KEYTRUDA® (pembrolizumab) Injection 100 mg

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

GUIDE FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

Information about dosing, administration, ordering, and support

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

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.
- 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–PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. For patients with TNBC treated with KEYTRUDA or KEYTRUDA QLEX in the neoadjuvant setting, monitor blood cortisol at baseline, prior to surgery, and as clinically indicated. 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.

TNBC=triple-negative breast cancer.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

SELECTED INDICATIONS AND USAGE FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

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Advanced Melanoma or Adjuvant Therapy for Melanoma

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with unresectable or metastatic melanoma.
- KEYTRUDA and KEYTRUDA QLEX are each indicated for the adjuvant treatment of adult and pediatric patients 12 years and older with stage IIB, IIC, or III melanoma following complete resection.

Advanced Non–Small Cell Lung Cancer (NSCLC), Neoadjuvant Followed by Adjuvant Therapy for NSCLC, or Adjuvant Therapy for NSCLC

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, for the first-line treatment of adult patients with metastatic squamous NSCLC.
- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the first-line treatment of adult patients with NSCLC expressing PD-L1 [tumor proportion score (TPS) ≥1%] as determined by an FDA-authorized test, with no EGFR or ALK genomic tumor aberrations, and is stage III where adult patients are not candidates for surgical resection or definitive chemoradiation, or metastatic.
- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA-authorized test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA or KEYTRUDA QLEX.
- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.

Advanced Non–Small Cell Lung Cancer (NSCLC), Neoadjuvant Followed by Adjuvant Therapy for NSCLC, or Adjuvant Therapy for NSCLC (*continued*)

- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥4 cm), II, or IIIA NSCLC.

Advanced Malignant Pleural Mesothelioma (MPM)

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with unresectable advanced or metastatic MPM.

Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) or Neoadjuvant Followed by Adjuvant Therapy for Resectable Locally Advanced HNSCC

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with resectable locally advanced HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-authorized test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent.
- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with platinum and fluorouracil (FU), for the first-line treatment of adult patients with metastatic or with unresectable, recurrent HNSCC.
- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the first-line treatment of adult patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the treatment of adult patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

Please see additional indications on pages 3 and 4.

EGFR=epidermal growth factor receptor; ALK=anaplastic lymphoma kinase; PD-L1=programmed death ligand 1.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

Immune-Mediated Pneumonitis (*continued*)

- Pneumonitis occurred in 7% (41/580) of adult patients with resected NSCLC who received KEYTRUDA as a single agent for adjuvant treatment of NSCLC, including fatal (0.2%), Grade 4 (0.3%), and Grade 3 (1%) adverse reactions. Patients received high-dose corticosteroids for a median duration of 10 days (range: 1 day to 2.3 months). Pneumonitis led to discontinuation of KEYTRUDA in 26 (4.5%) of patients. Of the patients who developed pneumonitis, 54% interrupted KEYTRUDA, 63% discontinued KEYTRUDA, and 71% had resolution.

SELECTED INDICATIONS AND USAGE FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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Locally Advanced or Metastatic Urothelial Cancer

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with enfortumab vedotin, for the treatment of adult patients with locally advanced or metastatic urothelial cancer.
- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma:
  - who are not eligible for any platinum-containing chemotherapy, or
  - who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Muscle Invasive Bladder Cancer (MIBC)

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment for the treatment of adult patients with MIBC who are ineligible for cisplatin-containing chemotherapy.

High-Risk Non-muscle Invasive Bladder Cancer (NMIBC)

- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the treatment of adult patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, NMIBC with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Advanced MSI-H/dMMR Cancers

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-authorized test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. For this indication, KEYTRUDA also is indicated for the treatment of pediatric patients, and KEYTRUDA QLEX also is indicated for the treatment of pediatric patients 12 years and older.

Advanced MSI-H/dMMR Colorectal Cancer (CRC)

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with unresectable or metastatic MSI-H or dMMR CRC as determined by an FDA-authorized test.

Advanced Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-positive gastric or GEJ adenocarcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.

Advanced Esophageal or GEJ Carcinoma

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with locally advanced or metastatic esophageal or GEJ (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation either:
  - in combination with platinum- and fluoropyrimidine-based chemotherapy for patients with tumors that express PD-L1 (CPS ≥1), or
  - as a single agent after one or more prior lines of systemic therapy for patients with tumors of squamous cell histology that express PD-L1 (CPS ≥10) as determined by an FDA-authorized test.

Please see additional indications on page 4.

HER2=human epidermal growth factor receptor 2.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

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.
- 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.

SELECTED INDICATIONS AND USAGE FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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Advanced Cervical Cancer

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with chemoradiotherapy (CRT), for the treatment of adult patients with locally advanced cervical cancer involving the lower third of the vagina, with or without extension to pelvic sidewall, or hydronephrosis/non-functioning kidney, or spread to adjacent pelvic organs (FIGO 2014 Stage III-IVA).
- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with chemotherapy, with or without bevacizumab, for the treatment of adult patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
- KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.

Hepatocellular Carcinoma (HCC)

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with HCC secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1–containing regimen.

Advanced Biliary Tract Cancer (BTC)

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with gemcitabine and cisplatin, for the treatment of adult patients with locally advanced unresectable or metastatic BTC.

Advanced Merkel Cell Carcinoma (MCC)

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with recurrent locally advanced or metastatic MCC. For this indication, KEYTRUDA also is indicated for the treatment of pediatric patients, and KEYTRUDA QLEX also is indicated for the treatment of pediatric patients 12 years and older.

Advanced Renal Cell Carcinoma (RCC) or Adjuvant Treatment for RCC

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with axitinib, for the first-line treatment of adult patients with advanced RCC.
- KEYTRUDA and KEYTRUDA QLEX are each indicated for the adjuvant treatment of adult patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

Advanced Endometrial Carcinoma

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with carboplatin and paclitaxel, followed by KEYTRUDA or KEYTRUDA QLEX as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.
- KEYTRUDA and KEYTRUDA QLEX, as a single agent, are each indicated for the treatment of adult patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-authorized test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

Advanced Cutaneous Squamous Cell Carcinoma (cSCC)

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with recurrent or metastatic cSCC or locally advanced cSCC that is not curable by surgery or radiation.

High-Risk Early-Stage or Advanced Triple-Negative Breast Cancer (TNBC)

- KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then each continued as a single agent as adjuvant treatment after surgery.
- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with chemotherapy, for the treatment of adult patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-authorized test.

Ovarian Cancer

- KEYTRUDA and KEYTRUDA QLEX are each indicated, in combination with paclitaxel, with or without bevacizumab, for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test, and who have received 1 or 2 prior systemic treatment regimens.

FIGO=International Federation of Gynecology and Obstetrics.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

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.

PATIENT SELECTION FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

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Patient Selection for NSCLC, HNSCC, Esophageal Cancer, Gastric or GEJ Cancer, Cervical Cancer, MSI-H or dMMR Solid Tumors, MSI-H or dMMR CRC, Ovarian, or TNBC

Information on FDA-authorized tests for patient selection is available at: https://www.fda.gov/CcompanionDiagnostics.

Patient Selection for Single-Agent Treatment

Select patients for treatment with KEYTRUDA or KEYTRUDA QLEX as a single agent based on the presence of positive PD-L1 expression in:

- Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation.
- Metastatic NSCLC.
- First-line treatment of metastatic or unresectable, recurrent HNSCC.
- Previously treated recurrent locally advanced or metastatic esophageal cancer.
- Recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA or KEYTRUDA QLEX as a single agent based on MSI-H/dMMR status in tumor specimens.

Because subclonal dMMR mutations and microsatellite instability may arise in high-grade gliomas during temozolomide therapy, it is recommended to test for MSI-H and dMMR in the primary tumor specimens obtained prior to initiation of temozolomide chemotherapy in patients with high-grade gliomas.

Additional Patient Selection Information for MSI-H or dMMR in Patients With Non-CRC Solid Tumors

Due to discordance between local tests and FDA-authorized tests, confirmation of MSI-H or dMMR status is recommended by an FDA-authorized test in patients with MSI-H or dMMR solid tumors, if feasible.

Patient Selection for Combination Therapy

For use of KEYTRUDA or KEYTRUDA QLEX as a single agent as neoadjuvant treatment, then in combination with RT with or without chemotherapy then continued as a single agent as adjuvant treatment, select patients based on presence of positive PD-L1 expression (CPS ≥1) in resectable locally advanced HNSCC.

For use of KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, select patients based on the presence of positive PD-L1 expression (CPS ≥1) in locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma, and esophageal or GEJ carcinoma.

- An FDA-authorized test for the detection of PD-L1 for the selection of patients with PD-L1 (CPS ≥1) expression in esophageal carcinoma in combination with platinum and fluoropyrimidine-based chemotherapy is not available.

For use of KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, with or without bevacizumab, select patients based on the presence of positive PD-L1 expression in persistent, recurrent, or metastatic cervical cancer.

For use of KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, select patients based on the presence of positive PD-L1 expression in locally recurrent unresectable or metastatic TNBC.

For use of KEYTRUDA or KEYTRUDA QLEX in combination with paclitaxel, with or without bevacizumab, select patients based on the presence of positive PD-L1 (CPS ≥1) expression in platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

Hepatotoxicity and Immune-Mediated Hepatitis (*continued*)

KEYTRUDA With Axitinib or KEYTRUDA QLEX With Axitinib

- KEYTRUDA and KEYTRUDA QLEX, when either is used in combination with axitinib, can cause hepatic toxicity. Monitor liver enzymes before initiation of and periodically throughout treatment. Consider monitoring more frequently as compared to when the drugs are administered as single agents. For elevated liver enzymes, interrupt KEYTRUDA and axitinib or KEYTRUDA QLEX and axitinib, and consider administering corticosteroids as needed.
- With the combination of KEYTRUDA and axitinib, Grades 3 and 4 increased alanine aminotransferase (ALT) (20%) and increased aspartate aminotransferase (AST) (13%) were seen at a higher frequency compared to KEYTRUDA alone. Fifty-nine percent of the patients with increased ALT received systemic corticosteroids. In patients with ALT ≥3 times upper limit of normal (ULN) (Grades 2-4, n=116), ALT resolved to Grades 0-1 in 94%. Among the 92 patients who were rechallenged with either KEYTRUDA (n=3) or axitinib (n=34) administered as a single agent or with both (n=55), recurrence of ALT ≥3 times ULN was observed in 1 patient receiving KEYTRUDA, 16 patients receiving axitinib, and 24 patients receiving both. All patients with a recurrence of ALT ≥3 ULN subsequently recovered from the event.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

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FDA-Approved Dosing

Melanoma

- The recommended dose of KEYTRUDA in adult patients with unresectable or metastatic melanoma is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression or unacceptable toxicity.
- The recommended dose of KEYTRUDA QLEX in adult patients with unresectable or metastatic melanoma is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression or unacceptable toxicity.
- The recommended dose of KEYTRUDA for the adjuvant treatment of stage IIB, IIC, or III melanoma in adult patients is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease recurrence, unacceptable toxicity, or up to 12 months.
- The recommended dose of KEYTRUDA in pediatric patients is 2 mg/kg (up to a maximum of 200 mg), administered after dilution as an IV infusion over 30 minutes every 3 weeks until disease recurrence, unacceptable toxicity, or up to 12 months.
- The recommended dose of KEYTRUDA QLEX for the adjuvant treatment of stage IIB, IIC, or III melanoma in adult patients is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease recurrence, unacceptable toxicity, or up to 12 months.
- The recommended dose of KEYTRUDA QLEX in pediatric patients[a] (12 years and older who weigh greater than 40 kg) is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease recurrence, unacceptable toxicity, or up to 12 months.

NSCLC

- The recommended dose of KEYTRUDA in adult patients is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks, 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks, until disease progression, unacceptable toxicity, or up to 24 months.
- The recommended dose of KEYTRUDA QLEX in adult patients is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks, until disease progression, unacceptable toxicity, or up to 24 months.
- The recommended dose of KEYTRUDA in adult patients with resectable (tumors ≥4 cm or node positive) NSCLC is 200 mg administered after dilution as an intravenous infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an intravenous infusion over 30 minutes every 6 weeks as neoadjuvant treatment in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as a single agent after surgery for 39 weeks or until disease recurrence or unacceptable toxicity.
- When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA QLEX in adult patients with resectable (tumors ≥4 cm or node positive) NSCLC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks as neoadjuvant treatment in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA QLEX as a single agent after surgery for 39 weeks or until disease recurrence or unacceptable toxicity.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

IV=intravenous.

[a]The recommended dosage for melanoma has not been established in pediatric patients 12 years and older who weigh 40 kg or less.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*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.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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FDA-Approved Dosing (*continued*)

NSCLC (*continued*)

- When administering KEYTRUDA QLEX in combination with chemotherapy, administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA for the adjuvant treatment of stage IB (T2a ≥4 cm), II, or IIIA NSCLC in adult patients is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks, until disease recurrence, unacceptable toxicity, or up to 12 months.
- The recommended dose of KEYTRUDA QLEX for the adjuvant treatment of stage IB (T2a ≥4 cm), II, or IIIA NSCLC in adult patients is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease recurrence, unacceptable toxicity, or up to 12 months.

Malignant Pleural Mesothelioma (MPM)

- The recommended dose of KEYTRUDA in adult patients is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA QLEX in adult patients is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA QLEX in combination with chemotherapy, administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

HNSCC

- The recommended dose of KEYTRUDA for the treatment of adult patients with resectable locally advanced HNSCC is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks. For neoadjuvant treatment, administer KEYTRUDA for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity. For adjuvant treatment, administer KEYTRUDA in combination with RT with or without cisplatin, then continue KEYTRUDA as a single agent. Continue KEYTRUDA until disease recurrence or unacceptable toxicity or up to 12 months.
- When administering KEYTRUDA in combination with cisplatin, administer KEYTRUDA prior to cisplatin when given on the same day. Refer to the Prescribing Information for cisplatin when administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA QLEX for the treatment of adult patients with resectable locally advanced HNSCC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks. For neoadjuvant treatment, administer KEYTRUDA QLEX for 6 weeks until disease progression that precludes definitive surgery or unacceptable toxicity. For adjuvant treatment, administer KEYTRUDA QLEX in combination with RT with or without cisplatin, then continue KEYTRUDA QLEX as a single agent. Continue KEYTRUDA QLEX until disease recurrence or unacceptable toxicity or up to 12 months.
- When administering KEYTRUDA QLEX in combination with cisplatin, administer KEYTRUDA QLEX prior to cisplatin when given on the same day. Refer to the Prescribing Information for cisplatin when administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA for adult patients with advanced HNSCC is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*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.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

KEYTRUDA® (pembrolizumab) Injection 100 mg | KEYTRUDA Qlex™ pembrolizumab + berahyaluronidase alfa-pmph Subcutaneous Injection | 165 mg + 2,000 units/mL

FDA-Approved Dosing (*continued*)

HNSCC (*continued*)

- When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA QLEX for adult patients with advanced HNSCC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA QLEX in combination with chemotherapy, administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

Gastric Cancer, Esophageal Cancer, or BTC (Combination Therapy)

- The recommended dose of KEYTRUDA is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- When administering KEYTRUDA in combination with trastuzumab and chemotherapy for adult patients with HER2-positive gastric cancer, administer KEYTRUDA prior to trastuzumab and chemotherapy when given on the same day.
- The recommended dose of KEYTRUDA QLEX is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.

Gastric Cancer, Esophageal Cancer, or BTC (Combination Therapy) (*continued*)

- When administering KEYTRUDA QLEX in combination with chemotherapy, administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.
- When administering KEYTRUDA QLEX in combination with trastuzumab and chemotherapy for adult patients with HER2-positive gastric cancer, administer KEYTRUDA QLEX prior to trastuzumab and chemotherapy when given on the same day.

MSI-H or dMMR CRC, Esophageal Cancer, HCC, cSCC (Monotherapy)

- The recommended dose of KEYTRUDA is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- The recommended dose of KEYTRUDA QLEX is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.

Cervical Cancer

- For neoadjuvant treatment, the recommended dose of KEYTRUDA is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months.
- When administering KEYTRUDA in combination with chemoradiotherapy or chemotherapy with or without bevacizumab, administer KEYTRUDA prior to chemoradiotherapy or prior to chemotherapy with or without bevacizumab when given on the same day. Refer to the Prescribing Information for bevacizumab and for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

Immune-Mediated Endocrinopathies (*continued*)

Hypophysitis (*continued*)

- 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.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

KEYTRUDA® (pembrolizumab) Injection 100 mg | KEYTRUDA Qlex™ pembrolizumab + berahyaluronidase alfa-pmph Subcutaneous Injection | 165 mg + 2,000 units/mL

FDA-Approved Dosing (*continued*)

Cervical Cancer (*continued*)

- The recommended dose of KEYTRUDA QLEX is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or for KEYTRUDA QLEX, up to 24 months.
- When administering KEYTRUDA QLEX in combination with chemoradiotherapy or chemotherapy with or without bevacizumab, administer KEYTRUDA QLEX prior to chemoradiotherapy or prior to chemotherapy with or without bevacizumab when given on the same day. Refer to the Prescribing Information for bevacizumab and for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

MSI-H or dMMR Solid Tumors, MCC

- The recommended dose of KEYTRUDA in adults is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- The recommended dose of KEYTRUDA in pediatric patients is 2 mg/kg (up to a maximum of 200 mg), administered after dilution as an IV infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- The recommended dose of KEYTRUDA QLEX in adults is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- The recommended dose of KEYTRUDA QLEX in pediatric patients[a] (12 years and older who weigh greater than 40 kg) is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.

Urothelial Cancer

- The recommended dose of KEYTRUDA in adult patients with locally advanced or metastatic urothelial carcinoma is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA in combination with enfortumab vedotin in adult patients with locally advanced or metastatic urothelial cancer, administer KEYTRUDA after enfortumab vedotin when given on the same day. Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA QLEX in adult patients with locally advanced or metastatic urothelial carcinoma is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA QLEX in combination with enfortumab vedotin in adult patients with locally advanced or metastatic urothelial cancer, administer KEYTRUDA QLEX after enfortumab vedotin when given on the same day. Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA in adult patients with high-risk BCG-unresponsive NMIBC is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months.
- The recommended dose of KEYTRUDA QLEX in adult patients with high-risk BCG-unresponsive NMIBC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

[a]The recommended dosage for MSI-H or dMMR cancer and MCC has not been established in pediatric patients 12 years and older who weigh 40 kg or less.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

Immune-Mediated Endocrinopathies (*continued*)

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.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

KEYTRUDA® (pembrolizumab) Injection 100 mg | KEYTRUDA Qlex™ pembrolizumab + berahyaluronidase alfa-pmph Subcutaneous Injection | 165 mg + 2,000 units/mL

FDA-Approved Dosing (*continued*)

Urothelial Cancer (*continued*)

- For neoadjuvant treatment, the recommended dose of KEYTRUDA in adult patients with MIBC is 200 mg every 3 weeks for 3 doses in combination with enfortumab vedotin or until disease progression that precludes curative-intent cystectomy or unacceptable toxicity. For adjuvant treatment, the recommended dose of KEYTRUDA is 200 mg every 3 weeks for 14 doses or 400 mg every 6 weeks for 7 doses in combination with enfortumab vedotin or until disease recurrence or unacceptable toxicity.
- When administering KEYTRUDA in combination with enfortumab vedotin in adult patients with MIBC, administer KEYTRUDA after enfortumab vedotin when given on the same day. Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- For neoadjuvant treatment, the recommended dose of KEYTRUDA QLEX in adult patients with MIBC is 395 mg/4,800 units every 3 weeks for 3 doses in combination with enfortumab vedotin or until disease progression that precludes curative-intent cystectomy or unacceptable toxicity. For adjuvant treatment, the recommended dose of KEYTRUDA QLEX is 395 mg/4,800 units every 3 weeks for 14 doses or 790 mg/9,600 units every 6 weeks for 7 doses in combination with enfortumab vedotin or until disease recurrence or unacceptable toxicity.
- When administering KEYTRUDA QLEX in combination with enfortumab vedotin in adult patients with MIBC, administer KEYTRUDA QLEX after enfortumab vedotin when given on the same day. Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

RCC

- The recommended dose of KEYTRUDA for the adjuvant treatment of adult patients with RCC is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease recurrence, unacceptable toxicity, or up to 12 months.
- The recommended dose of KEYTRUDA QLEX for the adjuvant treatment of adult patients with RCC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease recurrence, unacceptable toxicity, or up to 12 months.

RCC (*continued*)

- The recommended dose of KEYTRUDA for treatment of adult patients with advanced RCC is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks in combination with axitinib 5 mg orally twice daily until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months. When axitinib is used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5-mg dose may be considered at intervals of 6 weeks or longer. See also the Prescribing Information for recommended axitinib dosing information.
- The recommended dose of KEYTRUDA QLEX for treatment of adult patients with advanced RCC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks in combination with axitinib 5 mg orally twice daily until disease progression, unacceptable toxicity, or for KEYTRUDA QLEX, up to 24 months. When axitinib is used in combination with KEYTRUDA QLEX, dose escalation of axitinib above the initial 5-mg dose may be considered at intervals of 6 weeks or longer. See also the Prescribing Information for recommended axitinib dosing information.

Endometrial Carcinoma

- The recommended dose of KEYTRUDA is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA in combination with carboplatin and paclitaxel, administer KEYTRUDA prior to carboplatin and paclitaxel when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA QLEX is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA QLEX in combination with carboplatin and paclitaxel, administer KEYTRUDA QLEX prior to carboplatin and paclitaxel when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*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.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

KEYTRUDA® (pembrolizumab) Injection 100 mg | KEYTRUDA Qlex™ pembrolizumab + berahyaluronidase alfa-pmph Subcutaneous Injection | 165 mg + 2,000 units/mL

FDA-Approved Dosing (*continued*)

TNBC

- The recommended dose of KEYTRUDA in adult patients with high-risk early-stage TNBC is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks as neoadjuvant treatment in combination with chemotherapy for 24 weeks (8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks) or until disease progression or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as a single agent for up to 27 weeks (9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks) or until disease recurrence or unacceptable toxicity. Patients who experience disease progression or unacceptable toxicity related to KEYTRUDA with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single-agent KEYTRUDA.
- The recommended dose of KEYTRUDA QLEX in adult patients with high-risk early-stage TNBC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks as neoadjuvant treatment in combination with chemotherapy for 24 weeks (8 doses of 395 mg/4,800 units every 3 weeks or 4 doses of 790 mg/9,600 units every 6 weeks) or until disease progression or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA QLEX as a single agent for up to 27 weeks (9 doses of 395 mg/4,800 units every 3 weeks or 5 doses of 790 mg/9,600 units every 6 weeks) or until disease recurrence or unacceptable toxicity. Patients who experience disease progression or unacceptable toxicity related to KEYTRUDA QLEX with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single-agent KEYTRUDA QLEX.

TNBC (*continued*)

- The recommended dose of KEYTRUDA in adult patients with locally recurrent unresectable or metastatic TNBC is 200 mg administered after dilution as an IV infusion over 30 minutes every 3 weeks or 400 mg administered after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- The recommended dose of KEYTRUDA QLEX in adult patients with locally recurrent unresectable or metastatic TNBC is 395 mg/4,800 units administered as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units administered as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- When administering KEYTRUDA QLEX in combination with chemotherapy, administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

Ovarian Cancer

- The recommended dose of KEYTRUDA in adult patients with ovarian cancer is 200 mg administered after dilution as an IV infusion over 30 minutes every 2 weeks of 400 mg after dilution as an IV infusion over 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months. When administering KEYTRUDA in combination with paclitaxel, with or without bevacizumab, administer KEYTRUDA prior to paclitaxel with or without bevacizumab when given on the same day.
- The recommended dose of KEYTRUDA QLEX in adult patients with ovarian cancer is 395 mg/4,800 units as a subcutaneous injection over 1 minute every 3 weeks or 790 mg/9,600 units as a subcutaneous injection over 2 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months. When administering KEYTRUDA QLEX with paclitaxel with or without bevacizumab, administer KEYTRUDA QLEX prior to paclitaxel with or without bevacizumab when given on the same day.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders (*continued*)

- 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. The incidence of new or worsening hypothyroidism was higher in 1185 patients with HNSCC, occurring in 16% of patients receiving KEYTRUDA as a single agent or in combination with platinum and FU, including Grade 3 (0.3%) hypothyroidism. The incidence of new or worsening hyperthyroidism was higher in 580 patients with resected NSCLC, occurring in 11% of patients receiving KEYTRUDA as a single agent as adjuvant treatment, including Grade 3 (0.2%) hyperthyroidism. The incidence of new or worsening hypothyroidism was higher in 580 patients with resected NSCLC, occurring in 22% of patients receiving KEYTRUDA as a single agent as adjuvant treatment (KEYNOTE-091), including Grade 3 (0.3%) hypothyroidism.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

KEYTRUDA® (pembrolizumab) Injection 100 mg

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

Two dosing options for KEYTRUDA[a]

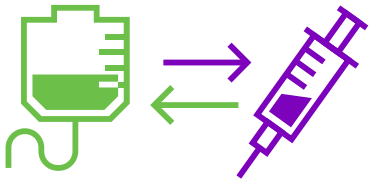
Q3W and Q6W

Q3W: Adults: 200 mg
Pediatric patients (12 years and older) for the adjuvant treatment of melanoma, pediatric patients with MSI-H/dMMR cancer or MCC: 2 mg/kg, up to a maximum of 200 mg (weight-based)

Q6W: Adults: 400 mg

Administered, after dilution, as an intravenous infusion

Over 30 minutes[c]



Patients have the option to switch from

KEYTRUDA → KEYTRUDA QLEX

or

KEYTRUDA QLEX → KEYTRUDA

at their next scheduled dose

Two dosing options for KEYTRUDA QLEX[a]

Q3W and Q6W

Adult & Pediatric (For the adjuvant treatment of melanoma, MSI-H/dMMR cancer, or MCC for patients who are 12 years and older who weigh greater than 40 kg[b]):

Q3W: 395 mg pembrolizumab and 4,800 units/mL berahyaluronidase alfa

Q6W: 790 mg pembrolizumab and 9,600 units/mL berahyaluronidase alfa

Two subcutaneous administration sites

Thigh or abdomen, avoiding the 5-cm area around the navel

KEYTRUDA QLEX must be administered by a healthcare provider

Injection volume

2.4 mL Q3W or 4.8 mL Q6W

Administered in 1 or 2 minutes subcutaneous

Over 1 minute for 2.4 mL Q3W

Over 2 minutes for 4.8 mL Q6W

- KEYTRUDA QLEX has different recommended dosage and administration instructions than KEYTRUDA.
- Inject 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.

Q3W=every 3 weeks; Q6W=every 6 weeks.

[a]For cis-ineligible adults with MIBC, dosing for the neoadjuvant phase of treatment only includes Q3W dosing.
[b]The recommended dosage for melanoma, MSI-H or dMMR cancer, and MCC has not been established in pediatric patients 12 years and older who weigh 40 kg or less.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders (*continued*)

- 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 accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

DOSAGE MODIFICATIONS FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

- No dose reduction for KEYTRUDA or KEYTRUDA QLEX is recommended.
- In general, withhold KEYTRUDA or KEYTRUDA QLEX for severe (Grade 3) immune-mediated adverse reactions.
- Permanently discontinue KEYTRUDA or KEYTRUDA QLEX for:
  - Life-threatening (Grade 4) immune-mediated adverse reactions
  - Recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment
  - An inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating steroids
- Dosage modifications for KEYTRUDA or KEYTRUDA QLEX for adverse reactions that require management different from these general guidelines are summarized on pages 14 to 17.

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.

Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.

- Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1-blocking antibodies.
- Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment.
- For patients with TNBC treated with KEYTRUDA or KEYTRUDA QLEX in the neoadjuvant setting, monitor blood cortisol at baseline, prior to surgery, and as clinically indicated.
- 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 or KEYTRUDA QLEX requires 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 immune-mediated adverse reactions are not controlled with corticosteroid therapy.
- Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (eg, endocrinopathies and dermatologic reactions) are discussed on the following pages.
- Additional monitoring and management considerations for selected immune-mediated adverse reactions are also discussed.

DOSAGE MODIFICATIONS FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

Adverse Reaction	Severity[a]	Dosage Modification
Immune-mediated adverse reactions		
Pneumonitis	Grade 2	Withhold[b]
	Grade 3 or 4	Permanently discontinue
Colitis	Grade 2 or 3	Withhold[b]
	Grade 4	Permanently discontinue
Hepatitis with no tumor involvement of the liver[c]	AST or ALT increases to more than 3 and up to 8 times ULN or Total bilirubin increases to more than 1.5 and up to 3 times ULN	Withhold[b]
	AST or ALT increases to more than 8 times ULN or Total bilirubin increases to more than 3 times ULN	Permanently discontinue

[a]Based on Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.
[b]Resume in patients with complete or partial resolution (Grades 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids.
[c]Recommended dosage modifications for liver enzyme elevations in patients treated with combination therapy with axitinib are shown on page 17.
ALT=alanine aminotransferase; AST=aspartate aminotransferase; ULN=upper limit of normal.

See additional dosage modifications on pages 15 to 17.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*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.

DOSAGE MODIFICATIONS FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Adverse Reaction	Severity[a]	Dosage Modification
Immune-mediated adverse reactions (*continued*)		
Hepatitis with tumor involvement of the liver[b]	Baseline AST or ALT is more than 1 and up to 3 times ULN and increases to more than 5 and up to 10 times ULN or Baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to 10 times ULN	Withhold[c]
	ALT or AST increases to more than 10 times ULN or Total bilirubin increases to more than 3 times ULN	Permanently discontinue
Endocrinopathies	Grade 3 or 4	Withhold until clinically stable or permanently discontinue depending on severity
Nephritis with renal dysfunction	Grade 2 or 3 increased blood creatinine	Withhold[c]
	Grade 4 increased blood creatinine	Permanently discontinue

[a]Based on Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.
[b]If AST and ALT are less than or equal to ULN at baseline, withhold or permanently discontinue KEYTRUDA based on recommendations for hepatitis with no liver involvement.
[c]Resume in patients with complete or partial resolution (Grades 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids.
ALT=alanine aminotransferase; AST=aspartate aminotransferase; ULN=upper limit of normal.

See additional dosage modifications on pages 16 and 17.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

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.
- 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.

DOSAGE MODIFICATIONS FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Adverse Reaction	Severity[a]	Dosage Modification
Immune-mediated adverse reactions (*continued*)		
Exfoliative dermatologic conditions	Suspected SJS, TEN, or DRESS	Withhold[b]
	Confirmed SJS, TEN, or DRESS	Permanently discontinue
Myocarditis	Grade 2, 3, or 4	Permanently discontinue
Neurological toxicities	Grade 2	Withhold[b]
	Grade 3 or 4	Permanently discontinue
Other adverse reactions		

[a]Based on Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.
[b]Resume in patients with complete or partial resolution (Grades 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids.
DRESS=drug rash with eosinophilia and systemic symptoms; SJS=Stevens-Johnson syndrome; TEN=toxic epidermal necrolysis.

See additional dosage modifications on page 17.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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

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.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

DOSAGE MODIFICATIONS FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Recommended Specific Dosage Modifications for Adverse Reactions for KEYTRUDA and KEYTRUDA QLEX

The following table represents dosage modifications that are specific to either KEYTRUDA or KEYTRUDA QLEX.

DOSAGE MODIFICATIONS FOR *KEYTRUDA*		
Adverse Reaction	**Severity[a]**	**Dosage Modification**
Infusion-related reactions	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue

DOSAGE MODIFICATIONS FOR *KEYTRUDA QLEX*		
Adverse Reaction	**Severity[a]**	**Dosage Modification**
Hypersensitivity- and administration-related systemic reactions	Grade 1 or 2	Interrupt injection (if not already fully administered). If symptoms resolve, resume injection
	Grade 3 or 4	Permanently discontinue

Recommended Specific Dosage Modifications for Adverse Reactions for KEYTRUDA in Combination With Axitinib and KEYTRUDA QLEX in Combination With Axitinib

The following table represents dosage modifications that are different from those described previously for KEYTRUDA and KEYTRUDA QLEX in the Full Prescribing Information for the drug administered in combination.

Treatment	Adverse Reaction	Severity	Dosage Modification
KEYTRUDA in combination with axitinib	Liver enzyme elevations[b]	ALT or AST increases to at least 3 times but less than 10 times ULN without concurrent total bilirubin at least 2 times ULN	Withhold both KEYTRUDA and axitinib until resolution to Grades 0 or 1[a]
		ALT or AST increases to more than 3 times ULN with concurrent total bilirubin at least 2 times ULN or ALT or AST ≥10 times ULN	Permanently discontinue both KEYTRUDA and axitinib
KEYTRUDA QLEX in combination with axitinib	Liver enzyme elevations[b]	ALT or AST increases to at least 3 times but less than 10 times ULN without concurrent total bilirubin at least 2 times ULN	Withhold both KEYTRUDA QLEX and axitinib until resolution to Grades 0 or 1[a]
		ALT or AST increases to more than 3 times ULN with concurrent total bilirubin at least 2 times ULN or ALT or AST ≥10 times ULN	Permanently discontinue both KEYTRUDA QLEX and axitinib

[a]Based on Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.
[b]Consider corticosteroid therapy.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*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 or KEYTRUDA QLEX, monitor for signs and symptoms of infusion- and administration-related 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.

PREPARATION AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX*

KEYTRUDA® (pembrolizumab) Injection 100 mg

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

Preparation of KEYTRUDA for IV Infusion

- Visually inspect the solution for particulate matter and discoloration. The solution is clear to slightly opalescent, colorless to slightly yellow. Discard the vial if visible particles are observed.
- Dilute KEYTRUDA injection (solution) prior to IV administration.
- Withdraw the required volume from the vial(s) of KEYTRUDA and transfer into an IV bag containing 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. **Mix diluted solution by gentle inversion.** Do not shake. The final concentration of the diluted solution should be between 1 mg/mL to 10 mg/mL.
- Discard any unused portion left in the vial.

Preparation of KEYTRUDA QLEX for Subcutaneous Injection

KEYTRUDA QLEX is a ready-to-use solution. Do not dilute KEYTRUDA QLEX. Do not shake.

Preparation of the Syringe for KEYTRUDA QLEX

- Remove KEYTRUDA QLEX vial from refrigerated storage [2 °C to 8 °C (36 °F to 46 °F)] and allow it to equilibrate to room temperature [20 °C to 25 °C (68 °F to 77 °F)] for at least 30 minutes.
- Prior to preparation for administration, if needed, the unpunctured vial may be stored at room temperature for up to 24 hours.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution is clear to slightly opalescent, colorless to slightly yellow. Discard the vial if visible particles are observed.
- Use a sterile, polypropylene or polycarbonate syringe and a stainless steel transfer needle (18 to 21 gauge) to withdraw KEYTRUDA QLEX from the vial.
  - Every 3-week dosing (395 mg pembrolizumab/4,800 units berahyaluronidase alfa): withdraw 2.4 mL into the syringe.
  - Every 6-week dosing (790 mg pembrolizumab/9,600 units berahyaluronidase alfa): withdraw 4.8 mL into the syringe.
- To avoid needle clogging, change the needle to a 25 to 30 gauge, ½-inch, stainless steel hypodermic injection needle immediately prior to subcutaneous injection.
- Discard any unused portion left in the vial.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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–PD-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.

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.

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 accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

DOSAGE AND ADMINISTRATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

KEYTRUDA® (pembrolizumab) Injection 100 mg

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

Storage of Diluted Solution of KEYTRUDA

The product does not contain a preservative.

Store the diluted solution from the KEYTRUDA 100 mg/4 mL vial either:

- At room temperature (temperatures at or below 25 °C) for no more than 6 hours from the time of dilution. This includes room temperature storage of the diluted solution, and the duration of infusion.
- Under refrigeration at 2 °C to 8 °C (36 °F to 46 °F) for no more than 96 hours from the time of dilution. If refrigerated, allow the diluted solution to come to room temperature prior to administration. Do not shake.

Discard after 6 hours at room temperature or after 96 hours under refrigeration.

Do not freeze.

Administration of KEYTRUDA

- Administer diluted solution intravenously over 30 minutes through an IV line containing a sterile, non-pyrogenic, low-protein binding 0.2 micron to 5 micron in-line or add-on filter.
- Do not co-administer other drugs through the same infusion line.[a]

Storage of Prepared Syringe of KEYTRUDA QLEX

The product does not contain a preservative and should be used immediately after withdrawing from the vial. If not used immediately, store the syringe containing KEYTRUDA QLEX with the transfer needle and cap in place:

- At room temperature 20 °C to 25 °C (68 °F to 77 °F) for up to 8 hours, or
- In the refrigerator at 2 °C to 8 °C (36 °F to 46 °F) for up to 24 hours. The 24-hour period may include up to 8 hours at room temperature.

Discard if storage time exceeds these limits.

If refrigerated, allow the filled syringe to come to room temperature for at least 30 minutes prior to administration.

Do not freeze.

Administration of KEYTRUDA QLEX

- KEYTRUDA QLEX has different recommended dosage and administration instructions than intravenous KEYTRUDA.
  - To reduce the risk of medication errors, check the vial labels to ensure that the drug being prepared and administered is KEYTRUDA QLEX for subcutaneous use and not intravenous KEYTRUDA.
  - Patients receiving intravenous KEYTRUDA can switch to subcutaneous KEYTRUDA QLEX at their next scheduled dose.
  - Patients receiving subcutaneous KEYTRUDA QLEX can switch to intravenous KEYTRUDA at their next scheduled dose.
  - Administer KEYTRUDA QLEX as a subcutaneous injection into the thigh or abdomen, avoiding the 5 cm area around the navel.
- Every 3-week dosing (395 mg/4,800 units): inject 2.4 mL subcutaneously over 1 minute.
- Every 6-week dosing (790 mg/9,600 units): inject 4.8 mL subcutaneously over 2 minutes.
- Inject 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 healthcare provider.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Adverse Reactions

- 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%).
- When KEYTRUDA was used as monotherapy, the most common adverse reactions (≥20%) were fatigue, musculoskeletal pain, rash, diarrhea, pyrexia, cough, decreased appetite, pruritus, dyspnea, constipation, pain, abdominal pain, nausea, and hypothyroidism.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

NATIONAL DRUG CODES (NDCs)

NDC and Packaging Information

The NDC is typically required when submitting a claim with a miscellaneous Healthcare Common Procedure Coding System (HCPCS) code. Please consult with the payer to understand specific billing requirements.

PRODUCT		
KEYTRUDA		
PACKAGE	**10-Digit NDC**	**11-Digit NDC**
Carton containing one 100 mg/4 mL (25 mg/mL), single-dose vial	0006-3026-02	00006-3026-02
Carton containing two 100 mg/4 mL (25 mg/mL), single-dose vials	0006-3026-04	00006-3026-04

Please note: The NDCs above are the billable NDCs that appear on the cartons. The NDC on the vial should not be used for billing purposes.

Vial may not be shown at actual size.

Vials may not be shown at actual size.

PRODUCT		
KEYTRUDA QLEX		
PACKAGE	**10-Digit NDC**	**11-Digit NDC**
One carton containing 395 mg pembrolizumab and 4,800 units berahyaluronidase alfa per 2.4 mL (165 mg and 2,000 units per mL), single-dose vial	0006-3083-01	00006-3083-01
One carton containing 790 mg pembrolizumab and 9,600 units berahyaluronidase alfa per 4.8 mL (165 mg and 2,000 units per mL), single-dose vial	0006-5083-01	00006-5083-01

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Adverse Reactions (*continued*)

- When KEYTRUDA was used in combination with chemotherapy or chemoradiotherapy, the most common adverse reactions (≥20%) were 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.
- When KEYTRUDA was used in combination with chemotherapy and bevacizumab, the most common adverse reactions (≥20%) were peripheral neuropathy, alopecia, anemia, fatigue/asthenia, nausea, neutropenia, diarrhea, hypertension, thrombocytopenia, constipation, arthralgia, vomiting, urinary tract infection, rash, leukopenia, hypothyroidism, decreased appetite, pyrexia, epistaxis, decreased white blood cell count, and stomatitis.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

BILLING CODES

Current Procedural Terminology (CPT®)[a] Administration Code for KEYTRUDA[1]

CPT CODE	DESCRIPTOR
96413	Injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration

Current Procedural Terminology (CPT®)[a] Administration Code for KEYTRUDA QLEX[3]

CPT CODE	DESCRIPTOR
96401	Injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration

[a]CPT® is a registered trademark of the American Medical Association. Copyright 2025 American Medical Association. All rights reserved.
Please consult with the applicable payer to understand the payer's specific billing requirements.

HCPCS Code for KEYTRUDA[2]

HCPCS CODE	DESCRIPTOR
J9271	IV, pembrolizumab, 1 mg

HCPCS Code for KEYTRUDA QLEX[4]

HCPCS CODE	DESCRIPTOR
J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph

Information about HCPCS codes is based on guidance issued by the Centers for Medicare & Medicaid Services applicable to Medicare Part B and may not apply to other public or private payers. Resources containing possible codes that could be relevant for KEYTRUDA and KEYTRUDA QLEX and their administration are available from The Merck Access Program. Please visit merckaccessprogram-keytruda.com/keytrudaqlex or call 855-257-3932 to speak with a representative (Monday through Friday, 8 AM to 8 PM ET). You are solely responsible for determining the appropriate codes and for any action you take in billing. Please consult with the applicable payer to understand the payer's specific billing requirements.

The information above may be relevant when billing for KEYTRUDA, KEYTRUDA QLEX, and their administration. This information is current as of March 2026. The information provided here is compiled from sources believed to be accurate, but Merck makes no representation that it is accurate. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of its use and for information on additional codes. Diagnosis codes should be selected only by a healthcare professional. This information is subject to change. Merck cautions that payer-coding requirements vary and can frequently change, so it is important to regularly check with each payer or, where applicable, the Medicare Administrative Contractor as to payer-specific requirements.

The information provided here is not intended to be definitive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. Diagnosis codes should be selected only by a healthcare professional. Merck and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs.

AMA=American Medical Association.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Adverse Reactions (*continued*)

- When KEYTRUDA was used in combination with axitinib, the most common adverse reactions (≥20%) were diarrhea, fatigue/asthenia, hypertension, hepatotoxicity, hypothyroidism, decreased appetite, palmar-plantar erythrodysesthesia, nausea, stomatitis/mucosal inflammation, dysphonia, rash, cough, and constipation.
- When KEYTRUDA was used in combination with enfortumab vedotin, the most common adverse reactions (≥20%) were rash, peripheral neuropathy, fatigue, pruritus, diarrhea, alopecia, weight loss, decreased appetite, nausea, constipation, dry eye, dysgeusia, and urinary tract infection.

DISTRIBUTION INFORMATION

Authorized Distributors

AUTHORIZED DISTRIBUTOR	PHONE NUMBER	ORDER ITEM # FOR *KEYTRUDA* Carton of one 100 mg/4 mL (25 mg/mL), single-use vial	ORDER ITEM # FOR *KEYTRUDA* Carton of two 100 mg/4 mL (25 mg/mL), single-use vials	ORDER ITEM # FOR *KEYTRUDA* QLEX Carton of one 395 mg pembrolizumab and 4,800 units berahyaluronidase alfa per 2.4 mL (165 mg/2,000 units per mL), single-dose vial	ORDER ITEM # FOR *KEYTRUDA* QLEX Carton of one 790 mg pembrolizumab and 9,600 units berahyaluronidase alfa per 4.8 mL (165 mg/2,000 units per mL), single-dose vial
ASD Healthcare	800-746-6273	10248338	10246707	10303838	10303887
Besse Medical	800-543-2111	10254504	10251288	10303859	10303926
Cardinal Health Specialty Distribution	877-453-3972	5058029	5555008	6054373	6054365
CuraScript Specialty Distribution	877-599-7748	260622	386235	10007199	10007200
McKesson Plasma and Biologics	877-625-2566	3425493	3979275	3061058	3061041
McKesson Specialty Care Distribution	800-482-6700	5005010	5009280	5021188	5021187
Morris & Dickson Specialty Distribution	800-710-6100	015090	015025	079187	079195
Oncology Supply	800-633-7555	10239747	10242461	10303868	10303927

Merck does not recommend the use of one authorized distributor over another.
Merck does not make any warranty as to the services offered by any particular authorized distributor.
The Supplemental Return Program for Oncology Products is available to eligible customers for eligible products purchased from a distributor.
The program is subject to applicable conditions and restrictions. For information, please contact the Supplemental Returns Program for Oncology Products at 800-611-7397.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

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.

Pediatric Use

- In KEYNOTE-051, 173 pediatric patients (65 pediatric patients aged 6 months to younger than 12 years and 108 pediatric patients aged 12 years to 17 years) were administered KEYTRUDA 2 mg/kg every 3 weeks. The median duration of exposure was 2.1 months (range: 1 day to 25 months).

THE MERCK ACCESS PROGRAM AND NURSE EDUCATOR PROGRAM

KEYTRUDA® (pembrolizumab) Injection 100 mg

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

The Merck Access Program
may be able to help answer questions about:

- Benefit investigations
- Billing and coding
- Co-pay assistance for eligible patients
- Prior authorization and appeals process
- Referral to the Merck Patient Assistance Program for eligibility determination (provided through the Merck Patient Assistance Program, Inc.)
- Product distribution

For more information, visit
merckaccessprogram-keytruda.com/keytrudaqlex

For more information about access and support, call The Merck Access Program at 855-257-3932
(Monday to Friday, 8 AM to 8 PM ET).

Nurse Educator Program

Nurse educators provide nurse-to-nurse staff education on appropriate dosing and administration, and information to help offices understand how to manage any potential adverse events.

For questions about KEYTRUDA or KEYTRUDA QLEX, call 855-257-3932 to request an appointment with a nurse educator.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Pediatric Use (*continued*)

- The safety and effectiveness of KEYTRUDA QLEX for the treatment of pediatric patients 12 years and older who weigh greater than 40 kg have been established for:
  - Stage IIB, IIC, or III melanoma following complete resection
  - Unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors
  - Recurrent locally advanced or metastatic Merkel cell carcinoma
- Use of KEYTRUDA QLEX in pediatric patients for these indications is supported by evidence from adequate and well-controlled studies of KEYTRUDA in adults and additional pharmacokinetic and safety data for KEYTRUDA in pediatric patients 12 years and older. Pembrolizumab exposures in pediatric patients 12 years and older who weigh greater than 40 kg are predicted to be within range of those observed in adults at the same dosage.
- The safety and effectiveness of KEYTRUDA as a single agent have been established in pediatric patients with melanoma (stage IIB, IIC, or III melanoma following complete resection in pediatric patients 12 and older), MCC, and MSI-H or dMMR cancer.
- Use of KEYTRUDA in pediatric patients for these indications is supported by evidence from adequate and well-controlled studies in adults with additional pharmacokinetic and safety data in pediatric patients.
- The safety and effectiveness of KEYTRUDA QLEX have not been established in pediatric patients younger than 12 years of age for the treatment of melanoma, MCC, and MSI-H or dMMR cancer.
- The safety and effectiveness of KEYTRUDA and KEYTRUDA QLEX have not been established in pediatric patients for other approved indications shown.
- Adverse reactions that occurred at a ≥10% higher rate in pediatric patients when compared to adults were pyrexia (33%), leukopenia (30%), vomiting (29%), neutropenia (28%), headache (25%), abdominal pain (23%), thrombocytopenia (22%), Grade 3 anemia (17%), decreased lymphocyte count (13%), and decreased white blood cell count (11%).

To learn more about KEYTRUDA QLEX, please visit keytrudahcp.com/qlex

To learn more about KEYTRUDA, please visit keytrudahcp.com

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* AND *KEYTRUDA QLEX* (*continued*)

Geriatric Use

- Of the 564 patients with locally advanced or metastatic urothelial cancer treated with KEYTRUDA in combination with enfortumab vedotin, 44% (n=247) were 65-74 years and 26% (n=144) were 75 years or older. No overall differences in effectiveness were observed between patients 65 years of age or older and younger patients. Patients 75 years of age or older treated with KEYTRUDA in combination with enfortumab vedotin experienced a higher incidence of fatal adverse reactions than younger patients. The incidence of fatal adverse reactions was 4% in patients younger than 75 and 7% in patients 75 years or older.
- Of the 167 patients with MIBC treated with KEYTRUDA in combination with enfortumab vedotin, 37% (n=61) were 65-74 years and 46% (n=77) were 75 years or older. Patients 75 years of age or older treated with KEYTRUDA in combination with enfortumab vedotin experienced a higher incidence of fatal adverse reactions than younger patients. The incidence of fatal adverse reactions was 4% in patients younger than 75 and 12% in patients 75 years or older.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

References: 1. AAPC Coder – CPT Code 96413. Accessed December 8, 2025. https://coder.aapc.com/cpt-codes/96413 **2.** CMS – 2020 Table of Drugs. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2020-Table-of-Drugs.pdf. **3.** AAPC Codify® Code 96401. Accessed July 30, 2025. https://www.aapc.com/codes/cpt-codes/96401 **4.** Healthcare Common Procedure Coding System (HCPCS) quarterly update: January 2026 alpha-numeric HCPCS. Centers for Medicare & Medicaid Services. Updated December 8, 2025. Accessed December 8, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update

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