Drug Monograph

Drug Name | Mechanism of Action and Pharmacokinetics | Indications and Status | Adverse Effects | Dosing | Administration Guidelines | Special Precautions | Interactions | Recommended Clinical Monitoring | Supplementary Public Funding | References | Disclaimer

A - Drug Name

teclistamab

COMMON TRADE NAME(S): Tecvayli®

back to top

B - Mechanism of Action and Pharmacokinetics

Teclistamab is an IgG4-PAA bispecific, T-cell engaging antibody that targets both the CD3 receptor expressed on the surface of T-cells and B-cell maturation antigen (BCMA) expressed on multiple myeloma cells. Teclistamab redirects CD3+ T-cells to BCMA-expressing myeloma cells and induces T-cell activation, the release of various proinflammatory cytokines, and subsequent lysis and death of BCMA-expressing cells.

Absorption	Approximately dose-proportional pharmacokinetics	
	Bioavailability	72% (subcutaneous)
	Time to reach steady state	~13th weekly treatment dose (90% of steady state achieved after 12 weekly treatment doses)
Distribution	Cross blood brain barrier?	Unknown
	PPB	Unknown
Metabolism	Expected to be catabolized into small peptides and amino acids	
Elimination	Elimination pathways described as time-independent (nonspecific clearance)	

and time-dependent (target-mediated clearance)	
Half-life	27.2 days (after the 13th weekly treatment dose)

back to top

C - Indications and Status

Health Canada Approvals:

- Multiple Myeloma

(Includes conditional approvals)

Refer to the product monograph for a full list and details of approved indications.

back to top

D - Adverse Effects

Emetogenic Potential: Minimal

The following adverse events were reported in a Phase I/ II study of adults with relapsed or refractory multiple myeloma. Adverse events were reported in ≥ 5% of patients who received teclistamab in this study; severe or life-threatening adverse events may also be included from other sources or post-marketing.

ORGAN SITE	SIDE EFFECT* (%)	ONSET**
Cardiovascular	Arrhythmia (18%) (2% severe)	E
	Hypertension (13%)	I E
	Hypotension (21%)	I E
Gastrointestinal	Anorexia (12%)	E
	Constipation (21%)	E
	Diarrhea (28%)	E
	Nausea, vomiting (28%) (< 1% severe)	E
General	Chills (18%)	I

	Edema (14%)	E
	Fatigue (41%)	E
	Fever (79%) (3% severe)	I E
Hematological	Myelosuppression ± infection, bleeding (71%) (64% severe)	E D
Immune	Cytokine release syndrome (72%) (< 1% severe)	I
	Other (11%) Hypogammaglobulinemia	E D
Injection site	Injection site reaction (38%) (< 1% severe)	I
Musculoskeletal	Musculoskeletal pain (52%) (8% severe)	E
Nervous System	Encephalopathy (10%) (none severe, PML - rare)	E D
	Headache (27%)	E
	Immune effector cell-associated neurotoxicity syndrome (3 - 6%)	I E
	Other (19%) Motor dysfunction (none severe)	E
	Peripheral neuropathy (16%)	E
Renal	Nephrotoxicity (11%) (4% severe)	E
Respiratory	Cough, dyspnea (24%)	E
	Hypoxia (20%) (4% severe)	I

* "*Incidence*" may refer to an absolute value or the higher value from a reported range.
"*Rare*" may refer to events with < 1% incidence, reported in post-marketing, phase 1 studies, isolated data or anecdotal reports.

** I = *immediate* (onset in hours to days) E = *early* (days to weeks)
D = *delayed* (weeks to months) L = *late* (months to years)

The most common side effects for teclistamab include fever, cytokine release syndrome, myelosuppression ± infection, musculoskeletal pain, fatigue, injection site reaction, diarrhea, nausea, headache, and cough/dyspnea.

Cytokine release syndrome (CRS) was commonly reported in patients receiving teclistamab (72%), with one-third of patients experiencing recurrence. Most CRS events were grade 1 or 2 in severity and generally occurred after step-up doses and initial treatment dose, with incidence and severity decreasing over time (incidence: 44% after Step-Up Dose 1, 35% after Step-Up Dose 2, and 24% after First Treatment Dose). The median time to onset was 2 days (range: 1 to 6 days) after dose administration and duration ranged from 1 to 9 days (median: 2 days). Signs and symptoms reported include fever, hypoxia, chills and hypotension tachycardia, headache, elevated liver enzymes, nausea and vomiting, myalgia or fatigue. Tocilizumab (alone or in combination with corticosteroids) was used to treat 35% of CRS events in the clinical trial. Although only 0.6% of CRS were severe, potentially life-threatening events have occurred and may include cardiac dysfunction, respiratory distress syndrome, renal or hepatic failure and disseminated intravascular coagulation. Step-up dosing and pre-medications prior to administration of teclistamab are important measures to reduce the risk of CRS.

Drug-related **neurologic toxicities** occurred in 15% of patients receiving teclistamab in the clinical trial (MajesTEC-1). Headache was the most common neurological side effect; others include motor dysfunction (such as hypokinesia, dysphonia, dysgraphia and tremor) and peripheral neuropathy. Serious or life-threatening toxicities such as **immune effector cell-associated neurotoxicity syndrome (ICANS)**, encephalopathy and Guillain-Barré syndrome have also occurred; however, most neurological toxicities reported were Grade 1 or 2. The most frequently reported clinical manifestations of ICANS were confusion and dysgraphia; onset of ICANS ranged from 2 to 8 days after the dose (median 4 days) and was irrespective of CRS (may occur concurrently, after, or in the absence of CRS).

Infections and **hypogammaglobulinemia** were frequent with teclistamab treatment. IV immunoglobulin was administered to 53% of patients who developed hypogammaglobulinemia in the MajesTEC-1 trial; immunoglobulin levels should be monitored during treatment and replacement therapy initiated accordingly. **Serious infections** were reported in 30% of patients receiving teclistamab. Approximately one third of infections were Grade 3 or 4 and 4% were fatal. Opportunistic infections and new or reactivated viral infections have also occurred during treatment (e.g. cytomegalovirus infection, herpes zoster, or hepatitis B reactivation). Prophylactic antimicrobials should be administered according to local guidelines.

Teclistamab can cause local injection-site, and rarely systemic administration-related **hypersensitivity reactions.** Most injection-site reactions were Grade 1 or 2 in severity. Doses larger than 2 mL should be divided into multiple syringes to reduce local reactions.

back to top

E - Dosing

Refer to protocol by which patient is being treated.

Do not start treatment with teclistamab in patients with active infection.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

Pre-medications (prophylaxis for CRS):

Give 1 to 3 hours prior to each step-up dose and first treatment dose*:

- Corticosteroid (oral or IV dexamethasone, 16 mg)
- Antihistamine (oral or IV diphenhydramine, 50 mg or equivalent)
- Antipyretic (oral or IV acetaminophen, 650 mg to 1000 mg or equivalent)

*May be required prior to other doses (e.g. repeat doses due to delays during the step-up schedule, or if patient experienced CRS with prior teclistamab dose)

Other Supportive care:

- Consider prophylaxis against Pneumocystis jirovecii pneumonia (PJP) and herpes virus infections.
- Consider other antimicrobial prophylaxis as per local guidelines.
- Teclistamab should be administered to adequately hydrated patients.

Adults:

Administer teclistamab using the following step-up dosing schedule to reduce the risk of CRS.

Cycle 1:

Table 1 - Step-up Dosing Schedule

Step-up Schedule	**Day**	**Dose* (mg/ kg, Subcut)**
Step-up Dose 1	Day 1	0.06
Step-up Dose 2	Day 3**	0.3
First Treatment Dose	Day 5***	1.5

*Dose should be based on actual body weight.
**Step-up dose 2 may be given between 2 to 7 days after Step-up dose 1.
***First treatment dose may be given between 2 to 7 days after Step-up dose 2.

Cycle 2 and onwards:

Subcutaneous: 1.5 mg/ kg Once weekly*

*Start Cycle 2 one week after the first treatment dose. Maintain a minimum of 5 days between weekly treatment doses.

Note: Inpatient admission may be required for CRS monitoring (e.g. during step-up schedule). ST-QBP funding for ambulatory administration only.

Refer to the dose banding tables in the product monograph to determine the total dose for step-up and treatment doses.

Dosage with Toxicity:

Dose reductions are not recommended.

Dose may be delayed due to toxicity; dose upon resuming treatment will depend on duration of delay and last administered dose (Table 4).

Table 2 - CRS and ICANS Toxicity Management

Recommendations below are based on the pivotal trial. Refer to Crombie et al. and Rodriguez-Otero et al. for alternative CRS and ICANS management guidelines.

Toxicity	Grade[a]	Management / Action	Next dose
CRS	Grade 1	Hold until CRS has resolved. Manage and treat symptoms as appropriate: • Consider tocilizumab.	Administer pre-treatment medication prior to dose. Resume dose as recommended in Table 4.
	Grade 2	Hold until CRS has resolved. Manage and treat symptoms as appropriate: • IV tocilizumab as per institutional guidelines • If no improvement within 24hr of starting tocilizumab, administer IV methylprednisolone 1 mg/kg BID or equivalent. • Continue corticosteroids until ≤ Grade 1, then taper over 3 days.	Administer pre-treatment medications prior to dose. Resume dose as recommended in Table 4. Monitor patient daily for 48 hours following dose.
	Grade 3 (<48hr duration)	Hold until CRS has resolved. Manage and treat symptoms as appropriate: • IV tocilizumab as per institutional guidelines • If no improvement, administer IV methylprednisolone 1 mg/kg BID or equivalent.	Administer pre-treatment medications prior to dose. Resume dose as recommended in Table 4. Monitor patient daily for 48 hours following dose.

		• Continue corticosteroids until ≤ Grade 1, then taper over 3 days.	
	Grade 3 (>48hr duration or recurrent)	Stop teclistamab. Manage and treat symptoms as appropriate: • IV tocilizumab as per institutional guidelines • Corticosteroids as above	Permanently discontinue.
	Grade 4	Stop teclistamab. Manage and treat symptoms as appropriate: • IV tocilizumab as per institutional guidelines • Corticosteroids as per Grade 3, OR • Methylprednisolone IV 1000 mg/ day x 3 days • If no improvement or worsens, consider alternate immunosuppressants as per institutional guidelines.	Permanently discontinue.
ICANS	Grade 1	Hold until ICANS has resolved. Manage and treat symptoms as appropriate[b]: • Monitor neurologic symptoms; consider neurology consultation. • Consider seizure prophylaxis (e.g. levetiracetam).	Resume dose as recommended in Table 4.
	Grade 2, or Grade 3 (1st occurrence)	Hold until ICANS has resolved. Manage and treat symptoms as appropriate[b]: • IV dexamethasone 10mg q6h, or equivalent • Continue dexamethasone (or equivalent) until ≤ Grade 1, then taper.	Resume dose as recommended in Table 4. Monitor patient daily for 48 hours following dose.

		• Consider neurology consultation and other specialists as needed. • Consider seizure prophylaxis (e.g. levetiracetam).	
	Grade 3 (recurrent)	Stop teclistamab. Manage and treat symptoms as appropriate[b]: • IV dexamethasone 10mg q6h, or equivalent • Continue dexamethasone (or equivalent) until ≤ Grade 1, then taper. • Consider neurology consultation and other specialists as needed. • Consider seizure prophylaxis (e.g. levetiracetam).	Permanently discontinue.
	Grade 4	Stop teclistamab. Manage and treat symptoms as appropriate[b]: • IV dexamethasone 10mg q6h, or equivalent. Continue dexamethasone (or equivalent) until ≤ Grade 1, then taper. OR • Consider IV methylprednisolone IV 1000 mg/ day x 3 days; if improves, manage as above. • Consider neurology consultation and other specialists as needed. • Consider seizure prophylaxis (e.g. levetiracetam).	Permanently discontinue.

[a] Grade based on American Society for Transplantation and Cellular Therapy (ASTCT) consensus grading (Lee et al 2019).

[b] Anticytokine therapy is recommended if ICANS occurs concurrently with CRS. Refer to MajesTEC-1 study protocol, or local institutional guidelines for management if concurrent CRS.

Table 3 - Hematologic and Other Non-hematologic Toxicities

Toxicity	Severity	Action
Infection	Any Grade (during step-up dosing schedule)	Hold* until infection has resolved (i.e. no active infection).
	Grade 3 (after step-up dosing schedule)	Hold* until infection improves to Grade ≤ 1.
	Grade 4 (after step-up dosing schedule)	Hold* until infection improves to Grade ≤ 1, OR Consider discontinue.
PML	Any Grade	Hold and investigate. Discontinue if confirmed.
Neurotoxicity (excluding ICANS)	Grade 1	Hold* until symptoms resolve or stabilize.
	Grade 2, or Grade 3 (first occurrence)	Hold* until symptoms improve to Grade ≤ 1. Provide supportive therapy.
	Grade 3 (recurrent), or Grade 4	Discontinue. Provide supportive therapy.
Neutropenia	ANC < 0.5 × 10^9/L	Hold* until ANC ≥ 0.5 × 10^9/L.
	Febrile neutropenia	Hold* until ANC ≥ 1 × 10^9/L and fever has resolved.
Thrombocytopenia	Platelets < 25 × 10^9/L	Hold* until platelets > 25 × 10^9/L and no evidence of bleeding.
	Platelets 25 - 50 × 10^9/L with bleeding	Hold* until platelets > 25 × 10^9/L and no evidence of bleeding.
Anemia	Hb < 80 g/L	Hold* until Hb ≥ 80 g/L.
Other non-hematological adverse effects	Grade 3	Hold* until toxicity improves to Grade ≤ 1.
	Grade 4	Hold* until toxicity improves to Grade ≤ 1, OR Consider discontinue.

*Resume at dose described in Table 4.

Table 4 - Recommended Restarting Doses After Dose Delay

Last Administered Dose (mg/ kg)	Duration of Delay	Action for Next Dose
Step-up Dose 1 (0.06)	≤ 7 days	Resume at 0.3 mg/kg and continue step-up dosing schedule.
	> 7 days	Resume at 0.06 mg/kg and continue step-up dosing schedule.
Step-up Dose 2 (0.3)	≤ 7 days	Resume at 1.5 mg/kg and continue once weekly.
	8 - 28 days	Resume at 0.3 mg/kg and continue step-up dosing schedule.
	> 28 days	Resume at 0.06 mg/kg and continue step-up dosing schedule.
Any Treatment Dose (1.5)	≤ 28 days	Resume at 1.5 mg/kg and continue once weekly.
	> 28 days	Resume at 0.06 mg/kg and continue step-up dosing schedule.

Dosage with Hepatic Impairment:

Severity	Bilirubin		AST	Teclistamab Dose
Mild	≤ ULN	AND	> ULN	No dose adjustment.
	> 1 to 1.5 x ULN	AND	any	No dose adjustment.
Moderate or Severe	> 1.5 x ULN	AND	any	No data.

Dosage with Renal Impairment:

Severity	Creatinine Clearance (mL/min)	Teclistamab Dose
Mild or Moderate	≥ 30	No dose adjustment.
Severe	< 30	Limited data.

Dosage in the elderly:

No dose adjustment is required. In the pivotal trial (MajesTEC-1), 48% and 15% of patients were 65 and 75 years of age or older, respectively. No overall differences in safety or effectiveness were observed between these patients and younger patients.

Dosage based on gender:

There were no clinically significant differences in the pharmacokinetics of teclistamab based on sex.

Dosage based on ethnicity:

There were no clinically significant differences in the pharmacokinetics of teclistamab based on race or ethnicity (white, Black or Hispanic patients).

Children:

The safety and efficacy of teclistamab in children have not been established.

back to top

F - Administration Guidelines

- Teclistamab should be administered by **subcutaneous injection only.** Do not administer IV.
- Vials are available in 2 different concentrations (10 mg/mL and 90 mg/mL). Ensure correct vial size is selected for preparation; do not combine. Refer to the product monograph for details on preparation.
- Allow vial to come to room temperature over 15 minutes; do not warm.
- Gently swirl vial to mix. Do not shake.
- Withdraw required volume into syringe. Injection volume should not exceed 2 mL; divide doses requiring > 2 mL into multiple syringes.
- Injection into the abdomen is preferred, but may be injected into thigh.

- Do not inject into areas where skin is red, bruised, scarred, tattooed or not intact.
- If multiple injections are required, injection sites should be at least 2 cm apart.
- Monitor patients for 48 hours after administration of all doses within the step-up dosing schedule for signs or symptoms of CRS or ICANS.
- Store unopened vials refrigerated (2°C to 8°C) and protect from light.

back to top

G - Special Precautions

Contraindications:

- Patients who are hypersensitive to this drug or to any of its components.

Other Warnings/Precautions:

- Severe CRS and ICANS have occurred with teclistamab; ensure step-up schedule is followed and infusions are administered where there is immediate access to medications and equipment required to manage CRS and ICANS.
- ICANS has been reported with teclistamab; caution in patients with a history of stroke, seizure or neurological conditions.
- Patients should avoid driving or operating heavy machinery during and for 48 hours after step-up dosing schedule, or if any new neurological symptoms present due to the risk of a depressed level of consciousness from ICANS.
- Patients with active infection should not receive teclistamab step-up dosing schedule.
- Vaccination with live virus vaccines is not recommended for at least 4 weeks prior to, during and for at least 4 weeks after treatment with teclistamab. The risk of vaccine-associated infection may be increased or immune response to vaccines may be reduced.
- Patients with conditions such as autoimmune disease or thyroiditis, Type 1 diabetes, allogenic stem cell transplant (within 6 months), CNS or meningeal involvement were excluded from clinical trials; assess benefit-risk of teclistamab treatment in these patients.

Other Drug Properties:

- Carcinogenicity: Unknown

Pregnancy and Lactation:

- Genotoxicity: Unknown
- Fetotoxicity: Possible
  - Human IgG is known to cross the placenta after the first trimester of pregnancy and teclistamab has the potential to be transmitted to the fetus.
  - Consider assessment of immunoglobulin levels in newborns of patients treated with teclistamab.

- Pregnancy:
  Teclistamab is not recommended for use in pregnancy.

  - Adequate contraception should be used by patients who can become pregnant and their partners during treatment, and for at least **5 months** after the last dose.
  - Adequate contraception should be used by patients who produce sperm and their partners during treatment, and for at least **3 months** after the last dose.

- Breastfeeding:
  Breastfeeding is not recommended during treatment and for at least **5 months** after the last dose.

- Fertility effects: Unknown
  Effects of teclistamab on fertility have not been evaluated in animal studies.

back to top

H - Interactions

Teclistamab causes a transient release of cytokines that may suppress CYP450 enzymes. The highest risk of drug interactions is from initiation of step-up dosing schedule up to 7 days after the First Treatment Dose or during a CRS event. Monitor patients receiving concomitant CYP450 substrates, especially those that have a narrow therapeutic index, for increased substrate concentrations or toxicity.

AGENT	EFFECT	MECHANISM	MANAGEMENT
CYP 2C9 substrates (e.g. warfarin, meloxicam, fluvastatin)	↑ substrate concentration and/or toxicity	cytokines may suppress CYP450	Monitor and adjust dose of substrates with narrow therapeutic index (e.g. warfarin) if necessary
CYP3A4 substrates (e.g. cyclosporine, pimozide, tacrolimus, triazolo-benzodiazepines, dihydropyridine calcium-channel blockers, certain HMG-CoA reductase inhibitors)	↑ substrate concentration and/or toxicity	cytokines may suppress CYP450	Monitor and adjust dose of substrates with narrow therapeutic index (e.g. cyclosporine) if necessary

back to top

I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the hepatitis B virus screening and management guideline for monitoring during and after treatment

Recommended Clinical Monitoring

Monitor Type	Monitor Frequency
CBC	Baseline and before each dose; more frequently if clinically indicated
Clinical toxicity assessment for CRS and ICANS	At each visit and for 48 hours after all doses in step-up dosing schedule
LFTs, bilirubin	Baseline and as clinically indicated
Renal function tests	Baseline and as clinically indicated
CRP, ferritin	Baseline and as clinically indicated
Coagulation tests (e.g. aPTT, INR, PT, fibrinogen)	Baseline and as clinically indicated
Immunoglobulin levels	As clinically indicated
Clinical toxicity assessment for infection, injection-site reactions, neurotoxicity, pulmonary and cardiac toxicity.	At each visit

Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

back to top

K - References

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November 2024 Updated units in Dosage with Renal Impairment section.

back to top

L - Disclaimer

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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back to top