

INSTRUCTIONS FOR THE EPIC® ELECTRONIC HEALTH RECORD (EHR) SYSTEM

EPIC®

UPDATING RELAPSED OR REFRACTORY MULTIPLE MYELOMA ORDER SETS WITH **TECVAYLI® (teclistamab-cqyv)**

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Initiate treatment with TECVAYLI® step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.

 **TECVAYLI®**
(teclistamab-cqyv) Injection for
subcutaneous use
10 mg/mL and 90 mg/mL

CONTENTS

1. Overview and Limitations	3
2. Background and Indication	3
3. Considerations	4
Recommended Dosage	4
Recommended Pretreatment Medications	5
Prophylaxis for Herpes Zoster Reactivation	5
Dosage Modifications for Adverse Reactions	5
4. Epic® Electronic Health Record Instructions	6
5. Disclaimers	12
6. Indication and Important Safety Information	13
7. Notes	16

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



1. Overview and Limitations

Back To
TOC

This document is intended to provide health systems with instructions to update relapsed or refractory multiple myeloma order sets with TECVAYLI® (teclistamab-cqyv), within the approved indication and consistent with the Prescribing Information. This document is not intended to provide any clinical advice or clinical recommendations, which are solely the responsibility of the health system.

These instructions are specific to adult relapsed or refractory multiple myeloma and to the Epic® EHR system, and are not appropriate for other conditions, treatments, therapeutic areas, or for other EHR systems.

The process outlined below is variable and not all steps will apply to every health system. Any steps or settings below that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

2. Background and Indication

Johnson & Johnson has identified a need to help health systems update EHR order sets with TECVAYLI®.

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Initiate treatment with TECVAYLI® step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



3. Considerations

Back To
TOC

The clinical data elements provided are only suggestions, and it is strongly recommended that clinical and operational leadership determine that the final elements align with the expectations and goals of the organization. A Notes section (located on [page 16](#) of this guide) can be used by clinical leadership to document any additions or changes that need to be made in order to align these instructions with practice protocols or pathways.

Consider reviewing appropriate order sets for the inclusion of TECVAYLI®. Order sets may benefit from regular updates to include new treatments, laboratory sets, and other orderable items.

End users of the order sets should be offered an update of the contents and availability of the new order sets (and training if needed). In many cases, end users will have already been trained on how to use order sets as part of the health system's best practices, thereby reducing the need for additional training.

The following provides an overview and quick reference guide for the dosing and administration details for TECVAYLI® for approved indication as per the Prescribing Information. Step-by-step instructions for applying these medication details in the order set update are shown in following pages of this guide.

Recommended Dosage

For subcutaneous injection only.

The recommended dosing schedule for TECVAYLI® is provided in Table 1 in the full Prescribing Information. The recommended dosage of TECVAYLI® is step-up doses of 0.06 mg/kg, 0.3 mg/kg, and a first treatment dose of 1.5 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity. In patients who have achieved and maintained a complete response or better for a minimum of 6 months, the dosing frequency may be decreased to 1.5 mg/kg every two weeks until disease progression or unacceptable toxicity.

Administer pretreatment medications prior to each dose of the TECVAYLI® step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose as described in Table 1 in the full Prescribing Information.

Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Table 1 in the full Prescribing Information to reduce the incidence and severity of cytokine release syndrome (CRS). Due to the risk of CRS and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), patients should be hospitalized for 48 hours after administration of all doses within the TECVAYLI® step-up dosing schedule.

Table 1: TECVAYLI® Dosing Schedule

Dosing schedule	Day	Dose	
All Patients			
Step-up dosing schedule^a	Day 1	Step-up dose 1	0.06 mg/kg
	Day 4 ^b	Step-up dose 2	0.3 mg/kg
	Day 7 ^c	First treatment dose	1.5 mg/kg
Weekly dosing schedule^a	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	1.5 mg/kg once weekly
Patients who have achieved and maintained a complete response or better for a minimum of 6 months			
Biweekly (every two weeks) dosing schedule^a	The dosing frequency may be decreased to 1.5 mg/kg every two weeks		

^aSee Table 2 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

^bStep-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.

^cFirst treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.

Refer to Tables 7-9 in the full Prescribing Information to determine the dosage based on predetermined weight ranges (see Dosage and Administration [2.5]).

Please read full Important Safety Information on [pages 13-15](#) and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

 **TECVAYLI®**
(teclistamab-cqvy) Injection for
subcutaneous use
10 mg/mL and 90 mg/mL

Recommended Pretreatment Medications

Administer the following pretreatment medications 1 to 3 hours before each dose of the TECVAYLI® step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose (see Table 1 in the full Prescribing Information), to reduce the risk of CRS.

- Corticosteroid (oral or intravenous dexamethasone 16 mg)
- Histamine-1 (H₁) receptor antagonist (oral or intravenous diphenhydramine 50 mg or equivalent)
- Antipyretics (oral or intravenous acetaminophen 650 mg to 1000 mg or equivalent)

Administration of pretreatment medications may be required prior to administration of subsequent doses of TECVAYLI® in the following patients:

- Patients who repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay
- Patients who experienced CRS following the prior dose of TECVAYLI®

Prophylaxis for Herpes Zoster Reactivation

Prior to starting treatment with TECVAYLI®, consider initiation of antiviral prophylaxis to prevent herpes zoster reactivation per guidelines.

Dosage Modifications for Adverse Reactions

Dosage reductions of TECVAYLI® are not recommended.

Dosage delays may be required to manage toxicities related to TECVAYLI®.

See Dosage and Administration Section 2.3 in the full Prescribing Information for guidance regarding restarting TECVAYLI® after dosage delay.

See Tables 3, 4, and 5 in the full Prescribing Information for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 6 in the full Prescribing Information for recommended actions for other adverse reactions following administration of TECVAYLI®.

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



Order sets are commonly used in the management of oncology patients. After initial release, order sets may benefit from a clinical update. The optimization of order sets, referred to as “Order Sets, Beacon protocols or SmartSets” in the Epic EHR, is a common process and provides an opportunity to incorporate treatment updates. Order sets are typically modified at the system level to help reduce practice variation.

Typically, a practice will conduct a clinical review process to confirm and approve the suggested optimization. Various stakeholders may participate in reviewing order set optimization requests prior to implementation.

There are 3 steps to update a Beacon protocol in the Epic EHR system.

- 4.1.** Create Order Groups for TECVAYLI® and its pre-medications (and/or any other system-preferred Order Groups).
- 4.2.** After the Order Groups have been created, add the appropriate Order Groups to the Beacon treatment plan.
- 4.3.** Add recommended reference information to medication record.

4.1 Create the Order Groups

4.1.1. Create a new TECVAYLI® Order Group:

1. Review the “Regimen Category” Order Group to confirm Medications is a value in the category list.

2. Select the Order Group Builder (Admin>Beacon Admin>Order Group Builder).

3. Create a new Order Group named **TECVAYLI®**.

4. Set the default category to Medications.

5. Add TECVAYLI® to the Order Group:

5.1. Right click in the empty field located at the bottom of the window.

5.2. Select Add Orders>Choose the appropriate Medication.

5.3. Select TECVAYLI®.

5.4. Complete the TECVAYLI® medication details (SIG, dose, route, frequency, offset time, admin over, and free form any special Admin instructions to the nurse).

→ See next page for additional steps.

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



5.5. For the Admin instructions, add all of the text below (up to step #6):

Recommended Dosage:

- For subcutaneous injection only
- The recommended dosage of TECVAYLI® is step-up doses of 0.06 mg/kg, 0.3 mg/kg, and a first treatment dose of 1.5 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity. In patients who have achieved and maintained a complete response or better for a minimum of 6 months, the dosing frequency may be decreased to 1.5 mg/kg every two weeks until disease progression or unacceptable toxicity
- Administer pretreatment medications as recommended prior to each dose of the TECVAYLI® step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose as described in Table 1 in the full Prescribing Information

Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Table 1 in the full Prescribing Information to reduce the incidence and severity of cytokine release syndrome (CRS). Due to the risk of CRS and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), patients should be hospitalized for 48 hours after administration of all doses within the TECVAYLI® step-up dosing schedule.

Table 1: TECVAYLI® Dosing Schedule

Dosing schedule	Day	Dose	
All Patients			
Step-up dosing schedule^a	Day 1	Step-up dose 1	0.06 mg/kg
	Day 4 ^b	Step-up dose 2	0.3 mg/kg
	Day 7 ^c	First treatment dose	1.5 mg/kg
Weekly dosing schedule^a	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	1.5 mg/kg once weekly
Patients who have achieved and maintained a complete response or better for a minimum of 6 months			
Biweekly (every two weeks) dosing schedule^a	The dosing frequency may be decreased to 1.5 mg/kg every two weeks		

^aSee Table 2 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

^bStep-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.

^cFirst treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.

Refer to Tables 7-9 in the full Prescribing Information to determine the dosage based on predetermined weight ranges (see Dosage and Administration [2.5]).

Dosage Modifications for Adverse Reactions:

- Dosage reductions of TECVAYLI® are not recommended
- Dosage delays may be required to manage toxicities related to TECVAYLI®
- See Dosage and Administration Section 2.3 in the full Prescribing Information for guidance regarding restarting TECVAYLI® after dosage delay
- See Tables 3, 4, and 5 in the full Prescribing Information for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 6 in the full Prescribing Information for recommended actions for other adverse reactions following administration of TECVAYLI®

→ See next page for additional steps.

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



- Once satisfied with the selections, **release and publish**.

4.1.2. Create a new TECVAYLI® Pre-medications Order Group:

If the organization is using Pre-medications Order Groups, consider adding (using steps below):

- Review the “Regimen Category” Order Group** to confirm Pre-medications is a value in the category list.
- Select the Order Group Builder** (Admin>Beacon Admin>Order Group Builder).
- Create a new Order Group** named **TECVAYLI® Pre-medications**.
- Set the default category to Pre-medications**.
- Add the TECVAYLI® pretreatment medications** to the Order Group:
 - Right click in the empty field** located at the bottom of the window
 - Select Add Orders>Choose the appropriate Medication**
 - Add the following text:**
 - Corticosteroid (oral or intravenous dexamethasone 16 mg)
 - Histamine-1 (H₁) receptor antagonist (oral or intravenous diphenhydramine 50 mg or equivalent)
 - Antipyretics (oral or intravenous acetaminophen 650 mg to 1000 mg or equivalent)
 - Complete the medication details (SIG, dose, route, frequency, offset time, admin over, and free form any special Admin instructions to the nurse)
 - Administer the pretreatment medications 1 to 3 hours before each dose of the TECVAYLI® step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose (see Table 1 in the full Prescribing Information), to reduce the risk of CRS. Administration of pretreatment medications may be required for subsequent doses of TECVAYLI® after a dose delay or CRS
 - Prophylaxis for herpes zoster reactivation: Prior to starting treatment with TECVAYLI®, consider initiation of antiviral prophylaxis to prevent herpes zoster reactivation per guidelines
- Once satisfied with the selections, **release and publish**.
- Add any other desired Order Groups** (treatment parameters, monitoring and hold parameters, pre-medications, antiemetics, supportive care, schedulable orders, emergency meds, provider communication, hydration, prehydration, posthydration).

→ See next page for additional steps.

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



4.2 Add the “TECVAYLI®” and “TECVAYLI® Pre-medications” Order Groups to the desired Beacon protocol

4.2.1. Once the Order Group has been created, **it may be added to existing Beacon protocol(s) or a new Beacon protocol may be created.**

4.2.2. Click the Epic logo>Admin>Beacon Admin>Protocol Builder.

4.2.3. **Search** for all existing order set(s) specific to **relapsed or refractory multiple myeloma**. Depending on naming conventions, consider using search terms such as **multiple myeloma** to find existing plans to optimize.

4.2.4. **Select the desired cycle and add the newly created Order Group** (medications and pre-medications) to the cycles. Confirm the treatment calendar:

- The recommended dosage of TECVAYLI® is step-up doses of 0.06 mg/kg, 0.3 mg/kg, and a first treatment dose of 1.5 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity. In patients who have achieved and maintained a complete response or better for a minimum of 6 months, the dosing frequency may be decreased to 1.5 mg/kg every two weeks until disease progression or unacceptable toxicity. See Table 2 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays
- Day 1: Step-up dose 1:
 - TECVAYLI®: 0.06 mg/kg
- Day 4: Step-up dose 2:
 - TECVAYLI®: 0.3 mg/kg—step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions
- Day 7: First treatment dose:
 - TECVAYLI®: 1.5 mg/kg—first treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions
- One week after first treatment dose and weekly thereafter (subsequent treatment doses) until disease progression or unacceptable toxicity:
 - TECVAYLI®: 1.5 mg/kg—once weekly
- In patients who have achieved and maintained a complete response or better for a minimum of 6 months, the dosing frequency may be decreased to every two weeks) until disease progression or unacceptable toxicity:
 - TECVAYLI®: 1.5 mg/kg—every two weeks

4.2.5. **Save the new Beacon protocol as “TECVAYLI® for relapsed or refractory multiple myeloma”.** Update the description to **“TECVAYLI® is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.”**

4.2.6. Complete testing before releasing the new protocol.

4.2.7. Complete the update process by releasing the protocol.

→ See next page for additional steps.

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



4.3 Add reference information to medication record

Note: Consider adding a link in the reference text of the **TECVAYLI®** medication record (<http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf>). The steps are described below:

4.3.1. Log into the Medication Master File (ERX) with authorized user credentials.

4.3.2. Use the search feature in the **Medication Master File (ERX)** to search and select **TECVAYLI®**.

4.3.3. Select the Patient Medication References Screen and **create four new rows**.

4.3.4. Row 1: For **Display Name**, enter “**Refer to full Prescribing Information**”.

In the text field, enter the following:

“For important information about administering TECVAYLI®, refer to the full Prescribing Information (<http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf>).”

In the URL field, **enter the hyperlink**: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf>.

Row 2: For **Display Name**, enter “**TECVAYLI REMS**”.

In the text field, enter the following:

“TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TECVAYLI® and TALVEY® REMS, which includes:

- Prescribers must be certified with the program by enrolling and completing training
- Prescribers must counsel patients receiving TECVAYLI® about the risk of CRS and neurologic toxicity, including ICANS, and provide patients with Patient Wallet Card
- Pharmacies and healthcare settings that dispense TECVAYLI® must be certified with the TECVAYLI® and TALVEY® REMS program and must verify prescribers are certified through the TECVAYLI® REMS and TALVEY® program

Further information about the TECVAYLI® and TALVEY® REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.”

In the URL field, **enter the hyperlink**: www.TEC-TALREMS.com.

→ See next page for additional steps.

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



4.3.4. (continued)

Row 3: For Display Name, enter “J&J withMe Savings Program”.

In the text field, enter the following:

“Your eligible patients will **pay \$5 per dose**. Maximum program benefit per calendar year shall apply. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medicines. Terms expire at the end of each calendar year. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply. For medicine costs only; program does not cover the cost to give patients their treatment. Patients may participate without sharing their income information. See program requirements at **TECVAYLI.JNJwithMeSavings.com**.”

In the URL field, **enter the hyperlink**: <https://TECVAYLI.JNJwithMeSavings.com>.

Row 4: For Display Name, enter “Transitions of Care”. In the text field, enter the following: “Consider planning for patients’ smooth transition between step-up dosing and weekly maintenance dosing, including necessary coverage and reimbursement planning.”

4.3.5. Save the record.**4.3.6. Release the record** to production after satisfactory testing has been completed.

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



- The Customer (eg, the medical group, Integrated Delivery Network [IDN], Organized Customer Group, and/or Health System) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each Customer's EHR system
- Capabilities, functionality, and set-up (customization) for each individual EHR system vary. Johnson & Johnson shall not be responsible for revising the implementation instructions it provides to any Customer in the event that the Customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Johnson & Johnson. The instructions are not guaranteed to work for all available EHR systems, and Johnson & Johnson shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and Johnson & Johnson shall have no liability thereto
- All products are trademarks of their respective holders, all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of Johnson & Johnson and/or its affiliates

Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



6. Indication and Important Safety Information

Back To
TOC

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Initiate treatment with TECVAYLI® step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome - TECVAYLI® can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI® at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI®. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

TECVAYLI® is available only through a restricted program under a REMS.

Please read full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



6. Important Safety Information (continued)

Back To
TOC

WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS - TECVAYLI® can cause serious, life-threatening or fatal neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®. The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

Due to the potential for neurologic toxicity, patients are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI® step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.

TECVAYLI® is available only through a restricted program under a REMS.

TECVAYLI® and TALVEY® REMS - TECVAYLI® is available only through a restricted program under a REMS called the TECVAYLI® and TALVEY® REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Hepatotoxicity - TECVAYLI® can cause hepatotoxicity, including fatalities. In patients who received TECVAYLI® at the recommended dose in the clinical trial, there was one fatal case of hepatic failure. Elevated aspartate aminotransferase (AST) occurred in 34% of patients, with Grade 3 or 4 elevations in 1.2%. Elevated alanine aminotransferase (ALT) occurred in 28% of patients, with Grade 3 or 4 elevations in 1.8%. Elevated total bilirubin occurred in 6% of patients with Grade 3 or 4 elevations in 0.6%. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Please read full Prescribing Information, including Boxed WARNING, for TECVAYLI®.



6. Important Safety Information (continued)

Back To
TOC

WARNINGS AND PRECAUTIONS (continued)

Neutropenia - TECVAYLI® can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI® at the recommended dose in the clinical trial, decreased neutrophils occurred in 84% of patients, with Grade 3 or 4 decreased neutrophils in 56%. Febrile neutropenia occurred in 3% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines. Monitor patients with neutropenia for signs of infection. Withhold TECVAYLI® based on severity.

Hypersensitivity and Other Administration Reactions - TECVAYLI® can cause both systemic administration-related and local injection-site reactions. Systemic Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, 1.2% of patients experienced systemic-administration reactions, which included Grade 1 recurrent pyrexia and Grade 1 swollen tongue. Local Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, injection-site reactions occurred in 35% of patients, with Grade 1 injection-site reactions in 30% and Grade 2 in 4.8%. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Embryo-Fetal Toxicity - Based on its mechanism of action, TECVAYLI® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TECVAYLI® and for 5 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 20\%$) were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities ($\geq 20\%$) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Please read full **Prescribing Information**, including **Boxed WARNING**, for TECVAYLI®.

cp-322928v5



Please read full Important Safety Information on [pages 13-15](#) and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.



Please read full Important Safety Information on pages 13-15 and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

REFERENCE: TECVAYLI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

Epic® is a registered trademark of Epic Systems Corporation.
For more information, visit www.TECVAYLIhcp.com.

© Johnson & Johnson and its affiliates 2025 10/25 cp-317538v6



Johnson&Johnson