Regimen Reference Order – GENU – pembrolizumab

ARIA: GENU - [pembro q 21 days (phase 1)]
GENU - [pembro q 42 days (phase 2)]

Planned Course: **Every 21 days for 8 cycles, followed by every 42 days until disease progression or unacceptable toxicity or up to a maximum of 2 years of therapy**

Indication for Use: **Urothelial Cancer Metastatic**

Drug Alert: Immune Checkpoint Inhibitor

CVAD: At Provider's Discretion

Proceed with treatment if:

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

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – GENU – pembrolizumab

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Phase 1 pembrolizumab every 21 days (Cycles 1 to 8)		
pembrolizumab	2 mg/kg	IV in normal saline 50 mL over 30 minutes *Use 0.2 or 0.22 micron filter*
Phase 2 starts three weeks after Cycle 8, Day 1 of Phase 1		
Phase 2 pembrolizumab every 42 days (Cycles 1 to 14)		
pembrolizumab	4 mg/kg	IV in normal saline 100 mL over 30 minutes *Use 0.2 or 0.22 micron filter*

Maximum pembrolizumab dose is 200 mg (every 21 days) or 400 mg (every 42 days)
All doses will be automatically rounded that fall within CCMB Approved Dose Bands. See Dose Banding document for more information

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

REQUIRED MONITORING

All Cycles

- CBC, creatinine, AST, ALT, total bilirubin, albumin, glucose, sodium, potassium, calcium and magnesium as per Physician Orders
- TSH every 6 weeks as per Physician Orders
- 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 O_2 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
None required		

DISCHARGE INSTRUCTIONS

- Patients should be instructed to contact their cancer team immediately if symptoms of hypersensitivity reactions occur after discharge
- 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

- pembrolizumab is an Immune Checkpoint Inhibitor. Consult with oncologist for immune-mediated adverse reactions; corticosteroids are often indicated
- **ARIA ordering**: Upon completion of 8 cycles of **GENU - [pembro q21 days (phase 1)]**, patients should be started on treatment with **GENU - [pembro q42 days (phase 2)]**
    - **GENU - [pembro q42 days (phase 2)]** regimen starts 21 days after Cycle 8, Day 1 of **GENU - [pembro q21 days (phase 1)]**