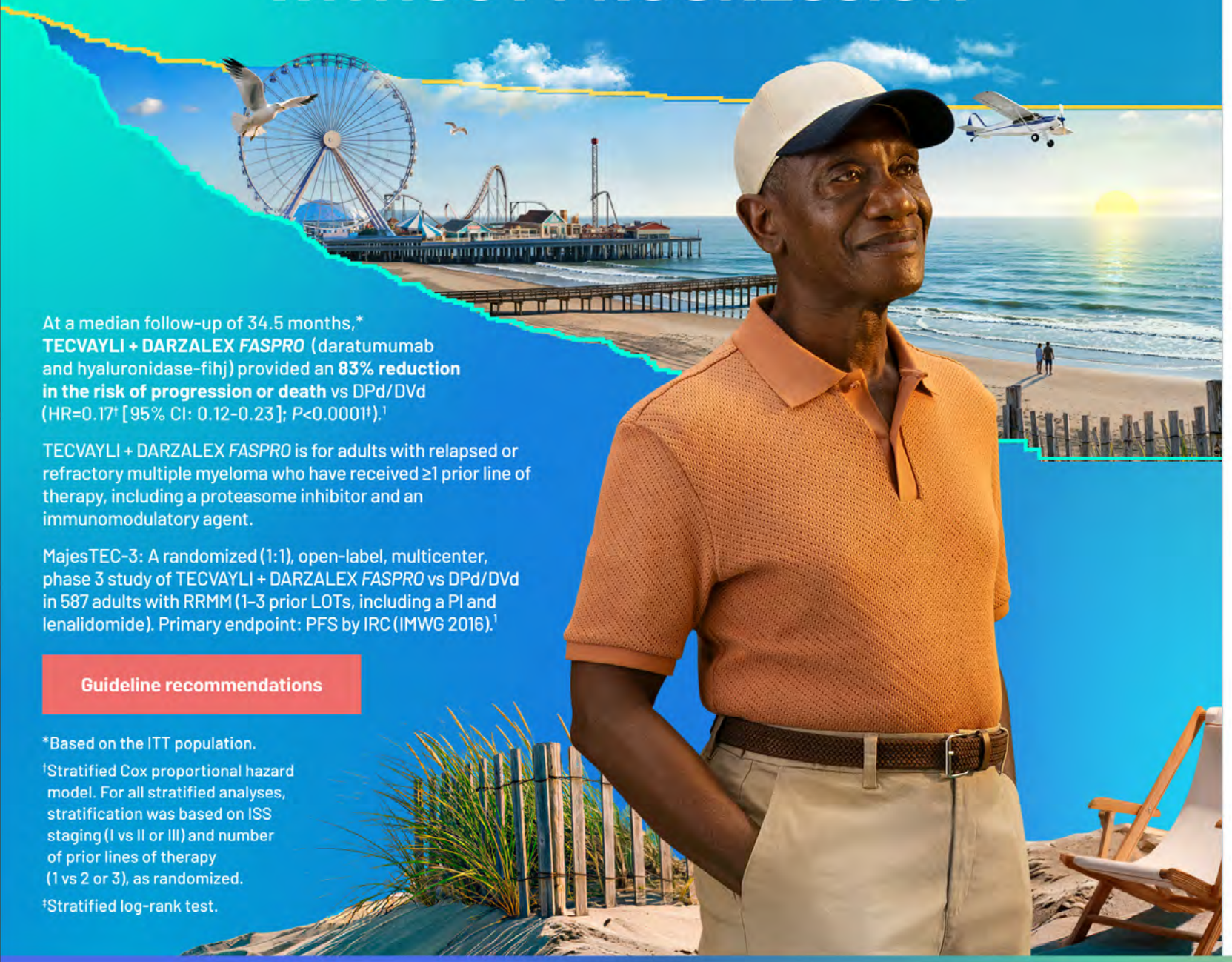
STAY AHEAD OF THE CURVE FOR A CHANCE TO LIVE LONGER WITHOUT PROGRESSION[1,2]



At a median follow-up of 34.5 months,* **TECVAYLI + DARZALEX *FASPRO*** (daratumumab and hyaluronidase-fihj) provided an **83% reduction in the risk of progression or death** vs DPd/DVd (HR=0.17[†] [95% CI: 0.12-0.23]; *P*<0.0001[‡]).[1]

TECVAYLI + DARZALEX *FASPRO* is for adults with relapsed or refractory multiple myeloma who have received ≥1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.

MajesTEC-3: A randomized (1:1), open-label, multicenter, phase 3 study of TECVAYLI + DARZALEX *FASPRO* vs DPd/DVd in 587 adults with RRMM (1-3 prior LOTs, including a PI and lenalidomide). Primary endpoint: PFS by IRC (IMWG 2016).[1]

Guideline recommendations

*Based on the ITT population.

[†]Stratified Cox proportional hazard model. For all stratified analyses, stratification was based on ISS staging (I vs II or III) and number of prior lines of therapy (1 vs 2 or 3), as randomized.

[‡]Stratified log-rank test.

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

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, life-threatening, or fatal 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).

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Mechanism of action

TECVAYLI® and DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj): An all-immunotherapy combination[1,4]

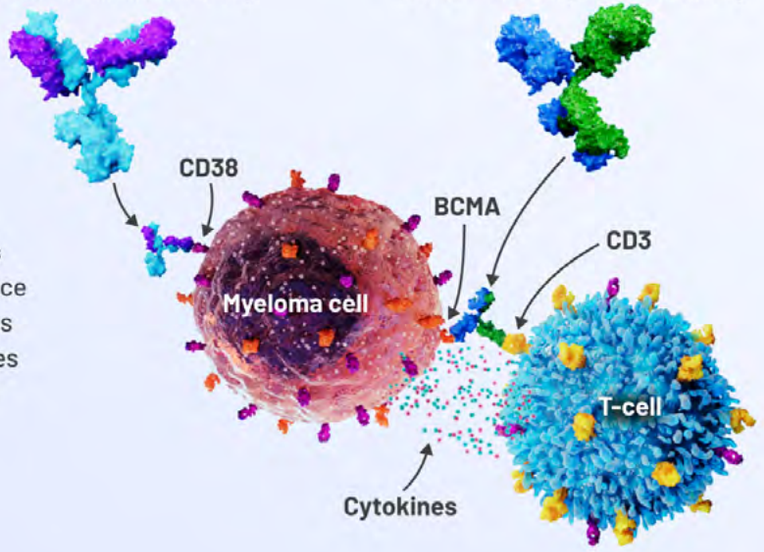
Daratumumab enables the CD38-mediated microenvironment by decreasing immunosuppressive CD38+T_{regs} and B_{regs}, in addition to its direct on-tumor effects[4]

+

The binding of **TECVAYLI®** to both BCMA and CD3 leads to the **activation of T-cells** and the release of various proinflammatory cytokines, resulting in the lysis of MM cells[1]

DARZALEX *FASPRO*®
Anti-CD38 monoclonal antibody

TECVAYLI®
BCMA × CD3 bispecific antibody



Daratumumab binds to CD38 on the surface of MM cells, as well as on certain other types of cells, such as red blood cells.[4]

TECVAYLI® binds to BCMA on the surface of MM cells and some healthy B-lineage cells, **as well as to CD3** on the surface of T-cells.[1]

DARZALEX *FASPRO*®, when used in combination with **TECVAYLI®**, **enables and enhances the immune-mediated lysis of MM cells[1,4]**

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IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome - TECVAYLI can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions.

In the clinical trials (monotherapy and combination therapy; N=448), CRS occurred in 64% of patients who received TECVAYLI at the recommended dosage, with Grade 1 CRS occurring in 46% of patients, Grade 2 in 18%, and Grade 3 in 0.2%. Recurrent CRS occurred in 27% of patients. Most patients experienced CRS during the initial step-up dosing schedule (step-up dose 1 [37%], step-up dose 2 [32%], or the initial treatment dose [20%]). CRS first occurred following subsequent doses of TECVAYLI in 2.5% of patients. The median time to onset of CRS was 2 (range: 1 to 9) days after the most recent dose and the median duration of CRS was 2 (range: 1 to 22) days.

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DARZALEX *FASPRO*® Indications and full Important Safety Information >

DARZALEX *FASPRO*® full Prescribing Information >

TECVAYLI® is the only bispecific antibody approved in combination with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)[1]

MajesTEC-3 was a randomized (1:1), multicenter, open-label study evaluating the efficacy of TECVAYLI® in combination with DARZALEX *FASPRO*® in adult patients with RRMM who received 1 to 3 prior lines of therapy, including a PI and lenalidomide. Patients who had received only 1 prior line of therapy must have been refractory to lenalidomide. Patients were excluded from the trial if they had disease refractory to a prior anti-CD38 monoclonal antibody therapy or had received any prior BCMA-directed therapy.



Major Efficacy Outcome Measure[1]: PFS*

Key Secondary Endpoints[1,2]: OS, ORR, ≥CR, MRD negativity (10^{-5})

*Assessment by IRC based on IMWG 2016 criteria.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Cytokine Release Syndrome (cont'd) - 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 the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold until CRS resolves or permanently discontinue TECVAYLI based on severity.

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

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The MajesTEC-3 trial included patients of various ages, ISS stages, and cytogenetic risks[1]

Baseline disease characteristics in MajesTEC-3

- Median prior lines of therapy: 2 (range: 1-3)
- 38% of patients had received 1 prior line of therapy
- 100% of patients were previously exposed to lenalidomide and 84% were refractory
- 99.8% of patients were previously exposed to a PI
- 74% of patients previously received autologous stem cell transplantation
- 5% of patients received a prior anti-CD38 monoclonal antibody*

Patient characteristics	N=587
Age (median)	**64 years (range: 25-88)**
≥75 years of age	**10%**
Male	**55%**
White	**65%**
Black or African American	**6%**
Asian	**22%**
ISS Stage I at screening	**63%**
ISS Stage II at screening	**29%**
ISS Stage III at screening	**8%**
High-risk cytogenetics (presence of del[17p], t[4;14], or t[14;16])	**35%**
Extramedullary disease	**5%**

*There are limited data with TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in patients who have received or are refractory to prior anti-CD38 monoclonal antibody therapy.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome – TECVAYLI can cause serious, life-threatening, or fatal neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

In the clinical trials (monotherapy and combination therapy trials; N=448), neurologic toxicity occurred in 60% of patients who received TECVAYLI at the recommended dosage, with Grade 3 or 4 neurologic toxicity in 6%. Neurologic toxicities reported in ≥5% of patients included headache (27%), sensory neuropathy (16%), motor dysfunction (15%), insomnia (12%), encephalopathy (11%), and dizziness (8%). Fatal neurologic toxicity occurred in 0.4% of patients, including Guillain-Barré syndrome and status epilepticus (one patient each).

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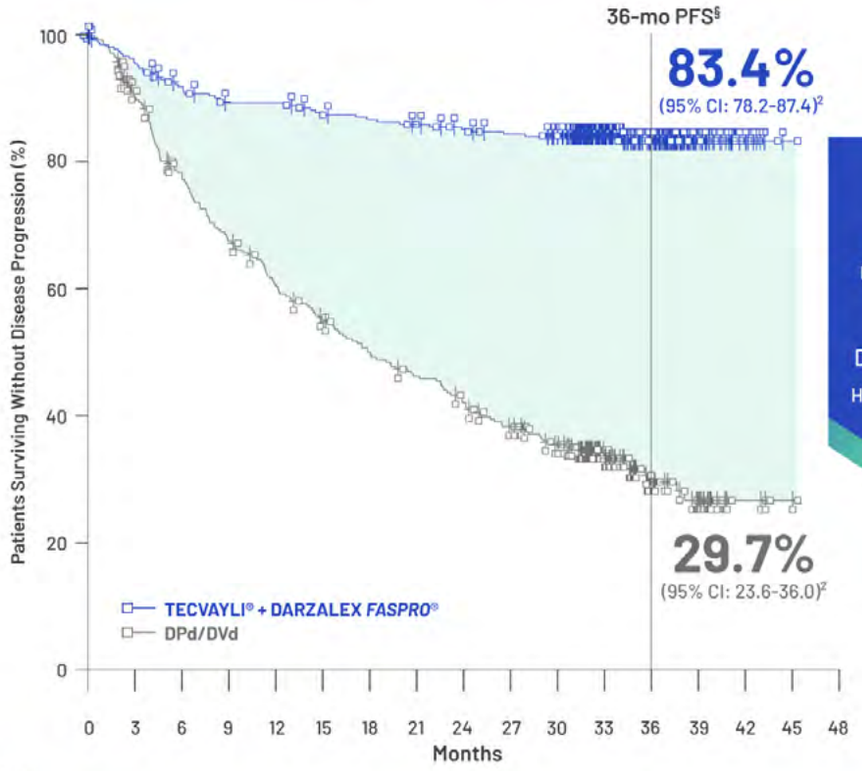
At a median follow-up of 34.5 months*

TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) demonstrated superior PFS vs DPd/DVd (HR=0.17†; *P*<0.001‡)[1,2,5]



No. at Risk

TEC-DARA SC	291	262	249	240	240	233	230	227	222	218	214	142	89	34	9	0	0
DPd/DVd	296	254	218	188	167	149	135	124	112	99	87	52	26	14	3	1	0

83%
Reduction in the risk of progression or death with TECVAYLI® + DARZALEX *FASPRO*®
HR=0.17† (95% CI: 0.12-0.23)
P<0.0001‡

*Based on the ITT population.
†Stratified Cox proportional hazard model. For all stratified analyses, stratification was based on ISS staging (I vs II or III) and number of prior lines of therapy (1 vs 2 or 3), as randomized.
‡Stratified log-rank test.
§Kaplan-Meier estimate.

Median PFS was not reached in the TECVAYLI® + DARZALEX *FASPRO*® arm (95% CI: NE-NE) vs 18.1 months (95% CI: 14.6-22.8) in the DPd/DVd arm[1]

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (cont'd) - In MajesTEC-1, ICANS was reported in 6% of patients who received TECVAYLI as monotherapy at the recommended dosage. 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 TECVAYLI doses. 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.

In MajesTEC-3, ICANS was reported in 1.1% of patients who received the recommended TECVAYLI dosage in combination with daratumumab and hyaluronidase-fihj, including Grade 4 ICANS in 1 patient. All events of ICANS occurred during the step-up dosing schedule. The median time to onset of ICANS was 2 (range: 1 to 3) days after the most recent dose and the median duration of ICANS

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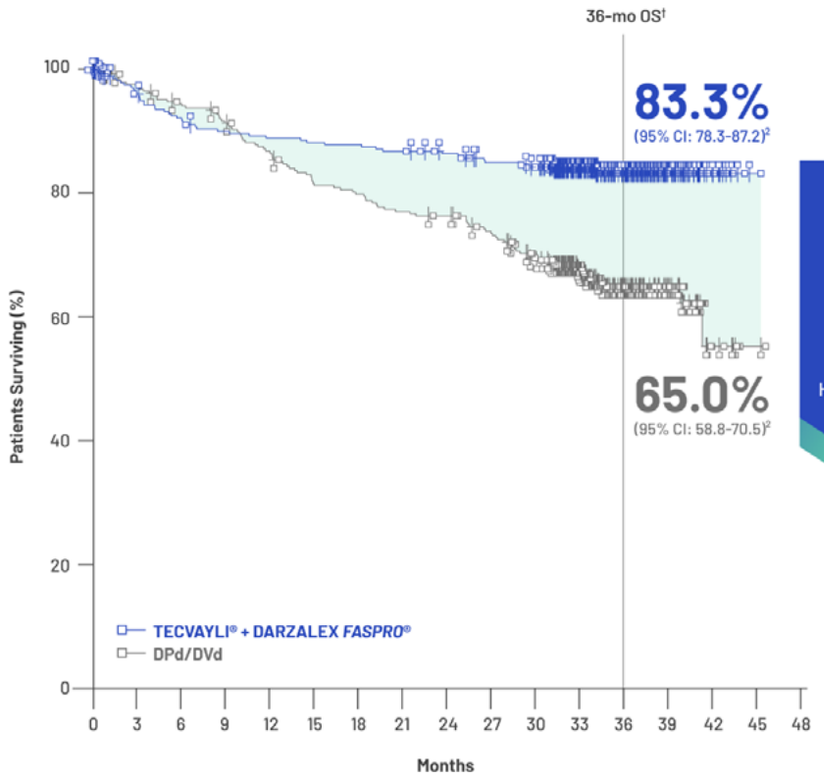
At a median follow-up of 34.5 months*

TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) demonstrated superior OS vs DPd/DVd[1,2,6]



No. at Risk

TEC-DARA SC	291	272	259	252	249	247	246	243	239	232	227	160	100	40	9	0	0
DPd/DVd	296	285	274	265	250	235	229	221	218	208	190	127	66	33	5	1	0

*Based on the ITT population.
†Kaplan-Meier estimate.
‡Stratified Cox proportional hazard model. For all stratified analyses, stratification was based on ISS staging (I vs. II or III) and number of prior lines of therapy (1 vs 2 or 3), as randomized.
§Stratified log-rank test.

Median OS was not reached in either the **TECVAYLI® + DARZALEX *FASPRO*® arm** (95% CI: NE-NE) or the **DPd/DVd arm** (95% CI: 41.4 months to NE)[1]

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (cont'd) - was 2 (range: 1 to 2) days. The clinical manifestations of ICANS reported were amnesia, encephalopathy and delirium.

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, including ICANS during TECVAYLI treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold until neurologic toxicity resolves 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 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

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The percentage of patients with MRD (10^{-5}) was 3x higher with TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)[1]

MRD negativity (10^{-5})*†
***P*<0.0001‡**

TECVAYLI® + DARZALEX *FASPRO*®	DPd/DVd
58.4%	**17.1%**
(n=153/262; 95% CI: 52.2-64.4)	(n=46/269; 95% CI: 12.8-22.1)

MRD negativity (10^{-5}) in patients with ≥CR†

TECVAYLI® + DARZALEX *FASPRO*®	DPd/DVd
70.8%	**53.5%**
(n=153/216; 95% CI: 64.3-76.8)	(n=46/86; 95% CI: 42.4-64.3)

*Based on MRD next-generation sequencing (NGS) primary analysis set, defined as all randomized patients enrolled at sites where NGS assay was available.
†Based on a threshold of 10^{-5} using an NGS assay (clonoSEQ).
‡Fisher's exact test.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (cont'd) - 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. There was one fatal case of hepatic failure in MajesTEC-1. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448) elevated aspartate aminotransferase (AST) occurred in 47% of patients, with Grade 3 or 4 elevations in 2.9%. Elevated alanine aminotransferase (ALT) occurred in 48% of patients, with Grade 3 or 4 elevations in

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Proven combination with a demonstrated safety profile[1]

Among patients who received TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) (N=283), the median exposure was 32 (range: 0.03 to 43) months. Among patients who received DPd or DVd (N=290), the median exposure was 16 (range: 0.03 to 45) months.[1]

Serious Adverse Reactions[1,7]

TECVAYLI® + DARZALEX *FASPRO*®	DPd/DVd*
71%	62%

Serious adverse reactions reported in ≥3% of patients receiving TECVAYLI® + DARZALEX *FASPRO*® included pneumonia (33%), upper respiratory tract infection (15%), cytokine release syndrome (10%), COVID-19 (7%), sepsis (6%), second primary malignancy (5%), pyrexia (4.9%), febrile neutropenia (4.6%), and gastroenteritis (4.2%).[1]

Fatal Adverse Reactions[1,5]

TECVAYLI® + DARZALEX *FASPRO*®	DPd/DVd*
2.5%	3.8%

Fatal adverse reactions in patients receiving TECVAYLI® + DARZALEX *FASPRO*® included sepsis (0.7%), pneumonia (0.4%), sudden death (0.4%), myocardial infarction (0.4%), enterovirus myocarditis (0.4%), and hemophagocytic lymphohistiocytosis (0.4%).[1]

*This information is not included in the current TECVAYLI® full Prescribing Information.

Specific populations ›

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hepatotoxicity (cont'd) – in 3.8%. Elevated total bilirubin occurred in 10% of patients with Grade 3 or 4 elevations in 0.7%. 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 MajesTEC-1 (N=165), in patients who received the recommended TECVAYLI dosage, serious infections, including opportunistic infections, occurred in 30% of patients, Grade 3 or 4 infections in 35% of patients, and fatal infections in 4.2% of patients.

In MajesTEC-3 (N=283), in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj at the recommended dosage, serious infections, including opportunistic infections, occurred in 54% of patients, Grade 3 or

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Proven combination with a demonstrated safety profile (cont'd)[1]

Permanent Discontinuation

6% of patients permanently discontinued TECVAYLI® due to adverse reactions

Adverse reactions leading to discontinuation of TECVAYLI® in more than 1 patient were pneumonia (1.1%), diarrhea (0.7%), fatigue (0.7%), second primary malignancy (0.7%), upper respiratory tract infection (0.7%), and cough (0.7%).

Dosage interruptions of TECVAYLI® due to an adverse reaction occurred in 94% of patients. Adverse reactions which required dosage interruption of TECVAYLI® in ≥5% of patients included neutropenia (53%), upper respiratory tract infection (48%), COVID-19 (34%), pneumonia (34%), thrombocytopenia (14%), cytokine release syndrome (13%), gastroenteritis (10%), cough (10%), pyrexia (8%), diarrhea (7%), sepsis (6%), and fatigue (5%).

The most common adverse reactions (≥20%) were hypogammaglobulinemia, upper respiratory tract infection, cytokine release syndrome, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight decreased.

The most common Grade 3 to 4 laboratory abnormalities (≥20%) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, and decreased platelets.

Clinically relevant adverse reactions in <10% of patients who received TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) included sepsis, encephalopathy, cytomegalovirus (CMV) infection, febrile neutropenia, and ICANS.

Specific populations ›

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd) – Grade 4 infections in 54% of patients, and fatal infections in 4.6% of patients.

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI and treat appropriately. Administer prophylactic antimicrobials according to current practice guidelines.

Withhold TECVAYLI or consider permanent discontinuation of TECVAYLI based on severity.

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI and administer subcutaneous or intravenous immunoglobulin (IVIG) to maintain the serum levels >400 mg/dL.

Neutropenia – TECVAYLI can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), decreased neutrophils occurred in 88% of patients, with Grade 3 or 4 decreased neutrophils in 70%. Febrile neutropenia occurred in 6% of patients.

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Adverse reactions (≥10%) in patients with RRMM who received TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)[1]

Adverse Reaction	TECVAYLI® + DARZALEX *FASPRO*® (N=283)		DPd/DVd (N=290)	
	Any Grade (%)	Grade 3/4 (%)	Any Grade (%)	Grade 3/4 (%)
Immune system disorders				
Hypogammaglobulinemia*	84%	6%	60%	1.4%
Cytokine release syndrome	60%	0	0	0
Infections				
Upper respiratory tract infection†	79%	17%	62%	13%
COVID-19‡	45%	6%	33%	2.1%
Pneumonia§‖	42%	33%	35%	28%
Gastroenteritis‡	20%	4.9%	8%	0.7%
Urinary tract infection‡	17%	2.8%	13%	1%
Herpes virus infection‡	11%	2.1%	6%	0.3%

Adverse reactions were graded according to NCI-CTCAE Version 5.0, with the exception of ICANS and CRS, which were graded by ASTCT 2019 consensus grading system; adverse reactions that were considered symptoms of CRS or ICANS were not included.

*Hypogammaglobulinemia includes hypogammaglobulinemia, hypoglobulinemia; and/or patients with laboratory IgG levels below 400 mg/dL following treatment with TECVAYLI®.

†Upper respiratory tract infection includes bronchitis, bronchiolitis, pharyngitis, rhinitis, sinusitis, sinobronchitis, tracheitis, and tracheobronchitis and other related terms.

‡Includes other related terms.

§Pneumonia includes atypical pneumonia, bacterial pneumonia, fungal pneumonia, viral pneumonia, and other related terms.

‖Includes the following fatal adverse reactions: TECVAYLI® + DARZALEX *FASPRO*®: pneumonia (n=1); DPd/DVd: pneumonia (n=2).

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neutropenia (cont'd) - 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 the recommended TECVAYLI dosage in the clinical trials (monotherapy and combination therapy trials; N=448), 2.5% of patients experienced systemic-administration reactions, which included recurrent pyrexia and rash.

Local Reactions - In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), injection-site reactions occurred in 37% of

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Adverse reactions (≥10%) in patients with RRMM who received TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) (cont'd)[1]

Adverse Reaction	TECVAYLI® + DARZALEX *FASPRO*® (N=283)		DPd/DVd (N=290)	
	Any Grade (%)	Grade 3/4 (%)	Any Grade (%)	Grade 3/4 (%)
Respiratory, thoracic, and mediastinal disorders				
Cough*	53%	0.7%	24%	0
Dyspnea*	13%	1.8%	20%	2.1%
Gastrointestinal disorders				
Diarrhea*	52%	3.9%	31%	2.4%
Nausea	23%	0	12%	0.3%
Vomiting	17%	0	7%	0
Abdominal pain*	16%	0.7%	13%	0
Constipation	14%	0	20%	0.3%

Adverse reactions were graded according to NCI-CTCAE Version 5.0, with the exception of ICANS and CRS, which were graded by ASTCT 2019 consensus grading system; adverse reactions that were considered symptoms of CRS or ICANS were not included.
*Includes other related terms.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Local Reactions (cont'd) - patients, with Grade 1 injection-site reactions in 29% and Grade 2 in 9%.

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 patient. Advise pregnant patients 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%) in patients who received TECVAYLI monotherapy were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common adverse reactions (≥20%) in patients who received TECVAYLI in combination with

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Adverse reactions (≥10%) in patients with RRMM who received TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) (cont'd)[1]

Adverse Reaction	TECVAYLI® + DARZALEX *FASPRO*® (N=283)		DPd/DVd (N=290)	
	Any Grade (%)	Grade 3/4 (%)	Any Grade (%)	Grade 3/4 (%)
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain*	50%	1.4%	47%	4.5%
General disorders and administration site conditions				
Injection site reaction*†	41%	0	4.5%	0
Fatigue*	39%	3.9%	40%	4.1%
Pyrexia	37%	1.4%	19%	0.3%
Edema*	13%	0.4%	22%	0.3%

Adverse reactions were graded according to NCI-CTCAE Version 5.0, with the exception of ICANS and CRS, which were graded by ASTCT 2019 consensus grading system; adverse reactions that were considered symptoms of CRS or ICANS were not included.
*Includes other related terms.
†Includes injection site reactions related to teclistamab, daratumumab and hyaluronidase-fihj, and bortezomib.

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

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (cont'd)

daratumumab and hyaluronidase-fihj were hypogammaglobulinemia, upper respiratory tract infection, CRS, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight decreased.

The most common Grade 3 to 4 laboratory abnormalities (≥20%) with TECVAYLI (as monotherapy or in combination with daratumumab and hyaluronidase-fihj) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

INDICATIONS 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:

- in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy,

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TECVAYLI® full Prescribing Information, including Boxed WARNING >

Adverse reactions (≥10%) in patients with RRMM who received TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) (cont'd)[1]

Adverse Reaction	TECVAYLI® + DARZALEX *FASPRO*® (N=283)		DPd/DVd (N=290)	
	Any Grade (%)	Grade 3/4 (%)	Any Grade (%)	Grade 3/4 (%)
Nervous system disorders				
Headache*	26%	1.4%	12%	0.3%
Sensory neuropathy†	17%	0.7%	25%	0.3%
Motor dysfunction‡	14%	0	30%	1%
Investigations				
Weight decreased	20%	2.8%	7%	1.4%
Metabolism and nutrition disorders				
Decreased appetite	19%	1.1%	7%	0

Adverse reactions were graded according to NCI-CTCAE Version 5.0, with the exception of ICANS and CRS, which were graded by ASTCT 2019 consensus grading system; adverse reactions that were considered symptoms of CRS or ICANS were not included.

*Includes other related terms.

†Sensory neuropathy includes dysaesthesia, hyperaesthesia, hypoaesthesia, paraesthesia, neuralgia, peripheral neuropathy, polyneuropathy, sciatica, and other related terms.

‡Motor dysfunction includes balance disorder, dysarthria, dysphonia, gait disturbance, muscle contracture, muscle spasms, muscle spasticity, muscle twitching, muscular weakness, myopathy, peripheral motor neuropathy, tremor, and other related terms.

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

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE (cont'd)

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:

- in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
- as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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Adverse reactions (≥10%) in patients with RRMM who received TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) (cont'd)[1]

Adverse Reaction	TECVAYLI® + DARZALEX *FASPRO*® (N=283)		DPd/DVd (N=290)	
	Any Grade (%)	Grade 3/4 (%)	Any Grade (%)	Grade 3/4 (%)
Cardiac disorders				
Cardiac arrhythmia*	11%	1.1%	8%	2.1%
Neoplasms				
Second primary malignancy*	11%	4.6%	9%	4.8%
Vascular disorders				
Hypertension*	11%	4.6%	6%	2.4%

Adverse reactions were graded according to NCI-CTCAE Version 5.0, with the exception of ICANS and CRS, which were graded by ASTCT 2019 consensus grading system; adverse reactions that were considered symptoms of CRS or ICANS were not included.
*Includes other related terms.

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

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, life-threatening, or fatal 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).

TECVAYLI® Indications and full Important Safety Information ›

TECVAYLI® full Prescribing Information, including Boxed WARNING ›

Laboratory abnormalities in MajesTEC-3[1]

Select laboratory abnormalities (≥30%) that worsened from baseline in patients with RRMM who received TECVAYLI® in combination with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in MajesTEC-3.

Laboratory Abnormality	TECVAYLI® + DARZALEX *FASPRO*® (N=283)		DPd/DVd (N=290)	
	All Grades (%)	Grade 3/4 (%)	All Grades (%)	Grade 3/4 (%)
Hematology				
Lymphocyte count decreased	99%	95%	93%	64%
White blood cell decreased	94%	60%	96%	74%
Neutrophil count decreased	91%	78%	94%	84%
Platelet count decreased	73%	21%	72%	25%
Hemoglobin decreased	64%	17%	61%	19%

Percentages calculated with the number of subjects with a baseline and at least one post-treatment value for each lab test as denominator.

Laboratory toxicity grades are derived based on NCI CTCAE Version 5.0.

The denominator used to calculate the incidence varied from 137 to 282 with TECVAYLI® + DARZALEX *FASPRO*® and 135 to 289 with DPd/DVd based on the number of patients with a baseline value and at least one post-treatment value.

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

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome – TECVAYLI can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions.

In the clinical trials (monotherapy and combination therapy; N=448), CRS occurred in 64% of patients who received TECVAYLI at the recommended dosage, with Grade 1 CRS occurring in 46% of patients, Grade 2 in 18%, and Grade 3 in 0.2%. Recurrent CRS occurred in 27% of patients. Most patients experienced CRS during the initial step-up dosing schedule (step-up dose 1 [37%], step-up dose 2 [32%], or the initial treatment dose [20%]). CRS first occurred following subsequent doses of TECVAYLI in 2.5% of patients. The median time to onset of CRS was 2 (range: 1 to 9) days after the most recent dose and the median duration of CRS was 2 (range: 1 to 22) days.

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Laboratory abnormalities in MajesTEC-3[1]

Select laboratory abnormalities (≥30%) that worsened from baseline in patients with RRMM who received TECVAYLI® in combination with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in MajesTEC-3.

Laboratory Abnormality	TECVAYLI® + DARZALEX *FASPRO*® (N=283)		DPd/DVd (N=290)	
	All Grades (%)	Grade 3/4 (%)	All Grades (%)	Grade 3/4 (%)
Chemistry				
Alanine aminotransferase increased	60%	5%	33%	2.4%
Aspartate aminotransferase increased	55%	3.9%	22%	1.7%
Potassium decreased	52%	15%	35%	8%
GGT increased	51%	5%	24%	0
Sodium decreased	46%	10%	37%	6%
Lipase increased	49%	18%	21%	4.7%
Serum amylase increased	31%	7%	13%	0

Percentages calculated with the number of subjects with a baseline and at least one post-treatment value for each lab test as denominator.

Laboratory toxicity grades are derived based on NCI CTCAE Version 5.0.

The denominator used to calculate the incidence varied from 137 to 282 with TECVAYLI® + DARZALEX *FASPRO*® and 135 to 289 with DPd/DVd based on the number of patients with a baseline value and at least one post-treatment value.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Cytokine Release Syndrome (cont'd) – 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 the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold until CRS resolves or permanently discontinue TECVAYLI based on severity.

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

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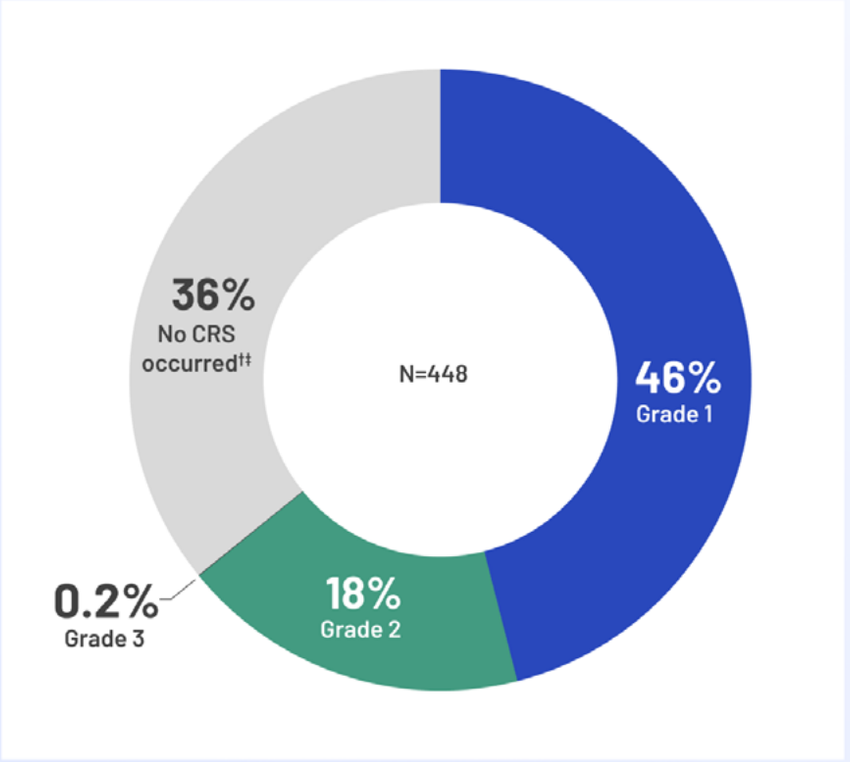
Most CRS events were Grade 1 and 2, median time to onset was 2 days, and median duration was 2 days[1]

Demonstrated CRS results across 448 patients and 2 clinical trials*



*In monotherapy and combination therapy trials; N=448.

†CRS, including life-threatening or fatal reactions, may occur in patients receiving TECVAYLI®.
‡CRS of any grade was reported in 64% of patients who received TECVAYLI® at the recommended dosage.

Median time to onset

2 days

(range: 1-9 days)
after most recent dosage

Median duration

2 days

(range: 1-22 days)

CRS grading and management ›

CRS in MajesTEC-3 ›

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome – TECVAYLI can cause serious, life-threatening, or fatal neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

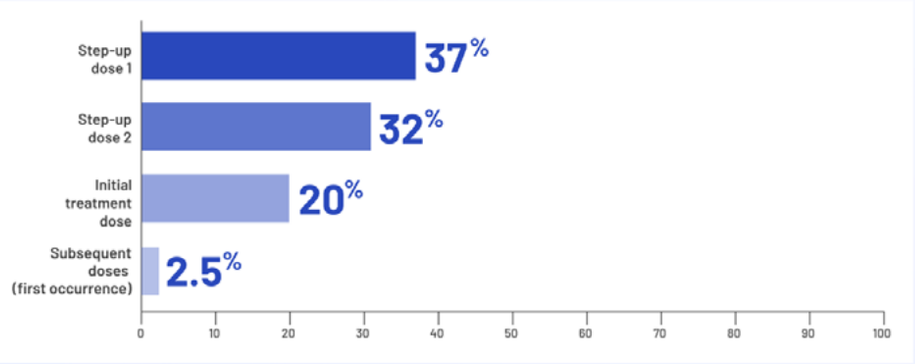
In the clinical trials (monotherapy and combination therapy trials; N=448), neurologic toxicity occurred in 60% of patients who received TECVAYLI at the recommended dosage, with Grade 3 or 4 neurologic toxicity in 6%. Neurologic toxicities reported in ≥5% of patients included headache (27%), sensory neuropathy (16%), motor dysfunction (15%), insomnia (12%), encephalopathy (11%), and dizziness (8%). Fatal neurologic toxicity occurred in 0.4% of patients, including Guillain-Barré syndrome and status epilepticus (one patient each).

TECVAYLI® Indications and full Important Safety Information ›

TECVAYLI® full Prescribing Information, including Boxed WARNING ›

Across 448 patients in 2 clinical trials,* most CRS events were Grade 1 and 2, median time to onset was 2 days, and median duration was 2 days[1]

Most CRS events occurred during the step-up dosing period



CRS grading and management ›

CRS in MajesTEC-3 ›

Recurrent CRS occurred in 27% of patients.

Clinical signs and symptoms of CRS included but were not limited to:

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

If not already hospitalized, 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 only available through a restricted program under a REMS.

*In monotherapy and combination therapy trials; N=448.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (cont'd) - In MajesTEC-1, ICANS was reported in 6% of patients who received TECVAYLI as monotherapy at the recommended dosage. 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 TECVAYLI doses. 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.

In MajesTEC-3, ICANS was reported in 1.1% of patients who received the recommended TECVAYLI dosage in combination with daratumumab and hyaluronidase-fihj, including Grade 4 ICANS in 1 patient. All events of ICANS occurred during the step-up dosing schedule. The median time to onset of ICANS was 2 (range: 1 to 3) days after the most recent dose and the median duration of ICANS

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Across 448 patients in 2 clinical trials,* most neurologic toxicities were Grade 1 and 2[1]

TECVAYLI® can cause serious, life-threatening, or fatal neurologic toxicity, including ICANS.

Neurologic toxicity occurred in 60% of patients who received TECVAYLI® at the recommended dosage.

- Grade 3 or 4 neurologic toxicity occurred in 6% of patients
- Neurologic toxicities reported in ≥5% of patients included headache (27%), sensory neuropathy (16%), motor dysfunction (15%), insomnia (12%), encephalopathy (11%), and dizziness (8%)
- Fatal neurologic toxicity occurred in 0.4% of patients, including Guillain-Barré syndrome and status epilepticus (1 patient each)

*In monotherapy and combination therapy trials; N=448.

In MajesTEC-3 (N=283), 1.1% of patients receiving TECVAYLI® at the recommended dosage with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) experienced ICANS

- A Grade 4 event occurred in 1 patient
- All events of ICANS occurred during the step-up dosing schedule
- The clinical manifestations of ICANS reported were amnesia, encephalopathy, and delirium

Median time to onset

2 days

(range: 1-3 days) after most recent dosage

Median duration

2 days

(range: 1-2 days)

Management of neurologic toxicity (excluding ICANS) >

Management of ICANS >

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (cont'd) - was 2 (range: 1 to 2) days. The clinical manifestations of ICANS reported were amnesia, encephalopathy and delirium.

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, including ICANS during TECVAYLI treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold until neurologic toxicity resolves 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 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

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Across 448 patients in 2 clinical trials,* most neurologic toxicities were Grade 1 and 2 (cont'd)[1]

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

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.

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

*In monotherapy and combination therapy trials; N=448.

Management of neurologic toxicity (excluding ICANS) ›

Management of ICANS ›

TECVAYLI® is available only through a restricted program under a REMS called the **TECVAYLI® and TALVEY® REMS. Visit TEC-TALREMS.com**

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (cont'd) – 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. There was one fatal case of hepatic failure in MajesTEC-1. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448) elevated aspartate aminotransferase (AST) occurred in 47% of patients, with Grade 3 or 4 elevations in 2.9%. Elevated alanine aminotransferase (ALT) occurred in 48% of patients, with Grade 3 or 4 elevations in

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Infections in the MajesTEC-3 trial

TECVAYLI® can cause severe, life-threatening, or fatal infections.[1]

Serious infections, including opportunistic infections, occurred in 54% of patients receiving TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) (N=283) at the recommended dosage compared with 42%* of patients receiving DPd/DVd (N=290).[1,5]

Grade 3 or Grade 4 infections were reported in 54% of patients receiving TECVAYLI® + DARZALEX *FASPRO*® (N=283) compared with 43%* of patients receiving DPd/DVd (N=290).[1,7]

Fatal infections occurred in 13 patients (4.6%) in the TECVAYLI® + DARZALEX *FASPRO*® group (3 from COVID-19) and 4 patients (1.4%)* in the DPd/DVd group.[1,2]

- Within 6 months after the initiation of treatment, fatal infections occurred in 12 patients in the TECVAYLI® + DARZALEX *FASPRO*® group and 2 patients in the DPd/DVd group[7]

Prior to starting treatment with TECVAYLI®, consider initiation of antiviral prophylaxis to prevent herpes zoster reactivation per guidelines.[1]

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI®, and treat appropriately. Administer prophylactic antimicrobials according to current practice guidelines.[1]

Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.[1]

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI®, and administer subcutaneous or intravenous IVIG to maintain the serum levels >400 mg/dL.[1]

*This information is not included in the current full TECVAYLI® Prescribing Information.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hepatotoxicity (cont'd) - in 3.8%. Elevated total bilirubin occurred in 10% of patients with Grade 3 or 4 elevations in 0.7%. 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 MajesTEC-1 (N=165), in patients who received the recommended TECVAYLI dosage, serious infections, including opportunistic infections, occurred in 30% of patients, Grade 3 or 4 infections in 35% of patients, and fatal infections in 4.2% of patients.

In MajesTEC-3 (N=283), in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj at the recommended dosage, serious infections, including opportunistic infections, occurred in 54% of patients, Grade 3 or

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TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) dosing schedule[1]

	Day 0	Day 1	Day 3	Day 7	Weeks 2-8 Once weekly	Weeks 9-24 Every 2 weeks	Week 25 onward Every 4 weeks
TECVAYLI® Step-up dosing schedule	N/A	**Step-up dose 1** **0.06** mg/kg	**Step-up dose 2** **0.3** mg/kg	**1st treatment dose** **1.5** mg/kg	–	–	–
TECVAYLI® Treatment dosing	–	–	–	–	**1.5** mg/kg	**3** mg/kg	**3** mg/kg
DARZALEX *FASPRO*®	**1,800** mg/ **30,000** units	N/A	N/A	**1,800** mg/ **30,000** units	**1,800** mg/ **30,000** units	**1,800** mg/ **30,000** units	**1,800** mg/ **30,000** units

See Table 3 in the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

Step-up dosing schedule

- The step-up dosing schedule is a component of the recommended TECVAYLI® dosage but is not applicable for the DARZALEX *FASPRO*® dosing
- **Step-up dose 1** must be administered **20 hours or more** after DARZALEX *FASPRO*®
- **Step-up dose 2** may be given between **2 to 4 days** after step-up dose 1 and, if adverse reactions occur, may be given **up to 7 days** after step-up dose 1 to allow for resolution of adverse reactions
- The **first treatment dose (1.5 mg/kg)** may be given between **2 to 4 days** after step-up dose 2 and, if adverse reactions occur, may be given **up to 7 days** after step-up dose 2 to allow for resolution of adverse reactions
- Administer **TECVAYLI®** at least **3 hours after DARZALEX *FASPRO*®** for the **first treatment dose**

Treatment dosing schedule

- Administer **TECVAYLI®** at least **15 minutes after DARZALEX *FASPRO*®** for all subsequent treatment doses
- Maintain a minimum of **5 days** between **1.5 mg/kg once-weekly doses**
- Maintain a minimum of **12 days** between **3 mg/kg every-2-week treatment doses**
- Maintain a minimum of **25 days** between **3 mg/kg every-4-week doses**

For dosage and administration instructions for DARZALEX *FASPRO*®, refer to its full Prescribing Information for the recommended dosage when used as a monotherapy.

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd) – Grade 4 infections in 54% of patients, and fatal infections in 4.6% of patients.

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI and treat appropriately. Administer prophylactic antimicrobials according to current practice guidelines.

Withhold TECVAYLI or consider permanent discontinuation of TECVAYLI based on severity.

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI and administer subcutaneous or intravenous immunoglobulin (IVIG) to maintain the serum levels >400 mg/dL.

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DARZALEX *FASPRO*® Indications and full Important Safety Information ›
DARZALEX *FASPRO*® full Prescribing Information ›

TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) dosing schedule (cont'd)[1]

Important dosing information

- TECVAYLI® and DARZALEX *FASPRO*® are administered via subcutaneous injection.
- Administer TECVAYLI® subcutaneously according to the step-up dosing schedule in Table 1 in the full Prescribing Information to reduce the incidence and severity of CRS.

Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of both step-up dose 1 and step-up dose 2. Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the TECVAYLI® step-up dosing schedule.

SELECT IMPORTANT SAFETY INFORMATION FOR DARZALEX *FASPRO*®

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX *FASPRO*®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX *FASPRO*®.

See full Important Safety Information for DARZALEX *FASPRO*® and full Prescribing Information for DARZALEX *FASPRO*®.

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Neutropenia – TECVAYLI can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), decreased neutrophils occurred in 88% of patients, with Grade 3 or 4 decreased neutrophils in 70%. Febrile neutropenia occurred in 6% 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.

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TECVAYLI® + DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) dosing schedule (cont'd)[1]

Important dosing information (cont'd)

- Administer pretreatment medications with TECVAYLI® as recommended in the next tab.
- TECVAYLI® and DARZALEX *FASPRO*® should be administered until disease progression or unacceptable toxicity.
- The dosage of TECVAYLI® is based on actual body weight. Please refer to Tables 8-11 in the full Prescribing Information to determine the dosage based on predetermined weight ranges.
- For pre-medication and post-medication requirements for management of administration-related reactions and other considerations for DARZALEX *FASPRO*®, see the Prescribing Information for DARZALEX *FASPRO*®.

SELECT IMPORTANT SAFETY INFORMATION FOR DARZALEX *FASPRO*®

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX *FASPRO*®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX *FASPRO*®.

See full Important Safety Information for DARZALEX *FASPRO*® and full Prescribing Information for DARZALEX *FASPRO*®.

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Other Administration Reactions – TECVAYLI can cause both systemic administration-related and local injection-site reactions.

Systemic Reactions - In patients who received the recommended TECVAYLI dosage in the clinical trials (monotherapy and combination therapy trials; N=448), 2.5% of patients experienced systemic-administration reactions, which included recurrent pyrexia and rash.

Local Reactions - In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), injection-site reactions occurred in 37% of patients, with Grade 1 injection-site reactions in 29% and Grade 2 in 9%.

TECVAYLI® Indications and full Important Safety Information ›
TECVAYLI® full Prescribing Information, including Boxed WARNING ›
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Pretreatment medications[1]

Prior to starting treatment with TECVAYLI®

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

1 to 3 hours before each dose of the TECVAYLI® step-up dosing schedule (step-up doses 1 and 2, and the first treatment dose)

Administer the following pretreatment medications 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)

Prior to administration of subsequent treatment 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 TECVAYLI® step-up dosing schedule following a dose delay
- Patients who experienced CRS following the prior dose of TECVAYLI®

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Other Administration Reactions (cont'd) - 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 patient. Advise pregnant patients 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.

TECVAYLI® Indications and full Important Safety Information >

TECVAYLI® full Prescribing Information, including Boxed WARNING >

DARZALEX *FASPRO*® Indications and full Important Safety Information >

DARZALEX *FASPRO*® full Prescribing Information >

Dosage modifications for adverse reactions[1]

Dosage reductions of TECVAYLI® are not recommended.

Refer to DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) Prescribing Information for information about dosage modifications for DARZALEX *FASPRO*®.

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

Permanent discontinuation of TECVAYLI® due to adverse reactions occurred in 6% of patients.

- Adverse reactions leading to discontinuation of TECVAYLI® in more than 1 patient were pneumonia (1.1%), diarrhea (0.7%), fatigue (0.7%), second primary malignancy (0.7%), upper respiratory tract infection (0.7%), and cough (0.7%)

CRS grading and management ›
Management of neurologic toxicity (excluding ICANS) ›
Management of ICANS ›
Dose modifications for other adverse reactions ›
Restarting TECVAYLI® after a dose delay ›

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10 mg/mL and 90 mg/mL

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (≥20%) in patients who received TECVAYLI monotherapy were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common adverse reactions (≥20%) in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj were hypogammaglobulinemia, upper respiratory tract infection, CRS, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight decreased.

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TECVAYLI® full Prescribing Information, including Boxed WARNING ›
DARZALEX *FASPRO*® Indications and full Important Safety Information ›
DARZALEX *FASPRO*® full Prescribing Information ›

Choose TECVAYLI® + DARZALEX *FASPRO*®

(daratumumab and hyaluronidase-fihj) as your 1st-choice treatment for appropriate patients

Superior PFS with TECVAYLI® + DARZALEX *FASPRO*®[1]

TECVAYLI® + DARZALEX *FASPRO*® (N=291) provided an **83% reduction in the risk of disease progression or death,** compared to DPd/DVd (N=296) at a median follow-up of 34.5 months* (HR=0.17†; 95% CI: 0.12-0.23; *P*<0.0001‡).

MajesTEC-3 was a randomized (1:1), multicenter, open-label study evaluating the efficacy of TECVAYLI® in combination with DARZALEX *FASPRO*® in adult patients with RRMM who had previously received 1 to 3 prior lines of therapy, including a PI and lenalidomide. Patients who had received only 1 prior line of therapy must have been refractory to lenalidomide. Patients were excluded from the trial if they had disease refractory to a prior anti-CD38 monoclonal antibody therapy or had received any prior BCMA-directed therapy. The major efficacy outcome measure was PFS.§

Proven combination with a demonstrated safety profile[1]

Of the 283 patients who received TECVAYLI® + DARZALEX *FASPRO*®, the median exposure was 32 (range: 0.03 to 43) months.

6% of patients permanently discontinued TECVAYLI® due to ARs. ARs leading to discontinuation of TECVAYLI® in more than 1 patient were pneumonia, diarrhea, fatigue, second primary malignancy, upper respiratory tract infection, and cough.

Boxed WARNINGS: CRS and Neurologic Toxicity, including ICANS. Warnings and Precautions: Hepatotoxicity, Infections, Neutropenia, Hypersensitivity and Other Administration Reactions, and Embryo-Fetal Toxicity.

First-of-its-kind immunotherapy combination[1]

TECVAYLI® + DARZALEX *FASPRO*® is the **1st and only** combination of its kind to be approved in 2L+ RRMM in adults after a PI and an immunomodulatory agent.

*Based on the ITT population. †Stratified Cox proportional hazard model. For all stratified analyses, stratification was based on ISS staging (I vs II or III) and number of prior lines of therapy (1 vs 2 or 3), as randomized. ‡Stratified log-rank test. §Assessed by Independent Review Committee (IRC) based on International Myeloma Working Group (IMWG) 2016 criteria.

2L+, second line and beyond; ARs, adverse reactions; BCMA, B-cell maturation antigen; CD38, cluster of differentiation 38; CI, confidence interval; CRS, cytokine release syndrome; DPd, daratumumab and hyaluronidase-fihj, pomalidomide, and dexamethasone; DVd, daratumumab and hyaluronidase-fihj, bortezomib, and dexamethasone; HR, hazard ratio; ICANS, immune effector cell-associated neurotoxicity syndrome; ISS, International Staging System; ITT, intent-to-treat; PFS, progression-free survival; PI, proteasome inhibitor; RRMM, relapsed or refractory multiple myeloma.

View guideline recommendations >

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

ADVERSE REACTIONS (cont'd)

The most common Grade 3 to 4 laboratory abnormalities (≥20%) with TECVAYLI (as monotherapy or in combination with daratumumab and hyaluronidase-fihj) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

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Glossary

2L+, second line and beyond

ASTCT, American Society for Transplantation and Cellular Therapy

BCMA, B-cell maturation antigen

B_{regs}, regulatory B-cells

CD3, cluster of differentiation 3

CD38, cluster of differentiation 38

CI, confidence interval

COVID-19, coronavirus disease 2019

CR, complete response

CRS, cytokine release syndrome

DPd, daratumumab, pomalidomide, and dexamethasone

DVd, daratumumab, bortezomib, and dexamethasone

ECOG PS, Eastern Cooperative Oncology Group Performance Status

GGT, gamma-glutamyl transferase

HR, hazard ratio

ICANS, immune effector cell-associated neurotoxicity syndrome

ICE, immune effector cell-associated encephalopathy

IgG, immunoglobulin G

IMWG, International Myeloma Working Group

IRC, Independent Review Committee

ISS, International Staging System

ITT, intent-to-treat

IVIG, intravenous immunoglobulin

LOT, line of therapy

MM, multiple myeloma

mSMART, Mayo Stratification for Myeloma and Risk-Adapted Therapy

MRD, minimal residual disease

N/A, not applicable

NCCN, National Comprehensive Cancer Network

NCI-CTCAE, National Cancer Institute-Common Terminology Criteria for Adverse Events

NE, not estimable

ORR, overall response rate

OS, overall survival

PFS, progression-free survival

PI, proteasome inhibitor

PR, partial response

QW, once weekly

Q2W, every 2 weeks

Q4W, every 4 weeks

REMS, Risk Evaluation and Mitigation Strategy

RRMM, relapsed or refractory multiple myeloma

SC, subcutaneous

sCR, stringent complete response

T_{regs}, regulatory T-cells

VGPR, very good partial response

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

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References

1. TECVAYLI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

2. Costa LJ, Bahlis NJ, Perrot A, et al. Teclistamab plus daratumumab in relapsed or refractory multiple myeloma. *N Engl J Med*. 2026;394(8):739-752.

3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.5.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed March 8, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

4. DARZALEX *FASPRO*® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

5. Data on file. Janssen Biotech, Inc.

6. Costa LJ, Bahlis NJ, Perrot A, et al. Teclistamab plus daratumumab in relapsed or refractory multiple myeloma. *N Engl J Med*. 2026;394(8)(protocol):739-752.

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8. Mayo Clinic. mSMART (Mayo Stratification for Myeloma and Risk-adapted Therapy): management of cytokine release syndrome (CRS) and immune cell associated neurotoxicity syndrome (ICANS) for bispecific antibodies: teclistamab, talquetamab, elrantamab. Version 3. Accessed March 8, 2026. https://www.msmart.org/s/mSMART-BsAb-guidelineV3_April_2025.pdf

9. Rodriguez-Otero P, Usmani S, Cohen AD, et al. International Myeloma Working Group immunotherapy committee consensus guidelines and recommendations for optimal use of T-cell-engaging bispecific antibodies in multiple myeloma. *Lancet Oncol*. 2024;25(5):e205-e216.

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TECVAYLI® (teclistamab-cqyv)

INDICATIONS 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:

- in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
- as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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, life-threatening, or fatal 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 trials (monotherapy and combination therapy; N=448), CRS occurred in 64% of patients who received TECVAYLI at the recommended dosage, with Grade 1 CRS occurring in 46% of patients, Grade 2 in 18%, and Grade 3 in 0.2%. Recurrent CRS occurred in 27% of patients. Most patients experienced CRS during the initial step-up dosing schedule (step-up dose 1 [37%], step-up dose 2 [32%], or the initial treatment dose [20%]). CRS first occurred following subsequent doses of TECVAYLI in 2.5% of patients. The median time to onset of CRS was 2 (range: 1 to 9) days after the most recent dose and the median duration of CRS was 2 (range: 1 to 22) days.

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TECVAYLI® (teclistamab-cqyv)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Cytokine Release Syndrome (cont'd) – 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 the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold until CRS resolves or permanently discontinue TECVAYLI based on severity.

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

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome – TECVAYLI can cause serious, life-threatening, or fatal neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

In the clinical trials (monotherapy and combination therapy trials; N=448), neurologic toxicity occurred in 60% of patients who received TECVAYLI at the recommended dosage, with Grade 3 or 4 neurologic toxicity in 6%. Neurologic toxicities reported in ≥5% of patients included headache (27%), sensory neuropathy (16%), motor dysfunction (15%), insomnia (12%), encephalopathy (11%), and dizziness (8%). Fatal neurologic toxicity occurred in 0.4% of patients, including Guillain-Barré syndrome and status epilepticus (one patient each).

In MajesTEC-1, ICANS was reported in 6% of patients who received TECVAYLI as monotherapy at the recommended dosage. 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 TECVAYLI doses. 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.

In MajesTEC-3, ICANS was reported in 1.1% of patients who received the recommended TECVAYLI dosage in combination with daratumumab and hyaluronidase-fihj, including Grade 4 ICANS in 1 patient. All events of ICANS occurred during the step-up dosing schedule. The median time to onset of ICANS was 2 (range: 1 to 3) days after the most recent dose and the median duration of ICANS was 2 (range: 1 to 2) days. The clinical manifestations of ICANS reported were amnesia, encephalopathy and delirium.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (cont'd) - 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, including ICANS during TECVAYLI treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold until neurologic toxicity resolves 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 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.

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. There was one fatal case of hepatic failure in MajesTEC-1. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448) elevated aspartate aminotransferase (AST) occurred in 47% of patients, with Grade 3 or 4 elevations in 2.9%. Elevated alanine aminotransferase (ALT) occurred in 48% of patients, with Grade 3 or 4 elevations in 3.8%. Elevated total bilirubin occurred in 10% of patients with Grade 3 or 4 elevations in 0.7%. 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 MajesTEC-1 (N=165), in patients who received the recommended TECVAYLI dosage, serious infections, including opportunistic infections, occurred in 30% of patients, Grade 3 or 4 infections in 35% of patients, and fatal infections in 4.2% of patients.

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TECVAYLI® (teclistamab-cqyv)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd) - In MajesTEC-3 (N=283), in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj at the recommended dosage, serious infections, including opportunistic infections, occurred in 54% of patients, Grade 3 or Grade 4 infections in 54% of patients, and fatal infections in 4.6% of patients.

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI and treat appropriately. Administer prophylactic antimicrobials according to current practice guidelines.

Withhold TECVAYLI or consider permanent discontinuation of TECVAYLI based on severity.

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI and administer subcutaneous or intravenous immunoglobulin (IVIG) to maintain the serum levels >400 mg/dL.

Neutropenia - TECVAYLI can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), decreased neutrophils occurred in 88% of patients, with Grade 3 or 4 decreased neutrophils in 70%. Febrile neutropenia occurred in 6% 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 the recommended TECVAYLI dosage in the clinical trials (monotherapy and combination therapy trials; N=448), 2.5% of patients experienced systemic-administration reactions, which included recurrent pyrexia and rash.

Local Reactions - In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), injection-site reactions occurred in 37% of patients, with Grade 1 injection-site reactions in 29% and Grade 2 in 9%.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Other Administration Reactions (cont'd) - 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 patient. Advise pregnant patients 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%) in patients who received TECVAYLI monotherapy were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common adverse reactions (≥20%) in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj were hypogammaglobulinemia, upper respiratory tract infection, CRS, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight decreased.

The most common Grade 3 to 4 laboratory abnormalities (≥20%) with TECVAYLI (as monotherapy or in combination with daratumumab and hyaluronidase-fihj) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

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

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DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

INDICATIONS

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib, lenalidomide, and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI)
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- As monotherapy in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

DARZALEX *FASPRO*® as monotherapy is indicated for the treatment of adult patients with high-risk smoldering multiple myeloma.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX *FASPRO*® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

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DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX *FASPRO*®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX *FASPRO*®.

Systemic Reactions

In a pooled safety population of 1446 patients with multiple myeloma (N=1235) or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO*® as mono therapy or as part of a combination therapy, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%). In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%).

In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) occurred on the day of DARZALEX *FASPRO*® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension, tachycardia, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritus, chills, vomiting, nausea, hypotension, and blurred vision.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen, and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX *FASPRO*®. Consider administering corticosteroids and other medications after the administration of DARZALEX *FASPRO*® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with daratumumab-containing products. If ocular symptoms occur, interrupt DARZALEX *FASPRO*® and seek immediate ophthalmologic evaluation prior to restarting DARZALEX *FASPRO*®.

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DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Other Administration Reactions (cont'd)

Local Reactions

In this pooled safety population of 1446 patients with multiple myeloma (N=1253) or light chain amyloidosis (N=193), injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 1.1%. The most frequent (>1%) injection-site reactions were injection site erythema and injection site rash. In patients with high-risk smoldering multiple myeloma (N=193), injection-site reactions occurred in 28% of patients, including Grade 2 reactions in 3%. These local reactions occurred a median of 6 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX *FASPRO*®. Monitor for local reactions and consider symptomatic management.

Infections

DARZALEX *FASPRO*® can cause serious, life-threatening, or fatal infections. In patients who received DARZALEX *FASPRO*® in a pooled safety population including patients with smoldering multiple myeloma and light chain (AL) amyloidosis (N=1639), serious infections, including opportunistic infections, occurred in 24% of patients, Grade 3 or 4 infections occurred in 22%, and fatal infections occurred in 2.5%. The most common type of serious infection reported was pneumonia (8.5%).

Monitor patients for signs and symptoms of infection prior to and during treatment with DARZALEX *FASPRO*® and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

Neutropenia

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX *FASPRO*® until recovery of neutrophils. In lower body weight patients receiving DARZALEX *FASPRO*®, higher rates of Grade 3-4 neutropenia were observed.

Thrombocytopenia

Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX *FASPRO*® until recovery of platelets.

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DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX *FASPRO*® can cause fetal harm when administered to a pregnant woman. DARZALEX *FASPRO*® may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX *FASPRO*® and for 3 months after the last dose.

The combination of DARZALEX *FASPRO*® with lenalidomide, thalidomide, or pomalidomide is contraindicated in pregnant women because lenalidomide, thalidomide, and pomalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, thalidomide, or pomalidomide prescribing information on use during pregnancy.

Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted.

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX *FASPRO*®. Type and screen patients prior to starting DARZALEX *FASPRO*®.

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some DARZALEX *FASPRO*®-treated patients with IgG kappa myeloma protein.

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

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DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj)

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

In multiple myeloma, the most common adverse reaction (≥20%) with DARZALEX *FASPRO*® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, sleep disorder, headache, rash, renal impairment, motor dysfunction, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, decreased appetite, urinary tract infection, abdominal pain, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, dizziness, bruising, and COVID-19.

The most common adverse reactions (≥20%) in patients with high-risk smoldering multiple myeloma who received DARZALEX *FASPRO*® monotherapy are upper respiratory tract infection, musculoskeletal pain, fatigue, diarrhea, rash, sleep disorder, sensory neuropathy, and injection site reactions.

The most common hematology laboratory abnormalities (≥40%) with DARZALEX *FASPRO*® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please click here to read full Prescribing Information for DARZALEX *FASPRO*®.

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

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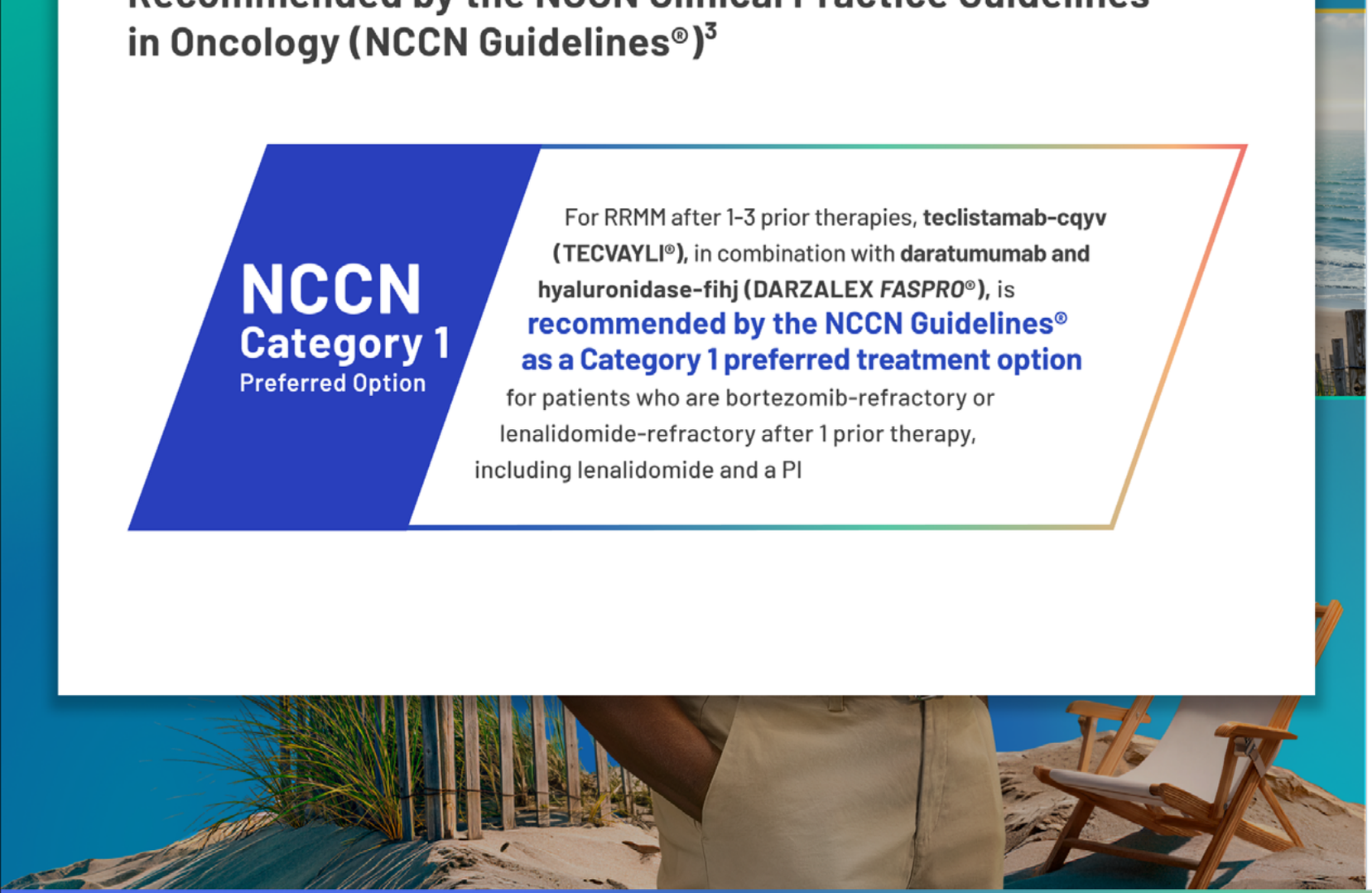
Recommended by the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[3]

NCCN Category 1 Preferred Option

For RRMM after 1-3 prior therapies, **teclistamab-cqyv (TECVAYLI®)**, in combination with **daratumumab and hyaluronidase-fihj (DARZALEX *FASPRO*®)**, is **recommended by the NCCN Guidelines® as a Category 1 preferred treatment option** for patients who are bortezomib-refractory or lenalidomide-refractory after 1 prior therapy, including lenalidomide and a PI



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

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, life-threatening, or fatal 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.

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Use in specific populations[1]

Pregnancy

Based on the mechanism of action, TECVAYLI® may cause fetal harm when administered to a pregnant patient. There are no available data on the use of TECVAYLI® in pregnant patients to evaluate for a drug-associated risk. No animal reproductive or developmental toxicity studies have been conducted with TECVAYLI®. Teclistamab-cqyv causes T-cell activation and cytokine release; immune activation may compromise pregnancy maintenance. Human immunoglobulin G (IgG) is known to cross the placenta; therefore, teclistamab-cqyv has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to the fetus.

TECVAYLI® is associated with hypogammaglobulinemia, therefore, assessment of immunoglobulin levels in newborns of mothers treated with TECVAYLI® should be considered.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Lactation

There are no data on the presence of teclistamab-cqyv in human milk, the effect on the breastfed child, or the effects on milk production. Maternal IgG is known to be present in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed child to TECVAYLI® are unknown. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with TECVAYLI® and for 5 months after the last dose.

Females and Males of Reproductive Potential

TECVAYLI® may cause fetal harm when administered to a pregnant patient.

- Pregnancy Testing: Verify pregnancy status of females of reproductive potential prior to initiating TECVAYLI®
- Contraception (females): Advise females of reproductive potential to use effective contraception during treatment and for 5 months after the last dose of TECVAYLI®

Pediatric Use

The safety and efficacy of TECVAYLI® have not been established in pediatric patients.

Geriatric Use

Of the 291 patients with relapsed or refractory multiple myeloma treated with TECVAYLI® at the recommended dosage in combination with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in MajesTEC-3, 51% were younger than 65 years of age, 39% were 65 to 74 years of age, and 11% were 75 years of age or older. No overall differences in effectiveness were observed between patients 65 to 74 years of age compared to younger patients. The study did not include a sufficient number of patients 75 years of age or older to assess whether there are differences in effectiveness compared to younger patients. There was a higher incidence of serious adverse reactions in patients 75 years of age or older (83%) and in patients 65 to 74 years of age (77%) as compared to patients younger than 65 years of age (63%).

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

IMPORTANT SAFETY INFORMATION

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TECVAYLI® Indications and full Important Safety Information

TECVAYLI® full Prescribing Information, including Boxed WARNING

Use in specific populations[1]

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

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.

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TECVAYLI® Indications and full Important Safety Information ›

TECVAYLI® full Prescribing Information, including Boxed WARNING ›

Recommendations for management of CRS[1]

Grade*	Presenting Symptoms	Actions
Grade 1	Temperature ≥100.4 °F (38 °C)†	• Withhold TECVAYLI® until CRS resolves
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®‡ • Monitor patients for 48 hours following the next dose of TECVAYLI®. Instruct patients to remain within proximity of a healthcare facility during daily monitoring, and consider hospitalization‡
Grade 3	Temperature ≥100.4 °F (38 °C)† with: Hypotension requiring 1 vasopressor with or without vasopressin, and/or Oxygen requirement of high-flow nasal cannula,§ facemask, 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®‡ 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 3 in the TECVAYLI® 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.

Practice guidelines to consider for further management include National Comprehensive Cancer Network® (NCCN®),[3] mSMART,[8] IMWG,[9] and individual institutional guidelines.

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

IMPORTANT SAFETY INFORMATION

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

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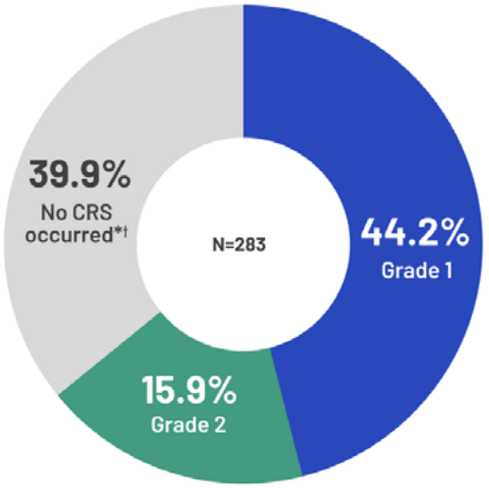
TECVAYLI® Indications and full Important Safety Information

TECVAYLI® full Prescribing Information, including Boxed WARNING

In MajesTEC-3, all CRS events were Grade 1 and 2, median time to onset was 2 days, and median duration was 2 days[2,7]



*CRS, including life-threatening or fatal reactions, may occur in patients receiving TECVAYLI®.[1]
†CRS of any grade was reported in 60.1% of patients who received TECVAYLI® at the recommended dosage in combination with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj).

Median time to onset

2 days

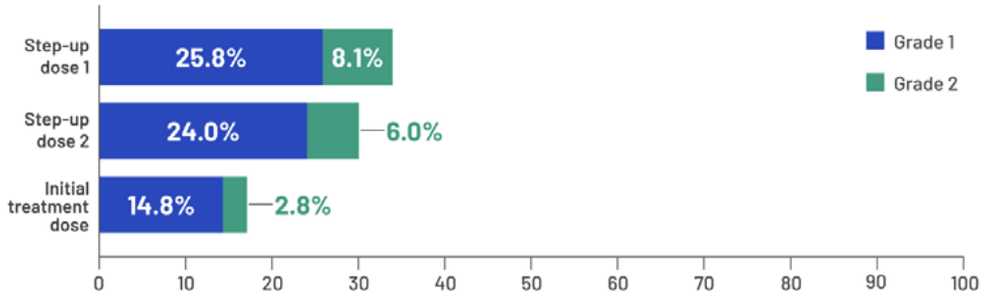
(range: 1-9 days) after most recent dose

Median duration

2 days

(range: 1-22 days)

Most CRS events occurred during the step-up dosing period



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

IMPORTANT SAFETY INFORMATION

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

IMPORTANT SAFETY INFORMATION

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

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TECVAYLI® Indications and full Important Safety Information

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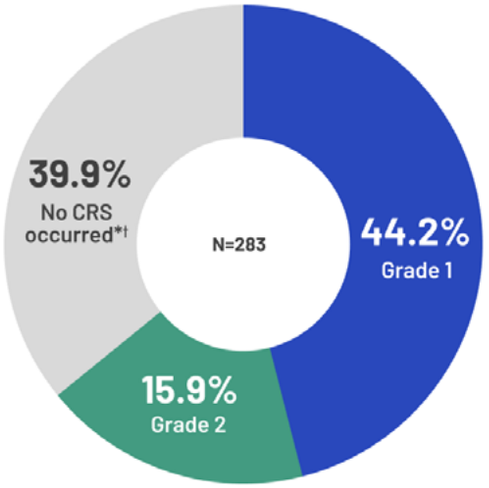

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(range: 1-9 days) after most recent dose

Median duration

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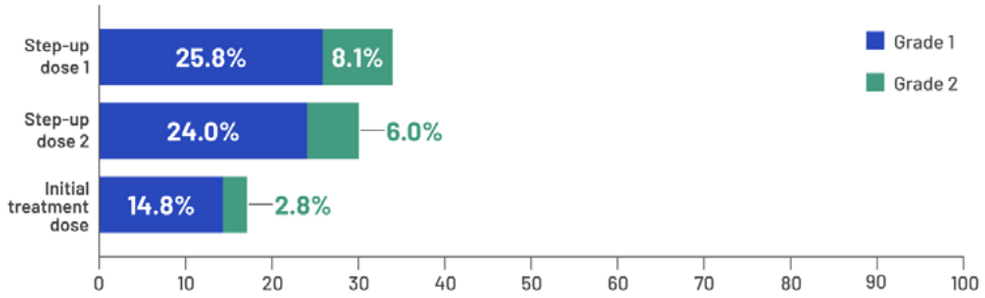
(range: 1-22 days)

Most CRS events occurred during the step-up dosing period



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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, life-threatening, or fatal 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).

TECVAYLI® Indications and full Important Safety Information

TECVAYLI® full Prescribing Information, including Boxed WARNING

Across 448 patients in 2 clinical trials,* most neurologic toxicities were Grade 1 and 2[1]

TECVAYLI® can cause serious, life-threatening, or fatal neurologic toxicity, including ICANS

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

Severity*	Actions
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

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), version 4.03.
†See Table 3 in the TECVAYLI® full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

(range: 1-3 days)
after most recent dosage

(range: 1-2 days)

Management of neurologic toxicity (excluding ICANS) >

Management of ICANS >

Next >

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

IMPORTANT SAFETY INFORMATION

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

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening, or fatal 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.

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TECVAYLI® Indications and full Important Safety Information >

TECVAYLI® full Prescribing Information, including Boxed WARNING >

Recommendations for management of ICANS[1]

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 drugs 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 and 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 drugs for seizure prophylaxis • Monitor patients for 48 hours following the next dose of TECVAYLI®. Instruct patients to remain within proximity of a healthcare facility during daily monitoring, and consider hospitalization‖

*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 3 for recommendations on restarting TECVAYLI® after dose delays.
¶All references to dexamethasone administration are dexamethasone or equivalent.

Grades 3-4 ›

Next

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

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, life-threatening, or fatal 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.

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TECVAYLI® Indications and full Important Safety Information ›

TECVAYLI® full Prescribing Information, including Boxed WARNING ›

Recommendations for management of ICANS[1]

Grade*	Presenting Symptoms†	Actions
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 and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI‖ Recurrent Grade 3 ICANS: • Permanently discontinue TECVAYLI® • Administer dexamethasone¶ 10 mg intravenously and repeat dose every 6 hours and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care

*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 3 for recommendations on restarting TECVAYLI® after dose delays.
¶All references to dexamethasone administration are dexamethasone or equivalent.

Grades 1-2 ›

Grade 4 ›

Next

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

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, life-threatening, or fatal 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.

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TECVAYLI® Indications and full Important Safety Information ›

TECVAYLI® full Prescribing Information, including Boxed WARNING ›

Recommendations for management of ICANS[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 and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care

*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.
¶All references to dexamethasone administration are dexamethasone or equivalent.

Grades 1-3 ›

Next

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

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, life-threatening, or fatal 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.

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TECVAYLI® Indications and full Important Safety Information ›

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Across 448 patients in 2 clinical trials,* most neurologic toxicities were Grade 1 and 2 (cont'd)[1]

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

Severity*	Actions
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

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), version 4.03.
†See Table 3 in the TECVAYLI® full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

Back

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

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, life-threatening, or fatal 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.

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TECVAYLI® Indications and full Important Safety Information ›

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Recommendations for management of ICANS[1]

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 drugs 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 and 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 drugs for seizure prophylaxis • Monitor patients for 48 hours following the next dose of TECVAYLI®. Instruct patients to remain within proximity of a healthcare facility during daily monitoring, and consider hospitalization‖

*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 3 for recommendations on restarting TECVAYLI® after dose delays.
¶All references to dexamethasone administration are dexamethasone or equivalent.

Grades 3-4 ›

Back

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

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, life-threatening, or fatal 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.

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Recommendations for management of ICANS[1]

Grade*	Presenting Symptoms†	Actions
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 and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI‖ Recurrent Grade 3 ICANS: • Permanently discontinue TECVAYLI® • Administer dexamethasone¶ 10 mg intravenously and repeat dose every 6 hours and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care

*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 3 for recommendations on restarting TECVAYLI® after dose delays.
¶All references to dexamethasone administration are dexamethasone or equivalent.

Grades 1-2 ›

Grade 4 ›

Back

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

IMPORTANT SAFETY INFORMATION

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

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening, or fatal 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.

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Recommendations for management of ICANS[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 and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care

*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.
¶All references to dexamethasone administration are dexamethasone or equivalent.

Grades 1-3 >

Back

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

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, life-threatening, or fatal 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.

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Recommendations for management of CRS[1]

Grade*	Presenting Symptoms	Actions
Grade 1	Temperature ≥100.4 °F (38 °C)†	• Withhold TECVAYLI® until CRS resolves
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®‡ • Monitor patients for 48 hours following the next dose of TECVAYLI®. Instruct patients to remain within proximity of a healthcare facility during daily monitoring, and consider hospitalization‡
Grade 3	Temperature ≥100.4 °F (38 °C)† with: Hypotension requiring 1 vasopressor with or without vasopressin, and/or Oxygen requirement of high-flow nasal cannula,§ facemask, 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®‡ 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 3 in the TECVAYLI® 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.

Practice guidelines to consider for further management include National Comprehensive Cancer Network® (NCCN®),[3] mSMART,[7] IMWG,[8] and individual institutional guidelines.

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

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, life-threatening, or fatal 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.

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Dosage modifications for adverse reactions[1]

Dosage reductions of TECVAYLI® are not recommended.

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

Severity*	Actions
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

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), version 4.03.
†See Table 3 in the TECVAYLI® full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

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

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, life-threatening, or fatal 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.

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Recommendations for management of ICANS[1]

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 drugs 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 and 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 drugs for seizure prophylaxis • Monitor patients for 48 hours following the next dose of TECVAYLI®. Instruct patients to remain within proximity of a healthcare facility during daily monitoring, and consider hospitalization‖

*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 3 for recommendations on restarting TECVAYLI® after dose delays.
¶All references to dexamethasone administration are dexamethasone or equivalent.

Grades 3-4 ›

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

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, life-threatening, or fatal 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.

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Recommendations for management of ICANS[1]

Grade*	Presenting Symptoms†	Actions
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 and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care • Patients should be hospitalized for 48 hours following the next dose of TECVAYLI®‖ Recurrent Grade 3 ICANS: • Permanently discontinue TECVAYLI® • Administer dexamethasone¶ 10 mg intravenously and repeat dose every 6 hours and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care

*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 3 for recommendations on restarting TECVAYLI® after dose delays.
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Grades 1-2 ›

Grade 4 ›

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening, or fatal 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.

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Recommendations for management of ICANS[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 and 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 drugs for seizure prophylaxis • Provide supportive therapy, which may include intensive care

*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.
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Grades 1-3 ›

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening, or fatal 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.

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Recommended dosage modifications for other adverse reactions[1]

Adverse Reactions	Severity	Actions
Infections*	All Grades	• Withhold TECVAYLI® in patients with active infection during the step-up dosing schedule†
	Grade 3	• Withhold subsequent doses of TECVAYLI® 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 doses of TECVAYLI® administered after TECVAYLI® step-up dosing schedule until infection improves to Grade 1 or less†
Hematologic Toxicities	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†
	Monotherapy: Platelet count less than 25,000/mcL or platelet count between 25,000/mcL and 50,000/mcL with bleeding Combination therapy: Platelet count less than 50,000/mcL	Monotherapy: • Withhold TECVAYLI® until platelet count is 25,000/mcL or higher and no evidence of bleeding† Combination therapy: • Withhold TECVAYLI® until platelet count is 50,000/mcL or higher and no evidence of bleeding†
Other Non-Hematologic Adverse Reactions*	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® 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 3 of the full Prescribing Information for recommendations on restarting TECVAYLI® after dose delays.

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening, or fatal 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.

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Recommendations for restarting therapy with TECVAYLI® after dose delay[1]

Last dose administered	Time since the last dose administered	Actions
Step-up dose 1	More than 7 days	Restart TECVAYLI® step-up dosing schedule at step-up dose 1 (0.06 mg/kg).*
Step-up dose 2	8 days to 28 days	Repeat step-up dose 2 (0.3 mg/kg)* and continue TECVAYLI® step-up dosing schedule.
	More than 28 days†	Restart TECVAYLI® step-up dosing schedule at step-up dose 1 (0.06 mg/kg).*
Weekly treatment dose	28 days or less	Continue TECVAYLI® 1.5 mg/kg once weekly.
	29 days to 56 days†	Restart TECVAYLI® step-up dosing schedule at step-up dose 2 (0.3 mg/kg).*
	More than 56 days†	Restart TECVAYLI® step-up dosing schedule at step-up dose 1 (0.06 mg/kg).*
Any biweekly (every two weeks) or every four weeks treatment dose	63 days or less†	Continue TECVAYLI® at last dose given every two weeks or every four weeks schedule.
	64 days to 112 days†	Restart TECVAYLI® step-up dosing schedule at step-up dose 2 (0.3 mg/kg).*
	More than 112 days†	Restart TECVAYLI® step-up dosing schedule at step-up dose 1 (0.06 mg/kg).*

*Administer pretreatment medications prior to TECVAYLI® dose and monitor patients accordingly.
†Consider benefit-risk of restarting TECVAYLI® in patients who require a dose delay of more than 28 days due to an adverse reaction.

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Choose TECVAYLI® + DARZALEX *FASPRO*®

(daratumumab and hyaluronidase-fihj) as your **1st-choice**

Recommended by the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[3]

NCCN Category 1 Preferred Option

For RRMM after 1-3 prior therapies, **teclistamab-cqyv (TECVAYLI®)**, in combination with **daratumumab and hyaluronidase-fihj (DARZALEX *FASPRO*®)**, is **recommended by the NCCN Guidelines® as a Category 1 preferred treatment option** for patients who are bortezomib-refractory or lenalidomide-refractory after 1 prior therapy, including lenalidomide and a PI

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