TECVAYLI®

(teclistamab-cqyv) Injection for subcutaneous use

10 mg/mL and 90 mg/mL

Access and Reimbursement Guide

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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

IMPORTANT SAFETY INFORMATION

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

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

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS).

Please read full Important Safety Information on pages 29-30 and read full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Janssen Oncology

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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Introduction

Janssen Biotech, Inc., is pleased to provide you with information to assist you in coding and billing for TECVAYLI® (teclistamab-cqyv) injection for subcutaneous use. This Reimbursement and Access Guide presents codes, guidelines, and claims examples that we hope will be helpful to you and your practice 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, 2022.

Indication and Usage

TECVAYLI® 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).[1]

CD38=cluster of differentiation 38; HCPCS=Healthcare Common Procedure Coding System.

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Coding Summary for TECVAYLI® (teclistamab-cqyv)

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	✓	✓	✓
TECVAYLI®	11 Digit NDC (5-4-2 format)	**57894-0449-01** (One 30 mg/3 mL (10 mg/mL) single-dose vial in a carton) **57894-0450-01** (One 153 mg/1.7 mL (90 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	**J9380** Injection, teclistamab-cqyv, 0.5 mg	N/A	✓	✓
Administration Procedure	ICD-10-PCS	**XW01348** Introduction of Teclistamab Antineoplastic into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 8	✓	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, 2022.
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.

TECVAYLI® (teclistamab-cqyv) Dosing and Administration

TECVAYLI® is for subcutaneous use only.

The recommended dosing schedule for TECVAYLI® is provided in Table 1 below. The recommended dosage of TECVAYLI® is step-up doses of 0.06 mg/kg and 0.3 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity.[1]

TECVAYLI® should be administered by a healthcare provider with adequate medical personnel and appropriate medical equipment to manage severe reactions, including CRS and ICANS.[1]

Dosage delays may be required to manage toxicities related to TECVAYLI®. Dosage reductions of TECVAYLI® are not recommended.[1]

Step-up Dosing Schedule

Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Table 1 to reduce the incidence and severity of cytokine release syndrome (CRS). 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 TECVAYLI® step-up dosing schedule.[1]

Table 1: TECVAYLI® Step-up Dosing Schedule[1]

Dosing schedule	Day	Dose	
Step-up dosing schedule*	Day 1	Step-up dose 1	0.06 mg/kg
	Day 4†	Step-up dose 2	0.3 mg/kg
	Day 7‡	First treatment dose	1.5 mg/kg
Weekly dosing schedule*	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	1.5 mg/kg once weekly

* See Table 2 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays *[see Dosage and Administration (2.3)]*.

† Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.

‡ First treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome - TECVAYLI® can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI® at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI®. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

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

TECVAYLI® (teclistamab-cqyv) Dosing and Administration (Cont'd)

Recommended Premedications

Administer the following pretreatment medications 1 to 3 hours before each dose of the TECVAYLI® step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose (see Table 1), to reduce the risk of CRS.[1]

Table 2: Recommended Pretreatment Medications

Recommended Pretreatment Medications[1]
• Corticosteroid (oral or intravenous dexamethasone 16 mg) • Histamine-1 (H1) receptor antagonist (oral or intravenous diphenhydramine 50 mg or equivalent) • Antipyretics (oral or intravenous acetaminophen 650 mg to 1,000 mg or equivalent)

Administration of pretreatment medications may be required prior to administration of subsequent doses of TECVAYLI® in the following patients[1]:

- Patients who repeat doses within the TECVAYLI® step-up dosing schedule following a dose delay *[see Dosage and Administration (2.3)]*.
- Patients who experienced CRS following the prior dose of TECVAYLI® *[see Dosage and Administration (2.4)]*.

Prophylaxis for Herpes Zoster Reactivation

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

IMPORTANT SAFETY INFORMATION (Cont'd)

Neurologic Toxicity including ICANS – TECVAYLI® can cause serious or life-threatening neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®. The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

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

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

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

TECVAYLI® (teclistamab-cqyv) Dosing and Administration (Cont'd)

TECVAYLI® 10 mg/mL single-dose vial and TECVAYLI® 90 mg/mL single-dose vial are supplied as ready-to-use solution for injection that do not need dilution prior to administration. TECVAYLI® is colorless to light yellow. It is very important that instructions for preparation and administration are strictly followed to minimize potential dosing errors with TECVAYLI®:

- Use aseptic technique to prepare and administer TECVAYLI®
- Do not use TECVAYLI® if the solution is discolored, cloudy, or if foreign particles are present
- Do not combine TECVAYLI® vials of different concentrations to achieve treatment dose[1]

Preparation[1]

1. Verify the prescribed dose for each TECVAYLI® injection. Use the Tables contained in the TECVAYLI® Full Prescribing Information (PI) to prepare the injection:
   - **For Step-up Dose 1 or Step-up Dose 2:** Use PI Table 7 and PI Table 8 to determine total dose, injection volume and number of vials required based on patient's actual body weight **using TECVAYLI® 30 mg/3 mL (10 mg/mL) vial**.
   - **For Treatment Dose:** Use PI Table 9 to determine total dose, injection volume and number of vials required based on patient's actual body weight **using TECVAYLI® 153 mg/1.7 mL (90 mg/mL) vial**.
2. Remove the appropriate strength TECVAYLI® 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 TECVAYLI® 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 TECVAYLI® 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
   - TECVAYLI® 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 TECVAYLI® into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, TECVAYLI® may be injected into the subcutaneous tissue at other sites (eg, thigh). If multiple injections are required, TECVAYLI® 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)

Hepatotoxicity - TECVAYLI® can cause hepatotoxicity, including fatalities. In patients who received TECVAYLI® at the recommended dose in the clinical trial, there was one fatal case of hepatic failure. Elevated aspartate aminotransferase (AST) occurred in 34% of patients, with Grade 3 or 4 elevations in 1.2%. Elevated alanine aminotransferase (ALT) occurred in 28% of patients, with Grade 3 or 4 elevations in 1.8%. Elevated total bilirubin occurred in 6% of patients with Grade 3 or 4 elevations in 0.6%. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Coverage for TECVAYLI® (teclistamab-cqyv)

Third-party payers (eg, commercial insurers, Medicare, Medicaid) are expected to cover TECVAYLI® 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 3: TECVAYLI® 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 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 TECVAYLI® (teclistamab-cqyv) (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 TECVAYLI® 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 TECVAYLI®.

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

NCDs=National Coverage Determinations.

Coverage for TECVAYLI® (teclistamab-cqyv) (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 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 TECVAYLI®, 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 TECVAYLI®
- 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 TECVAYLI® Prior Authorization checklist

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

Coverage for TECVAYLI® (teclistamab-cqyv) (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 TECVAYLI® 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 TECVAYLI® (teclistamab-cqyv)

Correct coding for TECVAYLI® 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 TECVAYLI®.

Inpatient Hospital

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

Physician Office

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

Table 4: 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. Codes with 3 characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by use of additional characters to provide greater detail. A 3-character code is to be used only if it is not further subdivided. 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 TECVAYLI® (teclistamab-cqyv).

Table 5: ICD-10-CM Diagnosis Codes[3] for Consideration*

Code	Description
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

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) and 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 6: TECVAYLI® (teclistamab-cqyv) NDCs

Description[1]	FDA Specified 10-Digit NDC[1] (5-3-2 format)	11-Digit NDC (5-4-2 format)
 One 30 mg/3 mL (10 mg/mL) single-dose vial in a carton	57894-449-01	57894-0449-01
 One 153 mg/1.7 mL (90 mg/mL) single-dose vial in a carton	57894-450-01	57894-0450-01

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 TECVAYLI® Step-up Dose 2, and the weekly Treatment Dose, both for a patient weighing 70-79 kg.

Table 7: NDC Reporting Example

Dose to Be Billed	11-Digit NDC (5-4-2 format)	Packaging	NDC Qualifier	NDC Unit of Measure*	NDC Units
22 mg (2.2 mL)[†] Step-up Dose 2	57894-0449-01	30 mg/3 mL single-dose vial	N4	ML	0.73[†]
108 mg (1.2 mL)[†] Treatment Dose	57894-0450-01	153 mg/1.7 mL single-dose vial	N4	ML	0.71[†]

*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, ML3 or ML1.7).

IMPORTANT SAFETY INFORMATION (Cont'd)

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

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 July 1, 2023, the HCPCS code for TECVAYLI® is:

J9380 - Injection, teclistamab-cqyv, 0.5 mg[7]

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

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 0.5 mg of TECVAYLI® represents 1 unit. When coding J9380, report the total number of 0.5 mg increments administered. Below is a summary of the correlation between TECVAYLI® vials, milligrams, and HCPCS units:

TECVAYLI® Vial	Total milligrams (mg)	HCPCS billing units based on J9380 descriptor (0.5 mg TECVAYLI® = 1 unit)
30 mg/3 mL (10 mg/mL)	30 mg	60
153 mg/1.7 mL (90 mg/mL)	153 mg	306

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. While CPT codes are not normally part of the code sets used for hospital inpatient claims, it is possible that some payers may require CPT codes when reporting TECVAYLI® administration. Please refer to specific payer policy.

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 TECVAYLI® (teclistamab-cqyv) is:

96401 – Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic[8]

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.[8] 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.[8] 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 in inpatient hospital healthcare settings. TECVAYLI® (teclistamab-cqyv) has been assigned the following unique ICD-10-PCS code:

- **XW01348** – Introduction of Teclistamab Antineoplastic into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 8[9]

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.[10]

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 TECVAYLI® and its administration:

Revenue Code[11]	Description[11]
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 TECVAYLI® (teclistamab-cqyv) 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.[8] 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 TECVAYLI® coding and billing in hospital outpatient departments and physician offices.

Table 8: 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[8]	• Patient requires distinct E/M service in addition to the drug administration procedure[8] • Must be substantiated with relevant documentation[8] • Append the modifier to the relevant E/M code[8]	✓ Required by Medicare	✓ Required by Medicare
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes[12]	• Must be reported by hospitals (except for rural sole community hospitals, children's hospitals, and PPS exempt cancer hospitals) to identify 340B drugs for informational purposes only[12] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[12]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities[12]	• Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes[12] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[12]	N/A	✓ Required by Medicare
JW	Drug amount discarded/not administered to any patient[13]	• Report on all claims that bill for drugs and biologicals separately payable under Medicare Part B with unused and discarded amounts from single-dose containers[13] • 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[13]	✓ Required by Medicare	✓ Required by Medicare
JZ	Zero drug amount discarded/ not administered to any patient[13]	• Report on claims that bill for single-dose container drugs separately payable under Medicare Part B to attest that no amount of drug was discarded[13] • Append the modifier to the HCPCS drug code on the claim line with the administered amount[13]	✓ Required by Medicare beginning July 1, 2023	✓ Required by Medicare beginning July 1, 2023

Additional Coding Considerations (Cont'd)

Reporting Administered and Discarded Drug from Single-use Containers[13]

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 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.[13]

Historically Medicare has not required a modifier when there are no discarded drug amounts from a single-use container. However, beginning July 1, 2023, on all claims for single use vials or single use packages payable under Part B, Medicare will require reporting either the JW modifier or the new JZ modifier. To align with the JW modifier policy, the JZ modifier will be 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 will attest that the entire contents of the single use vial or package were administered to a patient and no amount was discarded.[13]

Summary of Medicare Policies

- Beginning July 1, 2023, all Part B claims for single use vials must include a HCPCS modifier
- The JW modifier will continue to indicate a discarded amount
- The new JZ modifier will indicate 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.

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[14]	Name[14]	Descriptor[14]
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.

Additional Coding Considerations (Cont'd)

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.[15]

Thus CPT® 99211 cannot be paid on the same day as an office-based injection of TECVAYLI® (teclistamab-cqyv). 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.[15]

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 with no drug charge, it is common to require the drug HCPCS code on the same claim. To accommodate claim processing edits, it may also be necessary to include a nominal charge of $0.01 (one cent).[16] Payer policies may vary.

Sample Claim Forms for TECVAYLI® (teclistamab-cqyv)

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.

TECVAYLI® (teclistamab-cqyv)

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.

TECVAYLI® (teclistamab-cqyv)

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

A — 4 TYPE OF BILL: 0111

B 42 REV. CD.	C 43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	D 45 SERV. DATE	E 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

F — 66 DX: C90.02

G — 74 PRINCIPAL PROCEDURE CODE / DATE: XW01348 MM/DD/YY

Sample

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.

Please read full Important Safety Information on pages 29-30 and read full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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

TECVAYLI® (teclistamab-cqyv)

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).

TECVAYLI®
J9380 - Injection, teclistamab-cqyv, 0.5 mg

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

D

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

TECVAYLI®
J9380 - Enter the amount of drug in HCPCS units according to the HCPCS descriptor and dose:

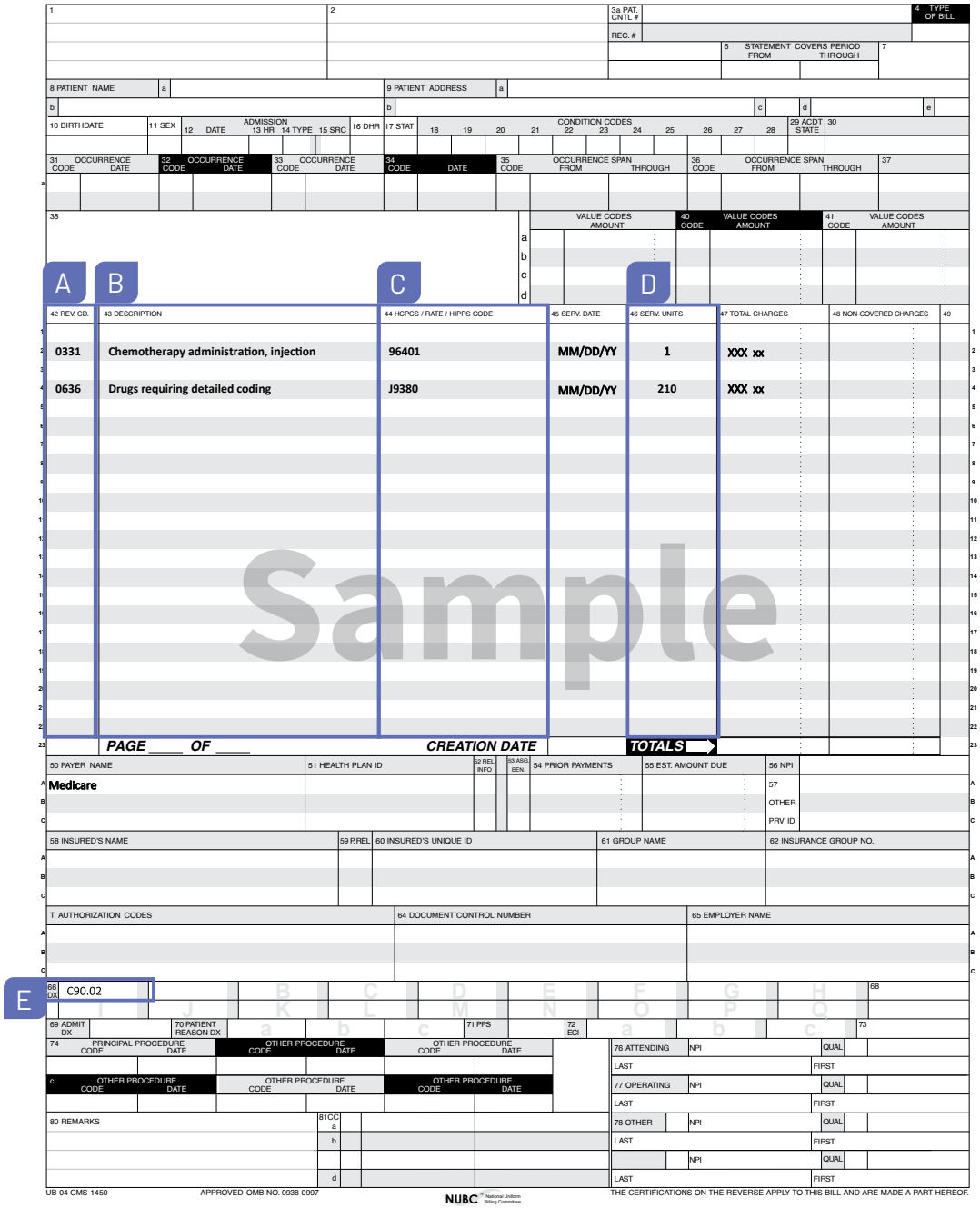
Descriptor:
0.5 mg = 1 unit

Dose example:
105 mg = 210 HCPCS units

Subcutaneous Injection
96401 – Enter 1 unit

TECVAYLI® (teclistamab-cqyv)

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



1 | 2 | 3a PAT. CNTL # | REC. # | 4 TYPE OF BILL | 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 19 20 21 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	J9380	MM/DD/YY	210	XXX xx		

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.

T 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 TECVAYLI® (teclistamab-cqyv)

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

TECVAYLI® (teclistamab-cqyv)

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).

TECVAYLI®
J9380 – Injection, teclistamab-cqyv, 0.5 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.

TECVAYLI®
J9380 – Enter the amount of drug in HCPCS units according to the HCPCS descriptor and dose:

Descriptor:
0.5 mg = 1 unit

Dose example:
105 mg = 210 HCPCS units

Subcutaneous Injection
96401 – Enter 1 unit

TECVAYLI® (teclistamab-cqyv)

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

HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE [X] (Medicare#) | MEDICAID [ ] (Medicaid#) | TRICARE [ ] (ID#/DoD#) | CHAMPVA [ ] (Member ID#) | GROUP HEALTH PLAN [ ] (ID#) | FECA BLK LUNG [ ] (ID#) | OTHER [ ] (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 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

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 J9380		C A		D 210		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.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

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

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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

IMPORTANT SAFETY INFORMATION

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

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

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS).

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome – TECVAYLI® can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI® at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI®. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

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

Neurologic Toxicity including ICANS – TECVAYLI® can cause serious or life-threatening neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®. The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

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

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

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

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

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

Hepatotoxicity - TECVAYLI® can cause hepatotoxicity, including fatalities. In patients who received TECVAYLI® at the recommended dose in the clinical trial, there was one fatal case of hepatic failure. Elevated aspartate aminotransferase (AST) occurred in 34% of patients, with Grade 3 or 4 elevations in 1.2%. Elevated alanine aminotransferase (ALT) occurred in 28% of patients, with Grade 3 or 4 elevations in 1.8%. Elevated total bilirubin occurred in 6% of patients with Grade 3 or 4 elevations in 0.6%. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Neutropenia - TECVAYLI® can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI® at the recommended dose in the clinical trial, decreased neutrophils occurred in 84% of patients, with Grade 3 or 4 decreased neutrophils in 56%. Febrile neutropenia occurred in 3% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines. Monitor patients with neutropenia for signs of infection. Withhold TECVAYLI® based on severity.

Hypersensitivity and Other Administration Reactions - TECVAYLI® can cause both systemic administration-related and local injection-site reactions. Systemic Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, 1.2% of patients experienced systemic-administration reactions, which included Grade 1 recurrent pyrexia and Grade 1 swollen tongue. Local Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, injection-site reactions occurred in 35% of patients, with Grade 1 injection-site reactions in 30% and Grade 2 in 4.8%. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Embryo-Fetal Toxicity - Based on its mechanism of action, TECVAYLI® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TECVAYLI® and for 5 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥20%) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

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

cp-322928v3

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