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

Dosing and Adverse Reaction Management Pocket Guide

SEE THE MajesTEC-1 FINAL ANALYSIS INSIDE

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).

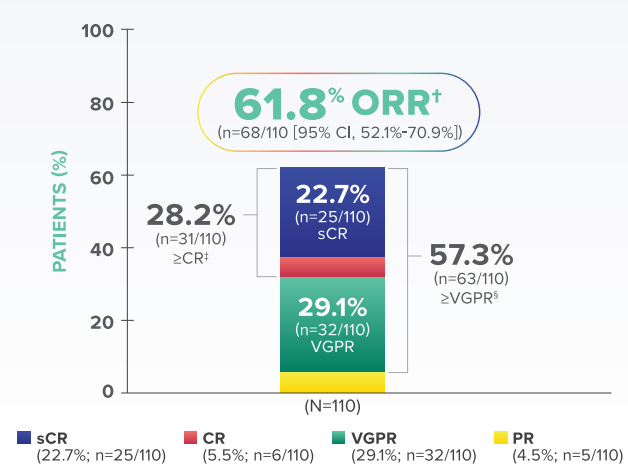
Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

TECVAYLI®, the first bispecific BCMA × CD3 T-cell engager, was evaluated in the MajesTEC-1 trial[1,2]

About TECVAYLI®

The efficacy of TECVAYLI® was evaluated in 110 patients with relapsed or refractory multiple myeloma in the single-arm, open-label, multi-center, phase 1/2 MajesTEC-1 trial. Patients had received at least 3 therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[1]

In the MajesTEC-1 primary analysis, TECVAYLI® delivered an ORR of 61.8%, with 57.3% of patients achieving a deep response of VGPR or better at a median follow-up of 7 months[1,3*]



28.2%
of patients
experienced ≥CR‡ with TECVAYLI® in the MajesTEC-1 trial[1]

TECVAYLI® provided a median time to first response of
1.2 months[1] (range: 0.2-5.5 months)

Median DOR not reached[1]
(95% CI, 9.0-NE)

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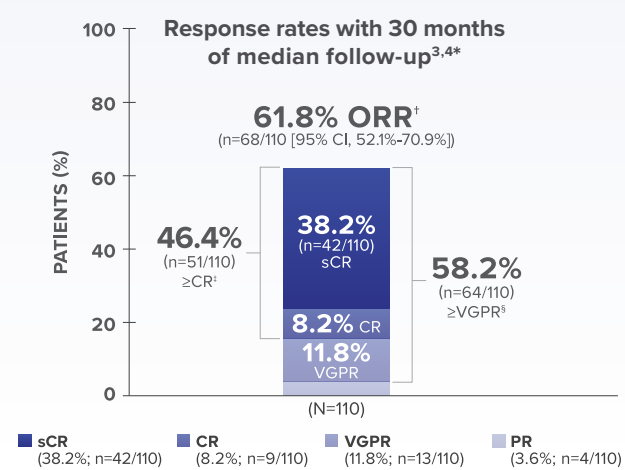
MajesTEC-1 final analysis at a median follow-up of 30 months[4‖]

You are now viewing a subsequent follow-up analysis of the MajesTEC-1 trial. This information is not included in the current full Prescribing Information.

At the time of the follow-up report, 25/110 (22.7%) of subjects were still on treatment.[3]



46.4%
of patients
experienced ≥CR‡ with TECVAYLI® in the MajesTEC-1 trial[4]

Patients achieved ≥CR‡ at a median time of
6.0 months[3] (range: 1.7-18.5 months)

*Results were based on ORR, the primary endpoint, as determined by the Independent Review Committee (IRC) assessment using International Myeloma Working Group (IMWG) 2016 criteria.[1]
†ORR: sCR+CR+VGPR+PR.
‡≥CR: sCR+CR.
§≥VGPR: sCR+CR+VGPR.
‖Based on a median duration of follow-up of 29.9 months.[3]

BCMA, B-cell maturation antigen; CD3, cluster of differentiation 3; CD38, cluster of differentiation 38; CI, confidence interval; CR, complete response; mDOR, median duration of response; NE, not estimable; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

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IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

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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.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS (continued) - 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.

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TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use
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Safety from the MajesTEC-1 trial[1]

Serious adverse reactions occurred in 54% of patients who received TECVAYLI®. Serious adverse reactions in >2% of patients included pneumonia (15%), cytokine release syndrome (8%), sepsis (6%), general physical health deterioration (6%), COVID-19 (6%), acute kidney injury (4.8%), pyrexia (4.8%), musculoskeletal pain (2.4%), and encephalopathy (2.4%).

Fatal adverse reactions occurred in 5% of patients who received TECVAYLI®, including COVID-19 (1.8%), pneumonia (1.8%), septic shock (0.6%), acute renal failure (0.6%), and hemoperitoneum (0.6%).

Permanent discontinuation of TECVAYLI® due to adverse reactions occurred in 1.2% of patients. Adverse reactions resulting in permanent discontinuation of TECVAYLI® included pneumonia (adenoviral and pneumocystis jirovecii pneumonia in the same patient) and hypercalcemia.

Adverse reactions (≥10%) in patients with RRMM treated with TECVAYLI® in the MajesTEC-1 trial

Adverse Reactions	TECVAYLI® (N=165)	
	Any Grade (%)	Grade 3 or 4 (%)
General disorders and administration site conditions		
Pyrexia	76	3[###]
Injection site reaction[*]	37	0.6[###]
Fatigue[†]	33	2.4[###]
Chills	16	0
Pain[‡]	15	1.8[###]
Edema[§]	13	0
Immune system disorders		
Cytokine release syndrome	72	0.6[###]
Hypogammaglobulinemia[¶]	11	1.2[###]
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[#]	44	4.2[###]
Bone pain	16	3[###]
Infections		
Upper respiratory tract infection[**]	26	2.4[###]
Pneumonia[††****]	24	15
Urinary tract infection[‡‡]	11	5[###]
Gastrointestinal disorders		
Nausea	25	0.6[###]
Diarrhea	21	2.4[###]
Constipation	18	0
Vomiting	12	0.6[###]
Nervous system disorders		
Headache	25	0.6[###]
Motor dysfunction[§§]	16	0
Sensory neuropathy[¶¶]	15	1.2[###]
Encephalopathy[##]	13	0
Vascular disorders		
Hypotension	18	1.2[###]
Hemorrhage[*** ****]	12	1.8
Hypertension[†††]	12	4.8[###]
Respiratory, thoracic, and mediastinal disorders		
Hypoxia	18	1.8
Cough[‡‡‡]	15	0
Cardiac disorders		
Cardiac arrhythmia[§§§]	16	1.8
Metabolism and nutrition disorders		
Decreased appetite	11	0.6[###]
Renal and urinary disorders		
Acute kidney injury[¶¶¶]	11	3.6

(Continued on next page)

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ASTCT, American Society for Transplantation and Cellular Therapy; COVID-19, coronavirus disease 2019; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; RRMM, relapsed or refractory multiple myeloma.
Adverse reactions were graded based on CTCAE Version 4.03, with the exception of CRS, which was graded per ASTCT 2019 criteria.
[*]Injection site reaction includes application site erythema, injection site bruising, injection site cellulitis, injection site discomfort, injection site erythema, injection site hematoma, injection site induration, injection site inflammation, injection site edema, injection site pruritus, injection site rash, injection site reaction and injection site swelling.
[†]Fatigue includes asthenia and fatigue.
[‡]Pain includes ear pain, flank pain, groin pain, oropharyngeal pain, pain, pain in jaw, toothache and tumor pain.
[§]Edema includes face edema, fluid overload, fluid retention, edema peripheral and peripheral swelling.
[¶]Hypogammaglobulinemia includes hypogammaglobulinemia and hypoglobulinemia.
[#]Musculoskeletal pain includes arthralgia, back pain, muscle discomfort, musculoskeletal chest pain, musculoskeletal pain, myalgia, neck pain, non-cardiac chest pain and pain in extremity.
Upper respiratory tract infection includes bronchitis, influenza like illness, nasopharyngitis, pharyngitis, respiratory tract infection, respiratory tract infection bacterial, rhinitis, rhinovirus infection, sinusitis, tracheitis, upper respiratory tract infection and viral upper respiratory tract infection.
[††]Pneumonia includes COVID-19 pneumonia, enterobacter pneumonia, lower respiratory tract infection, metapneumovirus pneumonia, pneumocystis jirovecii pneumonia, pneumonia, pneumonia adenoviral, pneumonia klebsiella, pneumonia moraxella, pneumonia pneumococcal, pneumonia pseudomonal, pneumonia respiratory syncytial viral, pneumonia staphylococcal and pneumonia viral.
[‡‡]Urinary tract infection includes cystitis, cystitis escherichia, cystitis klebsiella, escherichia urinary tract infection, urinary tract infection and urinary tract infection bacterial.
[§§]Motor dysfunction includes cogwheel rigidity, dysgraphia, dysphonia, gait disturbance, hypokinesia, muscle rigidity, muscle spasms, muscular weakness, peroneal nerve palsy, psychomotor hyperactivity, tremor and VI[th] nerve paralysis.
[¶¶]Sensory neuropathy includes dysesthesia, hypoesthesia, hypoesthesia oral, neuralgia, paresthesia, paresthesia oral, peripheral sensory neuropathy, sciatica and vestibular neuronitis.
[##]Encephalopathy includes agitation, apathy, aphasia, confusional state, delirium, depressed level of consciousness, disorientation, dyscalculia, hallucination, lethargy, memory impairment, mental status changes and somnolence.
[***]Hemorrhage includes conjunctival hemorrhage, epistaxis, hematoma, hematuria, hemoperitoneum, hemorrhoidal hemorrhage, lower gastrointestinal hemorrhage, melena, mouth hemorrhage and subdural hematoma.
[†††]Hypertension includes essential hypertension and hypertension.
[‡‡‡]Cough includes allergic cough, cough, productive cough and upper-airway cough syndrome.
[§§§]Cardiac arrhythmia includes atrial flutter, cardiac arrest, sinus bradycardia, sinus tachycardia, supraventricular tachycardia, tachycardia and ventricular tachycardia.
[¶¶¶]Acute kidney injury includes acute kidney injury and renal impairment.
[###]Only grade 3 adverse reactions occurred.
[****]Includes the following fatal adverse reactions: hemorrhage (n=1), pneumonia (n=3).

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Safety from the MajesTEC-1 trial (continued)[1]

Dose reductions are not recommended with TECVAYLI®

Dose interruptions of TECVAYLI® due to adverse reactions occurred in 73% of patients, and the most frequent (>5%) leading to dose interruptions were:

- Neutropenia
- Pneumonia
- Pyrexia
- CRS
- Upper respiratory tract infection
- COVID-19

Dosage delays may be required to manage toxicities related to TECVAYLI®.

Permanent discontinuation of TECVAYLI® due to adverse reactions occurred in 1.2% of patients

- The adverse reactions resulting in permanent discontinuation of TECVAYLI® included pneumonia (adenoviral and pneumocystis jirovecii pneumonia in the same patient) and hypercalcemia

See Tables 3, 4, and 5 in the full **Prescribing Information** for recommended actions for adverse reactions of CRS, neurologic toxicity, and ICANS. See Table 6 in the full **Prescribing Information** for recommended actions for other adverse reactions following administration of TECVAYLI®.

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

MajesTEC-1 final safety analysis at a median follow-up of 30.4 months[1,3,4]

You are now viewing a subsequent follow-up analysis of the MajesTEC-1 trial. This information is not included in the current full Prescribing Information.

At the time of the follow-up report, 38/165 (23%) of subjects were still on treatment.[3]

Reported since end of primary analysis:

- One patient experienced 2 recurrent CRS events after a treatment delay[3]
- No additional events of ICANS[4]

Reported since study initiation:

- Eight treatment-related deaths occurred (4 due to COVID-19)[3]
- Permanent discontinuation due to adverse reactions occurred in 5.5% of patients[1,3,4]

Adverse Reactions	(N=165)	
	Any Grade (%)	Grade 3 or 4 (%)
Any TEAE	100.0	94.5
Hematologic		
Neutropenia	71.5	65.5
Anemia	55.2	37.6
Thrombocytopenia	41.8	23.0
Lymphopenia	36.4	34.5
Leukopenia	20.0	9.1
Nonhematologic		
Infections	78.8	55.2
COVID-19	29.1	21.2
Cytokine release syndrome	72.1	0.6
Diarrhea	34.5	3.6
Pyrexia	30.9	0.6
Fatigue	30.3	2.4
Cough	27.9	0
Nausea	27.3	0.6
Injection site erythema	26.7	0
Arthralgia	25.5	1.2
Headache	24.2	0.6
Constipation	22.4	0
Hypogammaglobulinemia	21.8	1.8
Back pain	20.0	2.4

TEAE, treatment-emergent adverse event.

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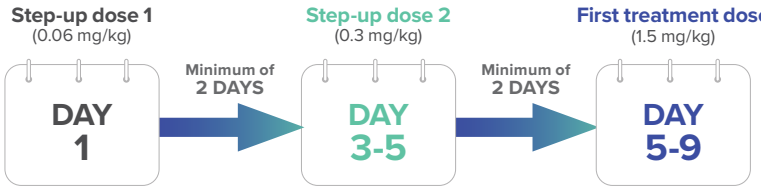
TECVAYLI® offers an adaptive step-up dosing schedule and personalized weight-based dosing[1]

Step-up doses



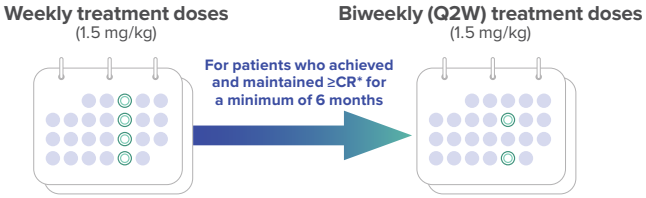
- **Step-up dose 2** may be given between **2 to 4 days after step-up dose 1** and may be given **up to 7 days after step-up dose 1** to allow for resolution of adverse reactions
- **First treatment dose** may be given between **2 to 4 days after step-up dose 2** and may be given **up to 7 days after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

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.

Following step-up dosing ongoing weekly dosing begins, followed by a biweekly (Q2W) treatment option for certain patients

Ongoing dosing with TECVAYLI®

After step-up dosing, patients will receive weekly treatment doses with the option of switching to biweekly (Q2W) dosing if they achieve and maintain ≥CR* for a minimum of 6 months



- **Weekly Dosing:** Once-weekly dosing until disease progression or unacceptable toxicity
- **Biweekly (Q2W) Dosing Option:** Extended dosing interval at or beyond 6 months. The dosing frequency may be decreased to once every 2 weeks after ≥6 months of achieving and maintaining ≥CR* during treatment until disease progression or unacceptable toxicity

Remember: Dose is personalized to each patient's actual body weight. Please refer to Tables 7-9 in the full Prescribing Information to determine the dosage based on predetermined weight ranges. Dose reductions are not recommended, and dose delays may be required to manage toxicities.

TECVAYLI® is administered by a healthcare provider according to the step-up dosing schedule to reduce the incidence and severity of CRS.

*≥CR: sCR+CR.

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Pretreatment medications[1]

Prior to starting treatment with TECVAYLI®

Consider initiation of antiviral prophylaxis to prevent herpes zoster reactivation per local institutional guidelines.

1 to 3 hours before dose

Administer the following pretreatment medications of the TECVAYLI® step-up dosing schedule to reduce the risk of CRS.

- 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)

Prior to administration of weekly doses

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

- Patients who repeat doses within the step-up dosing schedule following a dose delay
- Patients who experienced CRS following the prior dose of TECVAYLI®

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; Q2W, every 2 weeks.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

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

Recommended dosage modifications for other adverse reactions[1]

See Table 6 in the full **Prescribing Information** for recommended actions for other adverse reactions following administration of TECVAYLI®.

Adverse Reactions	Severity	Actions
Infections* *[see Warnings and Precautions (5.5) in the full Prescribing Information]*	All Grades	• Withhold TECVAYLI® in patients with active infection during the step-up dosing schedule†
	Grade 3	• Withhold subsequent treatment doses of TECVAYLI® (ie, doses administered after TECVAYLI® step-up dosing schedule) until infection improves to Grade 1 or less†
	Grade 4	• Consider permanent discontinuation of TECVAYLI® • If TECVAYLI® is not permanently discontinued, withhold subsequent treatment doses of TECVAYLI® (ie, doses administered after TECVAYLI® step-up dosing schedule) until infection improves to Grade 1 or less†

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Recommended dosage modifications for other adverse reactions (continued)[1]

Adverse Reactions	Severity	Actions
Hematologic Toxicities *[see Warnings and Precautions (5.6) and Adverse Reactions (6.1) in the full Prescribing Information]*	Absolute neutrophil count less than 0.5 × 10^9/L	• Withhold TECVAYLI® until absolute neutrophil count is 0.5 × 10^9/L or higher†
	Febrile neutropenia	• Withhold TECVAYLI® until absolute neutrophil count is 1 × 10^9/L or higher and fever resolves†
	Hemoglobin less than 8 g/dL	• Withhold TECVAYLI® until hemoglobin is 8 g/dL or higher†
	Platelet count less than 25,000/mcL Platelet count between 25,000/mcL and 50,000/mcL with bleeding	• Withhold TECVAYLI® until platelet count is 25,000/mcL or higher and no evidence of bleeding†
Other Non-Hematologic Adverse Reactions* *[see Warnings and Precautions (5.4) and Adverse Reactions (6.1) in the full Prescribing Information]*	Grade 3	• Withhold TECVAYLI® until adverse reaction improves to Grade 1 or less†
	Grade 4	• Consider permanent discontinuation of TECVAYLI® • If TECVAYLI® is not permanently discontinued, withhold subsequent treatment doses of TECVAYLI® (ie, doses administered after TECVAYLI® step-up dosing schedule) until adverse reaction improves to Grade 1 or less†

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.
†See Table 2 of the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS (continued) - 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.

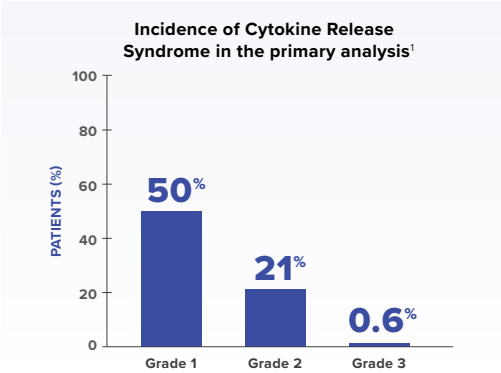
TECVAYLI® is available only through a restricted program under a REMS.

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

CRS, including life-threatening or fatal reactions, may occur in patients receiving TECVAYLI®[1]

- CRS of any grade was reported in 72% of patients receiving TECVAYLI® in the primary analysis

Median time to onset: 2 days (range: 1-6 days) after most recent dose
Median duration: 2 days (range: 1-9 days)



CRS experienced after specific dose of TECVAYLI® in the primary analysis

Step-up dose 1	42%
Step-up dose 2	35%
Initial treatment dose	24%
Subsequent doses (first occurrence)	<3%

- Recurrent CRS occurred in 33% of patients

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Recommendations for management of CRS[1]

Identify CRS based on clinical presentation. Evaluate and treat other causes of fever, hypoxia, and hypotension.

If CRS is suspected, withhold TECVAYLI® until CRS resolves. Manage according to the recommendations in Table 3 in the full Prescribing Information and consider further management per current practice guidelines. Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS. Consider laboratory testing to monitor for disseminated intravascular coagulation (DIC), hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function.

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.

Signs and symptoms of CRS may include:

- Fever
- Hypoxia
- Chills
- Hypotension
- Sinus tachycardia
- Headache
- Elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation)

Patient counseling

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Discuss the signs and symptoms associated with CRS, including fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes. Advise patients to immediately contact their healthcare provider if they experience signs or symptoms of CRS. Advise patients that they will be hospitalized for 48 hours after administration of all doses within the TECVAYLI® step-up dosing schedule.

CRS, cytokine release syndrome; REMS, risk evaluation and mitigation strategy.

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

Recommendations for management of CRS (continued)[1]

Manage CRS according to the recommendations in Table 3 in the full Prescribing Information and consider further management per current practice guidelines.

Grade*	Presenting Symptoms	Actions
Grade 1	Temperature ≥100.4°F (38°C)†	• Withhold TECVAYLI® until CRS resolves • Administer pretreatment medications prior to next dose of TECVAYLI®‡
Grade 2	Temperature ≥100.4°F (38°C)† with: Hypotension responsive to fluids and not requiring vasopressors, and/or, Oxygen requirement of low-flow nasal cannula§ or blow-by.	• Withhold TECVAYLI® until CRS resolves • Administer pretreatment medications prior to next dose of TECVAYLI®‡ • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI® *[see Dosage and Administration (2.1) in the full Prescribing Information]*‡
Grade 3	Temperature ≥100.4°F (38°C)† with: Hypotension requiring one vasopressor with or without vasopressin, and/or, Oxygen requirement of high-flow nasal cannula§, face mask, non-rebreather mask, or Venturi mask.	First Occurrence of Grade 3 CRS with Duration Less than 48 Hours: • Withhold TECVAYLI® until CRS resolves • Provide supportive therapy, which may include intensive care • Administer pretreatment medications prior to next dose of TECVAYLI®‡ • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI® *[see Dosage and Administration (2.1) in the full Prescribing Information]*‡ Recurrent Grade 3 CRS or Grade 3 CRS with Duration 48 Hours or Longer: • Permanently discontinue TECVAYLI® • Provide supportive therapy, which may include intensive care
Grade 4	Temperature ≥100.4°F (38°C)† with: Hypotension requiring multiple vasopressors (excluding vasopressin), and/or, Oxygen requirement of positive pressure (eg, continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), intubation, and mechanical ventilation).	• Permanently discontinue TECVAYLI® • Provide supportive therapy, which may include intensive care

*Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for CRS.
†Attributed to CRS. Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anticytokine therapy.
‡See Table 2 of the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.
§Low-flow nasal cannula is ≤6 L/min, and high-flow nasal cannula is >6 L/min.

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Serious or life-threatening neurologic toxicities, including ICANS, may occur following treatment with TECVAYLI®[1]

In the primary analysis, neurologic toxicities were reported in 57% of patients receiving TECVAYLI® at the recommended dose.

- The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%)
- With longer follow-up, 1 patient experienced Grade 4 seizure and 1 patient experienced fatal Guillain-Barré syndrome
- Grade 3 and Grade 4 neurologic toxicity events (2.4%) have been observed in patients treated with TECVAYLI®

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.

Immune effector cell-associated neurotoxicity syndrome (ICANS)

In the primary analysis, ICANS was reported in 6% of patients receiving TECVAYLI® at the recommended dose.

- Recurrent ICANS occurred in 1.8% of patients
- The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia
- Due to the potential for neurologic toxicity, patients receiving TECVAYLI® 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

ICANS experienced after specific dose of TECVAYLI® in the primary analysis

Step-up dose 1	1.2%
Step-up dose 2	0.6%
Initial treatment dose	1.8%
Subsequent doses (first occurrence)	<3%

Median time to onset: 4 days (range: 2-8)
Median duration: 3 days (range: 1-20)

The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TECVAYLI® and TALVEY® REMS. Visit TEC-TALREMS.com

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

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

Recommendations for management of neurologic toxicity[1]

At the first sign of neurologic toxicity, including ICANS, withhold TECVAYLI® and consider neurology evaluation. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care, for severe or life-threatening neurologic toxicities, including ICANS. Manage ICANS according to the recommendations in Table 5 in the full **Prescribing Information** and consider further management per current practice guidelines.

Signs and symptoms of neurologic toxicity may include:

- Headache
- Confusion
- Dysgraphia
- Motor dysfunction
- Neuropathy
- Encephalopathy

Patient counseling

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Discuss the signs and symptoms associated with neurologic toxicity, including ICANS, including headache, confusion, dysgraphia, motor dysfunction, neuropathy, or encephalopathy. Advise patients to immediately contact their healthcare provider if they experience any signs or symptoms of neurologic toxicity. 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.

ICE Grading

If patient is unarousable and unable to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment (Grade 4 ICANS) = 0 points

If patient is arousable and able to perform ICE Assessment, assess the following:

- Orientation: oriented to year, month, city, hospital = **4 points**
- Naming: name 3 objects, eg, point to clock, pen, button = **3 points**
- Following Commands: eg, “show me 2 fingers” or “close your eyes and stick out your tongue” = **1 point**
- Writing: ability to write a standard sentence = **1 point**
- Attention: count backwards from 100 by ten = **1 point**

Immune Effector Cell-Associated Encephalopathy (ICE) Assessment[5]

Grade	ICE Score
Grade 1	7-9
Grade 2	3-6
Grade 3	0-2
Grade 4	0 (due to patient being unarousable and unable to perform assessment)

Recommendations for management of neurologic toxicity (excluding ICANS)[1]

See Table 4 in the full **Prescribing Information** for recommended actions for neurologic toxicity.

Adverse Reactions	Severity*	Actions
Neurologic Toxicity* (excluding ICANS)	Grade 1	• Withhold TECVAYLI® until neurologic toxicity symptoms resolve or stabilize†
	Grade 2 Grade 3 (First occurrence)	• Withhold TECVAYLI® until neurologic toxicity symptoms improve to Grade 1 or less† • Provide supportive therapy
	Grade 3 (Recurrent) Grade 4	• Permanently discontinue TECVAYLI® • Provide supportive therapy, which may include intensive care

ICANS, immune effector cell-associated neurotoxicity syndrome.

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.

†See Table 2 of the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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

Recommendations for management of ICANS[1]

Manage ICANS according to the recommendations in Table 5 in the full **Prescribing Information** and consider further management per current practice guidelines.

Grade*	Presenting Symptoms†	Actions
Grade 1	ICE score 7-9‡, or depressed level of consciousness§: awakens spontaneously.	• Withhold TECVAYLI® until ICANS resolves.¶ • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines for seizure prophylaxis
Grade 2	ICE score 3-6‡, or depressed level of consciousness§: awakens to voice.	• Withhold TECVAYLI® until ICANS resolves • Administer dexamethasone# 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines for seizure prophylaxis • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI® *[see Dosage and Administration (2.1) in the full Prescribing Information]*#
Grade 3	ICE score 0-2‡, or depressed level of consciousness§: awakens only to tactile stimulus, or seizures§, either: • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local edema on neuroimaging§.	First Occurrence of Grade 3 ICANS: • Withhold TECVAYLI® until ICANS resolves • Administer dexamethasone# 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI® *[see Dosage and Administration (2.1) in the full Prescribing Information]*#
		Recurrent Grade 3 ICANS: • Permanently discontinue TECVAYLI® • Administer dexamethasone# 10 mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care

(Continued on next page)

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Recommendations for management of ICANS (continued)[1]

Grade*	Presenting Symptoms†	Actions
Grade 4	ICE score 0‡, or depressed level of consciousness§: either: • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, or seizures§, either: • life-threatening prolonged seizure (>5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, or motor findings§: • deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure/cerebral edema§, with signs/symptoms such as: • diffuse cerebral edema on neuroimaging, or • decerebrate or decorticate posturing, or • cranial nerve VI palsy, or • papilledema, or • Cushing's triad	• Permanently discontinue TECVAYLI® • Administer dexamethasone# 10 mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper • Alternatively, consider administration of methylprednisolone 1,000 mg per day intravenously and continue methylprednisolone 1,000 mg per day intravenously for 2 or more days • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, anti-seizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care

ICANS, immune effector cell-associated neurotoxicity syndrome.
*Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.
†Management is determined by the most severe event, not attributable to any other cause.
‡If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: **Orientation** (oriented to year, month, city, hospital = 4 points); **Naming** (name 3 objects, eg, point to clock, pen, button = 3 points); **Following Commands** (eg, "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); **Writing** (ability to write a standard sentence = 1 point; and **Attention** (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.
§Not attributable to any other cause.
¶See Table 2 of the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.
#All references to dexamethasone administration are dexamethasone or equivalent.

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

Preparation and administration[1]

- TECVAYLI® is intended for subcutaneous use by a healthcare provider only
- TECVAYLI® should be administered by a healthcare provider with adequate medical personnel and appropriate medical equipment to manage severe reactions, including CRS and ICANS. *[see Warnings and Precautions (5.1, 5.2) in the full Prescribing Information]*
- TECVAYLI® is a clear to slightly opalescent, colorless to light yellow solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit
  - Do not use if the solution is discolored, or cloudy, or if foreign particles are present
- TECVAYLI® 30 mg/3 mL (10 mg/mL) vial and TECVAYLI® 153 mg/1.7 mL (90 mg/mL) vial are supplied as ready-to-use solution that do not need dilution prior to administration
  - Do not combine TECVAYLI® vials of different concentrations to achieve treatment dose
  - Use aseptic technique to prepare and administer TECVAYLI®

Preparation of TECVAYLI®

Refer to the following reference tables for the preparation of TECVAYLI®.

Refer to Tables 7-9 in the full **Prescribing Information** to determine the dosage based on predetermined weight ranges.

Use Table 7 in the full **Prescribing Information** to determine total dose, injection volume and number of vials required based on patient's actual body weight for step-up dose 1 using TECVAYLI® 30 mg/3 mL (10 mg/mL) vial.

Step-up Dose 1 (0.06 mg/kg) Injection Volumes using TECVAYLI® 30 mg/3 mL (10 mg/mL) Vial

Patient Body Weight (kg)	Total Dose (mg)	Volume of Injection (mL)	Number of Vials (1 vial=3 mL)
35 to 39	2.2	0.22	1
40 to 44	2.5	0.25	1
45 to 49	2.8	0.28	1
50 to 59	3.3	0.33	1
60 to 69	3.9	0.39	1
70 to 79	4.5	0.45	1
80 to 89	5.1	0.51	1
90 to 99	5.7	0.57	1
100 to 109	6.3	0.63	1
110 to 119	6.9	0.69	1
120 to 129	7.5	0.75	1
130 to 139	8.1	0.81	1
140 to 149	8.7	0.87	1
150 to 160	9.3	0.93	1

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Use Table 8 in the full **Prescribing Information** to determine total dose, injection volume and number of vials required based on patient's actual body weight for step-up dose 2 using TECVAYLI® 30 mg/3 mL (10 mg/mL) vial.

Step-up Dose 2 (0.3 mg/kg) Injection Volumes using TECVAYLI® 30 mg/3 mL (10 mg/mL) Vial

Patient Body Weight (kg)	Total Dose (mg)	Volume of Injection (mL)	Number of Vials (1 vial=3 mL)
35 to 39	11	1.1	1
40 to 44	13	1.3	1
45 to 49	14	1.4	1
50 to 59	16	1.6	1
60 to 69	19	1.9	1
70 to 79	22	2.2	1
80 to 89	25	2.5	1
90 to 99	28	2.8	1
100 to 109	31	3.1	2
110 to 119	34	3.4	2
120 to 129	37	3.7	2
130 to 139	40	4	2
140 to 149	43	4.3	2
150 to 160	47	4.7	2

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

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

Preparation and administration (continued)[1]

Use Table 9 in the full **Prescribing Information** to determine total dose, injection volume and number of vials required based on patient's actual body weight for the treatment dose using TECVAYLI® 153 mg/1.7 mL (90 mg/mL) vial.

Treatment Dose (1.5 mg/kg) Injection Volumes using TECVAYLI® 153 mg/1.7 mL (90 mg/mL) Vial

Patient Body Weight (kg)	Total Dose (mg)	Volume of Injection (mL)	Number of Vials (1 vial=1.7 mL)
35 to 39	56	0.62	1
40 to 44	63	0.7	1
45 to 49	70	0.78	1
50 to 59	82	0.91	1
60 to 69	99	1.1	1
70 to 79	108	1.2	1
80 to 89	126	1.4	1
90 to 99	144	1.6	1
100 to 109	153	1.7	1
110 to 119	171	1.9	2
120 to 129	189	2.1	2
130 to 139	198	2.2	2
140 to 149	216	2.4	2
150 to 160	234	2.6	2

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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 Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Preparation of TECVAYLI®

TECVAYLI® is intended for subcutaneous use by a healthcare provider only.

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

TECVAYLI® is a clear to slightly opalescent, colorless to light yellow solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the solution is discolored, or cloudy, or if foreign particles are present.

TECVAYLI® 30 mg/3 mL (10 mg/mL) vial and TECVAYLI® 153 mg/1.7 mL (90 mg/mL) vial are supplied as ready-to-use solutions that do not need dilution prior to administration.

Do not combine TECVAYLI® vials of different concentrations to achieve treatment dose.

1. Remove the appropriate strength TECVAYLI® vial from refrigerated storage [2°C to 8°C (36°F to 46°F)].
2. Once removed from refrigerated storage, equilibrate TECVAYLI® 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.
5. Replace the transfer needle with an appropriately sized needle for injection.

Each injection volume should not exceed 2 mL. Divide doses requiring greater than 2 mL equally into multiple syringes.

TECVAYLI® is compatible with stainless steel injection needles and polypropylene or polycarbonate syringe material.

Administration of TECVAYLI®

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.

Any unused product or waste material should be disposed in accordance with local requirements.

Storage

If the prepared dosing syringe(s) of TECVAYLI® is not used immediately, store syringe(s) at 2°C to 8°C (36°F to 46°F) or at ambient temperature 15°C to 30°C (59°F to 86°F) for a maximum of 20 hours. Discard syringe(s) after 20 hours, if not used.

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

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

Comprehensive Support Throughout Your Patients' Treatment Journey

Once you have made the clinical decision to prescribe TECVAYLI®, Johnson & Johnson has resources to help you support your patients.

J&J withMe

At Johnson & Johnson, we are committed to helping people in their fight against cancer. Our J&J withMe program is here at every step to provide personalized support to help patients start and stay on their J&J medicines.

Access Support to Help Navigate Payer Processes
J&J withMe helps verify insurance coverage for your patients taking TECVAYLI®, providing benefits investigation support, prior authorization support, information on the exceptions and appeals process, and reimbursement information

Affordability Resources for Your Patients
Help patients discover ways to afford their TECVAYLI®, regardless of their insurance type or even if they have no insurance at all

Dedicated, free 1-on-1 support for your patients throughout their treatment journey–Offered through TECVAYLI withMe
Each patient's TECVAYLI® treatment journey is unique. We're here to help by providing personalized 1-on-1 support from oncology trained nurses*

*Care Navigators do not provide medical advice.

Affordability support for patients using commercial insurance

The **J&J withMe Savings Program** can help eligible patients save on their out-of-pocket medicine costs for TECVAYLI®. Your eligible patients will **pay $5 per dose**. Maximum program benefit per calendar year shall apply. Offer subject to change or end without notice. For medicine costs only; program does not cover the cost to give patients their treatment. Patients may participate without sharing their income information. See program requirements at TECVAYLI.JNJwithMeSavings.com

Easy access to key support needs in Provider Express at Portal.JNJwithMe.com without an account, password, or Business Associate Agreement (BAA):

- Request benefits investigations
- Enroll your eligible, commercially insured patients in the J&J withMe Savings Program
- Submit a Savings Program rebate request
- Sign up patients for Care Navigator support
- Enroll eligible patients in the Johnson & Johnson Patient Assistance Program

Get started with J&J withMe

- Visit Portal.JNJwithMe.com to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support
- Visit JNJwithMe.com/hcp/ for access and affordability information for the J&J medicine you prescribed
- Bookmark these links for quick and easy access!
- Questions? Call **833-JNJ-wMe1 (833-565-9631)**, Monday through Friday, 8:00 AM to 8:00 PM ET

Get your patient connected to J&J withMe support by asking them to enroll at TECVAYLIwithMe.com

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe TECVAYLI®.

With a Provider Portal account, you can view a patient dashboard with real-time status updates on your requests, like benefits investigation results and savings program claims, and initiate prior authorizations.

Please read full Important Safety Information on pages 4-5, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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Visit TecvayliHCP.com to learn more and to download helpful resources

References: 1. TECVAYLI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** U.S. Food and Drug Administration. FDA approves teclistamab-cqyv for relapsed or refractory multiple myeloma. Accessed May 24, 2024. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-teclistamab-cqyv-relapsed-or-refractory-multiple-myeloma **3.** Data on file. Janssen Biotech, Inc. **4.** Garfall AL, Nooka AK, Niels WCJ van de Donk, et al. Long-term follow-up from the phase 1/2 MajesTEC-1 trial of teclistamab in patients with relapsed/refractory multiple myeloma. Poster. Presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4, 2024; Chicago, IL.

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