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

UPDATING ORDER SETS WITH TECVAYLI®

Instructions for the Epic®, Oracle Health®, and OncoEMR® EHR Systems

INDICATIONS 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:

- in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
- as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 47-49 and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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How to Use This Guide

This guide is designed to support healthcare organizations in implementing, optimizing, and maintaining relapsed or refractory multiple myeloma (RRMM) workflows with TECVAYLI®, within the approved indications and consistent with the Prescribing Information, in the electronic health record (EHR). It provides step-by-step instructions to update order sets for RRMM with TECVAYLI® in the Epic®, Oracle Health®, and OncoEMR® EHR systems.

To use this guide, select the relevant EHR section (Epic, Oracle Health, or OncoEMR) and indication (2L+ or 5L+) and follow the instructions for setting up order sets. Each section includes practical tips, configuration steps, and sample content. Always consult your IT or EHR administrator for system-specific requirements and testing before deploying new tools.

J&J Health Information Technology (HIT) Specialists can educate organizations on approved EHR solutions that may address user experience, efficiency, and patient care gaps. **Reach out to your J&J contact to set up time with an HIT Specialist if you would like support or training on this HIT resource.**

Legend

For all the EHR systems, the icon below appears in the Instructions sections to indicate that these actions must be completed by an IT analyst.

IT Analyst

2L+, second line and beyond; 5L+, fifth line and beyond.

Table of Contents

Overview and Limitations

This guide provides instructions for use in the Epic, Oracle Health, and OncoEMR EHR systems to update order sets with TECVAYLI® for the treatment of RRMM (1) in combination with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in adult patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and (2) as monotherapy in adult patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. The instructions will not work for other conditions, treatments, or therapeutic areas or for other EHR systems.

The processes outlined in this document are variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for the implementation, testing, monitoring, and ongoing operation of any EHR tools.

Order Set Considerations

The clinical data elements provided in this section for the order sets 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 (page 50) 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 organization's best practices, thereby reducing the need for additional training.

The content in this section provides an overview and quick reference guide for the dosage and administration details for TECVAYLI® for its approved indications as per the Prescribing Information. Step-by-step instructions for applying these medication details in the order set update are shown in the Order Set Instructions section for each EHR system in this guide.

Order Set Considerations (Cont'd)

Important Dosage and Administration Information

TECVAYLI® is for subcutaneous injection only.

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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information.

Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full TECVAYLI® 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 both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule.

Refer to Tables 8, 9, 10, and 11 in the full TECVAYLI® Prescribing Information to determine the dosage based on predetermined weight ranges.

Recommended TECVAYLI® Dosage

In Combination With DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

The recommended dosing schedule for TECVAYLI® in combination with subcutaneous daratumumab and hyaluronidase-fihj is provided in Table 1 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity.

Table 1: TECVAYLI® Dosage Schedule in Combination With Daratumumab and Hyaluronidase-fihj

Dosing Schedule	Week/Day	TECVAYLI® Dosage[a]	Concomitant Therapy
Step-up dosing schedule[b]	Day 0	N/A	Daratumumab and hyaluronidase-fihj
	Day 1	Step-up dose 1 (0.06 mg/kg)[c]	N/A
	Day 3	Step-up dose 2 (0.3 mg/kg)[d]	N/A
	Day 7	First treatment dose (1.5 mg/kg)[e,f]	Daratumumab and hyaluronidase-fihj
Weekly dosing schedule	Weeks 2 to 8	1.5 mg/kg once weekly[f,g]	Daratumumab and hyaluronidase-fihj once weekly
Biweekly (every two weeks) dosing schedule	Weeks 9 to 24	3 mg/kg every two weeks[f,h]	Daratumumab and hyaluronidase-fihj every two weeks
Every four weeks dosing schedule	Week 25 onwards	3 mg/kg every four weeks[f,i]	Daratumumab and hyaluronidase-fihj every four weeks

[a] See Table 3 in the full TECVAYLI® Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.
[b] The step-up dosing schedule is a component of the recommended TECVAYLI® dosage but is not applicable for the daratumumab and hyaluronidase-fihj dosing.
[c] Step-up dose 1 must be administered 20 hours or more after the daratumumab and hyaluronidase-fihj dose.
[d] Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and if adverse reactions occur, step-up dose 2 may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.
[e] First treatment dose (1.5 mg/kg) may be given between 2 to 4 days after step-up dose 2 and if adverse reactions occur, first full treatment dose may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.
[f] Administer TECVAYLI® at least 3 hours after the daratumumab and hyaluronidase-fihj dose for the first treatment dose. For subsequent doses, administer TECVAYLI® at least 15 minutes after the daratumumab and hyaluronidase-fihj dose.
[g] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[h] Maintain a minimum of 12 days between 3 mg/kg every two weeks doses.
[i] Maintain a minimum of 25 days between 3 mg/kg every four weeks doses.

For dosage and administration instructions for daratumumab and hyaluronidase-fihj, see the Clinical Studies (14.1) section in the full TECVAYLI® Prescribing Information and refer to the daratumumab and hyaluronidase-fihj monotherapy Prescribing Information.

Order Set Considerations (Cont'd)

Recommended TECVAYLI® Dosage (Cont'd)

Monotherapy

The recommended dosing schedule for TECVAYLI® monotherapy is provided in Table 2 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity.

Table 2: TECVAYLI® Dosage Schedule for Monotherapy

Dosing Schedule	Day	Dosage	
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 once weekly thereafter[d]	Subsequent treatment doses	1.5 mg/kg once weekly[d]
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.[e]		

[a] See Table 3 in the full TECVAYLI® 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.
[d] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[e] Maintain a minimum of 12 days between 1.5 mg/kg every two week doses.

Order Set Considerations (Cont'd)

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 Tables 1 and 2 in the full TECVAYLI® 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 1,000 mg)

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

- Repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay
- 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.

Infections

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI® and administer subcutaneous or intravenous immunoglobulin (IVIG) to maintain the serum levels >400 mg/dL.

Dosage Modifications for Adverse Reactions

Dosage reductions of TECVAYLI® are not recommended.

Refer to DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.

Dosage delays may be required to manage toxicities related to TECVAYLI® *[see Warnings and Precautions (5)]*. See Tables 4, 5 and 6 for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 for recommended actions for other adverse reactions following administration of TECVAYLI®.

Epic®

Order Set Instructions

IT Analyst

Order sets are commonly used in the management of oncology patients. After their initial release, order sets may benefit from a clinical update. The optimization of order sets, referred to as "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 main steps to updating a Beacon protocol in the Epic EHR system:

Step 1: Create order groups for the medications, premedications, and supportive care (and/or any other system-preferred order groups).

Step 2: Add the order groups to the desired Beacon protocol.

Step 3: Add recommended reference information to the medication record.

Order Set Instructions (Cont'd)

TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) for 2L+ RRMM

Step 1: Create the order groups

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 the details for TECVAYLI® to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose TECVAYLI®
   - Complete the TECVAYLI® medication details (Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse)
   - For the admin instructions, consider the following text (pages 9-11):

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).

Important Dosage and Administration Information

- TECVAYLI® is for subcutaneous injection only.
- 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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information.

See next page for additional steps.

Order Set Instructions (Cont'd)

Important Dosage and Administration Information (Cont'd)

- Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full TECVAYLI® 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 both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule.
- Refer to Tables 8, 9, 10, and 11 in the full TECVAYLI® Prescribing Information to determine the dosage based on predetermined weight ranges.

Recommended TECVAYLI® Dosage

In Combination With DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

- The recommended dosing schedule for TECVAYLI® in combination with subcutaneous daratumumab and hyaluronidase-fihj is provided in Table 1 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity.

Table 1: TECVAYLI® Dosage Schedule in Combination With Daratumumab and Hyaluronidase-fihj

Dosing Schedule	Week/Day	TECVAYLI® Dosage[a]	Concomitant Therapy
Step-up dosing schedule[b]	Day 0	N/A	Daratumumab and hyaluronidase-fihj
	Day 1	Step-up dose 1 (0.06 mg/kg)[c]	N/A
	Day 3	Step-up dose 2 (0.3 mg/kg)[d]	N/A
	Day 7	First treatment dose (1.5 mg/kg)[e,f]	Daratumumab and hyaluronidase-fihj
Weekly dosing schedule	Weeks 2 to 8	1.5 mg/kg once weekly[f,g]	Daratumumab and hyaluronidase-fihj once weekly
Biweekly (every two weeks) dosing schedule	Weeks 9 to 24	3 mg/kg every two weeks[f,h]	Daratumumab and hyaluronidase-fihj every two weeks
Every four weeks dosing schedule	Week 25 onwards	3 mg/kg every four weeks[f,i]	Daratumumab and hyaluronidase-fihj every four weeks

[a] See Table 3 in the full TECVAYLI® Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.
[b] The step-up dosing schedule is a component of the recommended TECVAYLI® dosage but is not applicable for the daratumumab and hyaluronidase-fihj dosing.
[c] Step-up dose 1 must be administered 20 hours or more after the daratumumab and hyaluronidase-fihj dose.
[d] Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and if adverse reactions occur, step-up dose 2 may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.
[e] First treatment dose (1.5 mg/kg) may be given between 2 to 4 days after step-up dose 2 and if adverse reactions occur, first full treatment dose may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.
[f] Administer TECVAYLI® at least 3 hours after the daratumumab and hyaluronidase-fihj dose for the first treatment dose. For subsequent doses, administer TECVAYLI® at least 15 minutes after the daratumumab and hyaluronidase-fihj dose.
[g] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[h] Maintain a minimum of 12 days between 3 mg/kg every two weeks doses.
[i] Maintain a minimum of 25 days between 3 mg/kg every four weeks doses.

- For dosage and administration instructions for daratumumab and hyaluronidase-fihj, see the Clinical Studies (14.1) section in the full TECVAYLI® Prescribing Information and refer to the daratumumab and hyaluronidase-fihj monotherapy Prescribing Information.

See next page for additional steps.

Order Set Instructions (Cont'd)

Dosage Modifications for Adverse Reactions

Dosage reductions of TECVAYLI® are not recommended.

Refer to the daratumumab and hyaluronidase-fihj Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.

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

See Dosage and Administration Section 2.4 in the full TECVAYLI® Prescribing Information for guidance regarding restarting TECVAYLI® after dosage delay.

See Tables 4, 5, and 6 in the full TECVAYLI® Prescribing Information for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 in the full TECVAYLI® Prescribing Information for recommended actions for other adverse reactions following administration of TECVAYLI®.

6. Once all the desired information is added, release and publish.

Create a new DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) 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 "DARZALEX *FASPRO*®."
4. Set the default category to Medications.
5. Add the details for DARZALEX *FASPRO*® to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose DARZALEX *FASPRO*®
   - Complete the daratumumab and hyaluronidase-fihj medication details (Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse)
   - Consider the following text:
     - For dosage and administration instructions for daratumumab and hyaluronidase-fihj, see the Clinical Studies (14.1) section in the full TECVAYLI® Prescribing Information and refer to the daratumumab and hyaluronidase-fihj monotherapy Prescribing Information.
     - Patients received TECVAYLI® in combination with daratumumab and hyaluronidase-fihj as follows:
       - Subcutaneous TECVAYLI® step-up doses of 0.06 mg/kg and 0.3 mg/kg, followed by TECVAYLI® 1.5 mg/kg once weekly from Weeks 2 to 8, then 3 mg/kg every two weeks from Weeks 9 to 24, then 3 mg/kg every four weeks starting on Week 25 until disease progression or unacceptable toxicity.

       AND

       - Subcutaneous daratumumab and hyaluronidase-fihj 1,800 mg/30,000 units (1,800 mg of daratumumab and 30,000 units of hyaluronidase) starting one day prior to TECVAYLI® and continuing once weekly from Weeks 1 to 8, then every two weeks from Weeks 9 to 24, then every four weeks starting on Week 25 until disease progression or unacceptable toxicity.

See next page for additional steps.

Order Set Instructions (Cont'd)

Create a new TECVAYLI® premedications order group:

Note: If your organization is using premedications order groups, consider adding one (using the steps below).

1. Review the Regimen Category Order Group to confirm Premedications 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® Premedications."
4. Set the default category to Premedications.
5. Add the details for the TECVAYLI® pretreatment medications to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose the appropriate medication
   - Consider adding the following text, as well as the pretreatment medication orders and details, such as Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse:

     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 Tables 1 and 2 in the full TECVAYLI® 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 1,000 mg)

     Administration of pretreatment medications may be required prior to administration of subsequent doses of TECVAYLI® in patients who:
     - Repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay
     - Experienced CRS following the prior dose of TECVAYLI®

     Prior to starting treatment with TECVAYLI®, consider initiation of antiviral prophylaxis to prevent herpes zoster reactivation per guidelines.
6. Once all the desired information is added, release and publish.

See next page for additional steps.

Order Set Instructions (Cont'd)

Create a new TECVAYLI® supportive care order group:

Note: If your organization is using supportive care order groups, consider adding one (using the steps below).

1. Review the Regimen Category Order Group to confirm Supportive Care 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® Supportive Care."
4. Set the default category to Supportive Care.
5. Add the TECVAYLI® supportive care communication order to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose the appropriate communication order
   - Consider adding the following text:

     Consider reviewing consensus guidelines on supportive care medications for bispecific adverse reaction management from the organizations listed below, and order as clinically indicated.
     - mSmart
     - American Oncology Network
     - National Comprehensive Cancer Network® (NCCN®)
6. Once all the desired information is added, release and publish.
7. Add any other desired order groups (treatment parameters, monitoring and hold parameters, antiemetics, schedulable orders, emergency meds, provider communication, hydration, pre-hydration, post hydration).

See next page for additional steps.

Order Set Instructions (Cont'd)

Step 2: Add the TECVAYLI®, DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj), TECVAYLI® premedications, and TECVAYLI® supportive care order groups to the desired Beacon protocol

Note: Once the order groups have been created, they may be added to existing Beacon protocol(s), or a new Beacon protocol may be created.

1. Click the Epic logo > Admin > Beacon Admin > Protocol Builder.
2. Search for all existing protocol(s) specific to relapsed or refractory multiple myeloma. Depending on your organization's naming conventions, consider using search terms such as "multiple myeloma" to find existing protocols to optimize.
3. Select the desired cycle and add the newly created order group (medications, premedications, and supportive care) to the cycle. Set the treatment calendar:
   - TECVAYLI® Dosage Schedule in Combination With Daratumumab and Hyaluronidase-fihj
     - The recommended dosing schedule for TECVAYLI® in combination with subcutaneous daratumumab and hyaluronidase-fihj is provided in Table 1 in the full TECVAYLI® Prescribing Information. TECVAYLI® should be administered until disease progression or unacceptable toxicity
       - Day 0: Daratumumab and hyaluronidase-fihj
     - TECVAYLI® step-up dosing schedule
       - Day 1: Step-up dose 1
         - 0.06 mg/kg
       - Day 3: Step-up dose 2
         - 0.3 mg/kg
       - Day 7: First treatment dose
         - 1.5 mg/kg
         - Daratumumab and hyaluronidase-fihj
     - Weekly dosing schedule
       - Weeks 2 to 8
         - TECVAYLI® 1.5 mg/kg once weekly
         - Daratumumab and hyaluronidase-fihj once weekly
     - Biweekly (every two weeks) dosing schedule
       - Weeks 9 to 24
         - TECVAYLI® 3 mg/kg every two weeks
         - Daratumumab and hyaluronidase-fihj every two weeks
     - Every four weeks dosing schedule
       - Week 25 onwards
         - TECVAYLI® 3 mg/kg every four weeks
         - Daratumumab and hyaluronidase-fihj every four weeks

See next page for additional steps.

Order Set Instructions (Cont'd)

4. Save the new Beacon protocol as "TECVAYLI® and DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) for 2L+ relapsed or refractory multiple myeloma," or follow your organization's standard naming conventions. Update the description to "TECVAYLI® (teclistamab-cqyv) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent."
5. Complete testing before releasing the new protocol.
6. Complete the update process by releasing the protocol.

Step 3: Add reference information to the medication record

Note: Consider adding reference links and text to the TECVAYLI® medication record. The steps are described below.

1. Log in to the Medication Master File (ERX) with authorized user credentials.
2. Use the search feature in the Medication Master File (ERX) to search for and select TECVAYLI®.
3. Page down to the Reference Links screen and add 4 new rows:
4. Row 1: For Display Name, enter "TECVAYLI® Prescribing Information"

   In the URL field, enter this hyperlink: https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf

   Row 2: For Display Name, enter "TECVAYLI® REMS"

   In the URL field, enter this hyperlink: https://www.tec-talrems.com

   Row 3: For Display Name, enter "J&J withMe"

   In the URL field, enter this hyperlink: https://www.portal.jnjwithme.com

   Row 4: For Display Name, enter "Transitions of Care"

   In the URL field, enter this hyperlink: https://www.bispecificsguide.com/documents/cp-425903v1_TECVAYLITALVEY_Transition_of_Care_Checklist_for_Initiating_Treatment_Centers.pdf
5. Page down to where your organization includes additional drug-related information (administration instructions, ordering instructions, etc), and consider adding the following text:
   - For important information about administering TECVAYLI®, refer to the full TECVAYLI® Prescribing Information
   - TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the "TECVAYLI® and TALVEY® REMS" because of the risks of CRS and neurologic toxicity, including ICANS.

   Notable requirements of the TECVAYLI® and TALVEY® REMS include the following:
   - Prescribers must be certified with the REMS 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 the Patient Wallet Card.
   - Pharmacies and healthcare settings that dispense TECVAYLI® must be certified with this REMS and must verify prescribers are certified through this REMS.
   - Wholesalers and distributors must only distribute TECVAYLI® to certified pharmacies or healthcare settings.

   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.

Order Set Instructions (Cont'd)

- J&J withMe is here at every step to provide personalized support to help patients start and stay on their J&J medicines
  - Access Support—to help navigate payer processes
  - Affordability Resources—to help patients discover ways to afford their J&J treatment
  - Personalized, Free 1-on-1 Care Navigator Support for Your Patients—to support the nonclinical needs that may arise while on their prescribed medicine from J&J

Get started with J&J withMe:

Visit **Portal.JNJwithMe.com** or call **833-JNJ-wMe1** (833-565-9631) to investigate your patient's insurance coverage, enroll them in savings, or sign them up for Care Navigator support.

The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TECVAYLI®.

- Consider planning for patients' smooth transition between step-up dosing and ongoing dosing, including necessary coverage and reimbursement planning

6. Save the record.
7. Release the record to production after satisfactory testing has been completed.

Order Set Instructions (Cont'd)

TECVAYLI® for 5L+ RRMM

Step 1: Create the order groups

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 the details for TECVAYLI® to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose TECVAYLI®
   - Complete the TECVAYLI® medication details (Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse)
   - For the admin instructions, consider the following text (pages 17-18):

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).

Important Dosage and Administration Information

- TECVAYLI® is for subcutaneous injection only.
- 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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information.
- Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full TECVAYLI® 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 both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule.
- Refer to Tables 8, 9, 10, and 11 in the full TECVAYLI® Prescribing Information to determine the dosage based on predetermined weight ranges.

See next page for additional steps.

Order Set Instructions (Cont'd)

Recommended TECVAYLI® Dosage

Monotherapy

- The recommended dosing schedule for TECVAYLI® monotherapy is provided in Table 2 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity

Table 2: TECVAYLI® Dosage Schedule for Monotherapy

Dosing Schedule	Day	Dosage	
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 once weekly thereafter[d]	Subsequent treatment doses	1.5 mg/kg once weekly[d]
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.[e]		

[a] See Table 3 in the full TECVAYLI® 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.
[d] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[e] Maintain a minimum of 12 days between 1.5 mg/kg every two week doses.

Dosage Modifications for Adverse Reactions

Monotherapy: Dosage reductions of TECVAYLI® are not recommended.

Refer to daratumumab and hyaluronidase-fihj Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.

Dosage delays may be required to manage toxicities related to TECVAYLI® *[see Warnings and Precautions (5)]*.

See Tables 4, 5 and 6 for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 for recommended actions for other adverse reactions following administration of TECVAYLI®.

6. Once all the desired information is added, release and publish.

See next page for additional steps.

Order Set Instructions (Cont'd)

Create a new TECVAYLI® premedications order group:

Note: If your organization is using premedications order groups, consider adding one (using the steps below).

1. Review the Regimen Category Order Group to confirm Premedications 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® Premedications."
4. Set the default category to Premedications.
5. Add the details for the TECVAYLI® pretreatment medications to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose the appropriate medication
   - Consider adding the following text, as well as the pretreatment medication orders and details, such as Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse:

     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 Tables 1 and 2 in the full TECVAYLI® 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 1,000 mg)

     Administration of pretreatment medications may be required prior to administration of subsequent doses of TECVAYLI® in patients who:
     - Repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay
     - 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.
6. Once all the desired information is added, release and publish.

See next page for additional steps.

Order Set Instructions (Cont'd)

Create a new TECVAYLI® supportive care order group:

Note: If your organization is using supportive care order groups, consider adding one (using the steps below).

1. Review the Regimen Category Order Group to confirm Supportive Care 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® Supportive Care."
4. Set the default category to Supportive Care.
5. Add the TECVAYLI® supportive care communication order to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose the appropriate communication order
   - Consider adding the following text:

     Consider reviewing consensus guidelines on supportive care medications for bispecific adverse reaction management from the organizations listed below, and order as clinically indicated.
     - mSmart
     - American Oncology Network
     - National Comprehensive Cancer Network® (NCCN®)
6. Once all the desired information is added, release and publish.
7. Add any other desired order groups (treatment parameters, monitoring and hold parameters, antiemetics, schedulable orders, emergency meds, provider communication, hydration, pre-hydration, post hydration).

See next page for additional steps.

Order Set Instructions (Cont'd)

Step 2: Add the TECVAYLI®, TECVAYLI® premedications, and TECVAYLI® supportive care order groups to the desired Beacon protocol

Note: Once the order groups have been created, they may be added to existing Beacon protocol(s), or a new Beacon protocol may be created.

1. Click the Epic logo > Admin > Beacon Admin > Protocol Builder.
2. Search for all existing protocol(s) specific to relapsed or refractory multiple myeloma. Depending on your organization's naming conventions, consider using search terms such as "multiple myeloma" to find existing protocols to optimize.
3. Select the desired cycle and add the newly created order group (medications, premedications, and supportive care) to the cycle. Set the treatment calendar:
   - TECVAYLI® Dosage Schedule for Monotherapy
     - The recommended dosing schedule for TECVAYLI® monotherapy is provided in Table 2 in the full TECVAYLI® Prescribing Information. TECVAYLI® should be administered until disease progression or unacceptable toxicity

   All Patients
     - Step-up dosing schedule
       - Day 1: Step-up dose 1
         - 0.06 mg/kg
       - Day 4: Step-up dose 2
         - 0.3 mg/kg
       - Day 7: First treatment dose
         - 1.5 mg/kg
     - Weekly dosing schedule
       - One week after first treatment dose and once 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
       - The dosing frequency may be decreased to 1.5 mg/kg every two weeks
4. Save the new Beacon protocol as "TECVAYLI® for 5L+ relapsed or refractory multiple myeloma," or follow your organization's standard naming conventions. Update the description to "TECVAYLI® (teclistamab-cqyv) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma as monotherapy in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody."
5. Complete testing before releasing the new protocol.
6. Complete the update process by releasing the protocol.

See next page for additional steps.

Order Set Instructions (Cont'd)

Step 3: Add reference information to the medication record

Note: Consider adding reference links and text to the TECVAYLI® medication record. The steps are described below.

1. Log in to the Medication Master File (ERX) with authorized user credentials.
2. Use the search feature in the Medication Master File (ERX) to search for and select TECVAYLI®.
3. Page down to the Reference Links screen and add 4 new rows:
4. Row 1: For Display Name, enter "TECVAYLI® Prescribing Information"

   In the URL field, enter this hyperlink: https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf

   Row 2: For Display Name, enter "TECVAYLI® REMS"

   In the URL field, enter this hyperlink: https://www.tec-talrems.com

   Row 3: For Display Name, enter "J&J withMe"

   In the URL field, enter this hyperlink: https://www.portal.jnjwithme.com

   Row 4: For Display Name, enter "Transitions of Care"

   In the URL field, enter this hyperlink: https://www.bispecificsguide.com/documents/cp-425903v1_TECVAYLITALVEY_Transition_of_Care_Checklist_for_Initiating_Treatment_Centers.pdf
5. Page down to where your organization includes additional drug-related information (administration instructions, ordering instructions, etc), and consider adding the following text:
   - For important information about administering TECVAYLI®, refer to the full TECVAYLI® Prescribing Information
   - TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the "TECVAYLI® and TALVEY® REMS" because of the risks of CRS and neurologic toxicity, including ICANS.

   Notable requirements of the TECVAYLI® and TALVEY® REMS include the following:
   - Prescribers must be certified with the REMS 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 the Patient Wallet Card
   - Pharmacies and healthcare settings that dispense TECVAYLI® must be certified with this REMS and must verify prescribers are certified through this REMS
   - Wholesalers and distributors must only distribute TECVAYLI® to certified pharmacies or healthcare settings

   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.

Order Set Instructions (Cont'd)

- J&J withMe is here at every step to provide personalized support to help patients start and stay on their J&J medicines
  - Access Support—to help navigate payer processes
  - Affordability Resources—to help patients discover ways to afford their J&J treatment
  - Personalized, Free 1-on-1 Care Navigator Support for Your Patients—to support the nonclinical needs that may arise while on their prescribed medicine from J&J

Get started with J&J withMe:

Visit **Portal.JNJwithMe.com** or call **833-JNJ-wMe1** (833-565-9631) to investigate your patient's insurance coverage, enroll them in savings, or sign them up for Care Navigator support.

The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TECVAYLI®.

- Consider planning for patients' smooth transition between step-up dosing and weekly or biweekly (every 2 weeks) dosing, including necessary coverage and reimbursement planning

6. Save the record.
7. Release the record to production after satisfactory testing has been completed.

Oracle Health®

IT Analyst

Order Set Instructions

Order sets are commonly used in the management of oncology patients. After their initial release, order sets may benefit from a clinical update. The optimization of order sets, referred to as "PowerPlans" in the Oracle Health 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.

A PowerPlan may be used to set up TECVAYLI® in the Oracle Health EHR. Administrative user rights are required to access this build tool. An existing PowerPlan may be used as the foundation for a new one.

Consider modifying an existing PowerPlan as a starting template, while saving the original. If no relevant PowerPlans exist, create a new one.

There are 2 steps to update a PowerPlan in the Oracle Health EHR system:

Step 1: Find an existing PowerPlan to modify.

Step 2: Modify the identified PowerPlan to include TECVAYLI®.

Order Set Instructions (Cont'd)

TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) for 2L+ RRMM

Step 1: Find an existing PowerPlan to modify

1. Open DCP tools (dcptools.exe).
2. Select the PowerPlan tool in the Order Management section.
3. Click Task > Open Plan or click the folder icon to search for an existing PowerPlan.
4. Search for and select an existing PowerPlan to optimize. Double-click the plan to display its contents. If no relevant PowerPlans exist, create a new one: Click Tasks > New Plan, define all clinical subcategories, and select orderable items as desired.

   When looking for existing PowerPlans, consider searching for:

   - HEME, HEMATOLOGY, ONC, ONCP, RELAPSED REFRACTORY MULTIPLE MYELOMA, RRMM

Note: The existing PowerPlan will only serve as a template for the new TECVAYLI® PowerPlan. If the original PowerPlan used to create or optimize the new TECVAYLI® PowerPlan includes TECVAYLI®, confirm it is retired or removed from the EHR production system according to your organization's EHR governing principles.

Step 2: Modify the identified PowerPlan to include TECVAYLI®

1. While on the PowerPlan level, update the PowerPlan name by changing the Display Description in the Attribute pane. Consider "TECVAYLI® and daratumumab and hyaluronidase-fihj for 2L+ relapsed or refractory multiple myeloma," or follow your organization's naming conventions.
2. Update the description to "TECVAYLI® (teclistamab-cqyv) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent."
3. Click Save to create a new version of the PowerPlan that can now be modified.
4. While on the PowerPlan level, select the row for Reference Text in the Attribute pane and enter the following text:
   - For important information about administering TECVAYLI®, refer to the full TECVAYLI® Prescribing Information (https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf)
   - TECVAYLI® REMS

     TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the "TECVAYLI® and TALVEY® REMS" because of the risks of CRS and neurologic toxicity, including ICANS.

   Notable requirements of the TECVAYLI® and TALVEY® REMS include the following:

   - Prescribers must be certified with the REMS 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 the Patient Wallet Card
   - Pharmacies and healthcare settings that dispense TECVAYLI® must be certified with this REMS and must verify prescribers are certified through this REMS
   - Wholesalers and distributors must only distribute TECVAYLI® to certified pharmacies or healthcare settings

   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 this hyperlink: https://www.tec-talrems.com

See next page for additional steps.

Order Set Instructions (Cont'd)

- J&J withMe is here at every step to provide personalized support to help patients start and stay on their J&J medicines
  - Access Support—to help navigate payer processes
  - Affordability Resources—to help patients discover ways to afford their J&J treatment
  - Personalized, Free 1-on-1 Care Navigator Support for Your Patients—to support the nonclinical needs that may arise while on their prescribed medicine from J&J

  Get started with J&J withMe:

  Visit **Portal.JNJwithMe.com** or call **833-JNJ-wMe1** (833-565-9631) to investigate your patient's insurance coverage, enroll them in savings, or sign them up for Care Navigator support.

  The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TECVAYLI®.

  In the URL field, enter this hyperlink: https://www.portal.jnjwithme.com

- Consider planning for patients' smooth transition between step-up dosing and ongoing dosing, including necessary coverage and reimbursement planning

  In the URL field, enter this hyperlink: https://www.bispecificsguide.com/documents/cp-425903v1_TECVAYLITALVEY_Transition_of_Care_Checklist_for_Initiating_Treatment_Centers.pdf

5. Click OK.
6. Select the Order tab in the lower right-hand panel and enter "TECVAYLI®" in the Start Search At field. Select the TECVAYLI® order from the results, click the right arrow to move it into the Current list, and click Add.

   Note: Ensure the appropriate Clinical Category is selected for the order before clicking Add.
7. Click the checkbox next to include to include the order in the plan by default.
8. Scroll to the bottom of the Attribute pane for the TECVAYLI® order, and right-click the Order Sentence row to enter order details such as dose, route, frequency, admin over, and any free-form special administration instructions for the nurses, pharmacists, or healthcare professionals. Consider adding the following dosing information (pages 26-28):

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).

See next page for additional steps.

Order Set Instructions (Cont'd)

Important Dosage and Administration Information

- TECVAYLI® is for subcutaneous injection only
- 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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information
- Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full TECVAYLI® 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 both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule
- Refer to Tables 8, 9, 10, and 11 in the full TECVAYLI® Prescribing Information to determine the dosage based on predetermined weight ranges

Recommended TECVAYLI® Dosage

In Combination With DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

- The recommended dosing schedule for TECVAYLI® in combination with subcutaneous daratumumab and hyaluronidase-fihj is provided in Table 1 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity

Table 1: TECVAYLI® Dosage Schedule in Combination With Daratumumab and Hyaluronidase-fihj

Dosing Schedule	Week/Day	TECVAYLI® Dosage[a]	Concomitant Therapy
Step-up dosing schedule[b]	Day 0	N/A	Daratumumab and hyaluronidase-fihj
	Day 1	Step-up dose 1 (0.06 mg/kg)[c]	N/A
	Day 3	Step-up dose 2 (0.3 mg/kg)[d]	N/A
	Day 7	First treatment dose (1.5 mg/kg)[e,f]	Daratumumab and hyaluronidase-fihj
Weekly dosing schedule	Weeks 2 to 8	1.5 mg/kg once weekly[f,g]	Daratumumab and hyaluronidase-fihj once weekly
Biweekly (every two weeks) dosing schedule	Weeks 9 to 24	3 mg/kg every two weeks[f,h]	Daratumumab and hyaluronidase-fihj every two weeks
Every four weeks dosing schedule	Week 25 onwards	3 mg/kg every four weeks[f,i]	Daratumumab and hyaluronidase-fihj every four weeks

[a] See Table 3 in the full TECVAYLI® Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.
[b] The step-up dosing schedule is a component of the recommended TECVAYLI® dosage but is not applicable for the daratumumab and hyaluronidase-fihj dosing.
[c] Step-up dose 1 must be administered 20 hours or more after the daratumumab and hyaluronidase-fihj dose.
[d] Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and if adverse reactions occur, step-up dose 2 may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.
[e] First treatment dose (1.5 mg/kg) may be given between 2 to 4 days after step-up dose 2 and if adverse reactions occur, first full treatment dose may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.
[f] Administer TECVAYLI® at least 3 hours after the daratumumab and hyaluronidase-fihj dose for the first treatment dose. For subsequent doses, administer TECVAYLI® at least 15 minutes after the daratumumab and hyaluronidase-fihj dose.
[g] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[h] Maintain a minimum of 12 days between 3 mg/kg every two weeks doses.
[i] Maintain a minimum of 25 days between 3 mg/kg every four weeks doses.

- For dosage and administration instructions for daratumumab and hyaluronidase-fihj, see the Clinical Studies (14.1) section in the full TECVAYLI® Prescribing Information and refer to the daratumumab and hyaluronidase-fihj monotherapy Prescribing Information.

See next page for additional steps.

Order Set Instructions (Cont'd)

Dosage Modifications for Adverse Reactions

- Refer to daratumumab and hyaluronidase-fihj Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.
- Dosage delays may be required to manage toxicities related to TECVAYLI® *[see Warnings and Precautions (5)]*.
- See Tables 4, 5 and 6 for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 for recommended actions for other adverse reactions following administration of TECVAYLI®. Dosage reductions of TECVAYLI® are not recommended.
- Refer to daratumumab and hyaluronidase-fihj Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.
- Dosage delays may be required to manage toxicities related to TECVAYLI® *[see Warnings and Precautions (5)]*.
- See Tables 4, 5 and 6 for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 for recommended actions for other adverse reactions following administration of TECVAYLI®.

9. Select the Order tab in the lower right-hand panel and enter the following premedications:

- 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 1,000 mg)

10. Click the checkbox next to Include to include the order in the plan by default.

11. Scroll to the bottom of the Attribute pane for the premedication orders, and right-click the Order Sentence row to enter order details such as dose, route, frequency, admin over, and any free-form special administration instructions for the nurses, pharmacists, or healthcare professionals.

12. Select the Note tab in the lower right-hand panel, and enter the following information in the Note box:
"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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information), to reduce the risk of CRS."

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

- Repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay *[see Dosage and Administration (2.4)]*.
- Experienced CRS following the prior dose of TECVAYLI® *[see Dosage and Administration (2.5)]*.

Prophylaxis for Herpes Zoster Reactivation

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

Note: Ensure the appropriate Clinical Category is selected for the note before clicking Add.

See next page for additional steps.

Order Set Instructions (Cont'd)

13. Select the Note tab in the lower right-hand panel, and enter the following supportive care information in the Note box: "Consider reviewing consensus guidelines on supportive care medications for bispecific adverse reaction management from the organizations listed below, and order as clinically indicated.
    - mSmart
    - American Oncology Network
    - National Comprehensive Cancer Network® (NCCN®)"

    Note: Ensure the appropriate Clinical Category is selected for the note before clicking Add.
14. Click the Treatment Schedule section to update the treatment schedule (consider the clinical details below).

    Note: This will be at the PowerPlan level for single phase plans and at the phase level for multiple phase plans.

    - TECVAYLI® Dosage Schedule in Combination With DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)
      - The recommended dosing schedule for TECVAYLI® in combination with subcutaneous daratumumab and hyaluronidase-fihj is provided in Table 1 in the full TECVAYLI® Prescribing Information. TECVAYLI® should be administered until disease progression or unacceptable toxicity
        - Day 0: Daratumumab and hyaluronidase-fihj
      - TECVAYLI® step-up dosing schedule
        - Day 1: Step-up dose 1
          - 0.06 mg/kg
        - Day 3: Step-up dose 2
          - 0.3 mg/kg
        - Day 7: First treatment dose
          - 1.5 mg/kg
          - Daratumumab and hyaluronidase-fihj
      - Weekly dosing schedule
        - Weeks 2 to 8
          - TECVAYLI® 1.5 mg/kg once weekly
          - Daratumumab and hyaluronidase-fihj once weekly
      - Biweekly (every two weeks) schedule
        - Weeks 9 to 24
          - TECVAYLI® 3 mg/kg every two weeks
          - Daratumumab and hyaluronidase-fihj every two weeks
      - Every four weeks dosing schedule
        - Week 25 onwards
          - TECVAYLI® 3 mg/kg every four weeks
          - Daratumumab and hyaluronidase-fihj every four weeks
15. Validate the newly optimized PowerPlan.
16. Release to the production environment after satisfactory testing has been completed.

See next page for additional steps.

Order Set Instructions (Cont'd)

TECVAYLI® for 5L+ RRMM

Step 1: Find an existing PowerPlan to modify

1. Open DCP tools (dcptools.exe).
2. Select the PowerPlan tool in the Order Management section.
3. Click Task > Open Plan or click the folder icon to search for an existing PowerPlan.
4. Search for and select an existing PowerPlan to optimize. Double-click the plan to display its contents. If no relevant PowerPlans exist, create a new one: Click Tasks > New Plan, define all clinical subcategories, and select orderable items as desired.

   When looking for existing PowerPlans, consider searching for:

   - HEME, HEMATOLOGY, ONC, ONCP, RELAPSED REFRACTORY MULTIPLE MYELOMA, RRMM

Note: The existing PowerPlan will only serve as a template for the new TECVAYLI® PowerPlan. If the original PowerPlan used to create or optimize the new TECVAYLI® PowerPlan includes TECVAYLI®, confirm it is retired or removed from the EHR production system according to your organization's EHR governing principles.

Step 2: Modify the identified PowerPlan to include TECVAYLI®

1. While on the PowerPlan level, update the PowerPlan name by changing the Display Description in the Attribute pane. Consider "TECVAYLI® for 5L+ relapsed or refractory multiple myeloma," or follow your organization's naming conventions.
2. Update the description to "TECVAYLI® (teclistamab-cqyv) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma as monotherapy in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody."
3. Click Save to create a new version of the PowerPlan that can now be modified.
4. While on the PowerPlan level, select the row for Reference Text in the Attribute pane and enter the following text:

   - For important information about administering TECVAYLI®, refer to the full TECVAYLI® Prescribing Information (https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf)
   - TECVAYLI® REMS

     TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the "TECVAYLI® and TALVEY® REMS" because of the risks of CRS and neurologic toxicity, including ICANS.

   Notable requirements of the TECVAYLI® and TALVEY® REMS include the following:

   - Prescribers must be certified with the REMS 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 the Patient Wallet Card
   - Pharmacies and healthcare settings that dispense TECVAYLI® must be certified with this REMS and must verify prescribers are certified through this REMS
   - Wholesalers and distributers must only distribute TECVAYLI® to certified pharmacies or healthcare settings

   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 this hyperlink: https://www.tec-talrems.com

See next page for additional steps.

Order Set Instructions (Cont'd)

- J&J withMe is here at every step to provide personalized support to help patients start and stay on their J&J medicines
  - Access Support—to help navigate payer processes
  - Affordability Resources—to help patients discover ways to afford their J&J treatment
  - Personalized, Free 1-on-1 Care Navigator Support for Your Patients—to support the nonclinical needs that may arise while on their prescribed medicine from J&J

  Get started with J&J withMe:

  Visit **Portal.JNJwithMe.com** or call **833-JNJ-wMe1** (833-565-9631) to investigate your patient's insurance coverage, enroll them in savings, or sign them up for Care Navigator support.

  The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TECVAYLI®.

  In the URL field, enter this hyperlink: https://www.portal.jnjwithme.com

- Consider planning for patients' smooth transition between step-up dosing and weekly or biweekly (every 2 weeks) dosing, including necessary coverage and reimbursement planning

  In the URL field, enter this hyperlink: https://www.bispecificsguide.com/documents/cp-425903v1_TECVAYLITALVEY_Transition_of_Care_Checklist_for_Initiating_Treatment_Centers.pdf

5. Click OK.
6. Select the Order tab in the lower right-hand panel and enter "TECVAYLI®" in the Start Search At field. Select the TECVAYLI® order from the results, click the right arrow to move it into the Current list, and click Add.

   Note: Ensure the appropriate Clinical Category is selected for the order before clicking Add.
7. Click the checkbox next to include to include the order in the plan by default.
8. Scroll to the bottom of the Attribute pane for the TECVAYLI® order, and right-click the Order Sentence row to enter order details such as dose, route, frequency, admin over, and any free-form special administration instructions for the nurses, pharmacists, or healthcare professionals. Consider adding the following dosing information (pages 31-33):

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).

See next page for additional steps.

Order Set Instructions (Cont'd)

Important Dosage and Administration Information

- TECVAYLI® is for subcutaneous injection only
- 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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information
- Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full TECVAYLI® 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 both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule
- Refer to Tables 8, 9, 10, and 11 in the full TECVAYLI® Prescribing Information to determine the dosage based on predetermined weight ranges

Recommended TECVAYLI® Dosage

Monotherapy

- The recommended dosing schedule for TECVAYLI® monotherapy is provided in Table 2 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity

Table 2: TECVAYLI® Dosage Schedule for Monotherapy

Dosing Schedule	Day	Dosage	
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 once weekly thereafter[d]	Subsequent treatment doses	1.5 mg/kg once weekly[d]
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.[e]		

[a] See Table 3 in the full TECVAYLI® 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.
[d] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[e] Maintain a minimum of 12 days between 1.5 mg/kg every two week doses.

See next page for additional steps.

Order Set Instructions (Cont'd)

Dosage Modifications for Adverse Reactions

Dosage reductions of TECVAYLI® are not recommended.

Refer to daratumumab and hyaluronidase-fihj Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.

Dosage delays may be required to manage toxicities related to TECVAYLI® *[see Warnings and Precautions (5)]*.

See Tables 4, 5 and 6 for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 for recommended actions for other adverse reactions following administration of TECVAYLI®.

9. Select the Order tab in the lower right-hand panel and enter the following premedications:
   - 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 1,000 mg)
10. Click the checkbox next to Include to include the order in the plan by default.
11. Scroll to the bottom of the Attribute pane for the premedication orders, and right-click the Order Sentence row to enter order details such as dose, route, frequency, admin over, and any free-form special administration instructions for the nurses, pharmacists, or healthcare professionals.
12. Select the Note tab in the lower right-hand panel, and enter the following information in the Note box:

    "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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information), to reduce the risk of CRS."

    "Administration of pretreatment medications may be required prior to administration of subsequent doses of TECVAYLI® in patients who repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay and 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.

    Note: Ensure the appropriate Clinical Category is selected for the note before clicking Add.
13. Select the Note tab in the lower right-hand panel, and enter the following supportive care information in the Note box: "Consider reviewing consensus guidelines on supportive care medications for bispecific adverse reaction management from the organizations listed below, and order as clinically indicated.
    - mSmart
    - American Oncology Network
    - National Comprehensive Cancer Network® (NCCN®)"

    Note: Ensure the appropriate Clinical Category is selected for the note before clicking Add.

See next page for additional steps.

Order Set Instructions (Cont'd)

14. Click the Treatment Schedule section to update the treatment schedule (consider the clinical details below).

Note: This will be at the PowerPlan level for single phase plans and at the phase level for multiple phase plans.

- TECVAYLI® Dosage Schedule for Monotherapy
  - The recommended dosing schedule for TECVAYLI® monotherapy is provided in Table 2 in the full TECVAYLI® Prescribing Information. TECVAYLI® should be administered until disease progression or unacceptable toxicity

All Patients

- Step-up dosing schedule
  - Day 1: Step-up dose 1
    - 0.06 mg/kg
  - Day 4: Step-up dose 2
    - 0.3 mg/kg
  - Day 7: First treatment dose
    - 1.5 mg/kg
- Weekly dosing schedule
  - One week after first treatment dose and once 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
  - The dosing frequency may be decreased to 1.5 mg/kg every two weeks

15. Validate the newly optimized PowerPlan.
16. Release to the production environment after satisfactory testing has been completed.

OncoEMR®

Order Set Instructions

IT Analyst

Order sets are commonly used in the management of oncology patients. After their initial release, order sets may benefit from a clinical update. The optimization of order sets, referred to as "regimens" in the OncoEMR 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, an oncology 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 the implementation.

Order Set Instructions (Cont'd)

TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) for 2L+ RRMM

1. Click the user name in the top right corner and select Customize. A new window will show all customization options.
2. Select Regimen List to access all regimens and protocols.
3. Search for existing regimens specific to relapsed or refractory multiple myeloma by entering the regimen name and/or keywords.
4. Set the radio buttons to optimize the search process (My Practice, Me, etc).
5. If a regimen is available for optimization, select the regimen to start applying the desired changes.
6. Edit the Regimen Name. Consider "TECVAYLI® and daratumumab and hyaluronidase-fihj for 2L+ relapsed or refractory multiple myeloma" for the regimen name.
7. Set the version number.
8. Update the Description, Indication, and References as desired. Consider "TECVAYLI® (teclistamab-cqyv) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent."
9. In the reference text field, enter the following information:
   - For important information about administering TECVAYLI®, refer to the full TECVAYLI® Prescribing Information (https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf)
   - TECVAYLI® REMS: TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the "TECVAYLI® and TALVEY® REMS" because of the risks of CRS and neurologic toxicity, including ICANS. Notable requirements of the TECVAYLI® and TALVEY® REMS include the following:
     - Prescribers must be certified with the REMS 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 the Patient Wallet Card.
     - Pharmacies and healthcare settings that dispense TECVAYLI® must be certified with this REMS and must verify prescribers are certified through this REMS.
     - Wholesalers and distributers must only distribute TECVAYLI® to certified pharmacies or healthcare settings.

     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.

Order Set Instructions (Cont'd)

- J&J withMe is here at every step to provide personalized support to help patients start and stay on their J&J medicines
  - Access Support—to help navigate payer processes
  - Affordability Resources—to help patients discover ways to afford their J&J treatment
  - Personalized, Free 1-on-1 Care Navigator Support for Your Patients—to support the nonclinical needs that may arise while on their prescribed medicine from J&J

  Get started with J&J withMe:

  Visit **Portal.JNJwithMe.com** or call **833-JNJ-wMe1** (833-565-9631) to investigate your patient's insurance coverage, enroll them in savings, or sign them up for Care Navigator support.

  The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TECVAYLI®.
- Consider planning for patients' smooth transition between step-up dosing and ongoing dosing, including necessary coverage and reimbursement planning

10. For the ISI (Important Safety Information) and dosing information, consider the following information (pages 37-39):

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).

Important Dosage and Administration Information

- TECVAYLI® is for subcutaneous injection only.
- 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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information.
- Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full TECVAYLI® 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 both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule.
- Refer to Tables 8, 9, 10, and 11 in the full TECVAYLI® Prescribing Information to determine the dosage based on predetermined weight ranges.

See next page for additional steps.

Order Set Instructions (Cont'd)

Recommended TECVAYLI® Dosage

In Combination With DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

- The recommended dosing schedule for TECVAYLI® in combination with subcutaneous daratumumab and hyaluronidase-fihj is provided in Table 1 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity.

Table 1: TECVAYLI® Dosage Schedule in Combination With Daratumumab and Hyaluronidase-fihj

Dosing Schedule	Week/Day	TECVAYLI® Dosage[a]	Concomitant Therapy
Step-up dosing schedule[b]	Day 0	N/A	Daratumumab and hyaluronidase-fihj
	Day 1	Step-up dose 1 (0.06 mg/kg)[c]	N/A
	Day 3	Step-up dose 2 (0.3 mg/kg)[d]	N/A
	Day 7	First treatment dose (1.5 mg/kg)[e,f]	Daratumumab and hyaluronidase-fihj
Weekly dosing schedule	Weeks 2 to 8	1.5 mg/kg once weekly[f,g]	Daratumumab and hyaluronidase-fihj once weekly
Biweekly (every two weeks) dosing schedule	Weeks 9 to 24	3 mg/kg every two weeks[f,h]	Daratumumab and hyaluronidase-fihj every two weeks
Every four weeks dosing schedule	Week 25 onwards	3 mg/kg every four weeks[f,i]	Daratumumab and hyaluronidase-fihj every four weeks

[a] See Table 3 in the full TECVAYLI® Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.
[b] The step-up dosing schedule is a component of the recommended TECVAYLI® dosage but is not applicable for the daratumumab and hyaluronidase-fihj dosing.
[c] Step-up dose 1 must be administered 20 hours or more after the daratumumab and hyaluronidase-fihj dose.
[d] Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and if adverse reactions occur, step-up dose 2 may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.
[e] First treatment dose (1.5 mg/kg) may be given between 2 to 4 days after step-up dose 2 and if adverse reactions occur, first full treatment dose may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.
[f] Administer TECVAYLI® at least 3 hours after the daratumumab and hyaluronidase-fihj dose for the first treatment dose. For subsequent doses, administer TECVAYLI® at least 15 minutes after the daratumumab and hyaluronidase-fihj dose.
[g] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[h] Maintain a minimum of 12 days between 3 mg/kg every two weeks doses.
[i] Maintain a minimum of 25 days between 3 mg/kg every four weeks doses.

- For dosage and administration instructions for daratumumab and hyaluronidase-fihj, see the Clinical Studies (14.1) section in the full TECVAYLI® Prescribing Information and refer to the daratumumab and hyaluronidase-fihj monotherapy Prescribing Information.

See next page for additional steps.

Order Set Instructions (Cont'd)

Dosage Modifications for Adverse Reactions

- Refer to daratumumab and hyaluronidase-fihj Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.
- Dosage delays may be required to manage toxicities related to TECVAYLI® *[see Warnings and Precautions (5)]*.
- See Tables 4, 5 and 6 for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 for recommended actions for other adverse reactions following administration of TECVAYLI®.

11. Click Add Premed and consider adding the following text, as well as the pretreatment medication orders and details, such as Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse:

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 Tables 1 and 2 in the full TECVAYLI® 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 1,000 mg)

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

- Repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay
- Experienced CRS following the prior dose of TECVAYLI®

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

12. Click Add Supportive Care and add the following TECVAYLI® supportive care guidance:

Consider reviewing consensus guidelines on supportive care medications for bispecific adverse reaction management from the organizations listed below, and order as clinically indicated.

- mSmart
- American Oncology Network
- National Comprehensive Cancer Network® (NCCN®)

See next page for additional steps.

Order Set Instructions (Cont'd)

13. Click Add Drug to add TECVAYLI® to the regimen (consider the clinical details below).
    - TECVAYLI® Dosage Schedule in Combination With DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)
      - The recommended dosing schedule for TECVAYLI® in combination with subcutaneous daratumumab and hyaluronidase-fihj is provided in Table 1 in the full TECVAYLI® Prescribing Information. TECVAYLI® should be administered until disease progression or unacceptable toxicity
        - Day 0: Daratumumab and hyaluronidase-fihj
      - TECVAYLI® step-up dosing schedule
        - Day 1: Step-up dose 1
          - 0.06 mg/kg
        - Day 3: Step-up dose 2
          - 0.3 mg/kg
        - Day 7: First treatment dose
          - 1.5 mg/kg
          - Daratumumab and hyaluronidase-fihj
      - Weekly dosing schedule
        - Weeks 2 to 8
          - TECVAYLI® 1.5 mg/kg once weekly
          - Daratumumab and hyaluronidase-fihj once weekly
      - Biweekly (every two weeks) dosing schedule
        - Weeks 9 to 24
          - TECVAYLI® 3 mg/kg every two weeks
          - Daratumumab and hyaluronidase-fihj every two weeks
      - Every four weeks dosing schedule
        - Week 25 onwards
          - TECVAYLI® 3 mg/kg every four weeks
          - Daratumumab and hyaluronidase-fihj every four weeks
14. Set the cLen and cNum fields as desired.
15. Click Save once the regimen has been completed.
16. Validate the new regimen and, after satisfactory testing has been completed, release to a production environment.

Order Set Instructions (Cont'd)

TECVAYLI® for 5L+ RRMM

1. Click the user name in the top right corner and select Customize. A new window will show all customization options.
2. Select Regimen List to access all regimens and protocols.
3. Search for existing regimens specific to relapsed or refractory multiple myeloma by entering the regimen name and/or keywords.
4. Set the radio buttons to optimize the search process (My Practice, Me, etc).
5. If a regimen is available for optimization, select the regimen to start applying the desired changes.
6. Edit the Regimen Name. Consider "TECVAYLI® for 5L+ relapsed or refractory multiple myeloma" for the regimen name.
7. Set the version number.
8. Update the Description, Indication, and References as desired. Consider "TECVAYLI® (teclistamab-cqyv) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma as monotherapy in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody."
9. In the reference text field, enter the following information:
   - For important information about administering TECVAYLI®, refer to the full TECVAYLI® Prescribing Information (https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf)
   - TECVAYLI® REMS: TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the "TECVAYLI® and TALVEY® REMS" because of the risks of CRS and neurologic toxicity, including ICANS. Notable requirements of the TECVAYLI® and TALVEY® REMS include the following:
     - Prescribers must be certified with the REMS 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 the Patient Wallet Card.
     - Pharmacies and healthcare settings that dispense TECVAYLI® must be certified with this REMS and must verify prescribers are certified through this REMS.
     - Wholesalers and distributers must only distribute TECVAYLI® to certified pharmacies or healthcare settings.

   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.

Order Set Instructions (Cont'd)

- J&J withMe is here at every step to provide personalized support to help patients start and stay on their J&J medicines
  - Access Support—to help navigate payer processes
  - Affordability Resources—to help patients discover ways to afford their J&J treatment
  - Personalized, Free 1-on-1 Care Navigator Support for Your Patients—to support the nonclinical needs that may arise while on their prescribed medicine from J&J

  Get started with J&J withMe:

  Visit **Portal.JNJwithMe.com** or call **833-JNJ-wMe1** (833-565-9631) to investigate your patient's insurance coverage, enroll them in savings, or sign them up for Care Navigator support.

  The patient support and resources provided by J&J withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TECVAYLI®.
- Consider planning for patients' smooth transition between step-up dosing and weekly or biweekly (every 2 weeks) dosing, including necessary coverage and reimbursement planning

10. For the ISI (Important Safety Information) and dosing information, consider the following information (pages 42-43):

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).

Important Dosage and Administration Information

- TECVAYLI® is for subcutaneous injection only.
- 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 Tables 1 and 2 in the full TECVAYLI® Prescribing Information.
- Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full TECVAYLI® 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 both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule.
- Refer to Tables 8, 9, 10, and 11 in the full TECVAYLI® Prescribing Information to determine the dosage based on predetermined weight ranges.

See next page for additional steps.

Order Set Instructions (Cont'd)

Recommended TECVAYLI® Dosage

Monotherapy

- The recommended dosing schedule for TECVAYLI® monotherapy is provided in Table 2 below. TECVAYLI® should be administered until disease progression or unacceptable toxicity.

Table 2: TECVAYLI® Dosage Schedule for Monotherapy

Dosing Schedule	Day	Dosage	
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 once weekly thereafter[d]	Subsequent treatment doses	1.5 mg/kg once weekly[d]
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.[e]		

[a] See Table 3 in the full TECVAYLI® 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.
[d] Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
[e] Maintain a minimum of 12 days between 1.5 mg/kg every two week doses.

Dosage Modifications for Adverse Reactions

Monotherapy: Dosage reductions of TECVAYLI® are not recommended.

Refer to daratumumab and hyaluronidase-fihj Prescribing Information for information about dosage modifications for daratumumab and hyaluronidase-fihj.

Dosage delays may be required to manage toxicities related to TECVAYLI® *[see Warnings and Precautions (5)]*.

See Tables 4, 5 and 6 for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 7 for recommended actions for other adverse reactions following administration of TECVAYLI®.

See next page for additional steps.

Order Set Instructions (Cont'd)

11. Click Add Premed and consider adding the following text, as well as the pretreatment medication orders and details, such as Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse:

    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 Tables 1 and 2 in the full TECVAYLI® 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 1,000 mg)

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

    - Repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay
    - Experienced CRS following the prior dose of TECVAYLI®

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

12. Click Add Supportive Care and add the following TECVAYLI® supportive care guidance:

    Consider reviewing consensus guidelines on supportive care medications for bispecific adverse reaction management from the organizations listed below, and order as clinically indicated.

    - mSmart
    - American Oncology Network
    - National Comprehensive Cancer Network® (NCCN®)

See next page for additional steps.

Order Set Instructions (Cont'd)

13. Click Add Drug to add TECVAYLI® to the regimen (consider the clinical details below).
    - TECVAYLI® Dosage Schedule for Monotherapy
      - The recommended dosing schedule for TECVAYLI® monotherapy is provided in Table 2 in the full TECVAYLI® Prescribing Information. TECVAYLI® should be administered until disease progression or unacceptable toxicity

    All Patients
      - Step-up dosing schedule
        - Day 1: Step-up dose 1
          - 0.06 mg/kg
        - Day 4: Step-up dose 2
          - 0.3 mg/kg
        - Day 7: First treatment dose
          - 1.5 mg/kg
      - Weekly dosing schedule
        - One week after first treatment dose and once 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
        - The dosing frequency may be decreased to 1.5 mg/kg every two weeks
14. Set the cLen and cNum fields as desired.
15. Click Save once the regimen has been completed.
16. Validate the new regimen and, after satisfactory testing has been completed, release to a production environment.

Disclaimers

- The customer (eg, physician, medical group, integrated delivery network) 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 setup (customization) for each individual EHR system vary. Johnson & Johnson shall not be responsible for revising the implementation instructions it provides to any customer if that 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
- While Johnson & Johnson tests its implementation instructions on multiple EHR systems, 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, treatment, and referral, 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
- The instructions have not been designed for, and are not tools and/or solutions for, meeting Advancing Care Information and/or any other quality/accreditation requirement
- All products are trademarks of their respective holders. Reference to these products is not intended to imply affiliation with or sponsorship of Johnson & Johnson and/or its affiliates

INDICATIONS 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:

- in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
- as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 trials (monotherapy and combination therapy; N=448), CRS occurred in 64% of patients who received TECVAYLI at the recommended dosage, with Grade 1 CRS occurring in 46% of patients, Grade 2 in 18%, and Grade 3 in 0.2%. Recurrent CRS occurred in 27% of patients. Most patients experienced CRS during the initial step-up dosing schedule (step-up dose 1 [37%], step-up dose 2 [32%], or the initial treatment dose [20%]). CRS first occurred following subsequent doses of TECVAYLI in 2.5% of patients. The median time to onset of CRS was 2 (range: 1 to 9) days after the most recent dose and the median duration of CRS was 2 (range: 1 to 22) 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 the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold until CRS resolves or permanently discontinue TECVAYLI based on severity.

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

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome – TECVAYLI can cause serious, life-threatening, or fatal neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

In the clinical trials (monotherapy and combination therapy trials; N=448), neurologic toxicity occurred in 60% of patients who received TECVAYLI at the recommended dosage, with Grade 3 or 4 neurologic toxicity in 6%. Neurologic toxicities reported in ≥5% of patients included headache (27%), sensory neuropathy (16%), motor dysfunction (15%), insomnia (12%), encephalopathy (11%), and dizziness (8%). Fatal neurologic toxicity occurred in 0.4% of patients, including Guillain-Barré syndrome and status epilepticus (one patient each).

IMPORTANT SAFETY INFORMATION (Cont'd)
WARNINGS AND PRECAUTIONS (Cont'd)

In MajesTEC-1, ICANS was reported in 6% of patients who received TECVAYLI as monotherapy at the recommended dosage. 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 TECVAYLI doses. 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.

In MajesTEC-3, ICANS was reported in 1.1% of patients who received the recommended TECVAYLI dosage in combination with daratumumab and hyaluronidase-fihj, including Grade 4 ICANS in 1 patient. All events of ICANS occurred during the step-up dosing schedule. The median time to onset of ICANS was 2 (range: 1 to 3) days after the most recent dose and the median duration of ICANS was 2 (range: 1 to 2) days. The clinical manifestations of ICANS reported were amnesia, encephalopathy and delirium.

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, including ICANS during TECVAYLI treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold until neurologic toxicity resolves 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 receiving TECVAYLI 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. There was one fatal case of hepatic failure in MajesTEC-1. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448) elevated aspartate aminotransferase (AST) occurred in 47% of patients, with Grade 3 or 4 elevations in 2.9%. Elevated alanine aminotransferase (ALT) occurred in 48% of patients, with Grade 3 or 4 elevations in 3.8%. Elevated total bilirubin occurred in 10% of patients with Grade 3 or 4 elevations in 0.7%. 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 MajesTEC-1 (N=165), in patients who received the recommended TECVAYLI dosage, serious infections, including opportunistic infections, occurred in 30% of patients, Grade 3 or 4 infections in 35% of patients, and fatal infections in 4.2% of patients.

In MajesTEC-3 (N=283), in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj at the recommended dosage, serious infections, including opportunistic infections, occurred in 54% of patients, Grade 3 or Grade 4 infections in 54% of patients, and fatal infections in 4.6% of patients.

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI and treat appropriately. Administer prophylactic antimicrobials according to current practice guidelines.

Withhold TECVAYLI or consider permanent discontinuation of TECVAYLI based on severity.

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI and administer subcutaneous or intravenous immunoglobulin (IVIG) to maintain the serum levels >400 mg/dL.

IMPORTANT SAFETY INFORMATION (Cont'd)
WARNINGS AND PRECAUTIONS (Cont'd)

Neutropenia – TECVAYLI can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), decreased neutrophils occurred in 88% of patients, with Grade 3 or 4 decreased neutrophils in 70%. Febrile neutropenia occurred in 6% 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 the recommended TECVAYLI dosage in the clinical trials (monotherapy and combination therapy trials; N=448), 2.5% of patients experienced systemic-administration reactions, which included recurrent pyrexia and rash.

Local Reactions - In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), injection-site reactions occurred in 37% of patients, with Grade 1 injection-site reactions in 29% and Grade 2 in 9%.

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 patient. Advise pregnant patients 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%) in patients who received TECVAYLI monotherapy were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common adverse reactions (≥20%) in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj were hypogammaglobulinemia, upper respiratory tract infection, CRS, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight decreased.

The most common Grade 3 to 4 laboratory abnormalities (≥20%) with TECVAYLI (as monotherapy or in combination with daratumumab and hyaluronidase-fihj) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

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

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Notes

Please read full Important Safety Information on pages 47–49 and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Reference: 1. TECVAYLI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

For more information, visit https://www.tecvaylihcp.com/.