PROTOCOL

The Clatterbridge Cancer Centre NHS Foundation Trust

Systemic Anti Cancer Therapy Protocol

Maintenance Subcutaneous (s/c) Rituximab B-Cell Lymphomas

PROTOCOL REF: MPHASCRITHA
(Version No. 2.0)

Approved for use in:

- Maintenance therapy for patients with previously untreated follicular or mantle cell lymphoma who have responded to induction therapy
- Maintenance therapy for patients with relapsed/refractory follicular lymphoma who have responded to induction therapy

Dosage:

Drug	Dose	Route	Frequency
Rituximab	**1400mg**	s/c injection	Every 8 weeks or 12 weeks (see below)

Follicular Lymphoma:

- Every 8 weeks for two years for previously untreated patients (i.e. 12 doses)
- Every 12 weeks for two years for relapsed/refractory patients (i.e. 8 doses)

Mantle Cell Lymphoma:

- Every 8 weeks until disease progression or unacceptable toxicity in newly diagnosed patients who were not fit enough for high dose chemotherapy and who responded to RCHOP based therapy
- Every 8 weeks for three years in newly diagnosed patients who are in remission after cytarabine based induction and high dose chemotherapy (i.e. 18 doses).

Administration:

- Subcutaneous rituximab is not licensed for maintenance treatment in mantle cell lymphoma
- S/C rituximab should be administered over at least 5 minutes
- All patients receiving s/c rituximab should have tolerated a full dose of IV rituximab prior to first s/c rituximab administration
- The first dose of s/c rituximab should be given two months after the last dose of induction chemotherapy for previously untreated patients and three months after the last dose of induction chemotherapy for relapsed/refractory patients
- Patients should be observed for at least 15 minutes following administration
- S/C rituximab will not be made in an aseptic suite but drawn up from the vial on the day ward.
- Due to the long retention time of rituximab in B cell depleted patients, women of childbearing potential must employ effective contraceptive methods during and for 12 months after treatment with rituximab.

Emetogenic risk:

Not emetogenic.

Supportive treatments:

Pre-medication:

- Paracetamol oral 1g
- Chlorphenamine oral 4mg

Extravasation risk:

Non-vesicant

Refer to the CCC policy for the ‘Prevention and Management of Extravasation Injuries’

Interactions:

No known interactions

Treatment schedule:

Day	Drug	Dose	Route	Diluent and rate
1	**Paracetamol**	**1g**	**PO**	30 mins before rituximab
	Chlorphenamine	**4mg**	**PO**	30 mins before rituximab
	Rituximab	**1400mg**	**s/c**	Over 5 minutes. No diluent required

Main toxicities:

Thrombocytopenia, neutropenia, anaemia, nausea, vomiting, diarrhoea, progressive multifocal leukoencephalopathy, local skin reaction, cardiac disorders, infections.

Investigations and treatment plan:

	Pre	Cycle 1	Cycle 2	Cycle 3	Ongoing
Informed Consent	X				(Patients will already have been consented for rituximab prior to induction chemotherapy)
Clinical Assessment	X	X	X	X	As clinically indicated or at the end of treatment
FBC	X	X	X	X	Every cycle
U&E & LFTs	X	X	X	X	Every Cycle
CrCl (Cockcroft and Gault)	X	X	X	X	Every cycle
Blood pressure measurement	X				Repeat if clinically indicated
Respiratory Rate					If clinically indicated
Weight recorded	X				Repeat if clinically indicated
Blood glucose	X				Repeat if clinically indicated

Dose Modifications and Toxicity Management:

Haematological toxicity:

Proceed on day 1 if-

ANC ≥ 1.5 x 10^9/L	Plt ≥ 75 x 10^9/L	WCC ≤ 25 x 10^9/L

If case of cytopenias delay s/c rituximab and repeat FBC after a week. If WCC is greater than 25 x 10^9/L delay s/c rituximab and repeat FBC after a week.

These haematological guidelines assume that patients are well with good performance status, that other acute toxicities have resolved and the patient has not had a previous episode of neutropenic sepsis.

Non- Haematological toxicity:

Dosing in renal and hepatic impairment:

Renal	No dose reduction required

Hepatic	No dose reduction required

References:

1. https://www.medicines.org.uk/emc MabThera 1400mg. Accessed 11/04/23. Revised 20/09/2021.
2. NICE Guideline 52. Non-Hodgkin's lymphoma: diagnosis and management. 20th July 2016.
3. NICE TA 137. Rituximab for the treatment of relapsed or refractory stage III or IV follicular non-Hodgkin's lymphoma. 27th February 2008
4. NICE TA 226. Rituximab for the first-line maintenance treatment of follicular non-Hodgkin's lymphoma. 22nd June 2011

Circulation/Dissemination

Date added into Q-Pulse	31st August 2023
Date document posted on the Intranet	N/A

Version History

		Author name and designation	Summary of main changes
		Aileen McCaughey HO Pharmacist	New protocol
May 2023	2.0	**Aileen McCaughey HO Pharmacist**	updated template and included information concerning mantle cell lymphoma