OncoEMR®

TALVEY®
(talquetamab-tgvs) Injection for subcutaneous use
2 mg/mL and 40 mg/mL

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

UPDATING RELAPSED OR REFRACTORY MULTIPLE MYELOMA ORDER SETS WITH **TALVEY® (talquetamab-tgvs)**

INDICATION AND USAGE

TALVEY® (talquetamab-tgvs) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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

IMPORTANT SAFETY INFORMATION

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

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

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY® 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 14-16 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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TALVEY® (talquetamab-tgvs) Injection for subcutaneous use 2 mg/mL and 40 mg/mL

1. Overview and Limitations

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

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

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

2. Background and Indication

Johnson & Johnson has developed this resource for health systems who desire to update EHR order sets with TALVEY®.

INDICATION AND USAGE

TALVEY® (talquetamab-tgvs) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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

3. Considerations

The clinical data elements provided are only suggestions, and it is strongly recommended that clinical and operational leadership determine that the final elements align with the expectations and goals of the organization. A Notes section (located on page 17 of this guide) can be used by clinical leadership to document any additions or changes that need to be made in order to align these instructions with practice protocols or pathways.

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

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

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

Important Dosing Information

Administer TALVEY® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 to reduce the incidence and severity of cytokine release syndrome (CRS).

Administer pretreatment medications prior to each dose of TALVEY® in the step-up dosing schedule as recommended.

TALVEY® should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS).

Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of all doses within the TALVEY® step-up dosing schedule.

Recommended Dosage

For subcutaneous injection.

Administer pretreatment medications prior to each dose of TALVEY® in the step-up dosing schedule.

Administer TALVEY® subcutaneously on a weekly or biweekly (every 2 weeks) dosing schedule according to Table 1 or Table 2 in the full Prescribing Information. Continue treatment until disease progression or unacceptable toxicity.

Table 1: TALVEY® Weekly Dosing Schedule

Dosing schedule	Day	Dose[a]	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4[b]	Step-up dose 2	0.06 mg/kg
	Day 7[b]	First treatment dose	0.4 mg/kg
Weekly dosing schedule	One week after first treatment dose and weekly thereafter[c]	Subsequent treatment doses	0.4 mg/kg once weekly

[a]Based on actual body weight.

[b]Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

[c]Maintain a minimum of 6 days between weekly doses.

Table 2: TALVEY® Biweekly (Every 2 Weeks) Dosing Schedule

Dosing schedule	Day	Dose[a]	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4[b]	Step-up dose 2	0.06 mg/kg
	Day 7[b]	Step-up dose 3	0.4 mg/kg
	Day 10[c]	First treatment dose	0.8 mg/kg
Biweekly (every 2 weeks) dosing schedule	Two weeks after first treatment dose and every 2 weeks thereafter[d]	Subsequent treatment doses	0.8 mg/kg every 2 weeks

[a]Based on actual body weight.

[b]Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

[c]Dose may be administered between 2 to 7 days after step-up dose 3.

[d]Maintain a minimum of 12 days between biweekly (every 2 weeks) doses.

Recommended Pretreatment Medications

Administer the following pretreatment medications 1 to 3 hours before each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS:

- Corticosteroid (oral or intravenous dexamethasone, 16 mg or equivalent)
- Antihistamines (oral or intravenous diphenhydramine, 50 mg or equivalent)
- Antipyretics (oral or intravenous acetaminophen, 650 mg to 1,000 mg or equivalent)

Administration of pretreatment medications may be required for subsequent doses of TALVEY® in the following patients:

- Patients who repeat doses within the TALVEY® step-up dosing schedule due to dose delays (see Table 3 or Table 4 in the full Prescribing Information)
- Patients who experienced CRS (see Table 5 in the full Prescribing Information)

Dosage Modifications for Adverse Reactions

Dose delays may be required to manage toxicities related to TALVEY®.

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

See Table 5, Table 6, and Table 7 in the full Prescribing Information for recommended actions for the management of CRS, ICANS, and neurologic toxicity. See Table 8 in the full Prescribing Information for recommended dose modifications for other adverse reactions.

4. OncoEMR® Electronic Health Record Instructions

Order sets are commonly used in the management of oncology patients. After initial release, order sets may benefit from a clinical update. The optimization of order sets, referred to as "Regimens" in the OncoEMR EHR, is a common process and provides an opportunity to incorporate treatment updates. Regimens 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.

4.1. **Click the user name in the top right corner** and **select Customize**. A new window will show all customization options.

4.2. **Select Regimen List** to access all regimens and protocols.

4.3. **Search for existing regimens specific to "relapsed or refractory multiple myeloma"** by entering the regimen name and/or key words.

4.4. **Set the radio buttons** to optimize the search process (My Practice, Me, etc).

4.5. If a regimen is available for optimization, **select the regimen** to start applying the desired changes.

4.6. **Edit the Regimen Name**. Consider **"TALVEY® for relapsed or refractory multiple myeloma"** for the regimen name.

4.7. **Set** the version number.

4.8. **Update the Description, Indication, and References** as desired. Consider **"TALVEY® (talquetamab-tgvs) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody."**

→ *See next page for additional steps.*

4.9. In the **reference text field, enter**:

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

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

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

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 TALVEY®.

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

See next page for additional steps.

4.10. For the **ISI (Important Safety Information), enter**:

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 TALVEY®. Initiate TALVEY® treatment with step-up dosing to reduce the risk of CRS. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

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

Important Dosing Information:

– Administer TALVEY® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 to reduce the incidence and severity of cytokine release syndrome (CRS)

– Administer pretreatment medications prior to each dose of TALVEY® in the step-up dosing schedule as recommended

– TALVEY® should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS)

– Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of all doses within the TALVEY® step-up dosing schedule

Recommended Dosage:

– For subcutaneous injection

– Administer pretreatment medications prior to each dose of TALVEY® in the step-up dosing schedule

– Administer TALVEY® subcutaneously on a weekly or biweekly (every 2 weeks) dosing schedule according to Table 1 or Table 2 in the full Prescribing Information. Continue treatment until disease progression or unacceptable toxicity

See next page for additional steps.

4.10. (*continued*)

Table 1: TALVEY® Weekly Dosing Schedule

Dosing schedule	Day	Dose[a]	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4[b]	Step-up dose 2	0.06 mg/kg
	Day 7[b]	First treatment dose	0.4 mg/kg
Weekly dosing schedule	One week after first treatment dose and weekly thereafter[c]	Subsequent treatment doses	0.4 mg/kg once weekly

[a]Based on actual body weight.

[b]Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

[c]Maintain a minimum of 6 days between weekly doses.

Table 2: TALVEY® Biweekly (Every 2 Weeks) Dosing Schedule

Dosing schedule	Day	Dose[a]	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4[b]	Step-up dose 2	0.06 mg/kg
	Day 7[b]	Step-up dose 3	0.4 mg/kg
	Day 10[c]	First treatment dose	0.8 mg/kg
Biweekly (every 2 weeks) dosing schedule	Two weeks after first treatment dose and every 2 weeks thereafter[d]	Subsequent treatment doses	0.8 mg/kg every 2 weeks

[a]Based on actual body weight.

[b]Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

[c]Dose may be administered between 2 to 7 days after step-up dose 3.

[d]Maintain a minimum of 12 days between biweekly (every 2 weeks) doses.

Dosage Modifications for Adverse Reactions:

– Dose delays may be required to manage toxicities related to TALVEY®

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

– See Table 5, Table 6, and Table 7 in the full Prescribing Information for recommended actions for the management of CRS, ICANS, and neurologic toxicity. See Table 8 in the full Prescribing Information for recommended dose modifications for other adverse reactions

See next page for additional steps.

4.11. **Click Add Premed** and **add the TALVEY® premedications**:

Administer the following pretreatment medications 1 to 3 hours before each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS:

– Corticosteroid (oral or intravenous dexamethasone, 16 mg or equivalent)

– Antihistamines (oral or intravenous diphenhydramine, 50 mg or equivalent)

– Antipyretics (oral or intravenous acetaminophen, 650 mg to 1,000 mg or equivalent)

- Complete the medication details (SIG, dose, route, frequency, offset time, admin over, and free form any special Admin instructions to the nurse)
- Administration of pretreatment medications may be required for subsequent doses for patients who repeat doses within the TALVEY® step-up dosing schedule due to dose delays (see Table 3 or Table 4 in the full Prescribing Information) or for patients who experienced CRS (see Table 5 in the full Prescribing Information)

4.12. **Click Add Drug** to add TALVEY® to the regimen:

– Weekly dosing schedule

- The recommended dosage of TALVEY® (based on actual body weight) is step-up doses of 0.01 mg/kg, 0.06 mg/kg, and 0.4 mg/kg, followed by a weekly dose of 0.4 mg/kg with treatment continued once weekly until disease progression or unacceptable toxicity. See Table 3 in the full Prescribing Information for recommendations on restarting TALVEY® after dose delays for adverse reactions
- Step-up dosing
  - Day 1: Step-up dose 4
    - » TALVEY®: 0.01 mg/kg
  - Day 4: Step-up dose 2
    - » TALVEY®: 0.06 mg/kg—step-up dose 2 may be administered between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions
  - Day 7: First treatment dose
    - » TALVEY®: 0.4 mg/kg—first treatment dose may be administered 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
- Weekly dosing
  - One week after first treatment dose and weekly thereafter: Subsequent treatment doses
    - » TALVEY®: 0.4 mg/kg once weekly—maintain a minimum of 6 days between weekly doses

→ *See next page for additional steps.*

4.12. (*continued*)

– Biweekly (every 2 weeks) dosing schedule

- The recommended dosage of TALVEY® (based on actual body weight) is step-up doses of 0.01 mg/kg, 0.06 mg/kg, 0.4 mg/kg, and 0.8 mg/kg, followed by a biweekly dose of 0.8 mg/kg with treatment continued once every two weeks until disease progression or unacceptable toxicity. See Table 4 in the full Prescribing Information for recommendations on restarting TALVEY® after dose delays for adverse reactions
- Step-up dosing
  - Day 1: Step-up dose 1
    - » TALVEY®: 0.01 mg/kg
  - Day 4: Step-up dose 2
    - » TALVEY®: 0.06 mg/kg—step-up dose 2 may be administered between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions
  - Day 7: Step-up dose 3
    - » TALVEY®: 0.4 mg/kg—step-up dose 3 may be administered 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
  - Day 10: First treatment dose
    - » TALVEY®: 0.8 mg/kg—first treatment dose may be administered between 2 to 7 days after step-up dose 3
- Biweekly (every 2 weeks) dosing
  - Two weeks after first treatment dose and every 2 weeks thereafter: Subsequent treatment doses
    - » TALVEY®: 0.8 mg/kg every 2 weeks—maintain a minimum of 12 days between biweekly (every 2 weeks) doses

4.13. **Set the cLen and cNum fields** as desired.

4.14. **Click Save** once the regimen has been completed.

4.15. **Validate the new regimen** and, after satisfactory testing has been completed, **release to a production environment**.

5. Disclaimers

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

6. Important Safety Information

INDICATION AND USAGE

TALVEY® (talquetamab-tgvs) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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

IMPORTANT SAFETY INFORMATION

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

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

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

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

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS): TALVEY® can cause cytokine release syndrome, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 76% of patients who received TALVEY® at the recommended dosages, with Grade 1 CRS occurring in 57% of patients, Grade 2 in 17%, and Grade 3 in 1.5%. Recurrent CRS occurred in 30% of patients. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Initiate therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should be administered prior to the next TALVEY® dose.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity, and consider further management per current practice guidelines. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

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

TALVEY® (talquetamab-tgvs) Injection for subcutaneous use
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6. Important Safety Information (continued)

Neurologic Toxicity including ICANS: TALVEY® can cause serious, life-threatening neurologic toxicity or fatal neurologic toxicity, including ICANS.

In the clinical trial, neurologic toxicity, including ICANS, occurred in 55% of patients who received the recommended dosages, with Grade 3 or 4 neurologic toxicity occurring in 6% of patients. The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction, including ataxia/cerebellar ataxia (10%). ICANS was reported in 9% of 265 patients where ICANS was collected and who received the recommended dosages. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Monitor patients for signs and symptoms of neurologic toxicity during treatment and treat promptly. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive care based on severity. Withhold or permanently discontinue TALVEY® based on severity and consider further management per current practice guidelines [see Dosage and Administration (2.5)].

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

TECVAYLI® and TALVEY® REMS: TALVEY® 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.

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

Oral Toxicity and Weight Loss: TALVEY® can cause oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis.

In the clinical trial, 80% of patients had oral toxicity, with Grade 3 occurring in 2.1% of patients who received the recommended dosages. The most frequent oral toxicities were dysgeusia (49%), dry mouth (34%), dysphagia (23%), and ageusia (18%). The median time to onset of oral toxicity was 15 (range: 1 to 634) days, and the median time to resolution to baseline was 43 (1 to 530) days. Oral toxicity did not resolve to baseline in 65% of patients.

TALVEY® can cause weight loss. In the clinical trial, 62% of patients experienced weight loss, regardless of having an oral toxicity, including 29% of patients with Grade 2 (10% or greater) weight loss and 2.7% of patients with Grade 3 (20% or greater) weight loss. The median time to onset of Grade 2 or higher weight loss was 67 (range: 6 to 407) days, and the median time to resolution was 50 (range: 1 to 403) days. Weight loss did not resolve in 57% of patients who reported weight loss.

Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice, including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate clinically significant weight loss further. Withhold TALVEY® or permanently discontinue based on severity.

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

TALVEY® (talquetamab-tgvs) Injection for subcutaneous use 2 mg/mL and 40 mg/mL

6. Important Safety Information (continued)

Infections: TALVEY® can cause infections, including life-threatening or fatal infections.

In the clinical trial, serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis, and COVID-19 (2.7%).

Monitor patients for signs and symptoms of infection prior to and during treatment with TALVEY® and treat appropriately. Administer prophylactic antimicrobials according to local guidelines. Withhold or consider permanent discontinuation of TALVEY® as recommended based on severity.

Cytopenias: TALVEY® can cause cytopenias, including neutropenia and thrombocytopenia.

In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY®. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4 thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during treatment and withhold TALVEY® as recommended based on severity.

Skin Toxicity: TALVEY® can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash.

In the clinical trial, skin reactions occurred in 62% of patients, with Grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to Grade 1 or less was 33 days.

Monitor for skin toxicity, including rash progression. Consider early intervention and treatment to manage skin toxicity. Withhold TALVEY® as recommended based on severity.

Hepatotoxicity: TALVEY® can cause hepatotoxicity. Elevated ALT occurred in 33% of patients, with Grade 3 or 4 ALT elevation occurring in 2.7%; elevated AST occurred in 31% of patients, with Grade 3 or 4 AST elevation occurring in 3.3%. Grade 3 or 4 elevations of total bilirubin occurred in 0.3% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TALVEY® or consider permanent discontinuation of TALVEY® based on severity [see Dosage and Administration (2.5)].

Embryo-Fetal Toxicity: Based on its mechanism of action, TALVEY® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TALVEY® and for 3 months after the last dose.

Adverse Reactions: The most common adverse reactions (≥20%) are pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache.

The most common Grade 3 or 4 laboratory abnormalities (≥30%) are lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

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

cp-394174v6

TALVEY® (talquetamab-tgvs) Injection for subcutaneous use
2 mg/mL and 40 mg/mL

7. Notes

Please read full Important Safety Information on pages 14-16 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

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For more information, visit www.TALVEYhcp.com.

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Johnson&Johnson