Regimen Reference Order – MYEL – teclistamab

ARIA: MYEL - [teclistamab]

Planned Course: **Until disease progression or unacceptable toxicity (28-day cycle)**

Note: First three doses are administered in hospital

Indication for Use: **Multiple Myeloma, Relapsed/Refractory**

CVAD: At Provider's Discretion

Proceed with treatment if:

- ***ANC equal to or greater than 0.5 x 10^9/L AND Platelets equal to or greater than 50 x 10^9/L***
- ***Hemoglobin equal to or greater than 80 g/L***
  - ❖ **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – MYEL – teclistamab

Drug	Dose	CCMB Administration Guideline
Cycle 1		
Patients will be admitted to hospital for treatment with the first three doses of teclistamab and for 48 hours after each dose, as follows: • Step-up Dose 1 (Day 1) • Step-up Dose 2 (Day 4) • First treatment dose (Day 7)		
Day 1 - Step-up Dose 1 (inpatient administration). Follow inpatient orders		
cetirizine	20 mg	Orally **1 to 3 hours** prior to teclistamab
acetaminophen	975 mg	Orally **1 to 3 hours** prior to teclistamab
dexamethasone	16 mg	IV in normal saline 50 mL over 15 minutes **1 to 3 hours** prior to teclistamab **Nursing Alert: teclistamab starts at least **1 hour after completion** of dexamethasone infusion*
Wait at least 1 hour after completion of IV pre-medication(s) before starting teclistamab		
teclistamab	0.06 mg/kg	**Subcutaneous:** Administer into abdomen (preferred injection site) Use 25G needle **Pharmacy Alert: Use 10 mg/mL concentration of teclistamab for "Step-up Dose 1"*

Day 4 - Step-up Dose 2 (inpatient administration). Follow inpatient orders		
cetirizine	20 mg	Orally **1 to 3 hours** prior to teclistamab
acetaminophen	975 mg	Orally **1 to 3 hours** prior to teclistamab
dexamethasone	16 mg	IV in normal saline 50 mL over 15 minutes **1 to 3 hours** prior to teclistamab **Nursing Alert: teclistamab starts at least **1 hour after completion** of dexamethasone infusion*
Wait at least 1 hour after completion of IV pre-medication(s) before starting teclistamab		
teclistamab*	0.3 mg/kg	**Subcutaneous:** into abdomen (preferred injection site) Use 25G needle **Nursing Alert: Each injection volume should not exceed 2 mL. Divide doses requiring greater than 2 mL equally into multiple syringes. If multiple injections are required, injections should be at least 2 cm apart* **Pharmacy Alert: Use 10 mg/mL concentration of teclistamab for "Step-up Dose 2"*
Day 7 – First treatment dose (inpatient administration). Follow inpatient orders		
cetirizine	20 mg	Orally **1 to 3 hours** prior to teclistamab
acetaminophen	975 mg	Orally **1 to 3 hours** prior to teclistamab
dexamethasone	16 mg	IV in normal saline 50 mL over 15 minutes **1 to 3 hours** prior to teclistamab **Nursing Alert: teclistamab starts at least **1 hour after completion** of dexamethasone infusion*
Wait at least 1 hour after completion of IV pre-medication(s) before starting teclistamab		
teclistamab*	1.5 mg/kg	**Subcutaneous:** Administer into abdomen (preferred injection site) Use 25G needle **Nursing Alert: Each injection volume should not exceed 2 mL. Divide doses requiring greater than 2 mL equally into multiple syringes. If multiple injections are required, injections should be at least 2 cm apart* **Pharmacy Alert: Use 90 mg/mL concentration of teclistamab for treatment dose*
Day 14 (First potential dose at CCMB for outpatient administration)		
Premedication with cetirizine, acetaminophen and dexamethasone is required for patients who: • Repeat doses within the step-up dosing schedule following a dose delay AND/OR • Experience CRS following the prior dose of teclistamab ARIA orders for cetirizine, acetaminophen and dexamethasone will be discontinued for patients who do not require premedication. Administer premedication if agents not discontinued by treating physician		
cetirizine	20 mg	cetirizine only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab
acetaminophen	975 mg	acetaminophen only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab

dexamethasone	16 mg	dexamethasone only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab
teclistamab*	1.5 mg/kg	**Subcutaneous:** Administer into abdomen (preferred injection site) Use 25G needle **Nursing Alert: Each injection volume should not exceed 2 mL. Divide doses requiring greater than 2 mL equally into multiple syringes. If multiple injections are required, injections should be at least 2 cm apart* **Pharmacy Alert: Use 90 mg/mL concentration of teclistamab for treatment dose*

Day 21

Premedication with cetirizine, acetaminophen and dexamethasone is required for patients who:

- Repeat doses within the step-up dosing schedule following a dose delay AND/OR
- Experience CRS following the prior dose of teclistamab

ARIA orders for cetirizine, acetaminophen and dexamethasone will be discontinued for patients who do not require premedication. Administer premedication if agents not discontinued by treating physician

cetirizine	20 mg	cetirizine only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab
acetaminophen	975 mg	acetaminophen only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab
dexamethasone	16 mg	dexamethasone only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab
teclistamab*	1.5 mg/kg	**Subcutaneous:** Administer into abdomen (preferred injection site) Use 25G needle **Nursing Alert: Each injection volume should not exceed 2 mL. Divide doses requiring greater than 2 mL equally into multiple syringes. If multiple injections are required, injections should be at least 2 cm apart* **Pharmacy Alert: Use 90 mg/mL concentration of teclistamab for treatment dose*

Cycle 2 and Onwards

Premedication with cetirizine, acetaminophen and dexamethasone is required for patients who:

- Repeat doses within the step-up dosing schedule following a dose delay AND/OR
- Experience CRS following the prior dose of teclistamab

ARIA orders for cetirizine, acetaminophen and dexamethasone will be discontinued for patients who do not require premedication. Administer premedication if agents not discontinued by treating physician

cetirizine	20 mg	cetirizine only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab
acetaminophen	975 mg	acetaminophen only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab
dexamethasone	16 mg	dexamethasone only to be given ***at physician's discretion*** Orally **1 hour** prior to teclistamab

teclistamab*	1.5 mg/kg	**Subcutaneous:** Administer into abdomen (preferred injection site) on **Days 1, 8, 15 and 22** Use 25G needle **Nursing Alert: Each injection volume should not exceed 2 mL. Divide doses requiring greater than 2 mL equally into multiple syringes. If multiple injections are required, injections should be at least 2 cm apart* **Pharmacy Alert: Use 90 mg/mL concentration of teclistamab for treatment dose*

*The dose of teclistamab may be delayed *as per the Myeloma DSG or Leukemia/BMT (L/BMT) Physician's discretion* (usual criteria for dose delay: ANC less than 0.5 x 10^9/L; platelets less than 25 x 10^9/L or if patient is bleeding; signs or symptoms of infection; signs or symptoms of CRS or ICANS).

Following a dose delay, teclistamab dose schedule may require modification. If dosing of teclistamab is interrupted for greater than 4 weeks, dosing re-initiation should be discussed with Janssen. Refer to Pre-Approved Access (PAA) Named Patient Program (NPP) TREATMENT GUILDELINES for teclistamab for Treatment Physician Use document (page 10) for recommendations after a dose delay.

Any non-hematologic toxicity other than CRS or ICAN must resolve to equal to or less than grade 1 or baseline with no evidence of active bacterial, viral, or fungal infection before proceeding to the next dose. CRS and ICANS must fully resolve before proceeding to the next dose.

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

REQUIRED MONITORING

Baseline

- Hepatitis B serology

Throughout therapy

- 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
- Monitor for signs and symptoms of neurotoxicity. Symptoms may include: trembling, disturbance or loss of movement of parts of the body, speech or coordination disorders, apraxia, dizziness, confusion, disorientation, reversible seizures, encephalopathy, somnolence and agitation
- Hypogammaglobulinemia has been reported with teclistamab. Monitor immune globulin levels during treatment per physician orders

Cycle 1 - Follow inpatient bloodwork orders on Days 1 to 14

Cycle 1
Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- Serum Protein Electrophoresis (SPEP)/Free Light Chain Ratio (FLCH) (response assessment)

Day 14 and 21

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

Cycle 2
Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- Serum Protein Electrophoresis (SPEP)/Free Light Chain Ratio (FLCH) (response assessment)

Day 8, 15 and 22

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

Cycle 3 and Onwards
Day 1
- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- Serum Protein Electrophoresis (SPEP)/Free Light Chain Ratio (FLCH) (response assessment)

Day 15
- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
valACYclovir	500 mg	Orally once daily
sulfamethoxazole-trimethoprim	800/160 mg	Orally once daily on Mondays, Wednesdays and Fridays
levetiracetam	500 mg	Orally twice daily *Note: levetiracetam will only be prescribed for select patients if they have experienced ICANS*
metoclopramide	10 – 20 mg	Orally every 4 hours as needed for nausea and vomiting

DISCHARGE INSTRUCTIONS

- Patients should be instructed to contact their cancer team immediately if symptoms of hypersensitivity reactions occur after discharge
- Advise patient to immediately report any symptoms of cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity (ICANS)
- Patient should be instructed to notify about any signs or symptoms of infection or unusual bruising or bleeding
- Remind patient to take recommended support medications at home

ADDITIONAL INFORMATION

- teclistamab has been associated with hypogammaglobulinema
    - Due to potential for reactions to IVIG infusions, it is recommended to avoid IVIG for a minimum of 48 hours after each step-up dose and the first treatment dose of teclistamab
- teclistamab can cause hepatotoxicity
- Administration site restrictions are in place for teclistamab. teclistamab must be administered at CCMB MacCharles in Winnipeg