

Regimen Reference Order – CUTA – nivolumab (Adjuvant)

ARIA: CUTA – [nivolumab q 14 days (ADJ)]

CUTA – [nivolumab q 28 days (ADJ)]

Planned Course: Every 14 days for one year (26 cycles total)

OR

Every 28 days for one year (13 cycles total)

Indication for Use: Melanoma Advanced, Resected, Adjuvant

Drug Alert: Immune Checkpoint Inhibitor

CVAD: At Provider's Discretion

Proceed with treatment if:

- ANC equal to or greater than $1.5 \times 10^9/L$ AND Platelets equal to or greater than $50 \times 10^9/L$
- AST/ALT less than 3 times upper limit of normal
- Total bilirubin less than 1.5 times upper limit normal
- Creatinine clearance greater than 30 mL/min
- ❖ Contact Physician if parameters not met

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – CUTA – nivolumab (Adjuvant)

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
nivolumab	3 mg/kg (every 14 days)	IV in normal saline 100 mL over 30 minutes Use 0.2 or 0.22 micron filter
	OR	<i>Concentration dependent drug: Pharmacy will adjust diluent volume to ensure drug stability</i>
	6 mg/kg (every 28 days)	IV in normal saline 100 mL over 30 minutes Use 0.2 or 0.22 micron filter
		<i>Concentration dependent drug: Pharmacy will adjust diluent volume to ensure drug stability</i>

Maximum nivolumab dose is 240 mg (every 14 days) OR 480 mg (every 28 days)

All doses will be automatically rounded that fall within the DSG Approved Dose Bands. See CUTA DSG – Dose Banding document for more information

Flush after each medication:

- 50 mL over 6 minutes (500 mL/hr)

In the event of an infusion-related hypersensitivity reaction, refer to the 'Hypersensitivity Reaction Standing Order'

REQUIRED MONITORING

- CBC, serum creatinine, urea, electrolytes, AST, ALT, total and direct bilirubin and glucose prior to each dose as per Physician Orders
- TSH monthly
- Medical oncologist or designate (i.e. family practitioner in oncology) must assess patient for immune-mediated adverse reactions prior to each cycle
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O₂ saturation) at baseline and as clinically indicated
- No observation period is required
- Patient can be discharged from treatment room if stable whether they had a reaction or not

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
Not Applicable		

DISCHARGE INSTRUCTIONS

- Confirm that patient has received the CCMB Immune Checkpoint Inhibitor Medical Alert wallet card
- Reinforce to patient the immune-mediated adverse reactions and importance of reporting immediately
 - For severe symptoms, the patient should be instructed to go to the nearest emergency room. Oncologist on call should be contacted

ADDITIONAL INFORMATION

- nivolumab is an Immune Checkpoint Inhibitor. Consult with oncologist for immune-mediated adverse reactions; corticosteroids are often indicated