Patients with rapidly proliferating tumour and high tumour burden are at risk of TLS. Patients should be monitored closely by appropriate laboratory and clinical tests for electrolyte status, hydration and renal function, particularly in the first month of treatment, and managed according to best medical practice. Management of TLS may include aggressive hydration, correction of electrolyte abnormalities, anti-hyperuricaemic therapy, and supportive care.

Dermatological reactions (Mogamulizumab associated Rash)

Grade 1	Grade 2	Grade 3
Macules/papules covering <10% BSA with or without symptoms	Macules/papules covering 10-30% BSA with or without symptoms. Limiting daily activities. Rash covering >30%BSA with or without mild	Macules/papules covering >30% BSA with moderate or severe symptoms
• Continue Moga • Treat with superpotent topical steroids (e.g Dermovate) • Antihistamine • If no improvement in rash. Consider referral to Derm for skin bipsy	• Consider referral to Derm for Biopsy • Consider delaying Moga while treating rash and a/w biopsy results • Treat with superpotent topical steroids (e.g Dermovate) • Consider oral steroids (Pred 0.5-1 mg/kg/day)	• Biopsy and referral to Derm • Delay Moga • Treat with superpotent topical steroids (e.g Dermovate) • Consider oral steroids (Pred 0.5-1 mg/kg/day)



***If Disease Progression**

- Histology may suggest a more predominant population of CD4+cells, Loss of CD7 expression and T cell gene rearrangments
- For discussion at specialist skin Lymphoma MDT

≠If Histology suggests MAR

- Histology can commonly include psoriasiform/spongiotic/lichenoid/CD8+ interface and granulomatous with mixed pattern
- CD8+ cells more predominant
- Normalised or inverted CD4+/CD8+ ratio
- CD7 expression retianed
- For discussion at specialist skin Lymphoma MDT

ADVERSE EFFECTS/REGIMEN SPECIFIC COMPLICATIONS

The adverse effects listed are not exhaustive. For full details consult product literature/ reference texts.

ADVERSE EFFECTS	
Common side effects	**Serious side effects**
Anaemia, neutropenia, leukopenia, thrombocytopenia, Hypothyroidism, Constipation, diarrhoea, nausea, stomatitis, Vomiting, colitis, Fatigue, peripheral oedema, pyrexia, infections, upper respiratory tract infections, Infusion related reaction, Derranged LFTs, decreased lymphocyte count, headache, drug eruption (including skin rash)	Hepatitis, Tumour lysis syndrome

SIGNIFICANT DRUG INTERACTIONS

No interaction studies have been performed. Consider theoretical interactions and monitor therapy when relevant. This may include concurrent use of thyroid medications (monitor thyroid function) or immunosuppressants (which may increase immunosuppressive effects).

Immunisation with live vaccines is not recommended during Mogamulizumab therapy.

REFERENCES

1. **Poteligeo 4mg/ml concentrate for solution for infusion summary of product characteristics. Available at: Poteligeo 4 mg/mL, Concentrate for Solution for Infusion - Summary of Product Characteristics (SmPC) - (emc) | 11174**
2. **Kim YH, Bagot M, Pinter-Brown L, et al. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomised, controlled phase 3 trial. Lancet Oncol. 2018;19(9):1192-1204.**

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1	**June 2026**		**Alexandra Pritchard (Pharmacist)**	**Dr Luke Bennett (Consultant)**

This SACT protocol has been developed by the Wessex Cancer Alliance SACT protocol development group. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
NHS Isle of Wight
Portsmouth Hospitals NHS Trust
Salisbury NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS Foundation Trust
University Hospitals of Dorset

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors which occur as a result of following these guidelines.

The regimen summary that follows is to facilitate building the protocols in the Aria prescribing system for those Trusts that utilise this system.

REGIMEN SUMMARY

Cycle 1 Day 1

1. Paracetamol 1000mg oral
   Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

2. Chlorphenamine 10mg IV
   Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

3. Mogamulizumab 1mg/kg in Sodium Chloride 0.9% 250ml intravenous over 60 minutes.
   Administration instructions: Administer using a 0.22 micron (or equivalent) in-line filter.

To take home medication

1. Allopurinol 300mg once a day oral for 7 days

2. Aciclovir 400mg twice a day oral for 28 days
   Administration instructions: Please supply 28 days or an original pack if appropriate

3. Co-trimoxazole 960mg once a day on Monday, Wednesday and Fridays oral for 28 days.
   Administration instructions: This may be given as 480mg twice a day on Mondays, Wednesdays and Fridays according to local practice. Please supply 28 days

4. Metoclopramide 10mg three times a day when required oral.
   Administration instructions: Take 10mg up to three times a day when required for the relief of nausea. Please supply 5 days or an original pack if appropriate.

Day 8, 15, 22

1. Paracetamol 1000mg oral
   Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

2. Chlorphenamine 10mg IV
   Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

3. Mogamulizumab 1mg/kg in Sodium Chloride 0.9% 250ml intravenous over 60 minutes.
   Administration instructions: Administer using a 0.22 micron (or equivalent) in-line filter.

Cycle 2 Onwards

Day 1

4. Paracetamol 1000mg oral
   Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

5. Chlorphenamine 10mg IV

Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

6. Mogamulizumab 1mg/kg in Sodium Chloride 0.9% 250ml intravenous over 60 minutes.
   Administration instructions: Administer using a 0.22 micron (or equivalent) in-line filter.

To take home medication

5. Aciclovir 400mg twice a day oral for 28 days
   Administration instructions: Please supply 28 days or an original pack if appropriate

6. Co-trimoxazole 960mg once a day on Monday, Wednesday and Fridays oral for 28 days.
   Administration instructions: This may be given as 480mg twice a day on Mondays, Wednesdays and Fridays according to local practice. Please supply 28 days

7. Metoclopramide 10mg three times a day when required oral.
   Administration instructions: Take 10mg up to three times a day when required for the relief of nausea. Please supply 5 days or an original pack if appropriate.

Day 15

1. Paracetamol 1000mg oral
   Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

2. Chlorphenamine 10mg IV
   Administration instructions: To be taken 30 minutes to 2 hours before mogamulizumab

3. Mogamulizumab 1mg/kg in Sodium Chloride 0.9% 250ml intravenous over 60 minutes.
   Administration instructions: Administer using a 0.22 micron (or equivalent) in-line filter.