

Actor portrayal

Navigating Conversations With Your Patients About KEYTRUDA QLEX

This guide includes information that may be helpful when responding to patient questions. It is not intended to replace the Full Prescribing Information or Medication Guides for KEYTRUDA and KEYTRUDA QLEX.

KEYTRUDA QLEX is approved for use in adult patients across solid tumor indications for KEYTRUDA—whether alone or in combination with other therapies.

One such indication is for the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

SELECTED SAFETY INFORMATION

Contraindications

- KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to berahyaluronidase alfa, hyaluronidase or to any of its excipients.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or the programmed death ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, can affect more than one body system simultaneously, and can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 2, 3, 5–9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYTRUDA Qlex™ pembrolizumab + berahyaluronidase alfa-pmph Subcutaneous Injection | 165 mg + 2,000 units/mL

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SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti–programmed death receptor-1 (PD-1)/programmed death ligand 1 (PD-L1) treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (94/2799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (63/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) and withholding in 0.9% (26) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Pneumonitis resolved in 59% of the 94 patients. Immune-mediated pneumonitis occurred in 5% (13/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including fatal (0.4%), Grade 3 (2%), and Grade 2 (1.2%) adverse reactions.

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1, 3, 5–9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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KEYTRUDA QLEX

- KEYTRUDA QLEX is a fixed-combination drug product containing pembrolizumab and berahyaluronidase alfa.
  - Pembrolizumab is a monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.
  - Berahyaluronidase alfa, an endoglycosidase, is a variant of human hyaluronidase PH20 that temporarily and locally breaks down hyaluronan.
  - Hyaluronan is a polysaccharide found in the extracellular matrix of the subcutaneous tissue. Unlike the stable structural components of the interstitial matrix, hyaluronan has a half-life of approximately 0.5 days.
  - Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. In the doses administered, the effects of berahyaluronidase alfa are reversible and permeability of the subcutaneous tissue is restored within 24 to 48 hours.
  - Berahyaluronidase alfa facilitates delivery of the increased volume of pembrolizumab that is coadministered subcutaneously.

Potential Patient Questions

Patient question **What is KEYTRUDA QLEX?**

- Both KEYTRUDA and KEYTRUDA QLEX contain the same active immunotherapy called pembrolizumab, which is not chemotherapy—it is an immunotherapy and it works with your immune system to help fight certain cancers.[1] KEYTRUDA QLEX contains an additional active ingredient called berahyaluronidase alfa.
- Both KEYTRUDA and KEYTRUDA QLEX can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1; PD-L2 = programmed death ligand 2.

SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

Immune-Mediated Colitis *(continued)*

- Immune-mediated colitis occurred in 1.7% (48/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 69% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (3/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1, 2, 5–9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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MK-3475A-D77 Study Design

KEYTRUDA QLEX was studied to evaluate its comparability to KEYTRUDA

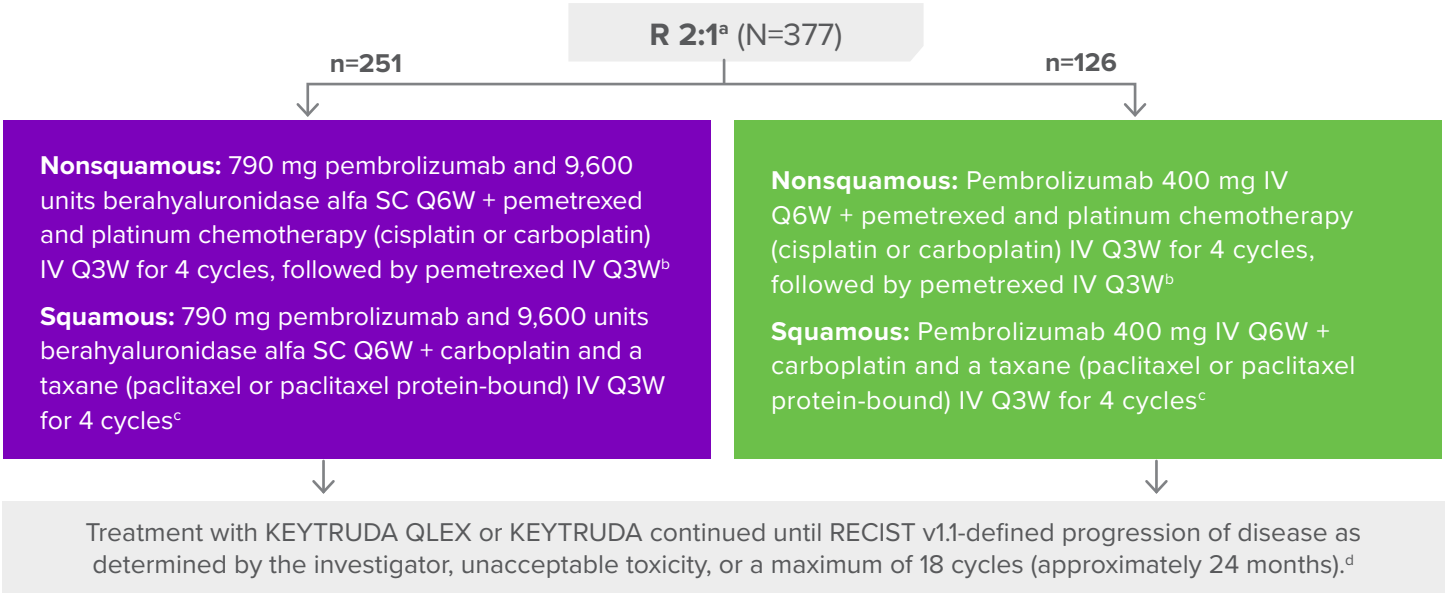
KEYTRUDA QLEX was evaluated in study MK-3475A-D77, a randomized, multicenter, open-label, active-controlled trial conducted in patients with treatment-naïve metastatic non–small cell lung cancer (NSCLC).

Key patient inclusion criteria:

- Treatment-naïve metastatic NSCLC
- No *EGFR*, *ALK*, or *ROS1* genomic tumor aberrations

Key patient exclusion criteria:

- Patients with a history of autoimmune disease that required systemic therapy within 2 years of treatment
- A medical condition that required immunosuppression
- Received more than 30 Gy of thoracic radiation within the prior 26 weeks



Primary outcome measure:

- Pembrolizumab exposure of KEYTRUDA QLEX as compared to KEYTRUDA (cycle 1 $AUC_{0–6wks}$ and cycle 3 [ie, steady state] C_{trough})

The pivotal study population and design were consistent with 2 of the approved indications for KEYTRUDA and KEYTRUDA QLEX, both in first-line treatment of NSCLC: For adult patients with metastatic nonsquamous NSCLC with no EGFR or ALK genomic tumor aberrations, in combination with pemetrexed and platinum chemotherapy; and for adult patients with metastatic squamous NSCLC, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound.

[a]Randomization was stratified by ECOG performance status (0 vs 1), histology (squamous vs nonsquamous), PD-L1 TPS (<50% vs ≥50%), and geographic region (East Asia vs North America/Western Europe/Australia/New Zealand vs Rest of the World). [b]Pemetrexed 500 mg/m² + cisplatin 75 mg/m² IV or carboplatin AUC 5 mg/mL/min IV Q3W for 4 cycles, followed by pemetrexed 500 mg/m² IV Q3W. [c]Carboplatin AUC 6 mg/mL/min + paclitaxel 200 mg/m² on day 1 of each 21-day cycle or paclitaxel protein-bound 100 mg/m² on days 1, 8, and 15 of each 21-day cycle IV Q3W for 4 cycles. [d]Administration of KEYTRUDA QLEX or KEYTRUDA was permitted beyond RECIST v1.1-defined disease progression by BICR or beyond discontinuation of pemetrexed if the patient was clinically stable and deriving clinical benefit as determined by the investigator.

ALK = anaplastic lymphoma kinase; AUC = area under the curve; BICR = blinded independent central review; C_{trough} = trough concentration; ECOG = Eastern Cooperative Oncology Group; *EGFR* = epidermal growth factor receptor; Gy = gray unit; IV = intravenous; PD-L1 = programmed death ligand 1; Q3W = every 3 weeks; Q6W = every 6 weeks; R = randomized; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors v1.1; *ROS1* = ROS proto-oncogene 1; SC = subcutaneous; TPS = tumor proportion score.

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Patient Baseline Demographics and Characteristics in Study MK-3475A-D77

Patient Characteristics	All Patients (N=377)
Median age, years (range)	65 (37–87)
Male sex (%)	71
Ethnicity/race (%)	
White	63
Asian	29
Multiracial	4
Black or African American	3
American Indian or Alaska Native	2
Hispanic or Latino	31
ECOG PS (%)	
0	35
1	65
PD-L1 expression (%)	
TPS ≥50%	19
Histology (%)	
Nonsquamous	66
Squamous	34
Brain metastases at baseline (%)	9

ECOG PS = Eastern Cooperative Oncology Group performance status; PD-L1 = programmed death ligand 1; TPS = tumor proportion score.

SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Adrenal insufficiency occurred in 2% (5/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 6–9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Dosage and Administration Information

KEYTRUDA

Administered, after dilution, as an intravenous infusion	Over 30 minutes	Q3W	200 mg	For adjuvant treatment of adult patients with RCC, treatment should continue until disease recurrence, unacceptable toxicity, or for up to 12 months.
		Q6W	400 mg	

KEYTRUDA QLEX

Administered as a subcutaneous injection into the thigh or abdomen, avoiding the 5-cm area around the navel	2.4 mL (395 mg/4,800 units)[a]	Over 1 minute	Q3W	For adjuvant treatment of adult patients with RCC, treatment should continue until disease recurrence, unacceptable toxicity, or for up to 12 months.
	4.8 mL (790 mg/9,600 units)[a]	Over 2 minutes	Q6W	

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

- KEYTRUDA QLEX has different recommended dosage and administration instructions than KEYTRUDA.
- Inject KEYTRUDA QLEX into healthy skin and never into areas where the skin is red, bruised, tender, or hard. Ensure the injection site is at least 2.5 cm from the previous injection site.
- During treatment with KEYTRUDA QLEX, do not administer other medications for subcutaneous use at the same site as KEYTRUDA QLEX.
- Do not administer KEYTRUDA QLEX intravenously.
- KEYTRUDA QLEX must be administered by a health care provider.
- See the Full Prescribing Information for dosage modifications for adverse reactions and preparation and administration instructions.

Q3W = every 3 weeks; Q6W = every 6 weeks; RCC = renal cell carcinoma.

SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

Immune-Mediated Endocrinopathies *(continued)*

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5, 7–9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Potential Patient Questions *(continued)*

Patient question

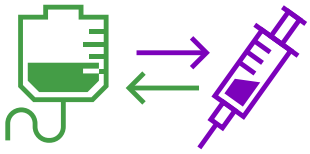
How is KEYTRUDA QLEX given?

- Your health care provider will give you KEYTRUDA QLEX as an injection under the skin (subcutaneous) in the stomach area (abdomen) or thigh.
  - KEYTRUDA QLEX does not require a port because it is not given into a vein. It is important to note that you may still need a port if your treatment plan involves another therapy that is given into a vein, such as chemotherapy.[2]
- KEYTRUDA QLEX is usually given every 3 weeks over 1 minute or every 6 weeks over 2 minutes depending on the dose of KEYTRUDA QLEX that you are receiving.[a]
- Your health care provider will decide how many treatments you need.
- Your health care provider will do blood tests to check you for side effects.
- If you miss any appointments, call your health care provider as soon as possible to reschedule your appointment.

Patient question

Am I able to switch from KEYTRUDA QLEX to KEYTRUDA, or from KEYTRUDA to KEYTRUDA QLEX?

- Your doctor may discuss switching your treatment from KEYTRUDA (infusion into a vein) to KEYTRUDA QLEX (injection under the skin), or from KEYTRUDA QLEX to KEYTRUDA.



[a]Over 1 minute for every-3-week dosing (2.4 mL containing 395 mg pembrolizumab/4,800 units berahyaluronidase alfa) or over 2 minutes for every-6-week dosing (4.8 mL containing 790 mg pembrolizumab/9,600 units berahyaluronidase alfa). Does not account for all aspects of treatment; actual clinic time may vary.

SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

Immune-Mediated Endocrinopathies *(continued)*

Thyroid Disorders (continued)

- Thyroiditis occurred in 0.6% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (237/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- Thyroiditis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hyperthyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (3.2%). Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5, 6, 8, 9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Primary Outcome Measure in Study MK-3475A-D77: Pembrolizumab Exposure of KEYTRUDA QLEX as Compared to KEYTRUDA

KEYTRUDA QLEX demonstrated comparable pharmacokinetics to KEYTRUDA

Pharmacokinetic Parameters	Geometric Mean Ratio[a]
Cycle 1 $AUC_{0–6wks}$ [b]	**1.14** (96% CI, 1.06–1.22)
Cycle 3 C_{trough} (ie, steady state)[c]	**1.67** (94% CI, 1.52–1.84)

- In MK-3475A-D77, the pembrolizumab exposure for KEYTRUDA QLEX was comparable to that for KEYTRUDA, as measured by cycle 1 $AUC_{0–6wks}$ and cycle 3 (ie, steady state) C_{trough}.

[a]Geometric mean ratio of KEYTRUDA QLEX to KEYTRUDA. [b]AUC was used to measure how much pembrolizumab was present in the bloodstream from 0 to 6 weeks. [c]Steady state C_{trough} was used to measure the lowest concentration of pembrolizumab at steady state during cycle 3.

AUC = area under the curve; CI = confidence interval; C_{trough} = trough concentration; PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1; wks = weeks.

SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

Immune-Mediated Endocrinopathies *(continued)*

Type 1 Diabetes Mellitus (DM), Which Can Present With Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.2% (6/2799) of patients receiving KEYTRUDA. It led to permanent discontinuation in <0.1% (1) and withholding of KEYTRUDA in <0.1% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 DM occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy.

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis.
- Immune-mediated nephritis occurred in 0.3% (9/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (8/9) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (3) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti–PD-1/PD-L1 treatments. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonexfoliative rashes. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.

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Safety Profile of KEYTRUDA QLEX

MK-3475A-D77 safety results in patients with mNSCLC who received KEYTRUDA QLEX in combination with chemotherapy

- Serious adverse reactions occurred in 39% of patients who received KEYTRUDA QLEX in combination with chemotherapy. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.6%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%).
- Fatal adverse reactions occurred in 10% of patients who received KEYTRUDA QLEX in combination with chemotherapy, including pneumonia (3.2%), neutropenic sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), parotitis (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%).
- Permanent discontinuation of KEYTRUDA QLEX in combination with chemotherapy due to an adverse reaction occurred in 16% of patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonia and pneumonitis.
- Dosage interruptions of KEYTRUDA QLEX in combination with chemotherapy due to an adverse reaction occurred in 45% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase.
- The most common adverse reactions (≥20%) in patients who received KEYTRUDA QLEX in combination with chemotherapy were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).

mNSCLC = metastatic non–small cell lung cancer; PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1.

SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(continued)*

Immune-Mediated Dermatologic Adverse Reactions *(continued)*

- Immune-mediated dermatologic adverse reactions occurred in 1.4% (38/2799) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 40% (15/38) of patients. These reactions led to permanent discontinuation in 0.1% (2) and withholding of KEYTRUDA in 0.6% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.6% (4/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA, KEYTRUDA QLEX, or were reported with the use of other anti–PD-1/PD-L1 treatments. Severe or fatal cases have been reported for some of these adverse reactions. *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis; *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; *Ocular*: Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss; *Gastrointestinal*: Pancreatitis, to include increases in serum amylase and lipase levels, gastritis (2.8%), duodenitis; *Musculoskeletal and Connective Tissue*: Myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis (1.5%), polymyalgia rheumatica; *Endocrine*: Hypoparathyroidism; *Hematologic/Immune*: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection; *Other*: Myocarditis-Myositis-Myasthenia Gravis (or Myasthenia-Like) Overlap syndrome, reported as the co-occurrence of either two or all three adverse reactions.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5–8, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Safety Profile of KEYTRUDA QLEX *(continued)*

The safety profile of KEYTRUDA QLEX was comparable to KEYTRUDA

Adverse reactions occurring in ≥10% of patients with mNSCLC receiving KEYTRUDA QLEX in combination with chemotherapy in study MK-3475A-D77

Adverse Reactions	KEYTRUDA QLEX and Platinum-Doublet Chemotherapy (n=251)		KEYTRUDA and Platinum-Doublet Chemotherapy (n=126)	
	All Grades[a] (%)	Grades 3–4 (%)	All Grades[a] (%)	Grades 3–4 (%)
Gastrointestinal				
Nausea	25	1.2	25	0.8
Diarrhea[b]	16	2	14	0.8
Constipation	14	0	18	1.6
General				
Fatigue[c]	25	3.6	26	3.2
Musculoskeletal and Connective Tissue				
Musculoskeletal pain[d]	21	2.4	30	2.4
Skin and Subcutaneous Tissue				
Rash[e]	18	2	19	0.8
Pruritus	12	0	13	0.8
Endocrine				
Hypothyroidism	14	0	12	0
Infections				
Pneumonia[f]	17	10	16	7
Nervous System				
Peripheral neuropathy[g]	11	0.4	14	0
Metabolism and Nutrition				
Decreased appetite	11	0.8	21	2.4
Hyperglycemia	11	0.8	11	0.8
Respiratory, Thoracic, and Mediastinal				
Cough[h]	10	0	11	0.8

Clinically relevant adverse reactions in <10% of patients who received KEYTRUDA QLEX included local injection-site reactions (2.4%).

[a]Graded per NCI-CTCAE v5.0. [b]Includes diarrhea, colitis, and enterocolitis. [c]Includes fatigue, asthenia. [d]Includes musculoskeletal pain, arthralgia, arthritis, back pain, bone pain, musculoskeletal chest pain, musculoskeletal stiffness, myalgia, noncardiac chest pain, and pain in extremity. [e]Includes rash, dermatitis, dermatitis acneiform, dermatitis bullous, dermatitis exfoliative, eczema, erythema multiforme, immune-mediated dermatitis, rash erythematous, rash follicular, rash generalized, rash macular, rash maculo-papular, rash papular, rash pruritic, and skin exfoliation. [f]Includes pneumonia, COVID-19 pneumonia, lower respiratory tract infection, lung abscess, pneumocystis jirovecii pneumonia, pneumonia bacterial, and pneumonia mycoplasmal. [g]Includes neuropathy peripheral, hypoaesthesia, neuralgia, paraesthesia, and peripheral sensory neuropathy. [h]Includes cough, productive cough, and upper-airway cough syndrome.

mNSCLC = metastatic non–small cell lung cancer; NCI-CTCAE = National Cancer Institute - Common Terminology Criteria for Adverse Events.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5–9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Safety Profile of KEYTRUDA QLEX *(continued)*

The safety profile of KEYTRUDA QLEX for its approved indications is based on study MK-3475A-D77 and the safety of KEYTRUDA given as a single agent or in combination

- The most common adverse reactions (≥20%) in patients who received KEYTRUDA QLEX in combination with chemotherapy were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- The most common adverse reactions (≥20%) in patients who received KEYTRUDA were:
  - As a single agent: Fatigue, musculoskeletal pain, rash, diarrhea, pyrexia, cough, decreased appetite, pruritus, dyspnea, constipation, pain, abdominal pain, nausea, and hypothyroidism.
  - In combination with chemotherapy or chemoradiotherapy: Fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, pyrexia, alopecia, peripheral neuropathy, mucosal inflammation, stomatitis, headache, weight loss, abdominal pain, arthralgia, myalgia, insomnia, palmar-plantar erythrodysesthesia, urinary tract infection, hypothyroidism, radiation skin injury, dysphagia, dry mouth, and musculoskeletal pain.

The safety of KEYTRUDA QLEX for its approved indications has been established in adequate and well-controlled studies of KEYTRUDA QLEX in combination with platinum-doublet chemotherapy (study MK-3475A-D77) and KEYTRUDA, as a single agent or in combination therapy, across tumor types.

SELECTED SAFETY INFORMATION *(continued)*

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. With KEYTRUDA and KEYTRUDA QLEX, monitor for signs and symptoms of infusion- and administration-related systemic reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 3.2% (8/251) of patients receiving KEYTRUDA QLEX in combination with platinum doublet chemotherapy, including Grade 2 (2.8%). Interrupt injection (if not already fully administered) and resume if symptoms resolve for mild or moderate systemic reactions. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after anti–programmed death receptor-1 (PD-1)/programmed death ligand 1 (PD-L1) treatments. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between anti–PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients closely for evidence of these complications and intervene promptly. Consider the benefit vs risks of using anti–PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5–9, and 12–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Potential Patient Questions *(continued)*

Patient question

What supported the approval of KEYTRUDA QLEX?

- **In a clinical trial comparing KEYTRUDA QLEX to KEYTRUDA**, 377 patients with advanced NSCLC received either KEYTRUDA QLEX every 6 weeks + chemotherapy (251 patients) or KEYTRUDA every 6 weeks + chemotherapy (126 patients). All patients in the trial had no previous drug treatment and did not have an abnormal *EGFR, ALK*, or *ROS1*.
  - People who received either treatment were shown to have similar amounts of medicine in the blood. (This was studied to determine whether the subcutaneous injection is comparable to the infusion.)
- In that same clinical trial, results also found that:
  - KEYTRUDA QLEX had consistent safety with KEYTRUDA.
- During treatment with KEYTRUDA QLEX, side effects can occur and should be treated as early as possible. In clinical trials with KEYTRUDA QLEX, some patients stopped treatment due to side effects. Tell your doctor if you have any side effect that bothers you or that does not go away.

Patient question

What are potential side effects of KEYTRUDA QLEX?

- Please discuss with your patients the Medication Guide for KEYTRUDA QLEX and Section 17 of the Prescribing Information for KEYTRUDA QLEX. It is important that you discuss the Warnings & Precautions and potential side effects of KEYTRUDA QLEX, including that KEYTRUDA QLEX can cause the patient's immune system to attack normal organs and tissues in any area of the patient's body and can affect the way those organs and tissues work. It is important to explain to your patients that they should report to you any new or worsening signs or symptoms that they feel as soon as possible. Be sure to have a copy of the Medication Guide available for your patients so that they can bring it home.

Patient question

Where can I go to learn more about KEYTRUDA QLEX?

- Patients can visit the consumer website for KEYTRUDA QLEX at **keytruda.com/qlex** for complementary videos and frequently asked questions to help with patient education and information about insurance coverage and local resources, such as housing or transportation.

ALK = anaplastic lymphoma kinase; *EGFR* = epidermal growth factor receptor; NSCLC = non–small cell lung cancer; PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1; *ROS1* = ROS proto-oncogene 1, receptor tyrosine kinase.

SELECTED SAFETY INFORMATION *(continued)*

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti–PD-1/PD-L1 treatment in this combination is not recommended outside of controlled trials.

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Additional Information to Consider Sharing With Your Patients

Before the appointment

- Arrange transportation to your appointment.
- Wear clothing that allows for easy access to the injection site.
  - For example, shorts and a loose-fitting shirt will give the doctor or nurse access to your stomach area (abdomen) and thighs.
- Be sure to bring any necessary paperwork, list of medications and/or supplements, and insurance cards to your treatment appointment.

During the appointment

- Remember, the injection will take a minute or two.[a]
  - Taking deep breaths may help you stay relaxed throughout your appointment.
- Make a note of where on your body you received the injection.
  - A different spot will be used for your next injection.
- Ask about your next appointment and any other questions you may have.

After the appointment

- If you get any follow-up instructions, keep them somewhere handy, like your refrigerator door.
- Track and manage how you're feeling.
- Stay in touch with your health care team.

Patients can visit the consumer website for KEYTRUDA QLEX (keytruda.com/qlex/) to download a Symptom Tracker to help them record how they are feeling.

[a]KEYTRUDA QLEX is injected under the skin (subcutaneously) over 1 minute every 3 weeks, or over 2 minutes every 6 weeks. Refers to injection time only. Actual clinic time may vary.

SELECTED SAFETY INFORMATION *(continued)*

Embryofetal Toxicity

- Based on their mechanism of action, KEYTRUDA and KEYTRUDA QLEX can each cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. In females of reproductive potential, verify pregnancy status prior to initiating KEYTRUDA or KEYTRUDA QLEX and advise them to use effective contraception during treatment and for 4 months after the last dose.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5–9, 11, 12, and 14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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SELECTED SAFETY INFORMATION *(continued)*

Adverse Reactions

- In study MK-3475A-D77, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non–small cell lung cancer (NSCLC), serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.6%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.2%), neutropenic sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), parotitis (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 16% of 251 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonia and pneumonitis. Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 45% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-189, when KEYTRUDA was administered with pemetrexed and platinum chemotherapy in metastatic nonsquamous NSCLC, KEYTRUDA was discontinued due to adverse reactions in 20% of 405 patients. The most common adverse reactions resulting in permanent discontinuation of KEYTRUDA were pneumonitis (3%) and acute kidney injury (2%). The most common adverse reactions (≥20%) with KEYTRUDA were nausea (56%), fatigue (56%), constipation (35%), diarrhea (31%), decreased appetite (28%), rash (25%), vomiting (24%), cough (21%), dyspnea (21%), and pyrexia (20%).
- In KEYNOTE-407, when KEYTRUDA was administered with carboplatin and either paclitaxel or paclitaxel protein-bound in metastatic squamous NSCLC, KEYTRUDA was discontinued due to adverse reactions in 15% of 101 patients. The most frequent serious adverse reactions reported in at least 2% of patients were febrile neutropenia, pneumonia, and urinary tract infection. Adverse reactions observed in KEYNOTE-407 were similar to those observed in KEYNOTE-189 with the exception that increased incidences of alopecia (47% vs 36%) and peripheral neuropathy (31% vs 25%) were observed in the KEYTRUDA and chemotherapy arm compared to the placebo and chemotherapy arm in KEYNOTE-407.
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA; the serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.2% including 1 case of pneumonia. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common (≥1%) were increased alanine aminotransferase (1.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

Lactation

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

References: 1. National Cancer Institute. Immunotherapy. Dictionary of Cancer Terms. Accessed September 22, 2025. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/immunotherapy **2.** National Cancer Institute. Port. Dictionary of Cancer Terms. Accessed July 15, 2025. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/port

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5–9, and 11–13) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Prescribing Information for **KEYTRUDA**

Medication Guide for **KEYTRUDA**

Prescribing Information for **KEYTRUDA QLEX**

Medication Guide for **KEYTRUDA QLEX**

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5–9, and 11–14) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available. For additional copies of the Prescribing Information, please call 800-672-6372, visit keytrudahcp.com/qlex, or contact your Merck representative.

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