Drug Monograph

A - Drug Name

teclistamab

COMMON TRADE NAME(S): Tecvayli®

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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)

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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.

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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
Metabolic / Endocrine	Hypoglycemia (23%)	L
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)

Refer to the T-Cell Engaging Antibodies guideline for a detailed description of CRS, ICANS and their management.

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.

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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)

**Central nervous system (CNS) effects of diphenhydramine may make it challenging to identify ICANS. Consider cetirizine, which has a lower incidence of CNS effects.

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 ramp-up dosing schedule to reduce the risk of CRS.

Table 1 - Dosing Schedule

Ramp-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
Weekly Schedule^		
Subsequent Treatment Doses	Once weekly^^	1.5

*Dose should be based on actual body weight.

**Step-up dose 2 and First treatment dose may be given between 2 to 7 days after previous dose.

^Consider reducing frequency to every 2 weeks in patients that have achieved CR for ≥ 6 months.

^^Start 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 ramp-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).

Refer to the T-Cell Engaging Antibodies guideline for a detailed description of CRS, ICANS and their management.

Table 2 - CRS and ICANS Toxicity Management

Toxicity	Grade[a]	Management / Action	Next dose
CRS	Grade 1	Hold until CRS has resolved. Manage and treat symptoms as appropriate. Refer to the T-Cell Engaging Antibody Guideline for details.	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. Refer to the T-Cell Engaging Antibody Guideline for details.	Administer pre-treatment medications prior to dose. Resume dose as recommended in Table 4. Monitor patient for at least 48 hours following dose, or as clinically indicated.
	Grade 3	**First occurrence:** • Hold until CRS has resolved.	Administer pre-treatment medications prior to dose.

		• Manage and treat symptoms as appropriate. Refer to the T-Cell Engaging Antibody Guideline for details. • If CRS duration > 48 hr, permanently discontinue **Recurrent:** Permanently discontinue	Resume dose as recommended in Table 4. Monitor patient for at least 48 hours following dose, or as clinically indicated. If Gr. ≥ 3 recurs, permanently discontinue
	Grade 4	Stop teclistamab. Manage and treat symptoms as appropriate. Refer to the T-Cell Engaging Antibody Guideline for details.	Permanently discontinue.
ICANS	Grade 1	Hold until ICANS has resolved. Manage and treat symptoms as appropriate.[b] Refer to the T-Cell Engaging Antibody Guideline for details.	Resume dose as recommended in Table 4.
	Grade 2	Hold until ICANS has resolved. Manage and treat symptoms as appropriate.[b] Refer to the T-Cell Engaging Antibody Guideline for details.	Resume dose as recommended in Table 4. Monitor patient for at least 48 hours following dose, or as clinically indicated.
	Grade 3	**First occurrence:** • Hold until ICANS has resolved. • Manage and treat symptoms as appropriate.[b] Refer to the T-Cell Engaging Antibody Guideline for details. **Recurrent:** Permanently discontinue	Resume dose as recommended in Table 4. Monitor patient for at least 48 hours following dose, or as clinically indicated. If Gr. ≥ 3 recurs, permanently discontinue
	Grade 4	Stop teclistamab. Manage and treat symptoms as appropriate.[b] Refer to the T-Cell Engaging Antibody Guideline for details	Permanently discontinue.

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

[b] Tocilizumab is not recommended for ICANS in the absence of concurrent CRS. For concurrent CRS, there is a low threshold to switch to anakinra. Refer to the T-Cell Engaging Antibody Guideline for more information.

Table 3 - Hematologic and Other Non-hematologic Toxicities

Toxicity	Severity	Action
Infection	Any Grade (during ramp-up dosing schedule)	Hold* until infection has resolved (i.e. no active infection).
	Grade 3 (after ramp-up dosing schedule)	Hold* until infection improves to Grade ≤ 1.
	Grade 4 (after ramp-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 ramp-up dosing schedule.
	> 7 days	Resume at 0.06 mg/kg and continue ramp-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 ramp-up dosing schedule.
	> 28 days	Resume at 0.06 mg/kg and continue ramp-up dosing schedule.
Any Treatment Dose (1.5)	≤ 28 days	Resume at last treatment dose (1.5 mg/kg once weekly or every 2 weeks).
	> 28 days	Resume at 0.06 mg/kg and continue ramp-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.

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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 at least 48 hours after administration of all doses within the ramp-up dosing schedule for signs or symptoms of CRS or ICANS. Refer to the T-Cell Engaging Antibodies guideline for more information.
- Store unopened vials refrigerated (2°C to 8°C) and protect from light.

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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 ramp-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 ramp-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 ramp-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.

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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	↑ substrate concentration and/or toxicity	cytokines may suppress CYP450	Monitor and adjust dose of substrates with narrow therapeutic index (e.g. cyclosporine) if necessary

reductase inhibitors)

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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.

Refer to the T-Cell Engaging Antibodies guideline for monitoring of CRS and ICANS 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	Monitor frequently during and after ramp-up doses.* At each visit and as clinically indicated after ramp-up phase.
CRP, ferritin, coagulation tests (e.g. aPTT, INR, PT, fibrinogen)	Baseline and as clinically indicated
LFTs, bilirubin	Baseline and as clinically indicated
Renal function tests	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

*Ramp-up doses are step-up dose 1, 2 and first treatment dose.

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

Suggested Clinical Monitoring

Monitor Type	Monitor Frequency

Blood glucose	As clinically indicated

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J - Supplementary Public Funding

High Cost Therapy Funding Program (HCTFP website)

- Teclistamab (Inpatient) - Relapsed or Refractory Multiple Myeloma

New Drug Funding Program (NDFP Website)

- Teclistamab (Outpatient) - Relapsed or Refractory Multiple Myeloma

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K - References

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Tecvayli Teclistamab injection Product Monograph. Janssen Inc. Toronto, Ontario; June 26, 2025.

July 2025 Updated Adverse Effects, Dosing and Recommended Clinical Monitoring sections, added links to T-Cell Engaging Antibody Guideline.

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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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