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

UPDATING AN ORDER SET AND CREATING A CLINICAL DECISION ALERT AND MACROS FOR A LETTER OF MEDICAL NECESSITY AND A TRANSITION OF CARE CHECKLIST FOR TALVEY®

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

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 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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 TALVEY®, within the approved indication and consistent with the Prescribing Information, in the electronic health record (EHR). It provides step-by-step instructions to set up order sets, clinical decision alerts, and documentation macros related to TALVEY® therapy in the Epic®, Oracle Health®, and OncoEMR® EHR systems. Users can follow the instructions to update order sets for RRMM with TALVEY® or to create alerts that prompt healthcare providers to manage adverse reactions appropriately in patients receiving TALVEY® therapy. Users can also create standardized macros for a letter of medical necessity or a transition of care checklist for TALVEY®, potentially helping to streamline prior authorization and care coordination processes.

To use this guide, select the relevant EHR section (Epic, Oracle Health, or OncoEMR) and follow the instructions for setting up order sets, an alert, or macros. Each section includes practical tips, configuration steps, and sample content. Appendixes provide suggested language for a letter of medical necessity for prior authorization and a transition of care checklist for initiating treatment, which can be adapted to your organization's workflow. 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 icons below appear in each functionality section (ie, order set, alert, and macros) to indicate which actions can be completed by an end user and which must be completed by an IT analyst.


End User


IT Analyst

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Overview and Limitations

This guide provides instructions for use in the Epic, Oracle Health, and OncoEMR EHR systems to (1) update RRMM order sets with TALVEY®, within the approved indication and consistent with the Prescribing Information; (2) create a clinical decision alert for adverse reaction management for patients currently on TALVEY®; and (3) create macros for a letter of medical necessity and a transition of care checklist for TALVEY®. The instructions will not work for other conditions, treatments, or therapeutic areas or for other EHR systems. Note: When creating the alert, additional clinical decision alert criteria, such as the presence of certain medication orders, can be included to further narrow the patients for whom the alert fires.

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 55) 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 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 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 order set instructions section for each EHR system in this guide.

Order Set Considerations *(cont'd)*

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.

Order Set Considerations *(cont'd)*

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:

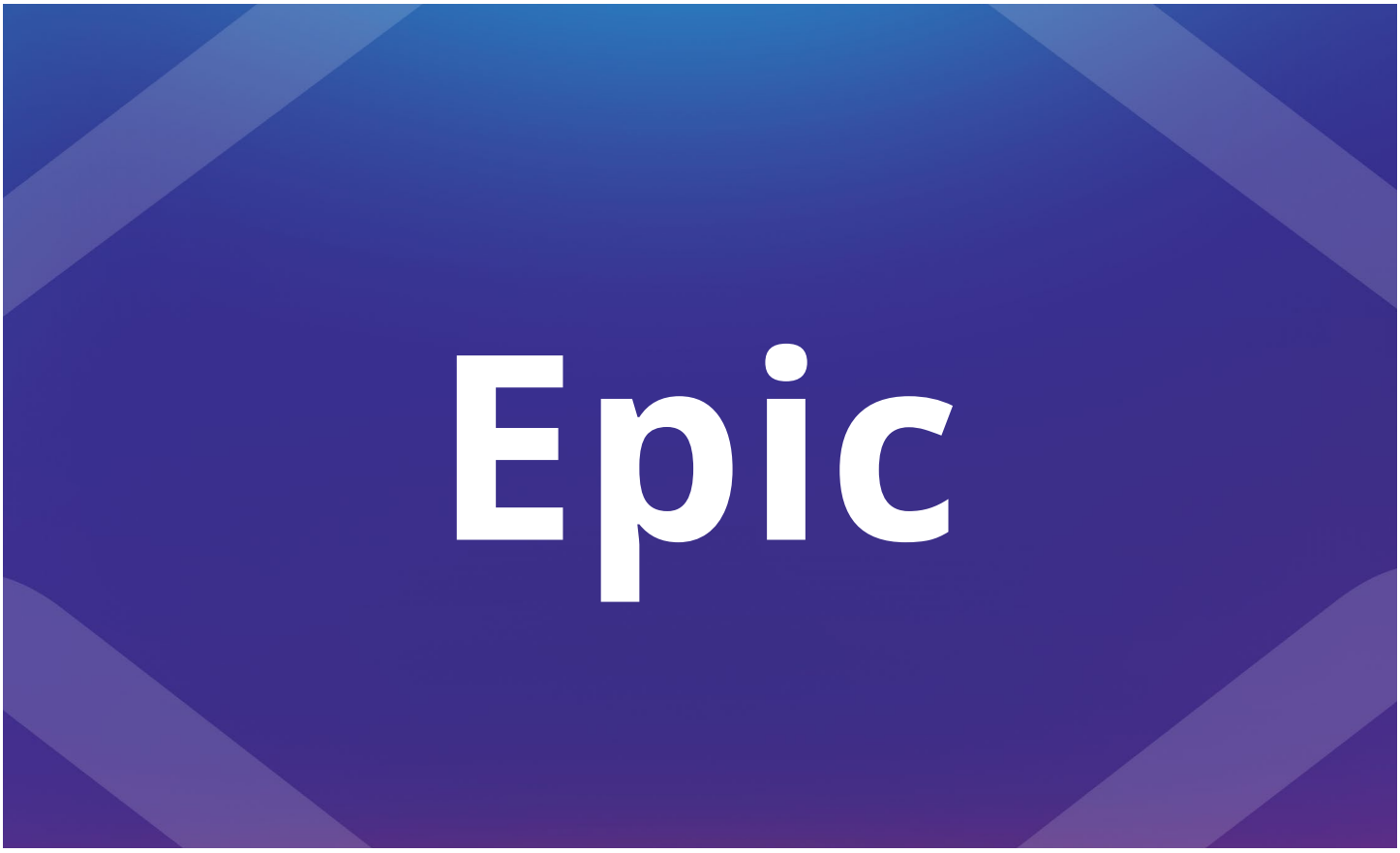
- Patients who repeat doses within the TALVEY® step-up dosing schedule due to dose delays (see Table 3 or Table 4 in the full Prescribing Information)
- Patients who experienced CRS (see Table 5 in the full Prescribing Information)

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.



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.

Please read full Important Safety Information on pages 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Order Set Instructions *(cont'd)*

IT Analyst

There are 3 main steps to updating a Beacon protocol in the Epic EHR system:

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

Step 2: After the order groups have been created, add them to the Beacon protocol.

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

Step 1: Create the order groups

Create a new TALVEY® 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 "TALVEY®."
4. Set the default category to Medications.
5. Add the details for TALVEY® to the order group:
   - Right-click in the empty field located at the bottom of the window
   - Select Add Orders and choose TALVEY®
   - Complete the TALVEY® medication details (Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions to the nurse)

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

- For the admin instructions, consider the following text:

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.

Order Set Instructions *(cont'd)*

IT Analyst

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

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

See next page for additional steps.

Please read full Important Safety Information on pages 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Order Set Instructions *(cont'd)*

IT Analyst

Create a new TALVEY® premedications order group:

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 "TALVEY® Premedications."
4. Set the default category to Premedications.
5. Add the details for the TALVEY® 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 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 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).
6. Once all the desired information is added, release and publish.

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

Create a new TALVEY® supportive care order group:

If the 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 "TALVEY® Supportive Care."
4. Set the default category to Supportive Care.
5. Add the TALVEY® 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®
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)*

IT Analyst

Step 2: Add the TALVEY®, TALVEY® premedications, and TALVEY® 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:
   - 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 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: 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.*

Order Set Instructions *(cont'd)*

IT Analyst

- 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 2 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. Save the new Beacon protocol as "TALVEY® for relapsed or refractory multiple myeloma," or follow your organization's standard naming conventions. Update the description to "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."
5. Complete testing before releasing the new protocol.
6. Complete the update process by releasing the protocol.

See next page for additional steps.

Please read full Important Safety Information on pages 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Order Set Instructions *(cont'd)*

IT Analyst

Step 3: Add reference information to the medication record

Note: Consider adding reference links and text to the TALVEY® 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 TALVEY®.
3. Page down to the Reference Links screen and add 4 new rows:
4. Row 1: For Display Name, enter "TALVEY® Prescribing Information"

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

   Row 2: For Display Name, enter "TALVEY® 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 TALVEY®, refer to the full Prescribing Information
   - 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 the 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

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

– Wholesalers and distributors 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®.
- 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.

Alert Instructions

IT Analyst

Consider using Epic's clinical decision support solution, an OurPractice Advisory (OPA), formerly known as a BestPractice Advisory (BPA), to create notifications in the form of alerts, In Basket messages, and/or emails for clinical staff that align with your organization's clinical preferences and workflows.

The criteria record and base record for the OPA can be completed to identify adult patients currently on TALVEY® for whom a notification can be sent to their healthcare provider to ensure appropriate adverse reaction management.

Step 1: Create the Medication Grouper Record for TALVEY®

Note: This step may be optional, depending on the availability of existing grouper records. Creating grouper records requires administrative rights. Consult your organization if administrative rights are required to access the reporting solutions.

Medication Grouper for TALVEY®

1. Access the Grouper Record Editor in Tools > Management Console.
2. Select the Medication Master File (ERX).
3. Add all relevant TALVEY® medications that exist in the system. Search by NDC, medication name, or synonym to locate all necessary records.
4. Click Save.

Step 2: Create the OPA Criteria and Base Records

OPA Criteria Record

Criteria Record 1: TALVEY®

1. Access the OPA Editor by searching for "OurPractice" or following the path Tools > Management Console > Decision Support.
2. Create the criteria record (select the criteria record type), start editing the record, and click + Add Criteria Type.
3. Select the Medications criteria type. In the Medication Grouper field, enter the TALVEY® grouper record.
4. When the criteria record is completed, select Released.

See next page for additional steps.

Alert Instructions *(cont'd)*

IT Analyst

OPA Base Record

1. Access the OPA Editor by searching for "OurPractice" or following the path Tools > Management Console > Decision Support.
2. Create the base record (select the base record type), start editing the record, and click + Add Criteria Type.
3. In the Display section:
   - Select Yes for Display to User (if your organization does not want the OPA to display within the healthcare provider workflow and only wishes to have an In Basket message and email sent to the healthcare provider, select No instead)
   - Enter the Summary Text to describe the advisory (eg, "Adverse Reaction Management for Patients on TALVEY®")
   - For the Unformatted Display Text, enter: "Ensure that appropriate management for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) has been ordered for patients receiving TALVEY®. Withhold or permanently discontinue TALVEY® based on the severity of the adverse reaction, and follow all monitoring and dose modification instructions as outlined in the Prescribing Information."
4. Since there is only 1 criteria record included in the OPA base record, Epic will automatically consider the single criterion for alerts/messages and no additional steps are needed for creating logic.
   - Use the Logic Tester to confirm the OPA works as expected
5. In the Restrictions, set any desired restrictions. In Encounter Limitation Inclusion, select the desired Location or Specialty (the selection of the filter may vary depending on how the Epic EHR system was set up). Select any Department Specialty and/or Provider Type desired.
6. Set the desired triggers for the OPA per the institution's conventions.
7. Set the desired actions:
   - Actions: In Basket message
     - Set the OPA to direct an In Basket message to the healthcare provider
     - If your organization has In Basket message forwarding turned on to automatically send In Basket messages to healthcare providers, they will also receive an email with the same information contained within the In Basket message. If your organization does not have this feature turned on and you want In Basket messages sent via email, consult with your internal IT staff
8. Preview the OPA to confirm the expected display result.
9. Select the test activity and complete any testing (troubleshooting) if needed. Consider additional end user testing before releasing the OPA.

Macros for Letter of Medical Necessity and Transition of Care Checklist

End User

SmartPhrase Considerations

SmartPhrases are a popular documentation shortcut tool in Epic that provide efficiencies for users. SmartPhrases can be leveraged to help with effective communication during critical care transitions and prior authorization documentation in the EHR for insurance approvals of TALVEY®. To retrieve a SmartPhrase, simply type the SmartPhrase abbreviation in the chart, which will generate useful TALVEY® information. SmartPhrases can be set up by end users in minimal time.

SmartLinks can be used in the SmartPhrase, if desired, to pull in patient chart information. The list of available SmartLinks may vary by organization.

Completing a Prior Authorization Request

Prior authorization (PA) is a routine process used by insurers to confirm that certain drugs or services are used correctly and only when medically necessary. PA requirements and the formulary (drug list) items subject to PA will vary among insurers.

The details below highlight information and items that may be needed to obtain a PA decision from an insurer.

1. If required, complete the PA request form and submit it to the insurer. PA forms can be obtained through the insurer's website or by contacting the insurer's customer service.
2. Submit a letter of medical necessity that includes the rationale for treatment, a summary of the patient's diagnosis, and a summary of the patient's history.
3. Consider providing the following information to the insurer if it is not already requested on the PA form: the patient's name, date of birth, and insurance policy number; physician and facility information; relevant procedure and HCPCS (Healthcare Common Procedure Coding System) codes for products/services to be provided/performed; and relevant information regarding the treatment decision.

Macros for Letter of Medical Necessity and Transition of Care Checklist *(cont'd)*

End User

SmartPhrase Instructions

Consider using a SmartPhrase to incorporate a letter of medical necessity (LMN) for prior authorization of TALVEY® or a transition of care (TOC) checklist for initiating treatment with TALVEY® into the EHR. Suggested LMN and TOC checklist content is included in Appendixes A and B, respectively. When uploading a document in the SmartText Editor, some graphic elements may be lost.

1. Open the SmartTool Editor and select the SmartPhrase option (click the Epic logo in the top left and select MySmartPhrases or use the search feature).
2. Create a new SmartPhrase with a unique mnemonic according to your organization's naming conventions (eg, ".TALVEYLMN" or ".TALVEYTOC").
3. Select the General button and copy and paste the suggested LMN content from Appendix A (page 49) or the TOC checklist content from Appendix B (page 51).

   Note: SmartLinks may be used to retrieve relevant patient chart information. SmartLinks can be adjusted as desired, as local naming conventions and available SmartLinks may vary.
4. Click Accept once uploaded and formatted as desired. Some manipulation of the SmartPhrase content or the SmartLinks may be required.
5. Open a patient chart and confirm the SmartPhrase renders the content as expected.

SmartPhrases can be created at the end-user level or at the system level. When SmartPhrases are created by an individual healthcare provider, they are stored in the MyPhrases folder. SmartPhrases can also be shared with other users by adding them in the Sharing section.

To copy SmartPhrases created by other users, navigate to the SmartPhrase tool, and in the Sharing section, use Copy User to find other SmartPhrases. Select 1 or more SmartPhrases of interest and copy to save to your personal MyPhrases.

Oracle Health

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 "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.

Please read full Important Safety Information on pages 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Order Set Instructions *(cont'd)*

IT Analyst

A PowerPlan may be used to set up TALVEY® 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 TALVEY®.

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 TALVEY® PowerPlan. If the original PowerPlan used to create or optimize the new TALVEY® PowerPlan includes TALVEY®, confirm it is retired or removed from the EHR production system according to your organization's EHR governing principles.

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

Step 2: Modify the identified PowerPlan to include TALVEY®

1. While on the PowerPlan level, update the PowerPlan name by changing the Display Description in the Attribute pane. Consider "TALVEY® for relapsed or refractory multiple myeloma," or follow your organization's naming conventions.
2. Update the description to "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."
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 TALVEY®, refer to the full Prescribing Information (https://www.jnjlabels.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 the 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.

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

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

- J&J withMe

  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®.

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

- 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.

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 "TALVEY®" in the Start Search At field. Select the TALVEY® 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 TALVEY® 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 dosing information starting on the next page.

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

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.*

Order Set Instructions *(cont'd)*

IT Analyst

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.*

Order Set Instructions *(cont'd)*

IT Analyst

9. Select the Order tab in the lower right-hand panel and enter the following premedications:
   - 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)
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 TALVEY® in the step-up dosing schedule to reduce the risk of CRS."

    "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)."

    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®"

    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 starting on the next page).

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

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

- 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 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: 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
- 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

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

- 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

15. Validate the newly optimized PowerPlan.

16. Release to the production environment after satisfactory testing has been completed.

Alert Instructions

IT Analyst

Consider using Oracle Health's clinical decision support tool, a Discern Alert, to create or customize notifications for clinical staff that align with your organization's clinical preferences and workflows. A Discern Alert creates a reminder for clinical staff and displays suggested follow-up recommendations to the end user.

1. To start creating an alert, open the Expert Knowledge Module by selecting DiscernDev.exe or DiscernLaunch.exe.
2. Complete the desired name (eg, "Adverse Reaction Management for Patients on TALVEY®"). Set the status to testing.
3. Create the Evoke section parameters:
   - E1:
     - Select OPENCHART
     - Select EKS_APPLICATION_E and for Application select HNA: PowerChart
   - E2:
     - Select OPENCHART
     - Select EKS_USER_POSITION_E and for Position select the desired Provider Type and set the desired role types (set to desired roles, settings, and clinics)
4. Set the Logic section parameters:
   - L1:
     - Select EKS_AGE_EVAL_L
     - Set to Where Person's Age is ≥18 years
     - Select Ok to complete setting the parameter
   - L2:
     - Select EKS_DIAGNOSIS_FIND_L
     - Set the OPT_DIAGNOSIS and select and include the ICD-10-CM codes C90.00 (Multiple myeloma not having achieved remission) and C90.02 (Multiple myeloma in relapse)
     - Select Ok to complete setting the parameter
   - L3:
     - Select EKS_ORDER_FIND_L
     - Set the ORD_METHOD to whose primary mnemonic is [ENTER MNEMONIC]
     - Set the OPT_ORDERS to TALVEY
     - Set the OPT_ORDERS_STATUS to COMPLETED
     - Select Ok to complete setting the parameter

→ *See next page for additional steps.*

Alert Instructions *(cont'd)*

IT Analyst

5. Set the Action section parameters:
   - Set the operator logic to L1 AND L2 AND L3
     - To set up a text alert, select EKS_BUILD_MESSAGE_A. Enter the following suggested message: "Ensure that appropriate management for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) has been ordered for patients receiving TALVEY®. Withhold or permanently discontinue TALVEY® based on the severity of the adverse reaction, and follow all monitoring and dose modification instructions as outlined in the Prescribing Information."
     - Create an order link to adverse reaction management order(s) and/or a link to the PowerPlan that includes the adverse reaction management orders
6. Test the new alert. Activate and release the alert once satisfactory testing has been completed and the servers have been cycled.

Macros for Letter of Medical Necessity and Transition of Care Checklist

End User

Auto Text Considerations

Auto Texts are a popular documentation shortcut tool in Oracle Health that provide efficiencies for users. Auto Texts can be leveraged to help with effective communication during critical care transitions and prior authorization documentation in the EHR for insurance approvals of TALVEY®. To retrieve the Auto Text, simply type the Auto Text abbreviation in the chart, which will generate useful TALVEY® information. Auto Texts can be set up by end users in minimal time.

Dynamic Text can be used in the Auto Text, if desired, to pull in patient chart information. The list of available Dynamic Text may vary by organization.

Completing a Prior Authorization Request

Prior authorization (PA) is a routine process used by insurers to confirm that certain drugs or services are used correctly and only when medically necessary. PA requirements and the formulary (drug list) items subject to PA will vary among insurers.

The details below highlight information and items that may be needed to obtain a PA decision from an insurer.

1. If required, complete the PA request form and submit it to the insurer. PA forms can be obtained through the insurer's website or by contacting the insurer's customer service.
2. Submit a letter of medical necessity that includes the rationale for treatment, a summary of the patient's diagnosis, and a summary of the patient's history.
3. Consider providing the following information to the insurer if it is not already requested on the PA form: the patient's name, date of birth, and insurance policy number; physician and facility information; relevant procedure and HCPCS (Healthcare Common Procedure Coding System) codes for products/services to be provided/performed; and relevant information regarding the treatment decision.

Macros for Letter of Medical Necessity and Transition of Care Checklist *(cont'd)*

End User

Auto Text Instructions

Consider using the Auto Text functionality to incorporate a letter of medical necessity (LMN) for prior authorization of TALVEY® or a transition of care (TOC) checklist for initiating treatment with TALVEY® into the EHR. Suggested LMN and TOC checklist content is included in Appendixes A and B, respectively. When uploading a document in the Auto Text Editor, some graphic elements may be lost.

1. Open a patient chart and access a text editing field (eg, a clinic or visit note).
2. Click the Manage Auto Text icon (usually the last icon in the menu toolbar of the note). Alternatively, click the Auto Text Utility icon in the toolbar. A new window with the My Phrases library will display.
3. In the new window, click the plus sign (Add New Phrase) to create the new Auto Text.
4. Enter the desired abbreviation in the Abbreviation field, starting with a symbol (eg, ".TALVEYLMN" or ".TALVEYTOC"). Enter a description in the Description field (eg, "TALVEY® Letter of Medical Necessity" or "TALVEY® Transition of Care Checklist").
5. In the Text field, copy and paste the suggested LMN content from Appendix A (page 49) or the TOC checklist content from Appendix B (page 51).
6. Click Save to save the new Auto Text.
7. To use the Auto Text, simply type the abbreviation (eg, ".TALVEYLMN") into a free text field and the saved text will appear.
8. To share the Auto Text, send a copy of the Auto Text to another user via Message Center. The recipient can copy the Auto Text and save it to their personal library.

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.

Please read full Important Safety Information on pages 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Order Set Instructions *(cont'd)*

IT Analyst

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 "TALVEY® for relapsed or refractory multiple myeloma" for the regimen name.
7. Set the version number.
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.*

Please read full Important Safety Information on pages 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Order Set Instructions *(cont'd)*

IT Analyst

9. In the reference text field, enter:
   - For important information about administering TALVEY®, refer to the full Prescribing Information (https://www.jnjlabels.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 the 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: 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.*

Order Set Instructions *(cont'd)*

IT Analyst

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.*

Order Set Instructions *(cont'd)*

IT Analyst

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.*

Please read full Important Safety Information on pages 45-48 and full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

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 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 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)

12. Click Add Supportive Care and add the following TALVEY® 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®

→ *See next page for additional steps.*

Order Set Instructions *(cont'd)*

IT Analyst

13. Click Add Drug to add TALVEY® to the regimen (consider the clinical details below).

- 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.*

Order Set Instructions *(cont'd)*

IT Analyst

- 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

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.

Alert Instructions

IT Analyst

Consider using OncoEMR's clinical decision support solution, an Alert, to create or customize notifications for clinical staff that align with your organization's clinical preferences and workflows. An Alert can be created to remind clinical staff to identify patients currently on TALVEY® for evaluation of adverse reaction management. Analyst administrative rights are typically required to create an Alert.

1. Click the User Name in the top right corner and click Customize. A new window will show all customization options.
2. Select Alerts in the General section.
3. Click New Alert.
4. Enter a unique name (eg, "Adverse Reaction Management for TALVEY®").
5. Select the desired trigger alert from the drop-down (consider Patient Login, Change Diagnosis, Order Activity, etc, based on EHR conventions).
6. Enter the desired expression. Click Show Field List for available fields that may be used in writing the expression. For the expression, consider:
   - DI_ICD and select C90.00 (Multiple myeloma not having achieved remission) and C90.02 (Multiple myeloma in relapse)
   - Order (Medications) and select any TALVEY® records
7. Set the logic to:
   - Multiple myeloma in relapse diagnosis

     AND
   - Treatment with TALVEY®
8. Set the alert message to: "Ensure that appropriate management for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) has been ordered for patients receiving TALVEY®. Withhold or permanently discontinue TALVEY® based on the severity of the adverse reaction, and follow all monitoring and dose modification instructions as outlined in the Prescribing Information."
9. Select the users to notify as desired.
10. Set the patient page, notifications, priority level, and acknowledgment expectations as desired.
11. Set the action to the adverse reaction management order(s).
12. Test the new alert and then activate and release it once satisfactory testing has been completed.

Macros for Letter of Medical Necessity and Transition of Care Checklist

End User

Macro Considerations

Macros in OncoEMR are designed to simplify documentation by allowing healthcare providers to insert standardized text quickly into patient records. These reusable text blocks help ensure consistency, accuracy, and efficiency across workflows and are helpful for cases where precise language and structured content are critical for compliance and care coordination. By leveraging macros for these tasks, healthcare providers may reduce manual effort, minimize errors, and improve turnaround times for essential documentation.

Completing a Prior Authorization Request

Prior authorization (PA) is a routine process used by insurers to confirm that certain drugs or services are used correctly and only when medically necessary. PA requirements and the formulary (drug list) items subject to PA will vary among insurers.

The details below highlight information and items that may be needed to obtain a PA decision from an insurer.

1. If required, complete the PA request form and submit it to the insurer. PA forms can be obtained through the insurer's website or by contacting the insurer's customer service.
2. Submit a letter of medical necessity that includes the rationale for treatment, a summary of the patient's diagnosis, and a summary of the patient's history.
3. Consider providing the following information to the insurer if it is not already requested on the PA form: the patient's name, date of birth, and insurance policy number; physician and facility information; relevant procedure and HCPCS (Healthcare Common Procedure Coding System) codes for products/services to be provided/performed; and relevant information regarding the treatment decision.

Macro Instructions

Consider using a macro to incorporate a letter of medical necessity (LMN) for prior authorization of TALVEY® or a transition of care (TOC) checklist for initiating treatment with TALVEY® into the EHR. Suggested LMN and TOC checklist content is included in Appendixes A and B, respectively. When uploading a document in the Macro Editor, some graphic elements may be lost.

1. Click the User Name in the top right corner and select Customize. A new window will show all customization options.
2. Select Macros from the Basic category list. Consider selecting Practice as the owner type to allow all users from the practice to use the macro. Select a desired key aligned to the practice's naming conventions.
3. Create a new macro by copying and pasting the suggested LMN content from Appendix A (page 49) or the TOC checklist content from Appendix B (page 51).
4. Save the macro.

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

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).

Important Safety Information *(cont'd)*

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.

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.

Important Safety Information *(cont'd)*

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.

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.

Important Safety Information *(cont'd)*

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

Appendix A: Suggested Letter of Medical Necessity Macro Content

Below is an example of suggested content for the letter of medical necessity for prior authorization of TALVEY®. Organizations can edit this copy or create their own copy for this letter as they see fit.

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State ZIP]

Re: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with TALVEY® (talquetamab-tgvs)

DIAGNOSIS: [Insert Diagnosis] [Insert ICD-10]

DOSE AND FREQUENCY: [Insert Dose & Frequency]

REQUEST TYPE: ❑ Standard ❑ EXPEDITED

Dear [Insert name of Medical Director or name of individual responsible for prior authorization],

I am writing to [support my request for an **authorization**] or [request a **formulary exception**] for the abovementioned patient to receive treatment with TALVEY® (talquetamab-tgvs) for [Insert Indication]. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition.]

Summary of Patient's History

[Insert:

- Previous therapies/procedures, including dose and duration, and response to those interventions
- Description of patient's recent symptoms/condition

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Appendix A: Suggested Letter of Medical Necessity Macro Content *(cont'd)*

Treatment Plan

- Describe medication, dose, frequency, and duration
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)

Rationale for Treatment

[Insert summary statement for rationale for treatment, such as: Considering the patient's history and condition and the full Prescribing Information supporting uses of TALVEY®, I believe treatment with TALVEY® at this time is medically necessary and should be a covered and reimbursed service.]

[Insert rationale for not using drugs that are on the plan's formulary.]

[You may consider including documents that provide additional clinical information to support the recommendation for TALVEY® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with TALVEY®.]

Please provide a timely authorization. Contact my office at [Insert phone number or email] if I can provide you with any additional information.

Sincerely,

[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

Appendix B: Suggested Transition of Care Checklist Macro Content

The suggested transition of care checklist content below provides helpful information for initiating treatment with TALVEY®. This is not intended to be a comprehensive list, and organizations should follow their own required procedures. Healthcare providers may utilize this checklist while either treating patients or arranging treatment at another facility.

Preparing to Initiate Treatment

Healthcare Team Preparation

- Ensure that treating prescribers and pharmacists have Risk Evaluation and Mitigation Strategy (REMS) certification
- Request all necessary patient records from the referring treatment practice
- Perform benefits investigation (eg, J-Code) and obtain prior authorization, if required
- Dosing Ordering Information:
  - **TALVEY®:** Order 3 mg/1.5 mL (2 mg/mL) vial size for the step-up dosing schedule and 40 mg/mL vial size for the first treatment dose; use Tables 9, 10, 11, and 12 in the full Prescribing Information to determine number of vials required based on patient's actual body weight
- Determine bed availability and coordinate with the healthcare team for patient's hospitalization period
- Provide education for staff regarding step-up dosing schedule, adverse reactions monitoring/management, and reporting protocols
- Ensure supportive therapies are available for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS)

  Please see the TALVEY® Treatment Management Guide or the TALVEY® Adverse Reaction Management Guide for reference.
  - Administer pretreatment medications as specified in the TALVEY® full Prescribing Information
  - Complete the TALVEY® Patient Wallet Card and provide it to patients prior to treatment initiation (first dose)
- Confirm the patient has received and is carrying the TALVEY® Patient Wallet Card

Appendix B: Suggested Transition of Care Checklist Macro Content *(cont'd)*

Patient/Care Partner Education and Logistics for Initiating Treatment

- Communicate and outline the step-up dosing schedule and administrative logistics to patients and their care partners
  - Ensure that the patient has support for each dose during the step-up dosing schedule, including travel and transportation, if needed
  - Provide guidance to patients and care partners regarding any potential side effects

    Please see Section 17 in the TALVEY® full Prescribing Information for patient counseling information.
  - Ensure care team has scheduled the next treatment dose with the patient to ensure treatment continuity
  - Provide the Medication Guide to the patient and advise them to read it
    - Share the TALVEY® Patient Brochure and My Journey With TALVEY® with patients
    - Share the TALVEY® Care Partner Brochure with family members/care partners
    - Provide resources for financial assistance to patients and care partners, including J&J withMe at www.jnjwithme.com
- Provide patients and care partners with information regarding the closest hospital in case of an emergency
- Ensure that patients and their care partners know who to talk to if they are experiencing or think they may be experiencing a side effect related to treatment
- Confirm the patient has received and is carrying the TALVEY® Patient Wallet Card

Appendix B: Suggested Transition of Care Checklist Macro Content *(cont'd)*

Important Steps for Ongoing Treatment

Healthcare Team Preparation

- Communicate with the ongoing treatment site to ensure successful transfer of the patient
  - Ensure that treating prescribers and pharmacists have REMS certification
- Forward any important discharge information, treatment notes, and records to the ongoing treatment site
- Ensure that the prior authorization for TALVEY® is closed out so the ongoing treatment facility can open a new prior authorization for the patient
- Ensure the ongoing treatment facility has supportive therapies available for ongoing treatment

Patient/Care Partner Preparation for Ongoing Treatment

- Discuss next steps with the patient regarding their ongoing treatment plan with TALVEY®
- Discuss with the patient's care partner(s) the importance of their role. If appropriate, consider giving the specific care partner support resources
- Provide the treatment center contact information for patients and care partners in case there are any potential health problems or complications, or in case patients want to remain in contact with the treatment center where they initiated treatment
- Provide patients and care partners with information regarding the closest hospital in case of an emergency
- Ensure that patients and their care partners know who to talk to if they are experiencing or think they may be experiencing a side effect related to treatment
- Confirm the patient/care partner continues to carry the Patient and/or Care Partner Wallet Card

Appendix B: Suggested Transition of Care Checklist Macro Content *(cont'd)*

Helpful Resources for Your Reference

TALVEY® Patient Education Resources

- TALVEY® Patient Brochure
- My Journey With TALVEY®
- TALVEY® Care Partner Brochure

TALVEY® Healthcare Provider Resources

- TALVEY® Prescribing Information
- TALVEY® Medication Guide
- TALVEY® Treatment Management Guide

Other J&J Resources

- J&J withMe
- REMS Fact Sheet and Cover letter, available on the REMS Website

Notes

Please read full Important Safety Information on pages 45-48 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.

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

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