CODING RESOURCE

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 resource summarizes the codes commonly associated with TECVAYLI® and its administration, when provided in inpatient or outpatient sites of care. For more detailed coding guidance, please refer to the full TECVAYLI® Access and Reimbursement Guide, available here.

ICD-10-CM Diagnosis Codes

Diagnosis codes support the rationale for a requested treatment and must be included on both inpatient and outpatient claims.[1] ICD-10-CM diagnosis codes use 3 to 7 alpha and numeric characters to achieve the greatest level of specificity. 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 consideration and are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. This code list is not exhaustive; additional codes may apply.

ICD-10-CM Code[2]	Description[2]
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

National Drug Code (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) and Medicaid fee-for-service claims,[3] and by some private payers.[4] 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. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated below:

Description[5]	FDA Specified 10-Digit NDC (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.

Healthcare Common Procedure Coding System (HCPCS)

Drugs and biologics are typically reported with permanent, product-specific HCPCS codes assigned by the Centers for Medicare and Medicaid Services (CMS). Effective July 1, 2023, the HCPCS code for TECVAYLI® is:

J9380 - Injection, teclistamab-cqyv, 0.5 mg[5]

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[5]	Total milligrams (mg)	HCPCS billing units based on J9380 descriptor[5] (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 an 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.

Current Procedural Terminology (CPT®)

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 and hospital outpatient 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 TECVAYLI® is:

CPT® Code	Description
96401[6]	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic[6]

ICD-10-PCS Procedure Code

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:

ICD-10-PCS Code	Description
XW01348[7]	Introduction of Teclistamab Antineoplastic into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 8[7]

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association, 2022.

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.

References: 1. CMS. ICD-10-CM Official Guidelines for Coding and Reporting FY 2023 (October 1, 2022 - September 30, 2023). Accessed July 13, 2023. https://www.cms.gov/files/document/fy-2023-icd-10-cm-coding-guidelines.pdf **2.** CMS. 2023 ICD-10-CM Tabular List of Diseases and Injuries. Accessed July 13, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs **3.** CMS. Medicare Claims Processing Manual, Chapter 26. Accessed July 13, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf **4.** UnitedHealthcare. (2023). National Drug Code (NDC) Requirement Policy, Professional and Facility. Accessed July 13, 2023. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-National-Drug-Code-Requirement-Policy.pdf **5.** CMS. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations First Quarter, 2023 HCPCS Coding Cycle. Accessed July 13, 2023. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-1-2023-drugs-and-biologicals-updated-07/05/2023.pdf **6.** American Medical Association. Current Procedural Terminology: CPT® 2023: Professional Edition. AMA Press; 2022. **7.** CMS. 2023 ICD-10-PCS Codes File. Accessed July 13, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs

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.

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