

Applicable Drugs: Keytruda (pembrolizumab),
Keytruda Qlex (pembrolizumab and
berahyaluronidase alfa-pmph)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/19/2017

Date Last Reviewed / Revised: 4/20/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documentation of one of the following FDA-approved diagnoses A through U AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indication(s)

A. Melanoma:

1. Unresectable or metastatic melanoma
 - a) Keytruda or Keytruda Qlex will be used as a single agent.
 - b) Maximum treatment duration: until disease progression or unacceptable toxicity.
2. Stage IIB, IIC, or III melanoma
 - a) Keytruda or Keytruda Qlex will be used as a single agent
 - b) Keytruda or Keytruda Qlex will be used for adjuvant treatment following complete resection
 - c) Minimum age requirement: 12 years old
 - d) Maximum treatment duration: 12 months

B. Non-small cell lung cancer (NSCLC) and meets one of the following criteria 1, 2, 3, 4, or 5:

1. Metastatic non-squamous NSCLC
 - a) Documentation that EGFR and ALK genomic tumor aberrations are not present.
 - b) Keytruda or Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy.
 - c) Used for first-line treatment.
 - d) Maximum treatment duration: 24 months
2. Metastatic squamous NSCLC
 - a) Keytruda or Keytruda Qlex will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound.
 - b) Used for first-line treatment.

- c) Maximum treatment duration: 24 months
- 3. NSCLC expressing Programmed Death-Ligand 1 (PD-L1) Tumor Proportion Score (TPS) greater than or equal to 1 percent
 - a) Keytruda or Keytruda Qlex will be used as a single agent and meets one of the following criteria (1) or (2):
 - (1) Documentation that EGFR and ALK genomic tumor aberrations are not present and meets one of the following criteria (a) or (b):
 - (a) Keytruda or Keytruda Qlex will be used first line for metastatic disease.
 - (b) Keytruda or Keytruda Qlex will be used first line for stage III disease and the patient is not a candidate for surgical resection or definitive chemoradiation.
 - (2) Documentation of disease progression on or after platinum-containing-chemotherapy.
 - (a) Documentation of metastatic NSCLC.
 - (b) Documentation of testing for EGFR and ALK genomic tumor aberrations and of disease progression, intolerance, or contraindication to FDA-approved therapy/therapies indicated for any EGFR and/or ALK genomic tumor aberrations present.
 - b) Maximum treatment duration: 24 months
- 4. Stage IB (T2a greater than or equal to four centimeters), II, or IIIA NSCLC
 - a) Keytruda or Keytruda Qlex will be used for adjuvant treatment following resection and platinum-based chemotherapy.
 - b) Keytruda or Keytruda Qlex will be used as a single agent
 - c) Maximum treatment duration: 12 months.
- 5. Resectable NSCLC (tumors greater than or equal to four centimeters or node positive) and meets one of the following a) or b)
 - a) Keytruda or Keytruda Qlex will be used in combination with platinum-containing chemotherapy as neoadjuvant treatment
 - (1) Maximum treatment duration: 12 weeks.
 - b) Keytruda or Keytruda Qlex will be continued as a single agent as adjuvant treatment after surgery
 - (1) Maximum treatment duration: 12 months.
- C. Head and neck squamous cell carcinoma (HNSCC) and meets one of the following criteria 1 or 2 or 3:

1. Metastatic or with unresectable recurrent HNSCC and meets one of the following criteria a) or b):
 - a) Keytruda or Keytruda Qlex used first line in combination with a platinum agent and fluorouracil.
 - (1) Maximum treatment duration: 24 months
 - b) Tumor expresses Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to one
 - (1) Keytruda or Keytruda Qlex will be used as a single agent for first line treatment.
 - (2) Maximum treatment duration: 24 months
 2. Recurrent or metastatic HNSCC
 - a) Documentation disease has progressed on or after platinum-containing chemotherapy.
 - b) Keytruda or Keytruda Qlex will be used as a single agent.
 - c) Maximum treatment duration: 24 months
 3. Resectable locally advanced disease
 - a) Tumor expresses Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to one
 - b) Keytruda or Keytruda Qlex will be used as a single agent for neoadjuvant treatment and continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent
 - c) Maximum treatment duration for neoadjuvant treatment: 6 weeks
 - d) Maximum treatment duration for adjuvant treatment: up to 1 year
- D. Classical Hodgkin lymphoma (cHL) and ONE of the following criteria are met 1 or 2:
1. Adult patients
 - a) Documentation that patient has tried and failed at least 1 prior systemic therapy.
 - b) Request is for Keytruda
 - c) Maximum treatment duration: 24 months
 2. Pediatric patients
 - a) Documentation that disease has relapsed after 2 or more lines of therapy.
 - b) Request is for Keytruda
 - c) Keytruda will be used as a single agent.
 - d) Minimum age requirement: 6 months old
 - e) Maximum treatment duration: 24 months

- E. Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
 - 1. Documentation of relapse after 2 or more prior lines of therapy
 - 2. Request is for Keytruda
 - 3. Keytruda will be used as a single agent
 - 4. Minimum age requirement: 6 months old
 - 5. Maximum treatment duration: 24 months
- F. Urothelial carcinoma and meets one of the following criteria 1, 2 or 3:
 - 1. Locally advanced or metastatic disease and meets one of the following criteria a) or b):
 - a) Keytruda or Keytruda Qlex will be used in combination with Padcev (enfortumab vedotin).
 - b) Keytruda or Keytruda Qlex will be used as a single agent and meets one of the following criteria (1) or (2)
 - (1) Documentation that the patient is not eligible for platinum-containing chemotherapy.
 - (2) Documentation that the patient has disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
 - c) Maximum treatment duration: 24 months
 - 2. High-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)
 - a) Documentation that disease is unresponsive to Bacillus Calmette-Guerin (BCG)
 - b) Documentation that patient is ineligible for or has elected to not undergo cystectomy.
 - c) Keytruda or Keytruda Qlex will be used as a single agent
 - d) Maximum treatment duration: 24 months
 - 3. Muscle invasive bladder cancer (MIBC)
 - a) Keytruda or Keytruda Qlex will be used in combination with Padcev (enfortumab vedotin)
 - b) Used as neoadjuvant treatment and continued after cystectomy as adjuvant treatment
 - c) Documentation patient is ineligible for cisplatin-containing chemotherapy
 - d) Maximum treatment duration (neoadjuvant treatment): 9 weeks

- e) Maximum treatment duration (adjuvant treatment): 14 doses if given every 3 weeks (200 mg dose) or 7 doses if given every 6 weeks (400 mg dose)

G. Microsatellite instability-high (MSI-H) or mismatch repair deficient cancer (dMMR)

1. Documentation the patient has an MSI-H or dMMR solid tumor.
2. Documentation the patient has an unresectable tumor or metastatic disease.
3. Documentation the patient has progressed following at least 1 prior systemic treatment.
4. Documentation that alternative treatment options are unavailable and/or contraindicated.
5. Keytruda or Keytruda Qlex will be used as a single agent
6. Minimum age requirement (Keytruda): 6 months old
7. Minimum age requirement (Keytruda Qlex): 12 years old and older
8. Maximum treatment duration: 24 months

H. Colorectal Cancer (CRC)

1. Documentation the patient has microsatellite instability-high (MSI-H) or mismatch repair deficient cancer (dMMR) CRC
2. Documentation the patient has unresectable or metastatic disease.
3. Keytruda or Keytruda Qlex will be used as a single agent.
4. Maximum treatment duration: 24 months

I. Gastric cancer

1. Documentation of locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma
2. Documentation that tumor(s) express Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to one and meets one of the following criteria a) or b):
 - a) Documentation of HER2-positive disease
 - (1) Keytruda or Keytruda Qlex will be used as first-line treatment in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy.
 - b) Documentation of HER2-negative disease
 - (1) Keytruda or Keytruda Qlex will be used as first-line in combination with fluoropyrimidine- and platinum-containing chemotherapy.
3. Maximum treatment duration: 24 months

J. Esophageal cancer

1. Documentation of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma.
 2. Documentation that disease is not amenable to surgical resection or definitive chemoradiation and meets one of the following criteria a) or b):
 - a) Documentation that tumor(s) expresses Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to one.
 - (1) Keytruda or Keytruda Qlex will be used in combination with platinum- and fluoropyrimidine-based chemotherapy.
 - b) Documentation that tumor(s) expresses Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to ten.
 - (1) Documentation of squamous cell histology.
 - (2) Documentation of disease progression on or after one or more prior lines of systemic therapy.
 - (3) Keytruda or Keytruda Qlex will be used as a single agent
 3. Maximum treatment duration: 24 months
- K. Cervical cancer, and meets one of the following criteria 1 or 2:
1. Documentation of FIGO 2014 Stage III-IVA cervical cancer
 - a) Keytruda or Keytruda Qlex will be used in combination with chemoradiotherapy (CRT).
 2. Tumor express Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to one and one of the following criteria is met a) or b):
 - a) Keytruda or Keytruda Qlex will be used in combination with chemotherapy, with or without bevacizumab.
 - (1) Documentation of persistent, recurrent or metastatic disease.
 - b) Keytruda or Keytruda Qlex will be used as a single agent.
 - (1) Documentation of recurrent or metastatic disease.
 - (2) Documentation of disease progression on or after at least one systemic chemotherapy.
 3. Maximum treatment duration: 24 months
- L. Hepatocellular Carcinoma (HCC)
1. Documentation of HCC secondary to hepatitis B
 2. Documentation of previous treatment with systemic therapy

3. Has not previously received prior treatment with a programmed death receptor-1 (PD-1)-blocking antibody or a programmed death-ligand 1 (PD-L1) blocking antibody (ie, Bravencio [avelumab, Imfinzi (durvalumab), Opdivo (nivolumab), Tecentriaq (atezolizumab), Keytruda (pembrolizumab), or Keytruda QLEX (pembrolizumab berahyaluronidase alpha, etc.].
4. Keytruda or Keytruda Qlex will be used as a single agent.
5. Maximum treatment duration: 24 months

M. Biliary tract cancer (BTC)

1. Documentation disease is locally advanced unresectable or metastatic.
2. Keytruda or Keytruda Qlex will be used in combination with gemcitabine and cisplatin.
3. Maximum treatment duration: 24 months

N. Merkel Cell Carcinoma (MCC)

1. Documentation disease is recurrent locally advanced or metastatic.
2. Keytruda or Keytruda Qlex will be used as a single agent.
3. Minimum age requirement (Keytruda): 6 months old
4. Minimum age requirement (Keytruda Qlex): 12 years old
5. Maximum treatment duration: 24 months.

O. Renal Cell Carcinoma (RCC) and meets ONE of the following criteria 1 or 2:

1. Advanced or stage IV RCC
 - a) Keytruda or Keytruda Qlex will be used first line in combination with Inlyta (axitinib) or Lenvima (lenvatinib).
 - b) Maximum treatment duration: 24 months
2. Following nephrectomy or following nephrectomy and resection of metastatic lesions.
 - a) Documentation of intermediate-high or high risk of recurrence.
 - b) Keytruda or Keytruda Qlex will be used for adjuvant treatment
 - c) Keytruda or Keytruda Qlex will be used as a single agent
 - d) Maximum treatment duration: 12 months

P. Endometrial carcinoma and meets one of the following criteria 1 or 2:

1. Documentation of primary advanced or recurrent endometrial carcinoma
 - a) Keytruda or Keytruda Qlex will be used in combination with carboplatin and paclitaxel and then continued as a single agent.

2. Documentation of advanced endometrial carcinoma and one of the following criteria is met a) or b):

a) Documentation disease is mismatch repair proficient (pMMR) or it is NOT microsatellite instability-high (MSI-H)

(1) Documentation of disease progression following prior systemic therapy.

(2) Documentation that patient is not a candidate for curative surgery or radiation.

(3) Keytruda or Keytruda Qlex will be used in combination with Lenvima (lenvatinib).

b) Documentation disease is mismatch repair deficient (dMMR) or is microsatellite instability-high (MSI-H).

(1) Documentation of disease progression following prior systemic therapy.

(2) Documentation that patient is not a candidate for curative surgery or radiation

(3) Keytruda or Keytruda Qlex will be used as a single agent.

3. Maximum treatment duration: 24 months

Q. Tumor mutational burden high (TMB-H) cancer

1. Documentation of TMB-H [≥ 10 mutations/megabase (mut/Mb)] unresectable or metastatic solid tumor(s).

2. Documentation the patient has no other satisfactory alternative treatment options.

3. Documentation of disease progression following at least 1 prior systemic treatment.

4. If patient is < 18 years old, patient does not have TMB-H central nervous system cancer.

5. Keytruda or Keytruda Qlex will be used as a single agent.

6. Minimum age requirement (Keytruda): 6 months old

7. Minimum age requirement (Keytruda Qlex): 12 years old

8. Maximum treatment duration: 24 months

R. Cutaneous squamous cell carcinoma (cSCC)

1. Documentation of recurrent, metastatic or locally advanced cSCC

2. Documentation disease is not curable by surgery or radiation.

3. Keytruda or Keytruda Qlex will be used as a single agent.

4. Maximum treatment duration: 24 months

S. Triple-Negative Breast Cancer (TNBC) and meets criteria 1 or 2:

1. High-risk early-stage TNBC

- a) Keytruda or Keytruda Qlex will be used in combination with chemotherapy as neoadjuvant treatment followed by adjuvant treatment with Keytruda or Keytruda Qlex as a single agent
- b) Maximum treatment duration (neoadjuvant treatment): up to 24 weeks
- c) Maximum treatment duration (adjuvant treatment): up to 27 weeks
- 2. Locally recurrent unresectable or metastatic TNBC
 - a) Documentation that tumor has expression of Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to ten
 - b) Keytruda or Keytruda Qlex will be used in combination with chemotherapy
 - c) Maximum treatment duration: 24 months
- T. Malignant pleural mesothelioma (MPM)
 - 1. Documentation that Keytruda or Keytruda Qlex will be used as first-line treatment.
 - 2. Documentation that disease is unresectable advanced or metastatic
 - 3. Keytruda or Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy
 - 4. Maximum treatment duration: 24 months.
- U. Ovarian Cancer
 - 1. Documentation of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma
 - 2. Documentation that tumor has expression of Programmed Death-Ligand 1 (PD-L1) Combined Positive Score (CPS) greater than or equal to one.
 - 3. Keytruda or Keytruda Qlex will be used in combination with paclitaxel, with or without bevacizumab
 - 4. Documentation of platinum-resistant disease
 - 5. Documentation of at least one prior systemic treatment regimen
 - 6. Maximum treatment duration: 24 months
- II. Minimum age requirement: 18 years old or older unless otherwise specified in criteria.
- III. Treatment is prescribed by or in consultation with an oncologist or a hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

See each indication for appropriate treatment duration and minimum age requirement.

- Keytruda adult dose:
 - 200 mg every 3 weeks or 400 mg every 6 weeks
- Keytruda pediatric dose:
 - 2mg/kg (maximum dose 200 mg) every 3 weeks
- Keytruda Qlex adult patients and pediatric patients 12 years of age and older weighing 40 kg or more:
 - 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks
 - The recommended dosage has not been established in pediatric patients 12 years old and older who weigh 40 kg or less

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

REFERENCES

1. Keytruda. Prescribing information. Merck & Co Inc. 2026. Accessed April 20, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2026/125514s195lbl.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Melanoma: Cutaneous. Version 2.2026. Updated April 17, 2026. Accessed April 20, 2026. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell lung Cancer. Version 5.2026. Updated March 13, 2026. Accessed April 20, 2026. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.

4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Head and Neck Cancers Version 1.2026. Updated December 8, 2025. Accessed April 20, 2026. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hodgkin Lymphoma. Version 1.2026. Updated October 22, 2025. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Hodgkin Lymphoma. Version 2.2025. Updated June 5, 2025. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/ped_hodgkin.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 1.2026. Updated March 16, 2026. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/bladder.pdf
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Colon Cancer. Version 2.2026. Updated April 7, 2026. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/colon.pdf
9. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Esophageal and Esophagogastric Junction Cancers. Version 2.2026. Updated January 21, 2026. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf
10. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Gastric Cancer. Version 2.2026. Updated January 21, 2026. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/gastric.pdf
11. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Cervical Cancer. Version 2.2026. Updated November 10, 2025. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/cervical.pdf
12. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hepatocellular Carcinoma. Version 1.2026. Updated March 10, 2026. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/hcc.pdf
13. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Biliary Tract Cancers. Version 1.2026. Updated March 10, 2026. Accessed April 20, 2026. www.nccn.org/professionals/physician_gls/pdf/btc.pdf

14. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Merkel Cell Carcinoma. Version 2.2026. Updated October 24, 2025. Accessed April 20, 2026.
www.nccn.org/professionals/physician_gls/pdf/mcc.pdf
15. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Kidney Cancer. Version 2.2026. Updated April 14, 2026. Accessed April 20, 2026.
www.nccn.org/professionals/physician_gls/pdf/kidney.pdf
16. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 2.2026. Updated November 14, 2025. Accessed April 20, 2026.
www.nccn.org/professionals/physician_gls/pdf/uterine.pdf
17. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 2.2026. Updated February 27, 2026. Accessed April 20, 2026.
www.nccn.org/professionals/physician_gls/pdf/breast.pdf
18. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Mesothelioma: Peritoneal. Version 2.2026. Updated October 3, 2025. Accessed April 20, 2026.
www.nccn.org/professionals/physician_gls/pdf/meso_peritoneal.pdf
19. Keytruda QLEX. Prescribing information. Merck & Co Inc. 2026. Accessed April 20, 2026.
www.accessdata.fda.gov/drugsatfda_docs/label/2026/761467s013lbl.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.