# DRUG NAME: Teclistamab

**SYNONYM(S):** teclistamab-cqyv [1]

**COMMON TRADE NAME(S):** TECVAYLI®

**CLASSIFICATION:** immunotherapy

*Special pediatric considerations are noted when applicable, otherwise adult provisions apply.*

## MECHANISM OF ACTION:

Teclistamab is a bispecific T-cell engager that targets both B cell maturation antigen (BCMA) and CD3 receptors. It is a humanized immunoglobulin G4-proline, alanine, alanine (IgG4-PAA) antibody. Teclistamab binds to CD3 receptors expressed on T-cells and BCMA expressed on the surface of multiple myeloma cells. With its dual binding sites, teclistamab is able to redirect and draw T-cells in close proximity to BCMA-expressing tumour cells leading to T-cell activation, release of cytokines, and subsequent cell lysis. [1-3]

## PHARMACOKINETICS:

| | | |
|---|---|---|
| Absorption | bioavailability = 72% when administered subcutaneously | |
| Distribution | 90% of steady state exposure achieved after 12 weekly treatment doses | |
| | cross blood brain barrier? | no information found |
| | volume of distribution | 5.63 L |
| | plasma protein binding | no information found |
| Metabolism | expected to undergo catabolism to small peptides and amino acids | |
| | active metabolite(s) | no information found |
| | inactive metabolite(s) | no information found |
| Excretion | time-dependent clearance | |
| | urine | no information found |
| | feces | no information found |
| | terminal half life [4] | 27.2 d |
| | clearance | 0.472 L/day |
| Sex | no clinically significant difference | |
| Elderly | no clinically significant difference | |
| Ethnicity | no clinically significant difference | |

Adapted from standard reference [2,5] unless specified otherwise.

## USES:

***Primary uses:***

*Multiple myeloma

***Other uses:***

*Health Canada approved indication



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## SPECIAL PRECAUTIONS:

***Caution:***
- severe ***cytokine release syndrome (CRS)*** can occur with teclistamab; recommended dosing regimen uses a step-up dosing schedule for initiation of treatment [2,5]
- ***premedication*** with corticosteroid, antihistamine, and antipyretic is recommended prior to all step-up doses and first full treatment dose to reduce the risk of CRS [2]
- ***immune effector cell-associated neurotoxicity syndrome (ICANS)*** has been reported; caution in patients with history of stroke or seizure, or pre-existing neurological problems [2,5]
- patients receiving teclistamab are at risk of ***reduced consciousness*** due to ICANS; patients should avoid ***driving or operating heavy machinery*** during the step-up schedule and for 48 hours after its completion or if experiencing neurologic symptoms [2,5]
- teclistamab step-up schedule should not be administered to patients with ***active infection*** [2]
- ***antimicrobial/antiviral prophylaxis*** may be required to prevent reactivation of infections such as herpes zoster in high risk patients [2,5]
- ***reactivation of Hepatitis B virus*** (HBV) has been reported with teclistamab; for recommended HBV screening and prophylaxis [2], see BC Cancer Protocol SCHBV ***Hepatitis B Virus Reactivation Prophylaxis***
- ***vaccine response*** may be diminished during treatment with teclistamab [2]
- ***immunization with live virus vaccines*** is not recommended for at least 4 weeks prior to treatment, during treatment, and for at least 4 weeks after the last dose of teclistamab [2]

***Carcinogenicity:*** No studies have been conducted.

***Mutagenicity:*** No studies have been conducted.

***Fertility:*** In animal toxicity studies, there were no notable effects in male or female reproductive organs at exposures approximately 22 times those seen following human clinical exposure. [2]

***Pregnancy:*** Teclistamab has not been studied in pregnant women. Teclistamab causes T-cell activation and cytokine release which may compromise pregnancy maintenance. Human IgG is also known to cross the placental barrier and therefore, teclistamab has the potential to be transmitted from mother to fetus. Because teclistamab is associated with hypogammaglobulinemia, consider assessment of immunoglobulin levels in newborns born to mothers treated with teclistamab. In females of childbearing potential, pregnancy tests are recommended prior to starting treatment and contraception is recommended during treatment and for five months after the last dose. In males with female partners of childbearing potential, contraception is recommended during treatment and for three months after the last dose. [2,5]

***Breastfeeding*** is not recommended due to the potential secretion into breast milk. Human IgG is known to be secreted in breast milk. Because of the potential for serious adverse reactions in breastfed infants, women should not breastfeed during treatment and for five months after the last dose. [2,5]

## SIDE EFFECTS:

The table includes adverse events that presented during drug treatment but may not necessarily have a causal relationship with the drug. Because clinical trials are conducted under very specific conditions, the adverse event rates observed may not reflect the rates observed in clinical practice. Adverse events are generally included if they were reported in more than 1% of patients in the product monograph or pivotal trials, and/or determined to be clinically important [6,7]



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| ORGAN SITE | SIDE EFFECT |
|---|---|
| Clinically important side effects are in ***bold, italics*** | |
| blood and lymphatic system/ febrile neutropenia | ***anemia*** (55%, severe 37%) |
| | ***febrile neutropenia*** (severe 4%) |
| | leukopenia (18%, severe 7%) |
| | lymphopenia (35%, severe 33%) |
| | ***neutropenia*** (71%, severe 64%) |
| | ***thrombocytopenia*** (40%, severe 21 %) |
| cardiac | arrhythmia (16-18%, severe 2%) |
| gastrointestinal | *emetogenic potential:* low [8,9] |
| | constipation (18-21%) |
| | diarrhea (21-28%, severe 2-4%) |
| | nausea (25-28%, severe 1%) |
| | vomiting (12-13%, severe 1%) |
| general disorders and administration site conditions | *extravasation hazard:* none [10] |
| | ***chills*** (16-18%) |
| | ***edema,*** peripheral and facial (13-14%) |
| | fatigue/asthenia (33-41%, severe 2-3%) |
| | hypersensitivity (1%) |
| | ***injection site reaction*** (35-38%, severe 1%); see paragraph following **Side Effects** table |
| | pain (15-21%, severe 2%) |
| | ***pyrexia*** (76-79%, severe 3%) |
| hepatobiliary | hepatic failure (<1%); fatalities reported |
| immune system | ***cytokine release syndrome*** (72%, severe 1%); see paragraph following **Side Effects** table |
| | hypogammaglobulinemia (11-75%, severe 2%) |
| infections and infestations | cellulitis (4%) |
| | COVID-19 (18%, severe 12%); fatalities reported |
| | herpes simplex (2%), herpes zoster (1%) |
| | reactivation of viral infection (1%) (e.g., adenovirus, hepatitis B virus, cytomegalovirus, varicella zoster virus) |
| | ***pneumonia*** (24-28%, severe 15-19%); fatalities reported |
| | sepsis (8%, severe 7%) |
| | ***upper respiratory tract infection*** (26-37%, severe 2%) |
| | urinary tract infection (11%, severe 5%) |
| investigations | activated partial thromboplastin time prolonged (8%, severe 1%) [11] |
| | albumin decrease (68-72%, severe 6%) |



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| ORGAN SITE | SIDE EFFECT |
|---|---|
| Clinically important side effects are in ***bold, italics*** | |
| | alkaline phosphatase increase (43%, severe 3%) |
| | ***ALT increase*** (35%, severe 4%); can occur with or without concurrent CRS |
| | amylase increase (24%, severe 4%) |
| | ***AST increase*** (41%, severe 3%); can occur with or without concurrent CRS |
| | creatinine increase (30-34%, severe 3%) |
| | calcium decrease (31-35%, severe 2%) |
| | calcium increase (28%, severe 4%) |
| | gamma-glutamyltransferase increase (38%, severe 9%) |
| | INR increase (6%, severe 1%) [11] |
| | lipase increase (25%, severe 5%) |
| | potassium decrease (31%, severe 5%) |
| | potassium increase (20%, severe 2%) |
| | magnesium decrease (28%) |
| | phosphate decrease (43%, severe 15%) |
| | sodium decrease (36%, severe 12%) |
| metabolism and nutrition | appetite decrease (11-12%, severe 1%) |
| musculoskeletal and connective tissue | bone pain (16%, severe 3%) |
| | musculoskeletal pain (44-52%, severe 4-8%) |
| nervous system (see paragraph following **Side Effects** table) | ***encephalopathy*** (10-13%) |
| | Guillain-Barre syndrome; fatalities reported |
| | headache (25-27%, severe <1%) |
| | ***immune effector cell-associated neurotoxicity syndrome*** (3%) |
| | ***motor dysfunction*** (16-19%) |
| | ***peripheral neuropathy*** (16%, severe <1%) |
| renal and urinary | acute kidney injury (11%, severe 4%) |
| respiratory, thoracic and mediastinal | cough (15-24%) |
| | ***dyspnea*** (13%, severe 2%) |
| | ***hypoxia*** (18-20%, severe 2-4%) |
| vascular | hemorrhage (12%, severe 2-3%); fatalities reported |
| | hypertension (12-13%, severe 5%) |
| | ***hypotension*** (18-21%, severe 1-2%) |

Adapted from standard reference [1,2,5,12] unless specified otherwise.



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***Cytokine release syndrome*** (CRS) occurs in 72% of patients treated with teclistamab and recurs in more than one-third of patients. [1] Signs and symptoms of CRS may include fever, chills, hypotension, tachycardia, hypoxia, headache, elevated liver enzymes, fatigue, nausea and vomiting. The majority of CRS events are grade 1 or 2. Although grade 3 events are uncommon (0.6%), potentially life-threatening complications of CRS have been reported, including cardiac dysfunction, respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation. Median time to onset of CRS is 2 days after the most recent dose (range 1-6 days), and the median duration is 2 days (range 1-9 days). The step-up dosing schedule and premedication with corticosteroids, antihistamine, and antipyretics are used to reduce the risk of CRS as most patients experience CRS following the initial step-up doses or first treatment dose. Failure to follow the recommended dosing schedule for initiation of therapy and re-initiation of therapy after dose delays may result in increased frequency and severity of CRS. Hold teclistamab until CRS resolves and provide supportive care as needed. Avoid using myeloid growth factors during CRS. Permanently discontinue teclistamab for recurrent grade 3 reactions, grade 3 reactions which last longer than 48 hours, and grade 4 reactions. [2,5] Refer to protocol by which patient is being treated. For further information, see BC Cancer Protocol SCCRS ***Cytokine Release Syndrome Management***.

***Local injection site reactions*** are reported in approximately one-third of patients. The majority of the reactions are grade 1 in severity. Reported reactions include injection site erythema, bruising, cellulitis, hematoma, induration, inflammation/swelling, discomfort, pruritus, and rash. The volume administered for each subcutaneous injection should not exceed 2 mL and this may require dividing the dosing volume into multiple syringes for administration. [2,5]

***Neurologic toxicity*** has been reported in 57% of patients, including headache, motor dysfunction (e.g., dysgraphia, dysphonia, tremor, hypokinesia and gait disturbance), peripheral neuropathy, and encephalopathy. The most frequently reported neurologic toxicity has been headache. Neurologic toxicity can occur days or weeks after the teclistamab injection and initial symptoms may be subtle. The majority of neurologic events are grade 1 or 2; however, serious or life-threatening toxicity such as ***Guillain-Barré*** and ***immune effector cell-associated neurotoxicity syndrome (ICANS)*** can also occur. The most frequent clinical manifestations of ICANS are confusional state and dysgraphia. Median time to onset of ICANS is 4 days after the most recent dose of teclistamab (range 2 to 8 days) and the median duration is 3 days (range 1 to 20 days). The onset of ICANS may be concurrent with CRS, follow the resolution of CRS, or it can occur in the absence of CRS. Neurology consult may be required. Hold teclistamab until neurologic toxicity resolves. Symptoms are managed depending on their severity and whether they occur concurrently with CRS. Permanently discontinue teclistamab for recurrent grade 3 and grade 4 events. Due to the potential for ICANS and the risk of reduced consciousness, patients receiving teclistamab should avoid driving or operating heavy machinery during the step-up schedule and for 48 hours after its completion or if experiencing neurologic symptoms. [1,2,5] For further information, see BC Cancer Protocol SCICANS ***Immune Effector Cell-Associated Neurotoxicity Syndrome Management.***

## INTERACTIONS:

The initial release of cytokines associated with teclistamab treatment may suppress CYP450 enzymes. Substrates of CYP450 enzymes with a narrow therapeutic index may require dose adjustment and monitoring for toxicity if given concurrently with teclistamab. The highest risk of interaction is predicted to occur during the teclistamab step-up regimen and up to 7 days after the first treatment dose, or during a CRS event. **[2,5]**

## SUPPLY AND STORAGE:

***Injection***: Janssen Inc. supplies teclistamab as ready-to-use, single use (preservative free) vials in two vial sizes: 30 mg vials in a concentration of 10 mg/mL and 153 mg vials in a concentration of 90 mg/mL. Refrigerate. Store in original carton to protect from light. Do not shake. [2]

***Additional information:***

- ***Caution:*** teclistamab vials are supplied as two different concentrations (10 mg/mL and 90 mg/mL); ensure selection of appropriate vial size for dose preparation



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***For basic information on the current brand used at BC Cancer, see Chemotherapy Preparation and Stability Chart in Appendix.***

## SOLUTION PREPARATION AND COMPATIBILITY:

***For basic information on the current brand used at BC Cancer, see Chemotherapy Preparation and Stability Chart in Appendix.***

***Additional information:***

- ***Caution:*** teclistamab vials are supplied as two different concentrations (10 mg/mL and 90 mg/mL); ensure selection of appropriate vial size for dose preparation
- injection volumes greater than 2 mL should be divided into separate syringes for administration [2]
- do not use closed system transfer devices (CSTD) for preparation of syringe volumes of 1 mL or less; use filtered venting needles (e.g., Chemo-Vent®) in place of a CSTD for volumes of 1 mL or less[15]

***Compatibility:*** consult detailed reference

## PARENTERAL ADMINISTRATION:

BC Cancer administration guideline noted in ***bold***, ***italics***

| | |
|---|---|
| ***Subcutaneous*** [2,16] | ***injection into abdomen is preferred***; may be administered into the thigh [2]<br>• up to 2 mL volume can be injected in a single site [2]<br>• if multiple injections are required, injections should be spaced at least 2 cm apart. [2] |
| Intramuscular | no information found |
| Direct intravenous | do NOT use [2] |
| Intermittent infusion | do NOT use [2] |
| Continuous infusion | do NOT use [2] |
| Intraperitoneal | no information found |
| Intrapleural | no information found |
| Intrathecal | no information found |
| Intra-arterial | no information found |
| Intravesical | no information found |

## DOSAGE GUIDELINES:

Refer to protocol by which patient is being treated. Numerous dosing schedules exist and depend on disease, response and concomitant therapy. Guidelines for dosing also include consideration of absolute neutrophil count (ANC). Dosage may be reduced, delayed or discontinued in patients with bone marrow depression due to cytotoxic/radiation therapy or with other toxicities.



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***Adults***: BC Cancer usual dose noted in ***bold, italics***

*Subcutaneous:*

Cycle Length:

***4 weeks*** [2,16,17]:

**Cycle 1:**

| Dosing Schedule | | Day of treatment | Dose (SC) |
|---|---|---|---|
| Step-up dosing schedule | Step-up dose 1 | day 1 | 0.06 mg/kg single dose |
| | Step-up dose 2 | day 3* | 0.3 mg/kg single dose |
| | First treatment dose | day 5** | 1.5 mg/kg single dose |

* may be given between 2 to 7 days after step-up dose 1
** may be given between 2 to 7 days after step-up dose 2
(total dose per cycle 1.86 mg/kg)

**Cycle 2** starting 7 days after the last dose of cycle 1 **and onwards**:
***1.5 mg/kg SC given once weekly on days 1, 8, 15, and 22***
(total dose per cycle 6 mg/kg)

minimum of 5 days should be maintained between weekly doses [2]

no dose reductions are recommended [2]

**Following dose delays**: refer to protocol by which patient is being treated for instruction as the step-up dose schedule is sometimes repeated when restarting teclistamab after a dose delay [2]

4 weeks [5]: 1.5 mg/kg SC once every other week on days 1 and 15
(total dose per cycle 3 mg/kg)

*Concurrent radiation:* no information found

*Dosage in myelosuppression:* modify according to protocol by which patient is being treated

*Dosage in renal failure:* mild/moderate renal impairment (CrCl ≥30 mL/min): no adjustment required [2]
severe renal impairment: no information found

$$\text{calculated creatinine clearance} = \frac{N^* \times (140 - \text{Age}) \times \text{weight in kg}}{\text{serum creatinine in micromol/L}}$$

* For males N=1.23; for females N=1.04

*Dosage in hepatic failure:* mild hepatic impairment (bilirubin ≤1.5 x ULN): no adjustment required [2]
moderate/severe hepatic impairment: no information found

*Dosage in dialysis:* no information found



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***Children***: safety and efficacy have not been established [2]

## REFERENCES:

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