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

iKnowMed®

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 and life-threatening 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 15-17 and full Prescribing Information, including Boxed WARNING, for TECVAYLI® .

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

CONTENTS

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1. Overview and Limitations

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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 iKnowMed® 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

Janssen Biotech, Inc., 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).

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening 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.

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

3. Considerations

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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 18 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		

[a]See Table 2 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

[b]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.

[c]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.

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]).

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TECVAYLI® (teclistamab-cqyv) 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 (H_1) 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®.

4. iKnowMed® Electronic Health Record Instructions

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Treatment Regimens are commonly used in the management of oncology patients. After initial release, Treatment Regimens may benefit from a clinical update. The optimization of Treatment Regimens is a common process and provides an opportunity to incorporate treatment updates.

The iKnowMed EHR allows for customizing a Treatment Regimen 1) outside of Clear Value Plus or (2) using the Clear Value Plus exception. Customers who do not use Clear Value Plus should proceed with the instructions in section 4.1 below. Customers who do use Clear Value Plus should proceed with the instructions in section 4.2 starting on page 10.

There are 2 options to optimize a Treatment Regimen in the iKnowMed EHR system.

4.1 Optimizing a Treatment Regimen for Customers Not Using Clear Value Plus

4.1.1. **Access the Regimens Templates** with admin credentials (Treatment Regimen Orders editor).

4.1.2. In the Regimen Search window, **Search by Diagnosis/Problem** by entering **“relapsed or refractory multiple myeloma”** in the Search field. **Click Search for Regimens** to display Treatment Regimens matching the search terms. Select the desired Treatment Regimen to optimize by copying and renaming it.

4.1.3. **Adjust the Regimens Search Rules and Problems Associations** if desired.

4.1.4. **Complete the Display Name** as **“TECVAYLI® for relapsed or refractory multiple myeloma”**.

4.1.5. Add in the Reference Name as **“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.”**

→ *See next page for additional steps.*

4.1.6. In the **Regimen Comments or Instructions to Provider field**, enter:

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		

[a]See Table 2 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

[b]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.

[c]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.

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.*

4.1.7. **Click + Add Group** and **add a Treatment Group** for the TECVAYLI® Premedications:

- Corticosteroid (oral or intravenous dexamethasone 16 mg)
- Histamine-1 (H_1) 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 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

4.1.8. **Add TECVAYLI® to the desired Treatment Group** by clicking the plus sign next to the Treatment Group.

4.1.9. In the **References**, enter:

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).

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® and TALVEY™ REMS 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.

→ *See next page for additional steps.*

4.1.9. *(continued)*

Janssen CarePath Savings Program: Eligible commercial patients pay $5 per dose for TECVAYLI® out-of-pocket medication costs. There is a limit to savings each year. Program does not cover the cost to give patients their injections. Patients may participate without sharing their income information. See program requirements at Tecvayli.JanssenCarePathSavings.com.

Transitions of Care: Consider planning for patients' smooth transition between step-up dosing and weekly maintenance dosing, including necessary coverage and reimbursement planning.

4.1.10. In the Order Review tab, **complete the Treatment Regimen and add**:

- 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

4.1.11. **Click Save** to complete the new Treatment Regimen.

→ *See next page for additional steps.*

4.2 Optimizing a Treatment Regimen for Customers Using the Exception in Clear Value Plus

4.2.1. **Open a patient chart and select Order Regimen** in the Value Pathways section.

4.2.2. **Enter "relapsed or refractory multiple myeloma"** in the Search field. **Click Search** to display Treatment Regimens matching the search terms. Select the desired Treatment Regimen.

4.2.3. **Select Chemotherapy/Immunotherapy/Targeted Therapy** from the Regimen Type menu.

4.2.4. **Complete the Clear Value Plus wizard** to finalize the pathway information. On the left-hand side, a summary will build while progressing through the wizard. The Treatment Options field will list all available options.

4.2.5. **Select Record Warranted Exception** for an off-pathway treatment.

4.2.6. **Select the desired Exception Reason** and **enter a reason** (for example, **"new research available"**).

4.2.7. **Click Submit Warranted Exception**.

4.2.8. **Click Add New** in the Treatment Regimen header. Find TECVAYLI® and add it to the Treatment Regimen.

4.2.9. **Complete the TECVAYLI® medication details** (SIG, dose, route, frequency, offset time, admin over, and free form any special Admin instructions for the nurse). In the Instructions field, add a link to the TECVAYLI® full Prescribing Information (http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf).

4.2.10. In the Regimen Comments or Instructions to Provider field, **enter**:

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.

→ *See next page for additional steps.*

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

4.2.10. *(continued)*

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		

[a]See Table 2 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

[b]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.

[c]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.

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®

4.2.11. In the Schedule column, **click TECVAYLI®** to edit the Treatment Regimen Order:

- 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

→ *See next page for additional steps.*

4.2.11. *(continued)*

– 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

4.2.12. In the References, **enter**:

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).

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– 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® and TALVEY™ REMS program

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Transitions of Care: Consider planning for patients' smooth transition between step-up dosing and weekly maintenance dosing, including necessary coverage and reimbursement planning.

→ *See next page for additional steps.*

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

4.2.13. **Add** the TECVAYLI® Premedications:

– Corticosteroid (oral or intravenous dexamethasone 16 mg)

– Histamine-1 (H_1) 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 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

4.2.14. **Rename the new Treatment Regimen** as **"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"** and **click Close**.

5. Disclaimers

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- 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. Janssen Biotech, Inc., 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 Janssen Biotech, Inc. The instructions are not guaranteed to work for all available EHR systems, and Janssen Biotech, Inc., 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 Janssen Biotech, Inc., 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 Janssen Biotech, Inc., and/or its affiliates

6. Indication and Important Safety Information

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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 and life-threatening 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®.

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

6. Important Safety Information (continued)

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WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS - TECVAYLI® can cause serious or life-threatening 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®.

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

6. Important Safety Information (continued)

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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 (≥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 (≥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-322928v3

TECVAYLI®
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10 mg/mL and 90 mg/mL

7. Notes

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Please read full Important Safety Information on pages 15-17 and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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

For more information, visit www.TECVAYLIhcp.com.

Johnson&Johnson

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