7.3 Treatment

Agent	Cycle(s) [1]	Day(s)	Dose	Route
Isatuximab	1	1, 8, 15, 22	20 mg/kg	IV
Isatuximab [3]	2 – 24	1, 15	20 mg/kg	IV

[1] Note: One cycle = 28 days
[2] Patient will continue on therapy until completion of 24 Cycles of therapy or until one of the criteria in Section 7.4 is met, whichever occurs first.
[3] For Cycles 2-24, C1D1 weight should be used for dosing, unless there is a > 10% change in weight.

7.4 Criteria for Removal from Protocol Treatment

a. Hematologic progression of disease or symptomatic deterioration (as defined in Sections 10.2 and 10.7). Organ progression (as defined in Section 10.4) in the absence of hematologic progression does not necessitate removal from treatment.

b. Unacceptable toxicity.

c. Treatment delay >14 days, unless approved by the Study Chair, as indicated in Section 8.3b. Treatment must not be delayed for any reason > 42 days. For treatment delay of >14 days, see Section 8.3b.

d. The patients may withdraw from the study at any time for any reason.

e. Treatment completed as planned.

f. Development of overt myeloma.

7.5 Discontinuation of Treatment

All reasons for discontinuation of treatment must be documented in the Off Treatment Notice.

7.6 Follow-Up Period

All patients will be followed until 4 years after registration or death, whichever occurs first.

8.0 TOXICITIES TO BE MONITORED AND DOSE MODIFICATIONS

8.1 NCI Common Terminology Criteria for Adverse Events

This study will utilize the CTCAE (NCI Common Terminology Criteria for Adverse Events) Version 4.0 for toxicity and Serious Adverse Event reporting. A copy of the CTCAE Version 4.0 can be downloaded from the CTEP home page (http://ctep.cancer.gov). All appropriate treatment areas should have access to a copy of the CTCAE Version 4.0.

8.2 Supportive Care

Blood product transfusion, intravenous albumin, intravenous fluids and electrolyte replacement, antiemetics, antidiarrheal medication, g-csf, anti- hypersensitivity medications are all allowable as per institutional standards and Section 3 of the protocol.

SWOG Authorized Document