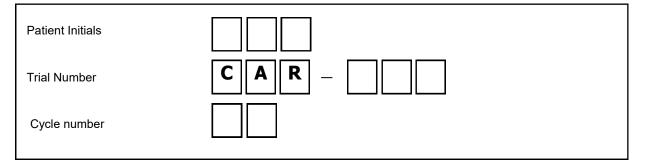


Carfilzomib/Cyclophosphamide/Dexamethasone with maintenance carfilzomib in untreated transplant-eligible patients with symptomatic MM to evaluate the benefit of upfront ASCT

Maintenance Form



(This form has 7 pages including cover sheet)

Please send forms to:

Cardamon Trial Coordinator CR UK & UCL Cancer Trials Centre 90 Tottenham Court Road London W1T 4TJ

General enquires: **020 7679 9860** Randomisations: **020 7679 9860** between 9.00am and 5.00pm Fax: **020 7679 9861** E-mail: <u>ctc.cardamon@ucl.ac.uk</u>



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Additional instructions for completing forms

Page 2 of 7

The Maintenance Form collects details of the patient's maintenance treatment; in the absence of PD, a patient may receive up to 18 cycles of maintenance.

Specific Fields

- Cycle number—please take cycle number from the start of maintenance not all treatment i.e. for patients on the consolidation arm the first cycle will be cycle 1 not cycle 9
- Omission/Reduction/Delay: Please do not leave these blank, if there were no omissions, reductions or delays please ensure that you have entered "0" in each box. A discrepancy will be raised for all fields left blank
- Please ensure that you are using the correct units (i.e. haemoglobin in g/dL). If your local report uses different units please convert these before entering them on the form.
- Response assessments should be only be carried out by the principal investigator or coinvestigator
- The response assessment section for cycle 1 should be left blank, however, paraprotein, serum free light chain and urinary Bence Jones protein levels must be recorded if available
- Disease response assessment should be based on blood and/or urine tests performed at the start of each cycle (day 1, ± 7 days), this must be assessed by the PI or delegated investigator (see appendix 3 of protocol)
- Disease response for each cycle must be assessed according to the paraprotein/BJP/SFLC results of tests performed at the beginning of the subsequent cycle, for example, response to cycle 1 would be assessed on cycle 2, day 1, and documented on the cycle 2 CRF
- At the end of maintenance, disease assessment must be performed within 14 days of the last treatment. This should be reported on the maintenance summary CRF
- Please ensure a progression/relapse form is submitted for patients with progressive disease

Completing forms

- Ensure all entries are clear, legible and written in black ink
- Avoid the use of abbreviations and acronyms
- Do not leave any fields blank. In case of missing data
 - ND (not done) if a test has not been performed or a measure not taken. If applicable state the reason
 - NA (not applicable) if a measure is not applicable
 - NK (not known) if data is unknown. This should only be used once every effort to obtain the data has been exhausted.
- CRFs may only be completed by an appropriately qualified individual delegated as responsible by the PI on the site delegation log
- CRF Footer section
 - The "completed by" Name should be legible
 - Each CRF should be signed and dated by the person completing the form
 - Do not complete the UCL CTC Use only section
- The CRF should be sent/faxed to the Cancer Trials Centre (CTC) with a copy retained at the Site (ensure when photocopying the page that the copy is added to the CRF booklet in the same place where the original was stored)



R



Patient

Initials

Maintenance Form	Ma	inte	nanc	e Fo	rm
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Page 3 of 7

Haematology

Test	Day 1 result	NCS?	Day 8 result	NCS?	Day 15 result	NCS?
Date (dd/mm/yyyy)						
Haemoglobin (g/dL)						
WBC (x10 ⁹ /L)						
Platelets (x 10 ⁹ /L)						
Neutrophils (x10 ⁹ /L)						
Lymphocytes (x 10 ⁹ /L)						
Blood pressure (mmHg) ^{1,2}						

Patients must have FBC and biochemistry tests prior to days 1, 8, & 15 of each cycle

Trial

Number

- The validity period is 48 hours for FBC and 72 hours for biochemistry. Blood pressure may be measured on day of treatment
- If a result is out of range as per CTCAE v4.03 and it is Not Clinically Significant, please tick the "NCS?" column next to it
- If a result is clinically significant, then add it to the Adverse Event form

¹To be completed if hypertensive blood pressure readings are not clinically significant

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Please provide an explanation if an incident of hypertension (>=120/80) is not clinically significant, e.g. white coat syndrome:

Day	1:
Day	8:
Dav	15:

²To be completed only if patient experiences grade 3 hypertension

If the patient experiences grade 3 hypertension (systolic BP ≥160 mmHg or diastolic BP ≥100 mmHg), treatment with carfilzomib can be continued without being held or reduced if the treating clinician considers the event:

- Sporadic
- Not medically significant
- Where there is additional information to support carfilzomib's uninterrupted use (please specify):

The investigator should confirm this by completing the below:

Investigator name (print):								
Investigator signature:								
Date signed:	D	D	М	М	Y	Y	Y	Y

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Initials:



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Trial

Number



Patient

Initials

Maintenance Form Page 4 of 7 Cycle No: If a result is out of range as per CTCAE v4.03 and it is Not Clinically Significant, please tick the "NCS?" column next to it **Biochemistry** If a result is out of range as per CTCAE v4.03 and/or clinically significant, then add it to the Adverse Event form NCS? NCS? Day 15 result NCS? Test Day 1 result Day 8 result Date (dd/mm/yyyy) Calcium (corrected) (mmol/L) Potassium (mmol/L) Phosphate (mmol/L) Urea (mmol/L) Sodium (mmol/L) Serum Urate (µmol/L) Creatinine (µmol/L) Creatinine clearance (ml/min) if clinically indicated, otherwise enter ND Albumin (g/L) Bilirubin (µmol/L) Alkaline Phosphatase (IU/L) Aspartate Transaminase (IU/L) Alanine Transaminase (IU/L) **Adverse events** 1 = Yes (please ensure adverse event form is submitted) Did the patient experience any adverse events? 2 = No Pregnancy test (for females of child bearing potential only) 1 = Negative Result: 2 = Positive Date of pregnancy test 3 = Not applicable

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Cardamon

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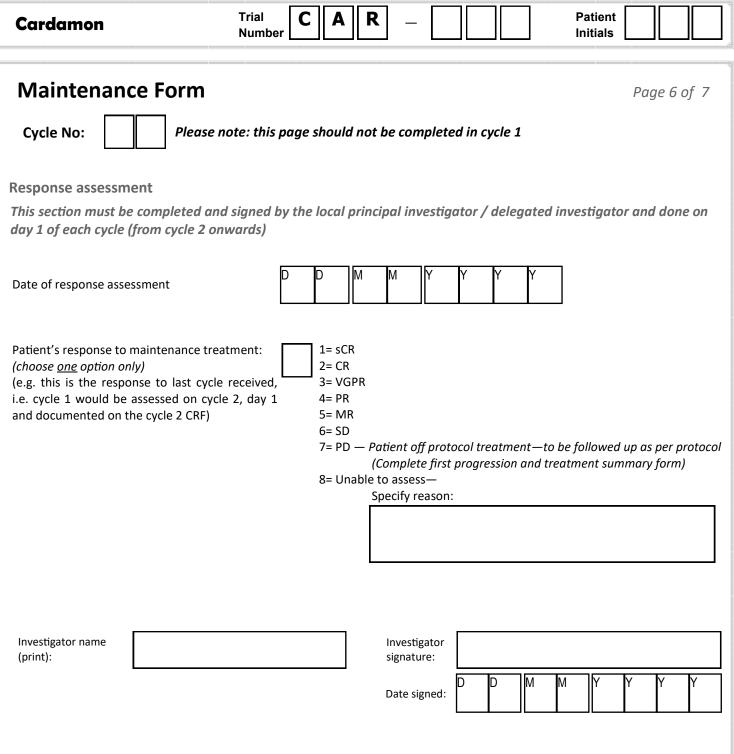
Maintenance Form	Page 5 of 7
Cycle No:	
Efficacy assessments	
Date of test D D M M Y Y Y Y	
Please complete this Paraprotein expression 1= Single paraprotein expressed section for all myeloma (choose one option only) 2= Light chain only patients: 1= Single paraprotein expressed Please complete this 2= Light chain only Biclonal 4= Non-secretory	
Paraprotein type key: 1 = IgG, 2 = IgA, 3 = IgM, 4 = IgD	
Specify paraprotein type: Serum paraprotein 4= Present, please complete result 5= Too faint to quantify 6= Absent 7= Not Done 7= Not Done	(g/L)
Specify paraprotein type: Serum paraprotein 4= Present, please complete result (If biclonal) 5= Too faint to quantify 6= Absent 7= Not Done 7= Not Done	(g/L)
Serum free light chain: Kappa (mg/L) • OR Tick if not done	
Serum free light chain: Lambda (mg/L) • OR Tick if not done	
Serum free light chain Kappa/Lambda ratio:	
Urinary light chain measurement	
1= Present, quantifiable Please complete 24h BJP result (in g/24h): Light chain type 2= Too faint to quantify (24h BJP only) (please choose (please choose 3= Absent one only): 4= Not Done 5= Present, not formally quantified (if unable to perform 24h BJP)	1 = Kappa 2 = Lambda 3 = N/A
Immunofixation (only required to confirm CR/sCR)	
Immunofixation Serum 1= Positive 2= Negative Date of test 3= Not done]
Immunofixation Urine 1= Positive 2= Negative Date of test 3= Not done]
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CRF Template V1– 19 Oct 2010 Modified for **Cardamon** on 09 Sep 2020, v5.0. Date form entered:



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- Disease response assessment should be based on blood and/or urine tests performed at the start of each cycle (day 1, ± 7 days), this must be assessed by the PI or delegated investigator (see appendix 3 of protocol)
- Disease response for each cycle must be assessed according to the paraprotein/BJP/SFLC results of tests performed at the beginning of the subsequent cycle, for example, response to cycle 1 would be assessed on cycle 2, day 1, and documented on the cycle 2 CRF.
- At the end of maintenance, disease assessment must be performed within 14 days of the last treatment. This should be reported on the maintenance summary CRF

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Cardaı	mon	Trial Number	A R –		Patient Initials			
Main	tenance Form				Page 7 of 7			
Cycle N	No:							
Date cy	cle started: D D	MMY	Y Y					
Actual I	BSA •	m ² Patients	with a BSA >2.2m ² should	receive dose based or	$n BSA of 2.2m^2$			
BSA use calculat		m ² The prev	ous cycle BSA should be u	sed here if there has b	een <20% change in BSA			
	Did the patient receive dexamethasone (10mg) on the day of ad- ministration and day after each dosing in line with the protocol? 1 = Yes 2 = No—please specify reason below:							
	Any delays reductions	or omissions during th	is cycle of maintenance	1 = Yes 2 = No	Please complete all boxes in table below (if no delay / reduction / omission, please enter = 0)			
	Drug Day Dose given Omission Reduction Delay (see codes below) (see codes below) (see codes below)							
	Carfilzomib (56mg/m ² , except cycle		mg					
	1 day 1 when patients should receive 20mg/ m ²)		mg					
0=No delay/reduction/omission, 1=Neurotoxicity, 2=Hepatotoxicity, 3=Cardiotoxicity 4=Haematological Toxicity, 5=Infusion-related toxicity 6=Pancreatitis 7=Patient Choice, 8=Clinician Choice, 9=Administrative, 10=Tumour Flare reaction, 11=Tumour Lysis syndrome, 12=Other (specify below), 13=Protocol approved reduction/omission								
Name of pers	son completing form:	Signature of perso	n completing form:	Date completed:	he he he he l			
The site PI o	r delegated investigator must si	ian to confirm that informati	on within the CRF is accurat		M Y Y Y Y			
	The site PI or delegated investigator must sign to confirm that information within the CRF is accurate Investigator name: Investigator signature: Date completed:							
				D D M	M Y Y Y Y			
aso roturn t	to: Cardamon Trial Coordi		cer Trials Control 00 To	ttenham Court Boa	d London WIT IT			

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