Regimen Reference Order – CUTA – tebentafusp (Outpatient)

ARIA: CUTA - [tebentafusp (Outpatient)]

Planned Course: **Once weekly until disease progression or unacceptable toxicity (1 cycle = 21 days)**

Note: First cycle of tebentafusp is administered in hospital. Refer to RRO CUTA- [tebentafusp (Cycle 1 INPATIENT)]

Indication for Use: **Uveal Melanoma**

Drug Alert: T-Cell Engager

CVAD: At Provider's Discretion

Proceed with treatment if:

Day 1

- ***ANC equal to or greater than 1 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 upper limit of normal***
- ***Total bilirubin equal to or less than 1.5 times the upper limit of normal***
- ***Systolic blood pressure greater than 100 mmHg***

Days 8 and 15

- ***AST/ALT equal to or less than 3 times upper limit of normal***
- ***Total bilirubin equal to or less than 1.5 times the upper limit of normal***
- ***Systolic blood pressure greater than 100 mmHg***
  - ❖ **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – CUTA – tebentafusp (Outpatient)

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Cycle 1		
Patients will be admitted to hospital for Cycle 1 tebentafusp (Days 1, 8 and 15). Follow inpatient orders		

Cycle 2 and Onwards - Outpatient Note: In ARIA, Cycle 1 of CUTA- [tebentafusp (Outpatient)] represents second cycle of treatment since Cycle 1 is administered in hospital		
Days 1, 8 and 15		
tebentafusp	68 mcg	IV in normal saline 100 mL over 15 minutes *Use 0.2 to 0.22 micron filter*

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

REQUIRED MONITORING (Outpatient)

Outpatient Cycle 2 and Onwards

All Doses

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) prior to tebentafusp administration and as clinically indicated
- Observe patient for 30 minutes after every tebentafusp infusion. Full vital signs prior to discharge
- Monitor for signs and symptoms of Cytokine Release Syndrome (CRS). Serious adverse events that may be associated with CRS include: pyrexia, headache, nausea, asthenia, hypotension, and elevations in serum aminotransferases and bilirubin
- Skin assessment for rash

Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders
- Lipase as per Physician Orders

Days 8 and 15

- Liver enzymes as per Physician Orders

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
None required		

DISCHARGE INSTRUCTIONS

- Patient to notify clinic if they develop fever, chills, nausea, vomiting, rash and/or headache

ADDITIONAL INFORMATION

- T-Cell Engagers can cause Cytokine Release Syndrome (CRS) and/or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). ICANS is uncommon with tebentafusp
- Cycle 1 of tebentafusp is restricted to inpatient hospital administration (ramp-up dosing) due to the highest risk of CRS during the first cycle of tebentafusp. Patients should be monitored for CRS throughout therapy
- tebentafusp can cause elevations in lipase and liver enzymes
- tebentafusp can cause skin rash
- tebentafusp preparations contain human albumin (blood product)
- Site restrictions are in place for tebentafusp. tebentafusp must be administered at CCMB MacCharles in Winnipeg