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

ACCESS AND REIMBURSEMENT GUIDE

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).

Johnson&Johnson

Please read full Important Safety Information on pages 29-31 and read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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Introduction

Janssen Biotech, Inc., is pleased to provide you with information to assist you in coding and billing for TALVEY® (talquetamab-tgvs) injection for subcutaneous use. This Reimbursement and Access Guide presents codes, guidelines, and claims examples that we hope will be helpful to you as you care for patients who require this therapy.

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and represent no statement, promise or guarantee by Janssen Biotech, Inc., that these codes will be appropriate or that reimbursement will be made. It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2023; HCPCS=Healthcare Common Procedure Coding System.

Indication

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CD38=cluster of differentiation 38.

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CONTRAINDICATIONS: None.

Coding Summary for TALVEY® (talquetamab-tgvs)

Information	Code Type	Code and Descriptor	Inpatient Hospital	Outpatient Hospital	Physician Office
Diagnosis	ICD-10-CM	**C90.00** Multiple myeloma not having achieved remission **C90.02** Multiple myeloma in relapse	✓	✓	✓
TALVEY®	11 Digit NDC (5-4-2 format)	**57894-0469-01** One 3 mg/1.5 mL (2 mg/mL) single-dose vial in a carton **57894-0470-01** One 40 mg/mL (40 mg/mL) single-dose vial in a carton	As required by payer	As required by payer	As required by payer
	Revenue Codes	**0636** Pharmacy, drugs requiring detailed coding	✓	✓	N/A
	HCPCS Level II	**J3055**	N/A	✓	✓
Administration Procedure	ICD-10-PCS	**XW01329** Introduction of Talquetamab antineoplastic into subcutaneous tissue, percutaneous approach, New Technology Group 9	✓	N/A	N/A
	Revenue Codes	**0331** Chemotherapy administration, injection	✓	✓	N/A
	CPT® Category I	**96401** Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic	N/A	✓	✓

The fact that a drug, device, procedure or service is assigned a HCPCS code, and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2023.
ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System; NDC=National Drug Code.

TALVEY® (talquetamab-tgvs) Dosing and Administration

TALVEY® is for subcutaneous use only.

Administer TALVEY® subcutaneously on a weekly or biweekly (every 2 weeks) dosing schedule. Continue treatment until disease progression or unacceptable toxicity.[1]

TALVEY® should only be administered by a qualified healthcare professional with appropriate support to manage severe reactions such as CRS and neurologic toxicity, including ICANS.[1] Dosage delays and restarting the step-up phase may be required to manage toxicities related to TALVEY®.

Step-up Dosing Schedule

Administer TALVEY® subcutaneously on a weekly or biweekly (every 2 weeks) dosing schedule according to Table 1 or Table 2. 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.[1]

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
Weekly dosing schedule	Day 7[b]	First treatment dose	0.4 mg/kg
	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
Biweekly (every 2 weeks) dosing schedule	Day 7[b]	Step-up dose 3	0.4 mg/kg
	Day 10[c]	First treatment dose	0.8 mg/kg
	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.

IMPORTANT SAFETY INFORMATION (cont'd)

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%. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. Recurrent CRS occurred in 30% of patients. 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).

TALVEY® (talquetamab-tgvs) Dosing and Administration (Cont'd)

Recommended Premedications

Administer the following pretreatment medications 1 to 3 hours before each dose of TALVEY® during the step-up phase to reduce the risk of cytokine release syndrome (CRS).[1]

Table 3: Recommended Pretreatment Medications

Recommended Pretreatment Medications[1]
• 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 phase due to dose delays or for patients who experienced CRS.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Cytokine Release Syndrome (CRS) (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 or life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including fatal reactions. In the clinical trial, neurologic toxicity 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 (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.

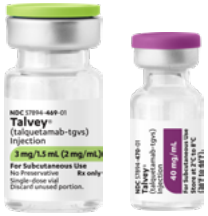
Further information about the TECVAYLI® and TALVEY® REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.

TALVEY® (talquetamab-tgvs) Dosing and Administration (Cont'd)

Administer TALVEY® via subcutaneous injection[1]

TALVEY® 3 mg/1.5 mL (2 mg/mL) vial and TALVEY® 40 mg/mL vial are supplied as ready-to-use solution for injection that do not need dilution prior to administration. It is very important that instructions for preparation and administration are strictly followed to minimize potential dosing errors with TALVEY®:

- Use aseptic technique to prepare and administer TALVEY®
- Check that the TALVEY® solution for injection is colorless to light yellow
- Do not use TALVEY® if the solution is discolored, cloudy, or if foreign particles are present
- Do not combine TALVEY® vials of different concentrations to achieve treatment dose[1]



Preparation[1]

1. Verify the prescribed dose for each TALVEY® injection. Use the reference Tables contained in the TALVEY® full Prescribing Information (PI) to prepare the injection:
   - **For the 0.01 mg/kg and 0.06 mg/kg doses:** Use **PI Table 9** and **PI Table 10** to determine total dose, injection volume and number of vials required based on patient's actual body weight **using TALVEY® 3 mg/1.5 mL (2 mg/mL) vial**
   - **For the 0.4 mg/kg and 0.8 mg/kg doses:** Use **PI Table 11 and PI Table 12** to determine total dose, injection volume and number of vials required based on patient's actual body weight **using TALVEY® 40 mg/mL (40 mg/mL) vial**
2. Remove the appropriate strength TALVEY® vial from refrigerated storage [2°C to 8°C (36°F to 46°F)] and equilibrate to ambient temperature [15°C to 30°C (59°F to 86°F)] for at least 15 minutes. Do not warm TALVEY® in any other way.
3. Once equilibrated, gently swirl the vial for approximately 10 seconds to mix. Do not shake.
4. Withdraw the required injection volume of TALVEY® from the vial(s) into an appropriately sized syringe using a transfer needle:
   - Each injection volume should not exceed 2.0 mL. Divide doses requiring greater than 2.0 mL equally into multiple syringes
   - TALVEY® is compatible with stainless steel injection needles and polypropylene or polycarbonate syringe material
5. Replace the transfer needle with an appropriately sized needle for injection.

Administration[1]

Inject the required volume of TALVEY® into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, TALVEY® may be injected into the subcutaneous tissue at other sites (eg, thigh). If multiple injections are required, TALVEY® injections should be at least 2 cm apart.

Do not inject into tattoos or scars or areas where the skin is red, bruised, tender, hard or not intact.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

TALVEY® can cause weight loss. In the clinical trial, 62% of patients experienced weight loss of 5% or greater, regardless of having an oral toxicity, including 28% 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.

Coverage for TALVEY® (talquetamab-tgvs)

Third-party payers (eg, commercial insurers, Medicare, Medicaid) typically cover TALVEY® for its approved U.S. Food and Drug Administration (FDA) indication, when administered in an authorized site of care, under the patient's medical benefit. However, coverage may vary depending on the payer and the specific plan in which a patient is enrolled.

Table 4: TALVEY® Coverage Summary

Site of Care	Medicare Part A	Medicare Part B	Commercial Payers/Medicare Advantage*
Inpatient Hospital (acute care)	• IPPS • Covered within the applicable MS-DRG	N/A	• May be covered within a MS-DRG • Other coverage methods may apply • Prior authorization may be required
Hospital Outpatient Department (HOPD)	N/A	• OPPS • Drug and administration services covered separately	• Drug is expected to be covered under a medical benefit • Prior authorization may be required • Drug and service typically covered separately • Payer policies may vary
Physician Office	N/A	• PFS • Drug and administration services covered separately	• Drug is expected to be covered under a medical benefit • Prior authorization may be required • Drug and service typically covered separately • Payer policies may vary

*Medicare Advantage provides all Medicare Parts A and B benefits through Medicare-approved private payers that must follow rules set by Medicare.

IPPS=Inpatient Prospective Payment System; MS-DRG=Medicare Severity Diagnosis Related Group; OPPS=Outpatient Prospective Payment System; PFS=Physician Fee Schedule.

Coverage for TALVEY® (talquetamab-tgvs) (Cont'd)

Medical Necessity

Medical necessity refers to healthcare services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms, and that meet accepted standards of medicine. Generally, insurers provide coverage only for health-related services that they define or determine to be medically necessary. Commercial insurers, Medicaid program coverage policies, Medicare NCDs, and Medicare Administrative Contractors' local coverage determinations define medical necessity requirements. These documents contain guidance on covered diagnoses, required documentation, and limitations of coverage for specific medical services or items.

When third-party payers review TALVEY® claims, they will first determine if the therapy is covered under their policies. Next, payers will look for evidence supporting medical necessity, which may include:

- Information about the patient's medical condition and history, including previous therapies/treatments
- Expected outcome(s) of treatment
- A provider's statement/Letter of Medical Necessity (LMN)
- Supporting literature (eg, peer-reviewed studies and compendia monographs)
- Prescribing Information
- Availability of other treatment alternatives

Some payers may require the treating physician submit a LMN before patients can obtain coverage for TALVEY®.

Click here to download the TALVEY® sample Letter of Medical Necessity

NCDs=National Coverage Determinations.

Coverage for TALVEY® (talquetamab-tgvs) (Cont'd)

Prior Authorization (PA)

Prior authorization (also referred to as pre-authorization or "pre-auth") is a common payer process that requires providers to substantiate why a therapy or service is medically necessary before coverage will be authorized. Many therapies, especially if they are new, are subject to PA; however, the requirements and processes can vary by payer. Some payers may handle oncology treatment requests through their routine PA process, while others may use a dedicated, specialty-specific approach. When requesting coverage for TALVEY®, it is essential to review the specific payer's policies and adhere to their required steps and timeline. This may include contacting a specific authorization line, submitting dedicated forms, or engaging directly with a payer's case manager. The following information may be helpful to organize when preparing to request a prior authorization:

- Summary of the patient's history, including timeline and course of the disease, previous treatments and responses, and current status
- Rationale for current request: expected result of providing the therapy; anticipated disease course without the therapy; reason(s) for requested site of care (inpatient or outpatient setting) coverage for TALVEY®
- Patient diagnosis (ICD-10-CM) and alignment with indications for requested therapy
- Supporting data: patient demographics; physician and facility information; product Prescribing Information and National Drug Code (NDC); any applicable, nationally recognized, clinical practice guidelines (eg, ASCO, NCCN®, others)

Click here to download the TALVEY® Prior Authorization checklist

ASCO=American Society of Clinical Oncology; NCCN®=National Comprehensive Cancer Network.

Coverage for TALVEY® (talquetamab-tgvs) (Cont'd)

Exception Request

An exception is a type of coverage determination that may apply when a medication is not included in a health plan's formulary, is subject to a National Drug Code (NDC) block, or if utilization management requirements (eg, prior authorization, step therapy) cannot be met. A request for formulary exception asks that the restrictions placed on a specific medication be released as the therapy is medically appropriate and necessary for a patient's treatment.

It is generally necessary for prescribers to submit a supporting statement, providing details about the rationale for the request. Payer policies may vary, so it is helpful to check with the payer for any required forms, processes, and the time in which a decision is to be expected.

Click here to download the TALVEY® sample Exception Letter

Appeals

An appeal is any of the procedures used to challenge a payer's denial of benefits that a beneficiary believes they are entitled to receive. If a payer denies an initial request for coverage, (ie, issues an adverse or "unfavorable" coverage determination), that decision may be appealed. The payer's notice of denial should include the reason for that decision, as well as instructions for filing an appeal. The appeals process is generally designed with progressive levels, allowing beneficiaries to continue advancing their request if initial efforts are not successful. The appeals process for Medicare Parts A and B includes 5 levels, beginning with redetermination. Although non-Medicare payer policies can vary, most plans also permit multiple levels of appeal.

Click here to download an Appeal Process Consideration checklist

Coding Considerations for TALVEY® (talquetamab-tgvs)

Correct coding for TALVEY® claims depends on the site of care in which it is administered, as well as on individual payer policies. This guide presents code sets and guidelines generally used by payers for both the inpatient and outpatient hospital settings, as well as the physician office. As individual payer policies may vary, please refer to specific payer requirements when submitting claims for TALVEY®.

Inpatient Hospital

When provided in the inpatient hospital setting, TALVEY® and its administration are often not paid separately but rather are included in a bundled payment amount that covers the inpatient stay. Medicare payment to acute care hospitals is made via Medicare Severity Diagnosis Related Groups (MS-DRGs). The patient's principal diagnosis, secondary diagnoses, procedures performed, sex, age, and discharge status determine MS-DRG assignment. Other payers may also use a DRG-based grouping methodology, but coding requirements and payment methods may vary.

Outpatient Hospital

When provided in the outpatient hospital setting, TALVEY® and its administration will be paid separately; however, coding requirements and payment methodologies may vary.

Physician Office

When provided in the physician office setting, TALVEY® and its administration will be paid separately; however, coding requirements and payment methodologies may vary.

Table 5: Commonly Required Code Sets by Site of Care

Site of Care	Current Procedural Terminology (CPT®) Codes	HCPCS Level II Codes	ICD-10-CM Diagnosis Codes	ICD-10-PCS Procedure Codes	National Drug Codes (NDC)	Revenue Codes
Inpatient Hospital			✓	✓		✓
Outpatient Hospital	✓	✓	✓		✓	✓
Physician Office	✓	✓	✓		✓	

Overview of Relevant Codes

ICD-10-CM Diagnosis Codes

Diagnosis codes support the rationale for a requested treatment and must be included on both inpatient and outpatient claims. ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve the greatest level of specificity. A code is invalid if it does not include the full number of characters required for that code, including the 7th character, if applicable.[2]

Payer requirements for ICD-10-CM codes will vary. It is essential to verify the correct diagnosis coding with each payer. The codes below are provided for your consideration when prescribing TALVEY® (talquetamab-tgvs).

Table 6: ICD-10-CM Diagnosis Codes for Consideration*

Code[3]	Description[3]
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

*These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive and additional codes may apply.

Overview of Relevant Codes (Cont'd)

National Drug Codes (NDC)

The NDC is a unique number that identifies a drug's labeler, product and trade package size. The NDC is required on Medicare claims for dual-eligible beneficiaries (Medicaid cross-over claims), Medicaid fee-for-service claims,[4] and by some private payers.[5] Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if an NDC is needed and the format the payer requires. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below:

Table 7: TALVEY® (talquetamab-tgvs) NDCs

Description[1]	FDA-Specified 10-Digit NDC[1] (5-3-2 format)	11-Digit NDC (5-4-2 format)
 One 3 mg/1.5 mL (2 mg/mL) single-dose vial in a carton	57894-469-01	57894-0469-01
 One 40 mg/mL (40 mg/mL) single-dose vial in a carton	57894-470-01	57894-0470-01

Payer requirements for NDC use and format can vary widely.

Please contact your payer for specific coding policies and more information on correct billing and claims submission.

The requirements for reporting NDCs on medical claims may vary, but typically payers will require the 11-digit format, the NDC qualifier, the NDC unit of measure, and the quantity administered, expressed in NDC units. The table below illustrates NDC reporting for a TALVEY® Day 1 Step-up dose and a Biweekly Treatment Phase dose, both for a patient weighing 76–85 kg.

Table 8: NDC Reporting Example

Dose to be Billed	11-Digit NDC (5-4-2 format)	Packaging	NDC Qualifier	NDC Unit of Measure*	NDC Units
0.8 mg (0.4 mL) Day 1 Step-up Dose	57894-0469-01	3 mg/1.5 mL single-dose vial	N4	ML	0.4†
64 mg (1.6 mL) Treatment Dose	57894-0470-01	40 mg/mL single-dose vial	N4	ML	1.6†

*The NDC unit of measure for liquid, solution, or suspension is mL (milliliter).
†To account for wastage with single-dose vials, if the actual dose administered is less than the entire package size, payers may require billing the NDC units for the entire vial (ie, 1.5 mL or 1 mL).

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Oral Toxicity and Weight Loss (cont'd):
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. 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%).

Overview of Relevant Codes (Cont'd)

Healthcare Common Procedure Coding System (HCPCS) Codes

Drugs are typically reported with HCPCS codes assigned by the Centers for Medicare & Medicaid Services (CMS). Effective April 1, 2024, the HCPCS code for TALVEY® is:

J3055 - Injection, talquetamab-tgvs, 0.25 mg[6]

This code applies in all sites of care and replaces all miscellaneous or temporary codes previously in use. While HCPCS codes are not typically used on inpatient claims, it is possible some payers may require the HCPCS code when reporting TALVEY® therapy. Please refer to specific payer policy.

Reporting HCPCS Units

Inaccurate reporting of drug HCPCS units is a common claims error and can result in denied or delayed payment. For billing purposes, HCPCS units are reported in multiples of the units in the HCPCS narrative description. Each 0.25 mg of TALVEY® represents one (1) HCPCS unit. When coding J3055, report the total number of 0.25 mg increments administered. Below is a summary of the correlation between TALVEY® vials, milligrams and HCPCS units:

TALVEY® Vial	Total milligrams (mg)	HCPCS billing units based on J3055 descriptor (0.25 mg TALVEY® = 1 unit)
3 mg/1.5 mL (2 mg/mL)	3 mg	12
40 mg/mL	40 mg	160

The fact that a drug, device, procedure or service is assigned a HCPCS code, and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure or service on an insurance claim. Payers such as Medicare Administrative Contractors (MACs) and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

Overview of Relevant Codes (Cont'd)

Current Procedural Terminology (CPT®) Codes

CPT® codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. Healthcare providers are responsible for selecting appropriate codes for any particular claim based on the patient's condition, the items and services that are furnished, and any specific payer requirements. The CPT® code most likely to be associated with the administration of TALVEY® (talquetamab-tgvs) is:

96401 – Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic[7]

This code is classified in CPT® under "Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration." Drug administration codes in this section, sometimes referred to as "complex" codes, apply to the parenteral administration of chemotherapy and also anti-neoplastic agents provided for treatment of non-cancer diagnoses, or to substances such as certain monoclonal antibodies and other biologic response modifiers.[7] Complex drug administration services require special considerations to prepare, dose, or dispose, and typically entail professional skill and patient monitoring significantly beyond that required for therapeutic infusions.[7] Payer requirements for drug administration codes may vary. Please contact your payer for specific coding and billing policies.

Overview of Relevant Codes (Cont'd)

ICD-10-PCS Procedure Codes

The ICD-10-PCS is a procedure classification system used to report procedures performed the hospital inpatient setting. The following ICD 10 PCS code should be reported for the administration of TALVEY® (talquetamab-tgvs):

- **XW01329** – Introduction of Talquetamab Antineoplastic into Subcutaneous Tissue, Percutaneous Approach[8]

If more than one procedure is performed during an inpatient stay, report the procedure performed for definitive treatment most related to the principal diagnosis as the principal procedure.[9]

Revenue Codes

Medicare and many other payers require use of American Hospital Association revenue codes to bill for services provided in the inpatient hospital and hospital outpatient departments. Revenue codes consist of a leading zero followed by 3 other digits and are used on CMS-1450 claim forms to assign costs to broad categories of hospital revenue centers. Codes used for Medicare claims are available from Medicare contractors.

Generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes as hospital assignment of costs can vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.

The following revenue codes may be applicable to hospital claims for TALVEY® and its administration:

Revenue Code[10]	Description[10]
0331	Chemotherapy administration, injection
0636	Pharmacy, drugs requiring detailed coding

The codes provided are not exhaustive; additional codes may apply.

Additional Coding Considerations

When coding and billing for TALVEY® (talquetamab-tgvs) and drug administration services, you may also need to provide additional coding detail, describe concomitant services or supplies, or account for modification to a service. This section reviews some of those additional considerations.

CPT® and HCPCS Modifiers

Modifiers are used to indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code.[7] They add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. The following table summarizes modifiers that may be applicable to TALVEY® coding and billing in hospital outpatient departments and physician offices.

Table 9: Summary of Code Modifiers

Modifier	Description	Indication and Placement	Physician Office Claims (CMS-1500)	Hospital Outpatient Claims (CMS-1450)
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional (HCP) on the same day of the procedure or other service[7]	• Patient requires distinct E/M service in addition to the drug administration procedure[7] • Must be substantiated with relevant documentation[7] • Append the modifier to the relevant E/M code[7]	✓ Required by Medicare	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount reported for informational purposes[11]	• Must be reported by all 340B providers not designated as select entities[11] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[11]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with the 340B Drug Pricing Program Discount, reported for informational purposes for select entities[11]	• Must be reported by select entities including rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals[11] • Must be reported by all OPPS providers for pass-through drugs (status indicator "G")[11] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[11]	N/A	✓ Required by Medicare
JW	Drug amount discarded[12]	• Unused drug remains after applicable dose is administered from single-use vial[12] • Append the modifier to the HCPCS drug code on a line separate from that reporting the administered dose, and document administered and discarded amounts in the medical record[12]	✓ Required by Medicare	✓ Required by Medicare
JZ	No discarded drug amounts[12]	• Applies to single dose containers of drugs for which the JW modifier would be required if there were discarded amounts[12] • Append the modifier to the HCPCS drug code on the claim line with the administered amount[12]	✓ Required by Medicare	✓ Required by Medicare

PPS=Prospective Payment System.

Additional Coding Considerations (Cont'd)

JW and JZ Modifiers for Separately Payable Drugs

Medicare's JW and JZ modifier policy applies to all drugs separately payable under Medicare Part B that are described as being supplied in a "single-dose" container or "single-use" package based on FDA-approved labeling. As of July, 2023, on all claims for single use vials or single use packages payable under Part B, Medicare requires reporting either the JW or the JZ modifier. This policy does not apply to drugs from multiple-dose containers.[12]

Discarded Drug

When a physician, hospital, or other provider or supplier must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label. Medicare contractors require the modifier JW to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded. This modifier, billed on a separate claim line, supports payment for the amount of discarded drug or biological. For example, a single-use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95-unit dose is billed on one line, while the discarded 5 units are billed on another line, accompanied by the JW modifier. Both line items will be processed for payment. Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.[12]

No Discarded Amount

To align with the JW modifier policy, the JZ modifier is required when there are no discarded drug amounts from single use vials or packages for which the JW modifier would be required if there were discarded amounts. The JZ modifier attests the entire contents of the single use vial or package were administered to a patient and no amount was discarded. For the administered amount, the claim line should include the given drug's HCPCS code and the JZ modifier. When the actual dose of the drug administered is less than the billing unit, the JW modifier is not permitted and the JZ modifier should be used.[12]

Summary of Medicare Policies

- All Medicare Part B claims for single use vials must include either a JZ or JW modifier
- The JW modifier indicates a discarded amount
- The JZ modifier indicates that no amount was discarded
- Multi-use vials are not subject to this policy

Payer requirements for modifier use can vary. Please contact your payer for specific coding policies and more information on correct billing and claims submission.

Additional Coding Considerations (Cont'd)

Place of Service (POS) Codes

The POS code set provides setting information necessary to appropriately pay professional service claims. The place of service is the location of the provider's face-to-face encounter with the patient. POS codes are required on all claims for professional services (billed on CMS-1500). The physician practice setting is indicated with POS code 11. Professional services delivered in outpatient hospital settings must specifically include the off-campus or on-campus POS codes on the claim form. To differentiate between on-campus and off-campus provider-based departments (PBDs), CMS created POS code 19, and revised the description for outpatient hospitals, POS code 22.

Code[13]	Name[13]	Descriptor[13]
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the healthcare provider routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus - Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
22	On Campus - Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

Same Day Evaluation and Management (E/M) Services

It may be necessary to provide E/M services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate and distinct from the drug administration procedure, and documented appropriately, are generally covered. A significant, separately identifiable E/M service is defined or substantiated by documentation that satisfies the relevant criteria for the respective E/M service. Please note that Medicare has a specific policy regarding the use of CPT® code 99211 in the physician office:

CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or nonchemotherapy drug administration code.[14]

Thus CPT® 99211 cannot be paid on the same day as an office-based injection of TALVEY® (talquetamab-tgvs). If a chemotherapy service and a significantly identifiable E/M service (other than 99211) are provided on the same day, a different diagnosis is not required.[14]

Drugs Supplied at No Cost to Provider

Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider. When the drug was supplied by a third party, at no cost to the provider, it should not be billed by the provider to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the provider. Therefore, administration of the drug is payable if the drug would have been covered if the provider purchased it. When reporting drug administration services for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "$0.01" charges.[15] Payer policies may vary.

Sample Claim Forms for TALVEY® (talquetamab-tgvs)

The CMS-1450 (UB-04) Claim Form

The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The ANSI ASC X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites.

For more information on electronic claims, please see the CMS website at https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html

HOPDs=hospital outpatient departments.

TALVEY® (talquetamab-tgvs)

Sample CMS-1450 (UB-04) Claim Form for **Inpatient Hospital Facilities**

A **Form Locator (FL) 4:** Enter 0111 for inpatient hospital bill type.

B **FL 42:** List revenue codes in ascending order for each reported line.

C **FL 43:** Enter narrative description for corresponding revenue codes.

D **FL 45:** Enter the corresponding dates of service.

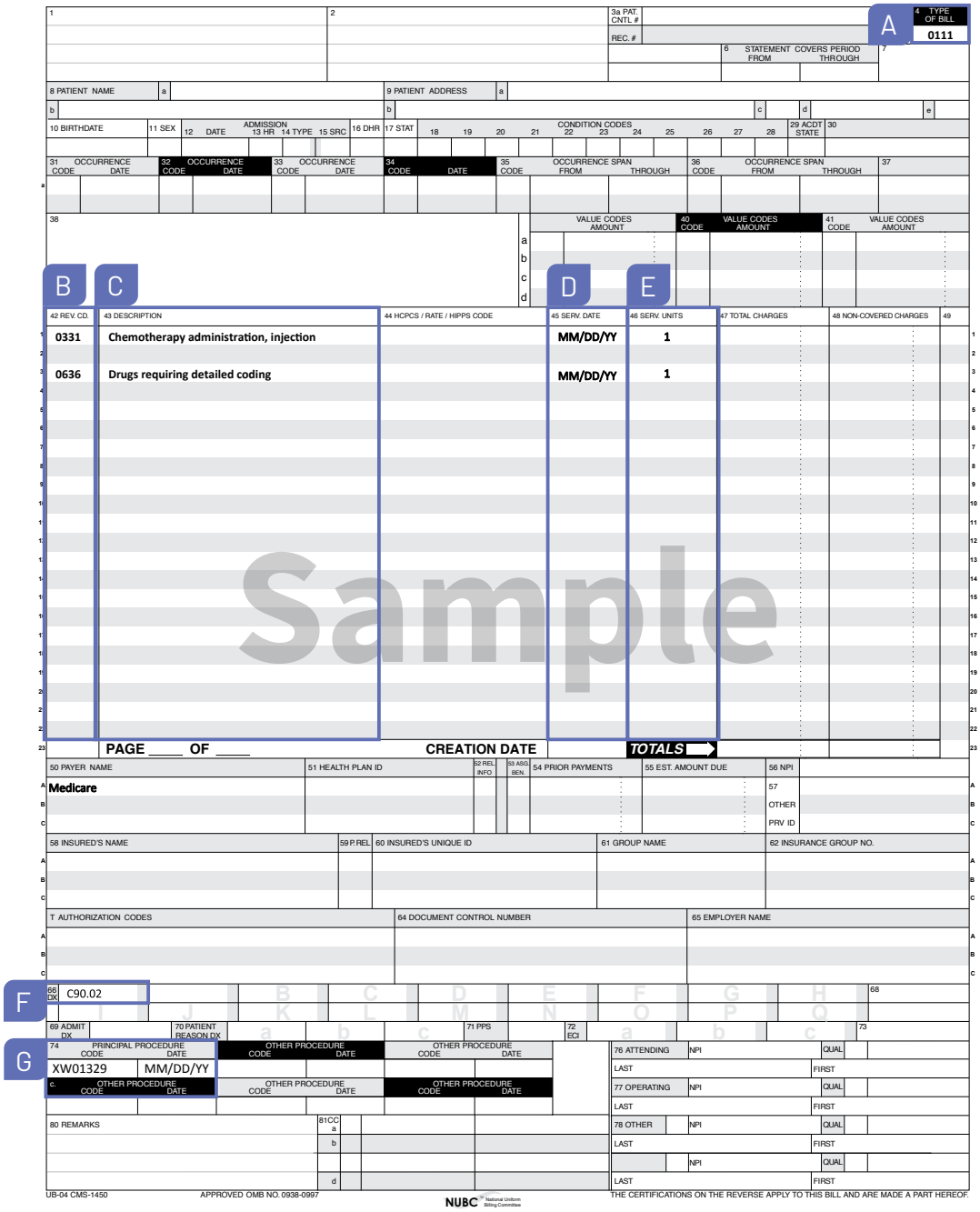
E **FL 46:** Enter the units of service.

F **FL 67:** Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter diagnoses in priority order.

G **FL 74:** Enter relevant ICD-10-PCS procedure codes with corresponding dates of service.

TALVEY® (talquetamab-tgvs)

Sample CMS-1450 (UB-04) Claim Form for **Inpatient Hospital Facilities**



1 | 2 | 3a PAT. CNTL # / REC. # | A 4 TYPE OF BILL: 0111 | 6 STATEMENT COVERS PERIOD FROM THROUGH | 7

8 PATIENT NAME | 9 PATIENT ADDRESS | 10 BIRTHDATE | 11 SEX | 12 ADMISSION DATE | 13 HR | 14 TYPE | 15 SRC | 16 DHR | 17 STAT | CONDITION CODES 18–28 | 29 ACDT STATE | 30

31 OCCURRENCE CODE DATE | 32 OCCURRENCE CODE DATE | 33 OCCURRENCE CODE DATE | 34 OCCURRENCE CODE DATE | 35 OCCURRENCE SPAN CODE FROM THROUGH | 36 OCCURRENCE SPAN CODE FROM THROUGH | 37

38 | VALUE CODES AMOUNT | 40 VALUE CODES CODE AMOUNT | 41 VALUE CODES CODE AMOUNT

B C D E

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0331	Chemotherapy administration, injection		MM/DD/YY	1			
0636	Drugs requiring detailed coding		MM/DD/YY	1			

PAGE ____ OF ____ | CREATION DATE | TOTALS

50 PAYER NAME: Medicare | 51 HEALTH PLAN ID | 52 REL. INFO | 53 ASG. BEN. | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | 57 OTHER PRV ID

58 INSURED'S NAME | 59 P. REL | 60 INSURED'S UNIQUE ID | 61 GROUP NAME | 62 INSURANCE GROUP NO.

T AUTHORIZATION CODES | 64 DOCUMENT CONTROL NUMBER | 65 EMPLOYER NAME

F 66 DX: C90.02 | 68

69 ADMIT DX | 70 PATIENT REASON DX | 71 PPS | 72 ECI | 73

G 74 PRINCIPAL PROCEDURE CODE DATE: XW01329 MM/DD/YY | OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE | c. OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE

76 ATTENDING NPI QUAL LAST FIRST | 77 OPERATING NPI QUAL LAST FIRST | 78 OTHER NPI QUAL LAST FIRST | NPI QUAL LAST FIRST

80 REMARKS | 81CC a b d

UB-04 CMS-1450 | APPROVED OMB NO. 0938-0997 | NUBC National Uniform Billing Committee | THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

TALVEY® (talquetamab-tgvs)

Sample CMS-1450 (UB-04) Claim Form for **Outpatient Hospital Facilities**

A

FL 42 – List revenue codes in ascending order.

B

FL 43 – Enter narrative description for corresponding revenue codes.

C

FL 44 – Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable).

TALVEY®
J3055 – Injection, talquetamab-tgvs, 0.25 mg

Subcutaneous Injection
96401 – Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

D

FL 46 – Enter the units for items/services provided.

TALVEY®
J3055 – Enter the amount of drug in HCPCS units according to the HCPCS descriptor and dose:

Descriptor: 0.25 mg = 1 unit

Dose example: 28 mg TALVEY® = 112 HCPCS units

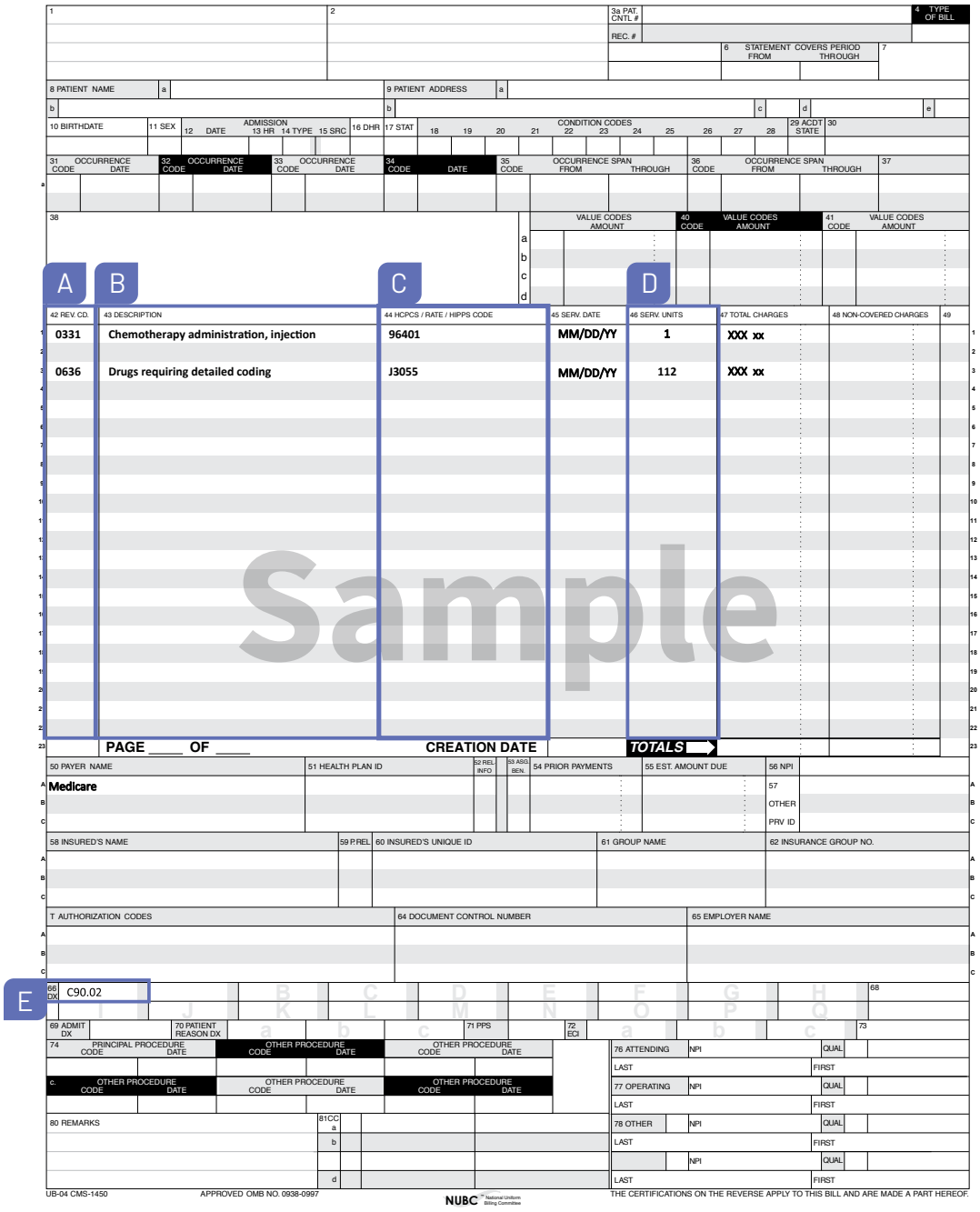
Subcutaneous Injection
96401 – Enter 1 unit

E

FL 67 – Indicate diagnoses using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

TALVEY® (talquetamab-tgvs)

Sample CMS-1450 (UB-04) Claim Form for **Outpatient Hospital Facilities**



1 | 2 | 3a PAT. CNTL # | REC. # | 4 TYPE OF BILL | 5 FED. TAX NO. | 6 STATEMENT COVERS PERIOD FROM THROUGH | 7

8 PATIENT NAME | 9 PATIENT ADDRESS | 10 BIRTHDATE | 11 SEX | 12 ADMISSION DATE | 13 HR | 14 TYPE | 15 SRC | 16 DHR | 17 STAT | 18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28 | 29 ACDT STATE | 30

31 OCCURRENCE CODE DATE | 32 OCCURRENCE CODE DATE | 33 OCCURRENCE CODE DATE | 34 OCCURRENCE CODE DATE | 35 OCCURRENCE SPAN CODE FROM THROUGH | 36 OCCURRENCE SPAN CODE FROM THROUGH | 37

38 | VALUE CODES CODE AMOUNT | 40 VALUE CODES CODE AMOUNT | 41 VALUE CODES CODE AMOUNT

A B C D

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0331	Chemotherapy administration, injection	96401	MM/DD/YY	1	XXX xx		
0636	Drugs requiring detailed coding	J3055	MM/DD/YY	112	XXX xx		

Sample

PAGE ____ OF ____ | CREATION DATE | TOTALS

50 PAYER NAME | 51 HEALTH PLAN ID | 52 REL. INFO | 53 ASG. BEN. | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | 57 OTHER PRV ID

A Medicare

58 INSURED'S NAME | 59 P REL | 60 INSURED'S UNIQUE ID | 61 GROUP NAME | 62 INSURANCE GROUP NO.

63 AUTHORIZATION CODES | 64 DOCUMENT CONTROL NUMBER | 65 EMPLOYER NAME

E 66 DX C90.02 | 68

69 ADMIT DX | 70 PATIENT REASON DX | 71 PPS | 72 ECI | 73

74 PRINCIPAL PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE

c. OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE | OTHER PROCEDURE CODE DATE

80 REMARKS | 81CC a b d

76 ATTENDING NPI QUAL LAST FIRST

77 OPERATING NPI QUAL LAST FIRST

78 OTHER NPI QUAL LAST FIRST

NPI QUAL LAST FIRST

UB-04 CMS-1450 | APPROVED OMB NO. 0938-0997 | NUBC™ National Uniform Billing Committee | THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Sample Claim Forms for TALVEY® (talquetamab-tgvs)

The CMS-1500 Claim Form

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and noninstitutional providers that qualify for a waiver from the Administrative Simplification Compliance Act requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf

The 837P (Professional) is the standard format used by healthcare providers and suppliers to transmit healthcare claims electronically. The ANSI ASC X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that 1 processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites.

For more information on electronic claims, please see the CMS website at https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html

TALVEY® (talquetamab-tgvs)

Sample CMS-1500 Claim Form for **Physician Offices**

A

Item 21 – Indicate diagnoses using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

B

Item 24D – Indicate appropriate CPT®, HCPCS codes, and modifiers (if applicable).

TALVEY®
J3055 – Injection, talquetamab-tgvs, 0.25 mg

Subcutaneous Injection
96401 – Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

C

Item 24E – Refer to the diagnosis for this service (see Item 21). Enter only 1 diagnosis pointer per line.

D

Item 24G – Enter the units for items/services provided.

TALVEY®
J3055 – Enter the amount of drug in HCPCS units according to the HCPCS descriptor and dose:

Descriptor: 0.25 mg = 1 unit

Dose example: 28 mg TALVEY® = 112 HCPCS units

Subcutaneous Injection
96401 – Enter 1 unit

TALVEY® (talquetamab-tgvs)

Sample CMS-1500 Claim Form for Physician Offices

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE	MEDICAID	TRICARE	CHAMPVA	GROUP HEALTH PLAN	FECA BLK LUNG	OTHER	1a. INSURED'S I.D. NUMBER (For Program in Item 1)
X (Medicare#)	(Medicaid#)	(ID#/DoD#)	(Member ID#)	(ID#)	(ID#)	(ID#)	000-00-1234

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John B	3. PATIENT'S BIRTH DATE MM DD YY 07 01 50 SEX M X F	4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John B
5. PATIENT'S ADDRESS (No., Street) 123 Any Street	6. PATIENT RELATIONSHIP TO INSURED Self X Spouse Child Other	7. INSURED'S ADDRESS (No., Street)
CITY: Any Town STATE: AS	8. RESERVED FOR NUCC USE	CITY STATE
ZIP CODE: 12345 TELEPHONE (Include Area Code): (555)555-5555		ZIP CODE TELEPHONE (Include Area Code): ( )
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) YES NO	a. INSURED'S DATE OF BIRTH MM DD YY SEX M F
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? YES NO PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? YES NO	c. INSURANCE PLAN NAME OR PROGRAM NAME
d. INSURANCE PLAN NAME OR PROGRAM NAME Medicare	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.
SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.	15. OTHER DATE QUAL. MM DD YY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a. 17b. NPI	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? YES NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. A. C90.02 B. C. D. E. F. G. H. I. J. K. L.		22. RESUBMISSION CODE ORIGINAL REF. NO. 23. PRIOR AUTHORIZATION NUMBER

A

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY	MM DD YY	11		B J3055		C A	D	112		NPI	
2 MM DD YY	MM DD YY	11		96401		A		1		NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN	26. PATIENT'S ACCOUNT NO.	27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO	28. TOTAL CHARGE $	29. AMOUNT PAID $	30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED DATE	32. SERVICE FACILITY LOCATION INFORMATION a. NPI b.		33. BILLING PROVIDER INFO & PH # ( ) a. NPI b.		

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

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

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

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

Neurologic Toxicity including ICANS: TALVEY® can cause serious or life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including fatal reactions. In the clinical trial, neurologic toxicity

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 (10%).

ICANS was reported in 9% of 265 patients where ICANS was collected and who received the recommended dosages. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

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

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

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

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

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

TALVEY® can cause weight loss. In the clinical trial, 62% of patients experienced weight loss of 5% or greater, regardless of having an oral toxicity, including 28% 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. Serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis and COVID-19 (2.7%).

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

Cytopenias: TALVEY® can cause cytopenias, including neutropenia and thrombocytopenia. In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY®. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4

thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during treatment and withhold TALVEY® as recommended, based on severity.

Skin Toxicity: TALVEY® can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash. In the clinical trial, skin reactions occurred in 62% of patients, with grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to grade 1 or less was 33 days.

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

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

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

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

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

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

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

cp-394174v4

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