Reference number(s)
1889-A

Specialty Guideline Management Keytruda

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Keytruda	pembrolizumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Melanoma

- Keytruda (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma.
- Keytruda is indicated for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC, or III melanoma following complete resection.

Non-Small Cell Lung Cancer

- Keytruda, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
- Keytruda, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of patients with metastatic squamous NSCLC.

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- Keytruda, as a single agent, is indicated for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and is:
    - stage III where patients are not candidates for surgical resection or definitive chemoradiation, or
    - metastatic.
- Keytruda, as a single agent, is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA approved 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.
- Keytruda, in combination with platinum-containing chemotherapy, is indicated for the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- Keytruda, as a single agent, is indicated for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage 1B (T2a ≥ 4cm), II, or IIIA NSCLC.

Malignant Pleural Mesothelioma

Keytruda, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).

Head and Neck Squamous Cell Cancer

- Keytruda is 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-approved 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, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).
- Keytruda, as a single agent, is indicated for the first line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test.
- Keytruda, as a single agent, is indicated for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

Classical Hodgkin Lymphoma

- Keytruda is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL).
- Keytruda is indicated for the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more prior lines of therapy.

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Primary Mediastinal Large B-cell Lymphoma

Keytruda is indicated for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after 2 or more prior lines of therapy.

Limitations of Use

Keytruda is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.

Urothelial Carcinoma

- Keytruda, in combination with enfortumab vedotin, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer.
- Keytruda, as a single agent, is indicated for the treatment of 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.
- Keytruda, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC).
- Keytruda, as a single agent, is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Microsatellite Instability-High Cancer or Mismatch Repair Deficient Cancer

Keytruda is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer (CRC)

Keytruda is indicated for the treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-approved test.

Gastric Cancer

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

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HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.

Esophageal Cancer

Keytruda is indicated for the treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (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-approved test.

Cervical Cancer

- Keytruda in combination with chemotherapy, with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
- Keytruda, as a single agent, is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumor express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.
- Keytruda, in combination with chemoradiotherapy (CRT), is indicated for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer.

Hepatocellular Carcinoma

Keytruda is indicated for the treatment of patients with hepatocellular carcinoma (HCC) secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1- containing regimen.

Biliary Tract Cancer

Keytruda, in combination with gemcitabine and cisplatin is indicated for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC).

Merkel Cell Carcinoma

Keytruda is indicated for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC).

Renal Cell Carcinoma

- Keytruda, in combination with axitinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).
- Keytruda, in combination with lenvatinib, is indicated for the first-line treatment of adult patients with advanced RCC.
- Keytruda is indicated for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

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Endometrial Carcinoma

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

Tumor Mutational Burden-High Cancer

Keytruda is indicated for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

Limitations of use

The safety and effectiveness of Keytruda in pediatric patients with TMB-H central nervous system cancers have not been established.

Cutaneous Squamous Cell Carcinoma

Keytruda is indicated for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC that is not curable by surgery or radiation.

Triple-Negative Breast Cancer

- Keytruda is indicated for the treatment of patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- Keytruda, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by an FDA approved test.

Adult Classical Hodgkin Lymphoma and Adult Primary Mediastinal Large B-Cell Lymphoma

Additional Dosing Regimen of 400mg Every 6 Weeks.

Keytruda is indicated for use at an additional recommended dosage of 400mg every 6 weeks for classical Hodgkin lymphoma and primary mediastinal large B-cell lymphoma in adults.

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Ovarian Cancer

Keytruda, in combination with paclitaxel, with or without bevacizumab, is indicated 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 one or two prior systemic treatment regimens.

Compendial Uses[2]

- Cutaneous Melanoma
- Non-Small Cell Lung Cancer
- Head And Neck Cancer
- Classical Hodgkin Lymphoma
- Urothelial Carcinoma
    - Bladder Cancer
    - Primary Carcinoma of the Urethra
    - Upper Genitourinary Tract Tumors
    - Urothelial Carcinoma of the Prostate
- Anaplastic Thyroid Carcinoma
- Follicular, Oncocytic (Hürthle Cell), or Papillary Thyroid Carcinoma
- Colorectal Cancer
- Small Bowel Adenocarcinoma
- Gastric Cancer
- Esophageal Cancer and Esophagogastric Junction Cancer
- Cervical Cancer
- Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
- Uveal Melanoma
- Endometrial Carcinoma
- Anal carcinoma
- Central Nervous System (CNS) Brain Metastases
- Primary Mediastinal Large B-Cell Lymphoma
- Pancreatic Adenocarcinoma
- Biliary Tract Cancers
- Hepatocellular Carcinoma
- Vulvar Cancer
- Renal Cell Carcinoma
- Thymic Carcinoma
- Primary Cutaneous Lymphomas
    - Mycosis Fungoides/Sezary Syndrome
    - Anaplastic Large Cell Lymphoma (ALCL)
- Extranodal NK/T-cell lymphoma
- Gestational Trophoblastic Neoplasia
- Neuroendocrine and Adrenal Tumors

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    - Well Differentiated Grade 3 Tumors
    - Adrenal Gland Tumors
    - Extrapulmonary Poorly Differentiated/Large or Small Cell Carcinoma
    - Adrenocortical carcinoma
- Soft Tissue Sarcomas
    - Alveolar Soft Part Sarcoma (ASPS)
    - Cutaneous Angiosarcoma
    - Extremity/Body Wall Sarcoma
    - Head/Neck Sarcoma
    - Retroperitoneal/Intra-Abdominal Sarcoma
    - Rhabdomyosarcoma
    - Dedifferentiated Liposarcoma
    - Epithelioid Hemangioendothelioma
    - Borderline/Malignant Phyllodes Tumor of the Breast
- Occult Primary Cancer
- Prostate Cancer
- Bone Cancer
    - Chondrosarcoma
    - Chordoma
    - Ewing Sarcoma
    - Osteosarcoma
- Breast Cancer
- Salivary Gland Tumors
- Merkel Cell Carcinoma
- Penile Cancer
- Uterine Sarcoma
- Small Cell Lung Cancer
- Ampullary Adenocarcinoma
- Pediatric Diffuse High-Grade Gliomas
- Cutaneous Squamous Cell Skin Carcinoma
- Nasopharyngeal Cancer
- Kaposi Sarcoma
- Vaginal Cancer
- Pleural or Peritoneal Mesothelioma
- Histologic (Richter) Transformation to Diffuse Large B-Cell Lymphoma
- Malignant Histiocytic Neoplasms

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

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- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
- Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumor status with tumor mutational burden, where applicable.
- Documentation of laboratory report confirming high tumor mutational burden (≥10 mutations/megabase [mut/Mb]), where applicable.
- Documentation of laboratory report confirming that the cancer cells status for the following receptors, where applicable:
    - Human epidermal growth factor receptor 2 (HER-2)
    - Estrogen
    - Progesterone
- Documentation of the absence of EGFR exon 19 deletions, exon 21 L858R mutations and ALK, RET and ROS1 gene fusions, where applicable.
- Documentation of laboratory results confirming hormone receptor (HR), where applicable.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Pediatric members with TMB-H central nervous system cancers.
- Members who have experienced disease progression while on programmed death receptor-1 (PD-1) or PD-L1 inhibitor therapy (other than when used for metastatic or unresectable melanoma in combination with ipilimumab or lenvatinib as subsequent therapy or in combination with trametinib/dabrafenib for re-induction).

Coverage Criteria

Cutaneous Melanoma[1,2]

Authorization of 6 months may be granted for treatment of cutaneous melanoma in any of the following settings:

- For unresectable or metastatic disease as a single agent.
- As subsequent therapy for metastatic or unresectable disease, in combination with ipilimumab or lenvatinib.
- As neoadjuvant treatment as a single agent.
- As adjuvant treatment following complete lymph node resection or complete resection of stage IIB, IIC, III, or metastatic disease as a single agent.
- As subsequent or re-induction therapy in combination with trametinib and dabrafenib for metastatic or unresectable disease with a BRAF V600 activating mutation.

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Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 6 months may be granted:

- For treatment of recurrent, advanced, or metastatic NSCLC when there are no EGFR exon 19 deletions or exon 21 L858R mutations, or ALK, RET or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue) and any of the following criteria are met:
    - The requested medication will be used as a single agent for PD-L1 positive disease.
    - The requested medication will be used as single agent or in combination with pemetrexed for maintenance therapy.
    - The requested medication will be used in combination with pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology.
    - The requested medication will be used in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous cell histology.
- As neoadjuvant treatment when used in combination with platinum containing chemotherapy for resectable (tumors ≥4 cm or node positive) NSCLC when there are no EGFR exon 19 deletions or exon 21 L858R mutations, or ALK, RET or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue).
- As adjuvant therapy as a single agent after adjuvant chemotherapy or after neoadjuvant therapy with the requested medication plus chemotherapy when there are no EGFR exon 19 deletions or exon 21 L858R mutations, or ALK, RET or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue).

Head and Neck Cancer[1,2]

Authorization of 6 months may be granted for resectable stage III-IVa non-nasopharyngeal head and neck squamous cell carcinoma when PD-L1 ≥ 1 and the requested medication will be used 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.

Authorization of 6 months may be granted for treatment of members with very advanced head and neck squamous cell carcinoma and mixed subtypes (HNSCC) or nasopharyngeal cancer when any of the following criteria is met:

- The requested medication will be used as a single agent for first-line treatment in members whose tumors express PD-L1 (CPS ≥1), are microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [≥ 10 mut/Mb].
- The requested medication will be used as a single agent for subsequent therapy.
- The requested medication will be used in combination with cetuximab or chemotherapy.

Authorization of 6 months may be granted for treatment of MSI-H, dMMR, TMB-H (≥ 10 mut/Mb), or PD-L1 positive recurrent salivary gland tumors as a single agent.

Classic Hodgkin Lymphoma[1,2]

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Authorization of 6 months may be granted for treatment of relapsed or refractory classic Hodgkin lymphoma in any of the following regimens:

- As a single agent
- In combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin)
- In combination with ICE (ifosfamide, carboplatin, etoposide)
- In combination with decitabine or vorinostat if refractory to at least 3 prior lines of therapy

Urothelial Carcinoma[1,2]

Authorization of 6 months may be granted as a single agent for treatment of urothelial carcinoma when used in any of the following subtypes:

- Urothelial carcinoma of the bladder in any of the following settings:
  - First line therapy for stage II, recurrent, locally advanced or metastatic disease
  - Subsequent therapy for stage II, recurrent, locally advanced or metastatic disease
  - Adjuvant therapy
  - For the treatment of members with high risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) when disease is Bacillus Calmette Guerin (BCG) unresponsive, and member will not undergo cystectomy
- Primary carcinoma of the urethra in any of the following settings:
  - Locally advanced, recurrent or metastatic disease for members who are not eligible for any platinum-containing chemotherapy
  - Recurrent or metastatic disease post-platinum or other chemotherapy
  - Adjuvant therapy
- Urothelial carcinoma of the upper genitourinary tract in any of the following settings:
  - Metastatic disease for members who are not eligible for any platinum-containing chemotherapy
  - Metastatic disease post-platinum or other chemotherapy
  - Adjuvant therapy if platinum-based neoadjuvant chemotherapy was given
- Urothelial carcinoma of the prostate in any of the following settings:
  - Metastatic disease for members who are not eligible for any platinum-containing chemotherapy
  - Metastatic disease post-platinum or other chemotherapy
  - Adjuvant therapy if platinum-based neoadjuvant chemotherapy was not given

Authorization of 6 months may be granted in combination with enfortumab vedotin-ejfv for treatment of stage II, recurrent, locally advanced or metastatic urothelial carcinoma.

Solid Tumors[1]

Authorization of 6 months may be granted as a single agent for treatment of solid tumors in members with unresectable or metastatic disease that has progressed following prior treatment and who have no satisfactory alternative treatment options when either of the following criteria is met:

- The requested medication will be used for microsatellite instability-high or mismatch repair deficient solid tumors.

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- The requested medication will be used for tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) solid tumors.

Anaplastic Thyroid Carcinoma[2]

Authorization of 6 months may be granted as a single agent or in combination with lenvatinib (Lenvima) for treatment of stage IVC anaplastic thyroid carcinoma.

Follicular, Oncocytic (Hürthle Cell), or Papillary Thyroid Carcinoma[2]

Authorization of 6 months may be granted for treatment of follicular, oncocytic (Hürthle cell), or papillary thyroid carcinoma when all of the following criteria are met:

- The disease is locoregional, unresectable, progressive and/or symptomatic, or metastatic.
- Radioactive iodine (RAI) therapy is not indicated, contraindicated, or has been unsuccessful.
- Member meets either of the following criteria:
    - The disease is microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) (TMB-H)
    - The member experienced disease progression on single agent lenvatinib and the requested medication will be used in combination with lenvatinib

Colorectal Cancer[1,2]

Authorization of 6 months may be granted as a single agent for treatment of colorectal cancer, including appendiceal neoplasms and carcinoma, for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (TMB > 50 mut/Mb).

Small Bowel Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for neoadjuvant therapy for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (TMB > 50 mut/Mb).

Authorization of 6 months may be granted as a single agent for the treatment of unresectable or medically inoperable small bowel adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (TMB > 50 mut/Mb).

Authorization of 6 months may be granted as a single agent for the treatment of advanced or metastatic small bowel adenocarcinoma for tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb)) or microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (TMB > 50 mut/Mb).

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Merkel Cell Carcinoma[1,2]

Authorization of 6 months may be granted as a single agent for treatment of Merkel cell carcinoma in members with locally advanced, regional, recurrent or metastatic disease.

Gastric Cancer[1,2]

Authorization of 6 months may be granted:

- For treatment of gastric adenocarcinoma in members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease when any of the following criteria is met:
    - The requested medication will be used as subsequent therapy as a single agent for microsatellite instability-high (MSI-H), or deficient mismatch repair (dMMR), or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb)) tumors.
    - The requested medication will be used as first line therapy as a single agent or in combination with chemotherapy for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
    - The requested medication will be used as first-line therapy in combination with trastuzumab and chemotherapy for HER2 overexpression positive disease with PD-L1 ≥ 1.
    - The requested medication will be used as first-line therapy in combination with chemotherapy for the first-line treatment of HER2-negative disease with PD-L1 ≥ 1.
- For treatment of gastric adenocarcinoma in members who are medically fit for surgery when any of the following criteria are met:
    - The requested medication will be used as a single agent or in combination with chemotherapy to treat microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
    - The requested medication will be used as primary treatment in combination with trastuzumab and chemotherapy for surgically unresectable locoregional disease that is HER2 overexpression positive and PD-L1 ≥ 1.
    - The requested medication will be used as primary treatment in combination with chemotherapy for surgically unresectable locoregional disease that is HER2 overexpression negative with PD-L1 tumor expression by CPS ≥ 1.

Esophageal Cancer and Esophagogastric Junction (EGJ) Cancer[1,2]

Authorization of 6 months may be granted:

- In combination with platinum and fluoropyrimidine-based chemotherapy for treatment of esophageal and EGJ cancer with PD-L1 tumor expression by CPS ≥ 1 in members who are surgical candidates.
- As a single agent or in combination with platinum and fluoropyrimidine-based chemotherapy for treatment of esophageal and EGJ cancer in members who are surgical candidates when the

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requested medication will be used to treat microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.

- For treatment of esophageal cancer (including EGJ cancer) in members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease when any of the following criteria is met:
    - The requested medication will be used as subsequent therapy as a single agent for microsatellite instability-high (MSI-H), deficient mismatch repair (dMMR) or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb)) tumors.
    - The requested medication will be used as first line therapy as a single agent or in combination with platinum and fluoropyrimidine- based chemotherapy for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
    - The requested medication will be used as single agent subsequent therapy for squamous cell carcinoma with PD-L1 tumor expression by CPS ≥ 10.
    - The requested medication will be used as first-line therapy in combination with platinum and fluoropyrimidine-based chemotherapy for squamous cell carcinoma or HER2 overexpression negative adenocarcinoma with PD-L1 tumor expression by CPS ≥ 1.
    - The requested medication will be used as first-line therapy in combination with trastuzumab and platinum and fluoropyrimidine-based chemotherapy for HER2 overexpression positive adenocarcinoma with PD-L1 tumor expression by CPS ≥ 1.

Cervical Cancer[1,2]

Authorization of 6 months may be granted for the treatment of cervical cancer in any of the following settings:

- Persistent, recurrent or metastatic disease in combination with chemotherapy with or without bevacizumab in members whose tumors express PD-L1 (CPS ≥1).
- Recurrent or metastatic disease as single agent or in combination with tisotumab vedotin-tftv subsequent therapy in members whose tumors express PD-L1 (CPS ≥1) or are microsatellite instability-high or mismatch repair deficient
- FIGO stage III-IVA disease in combination with chemoradiation.

Epithelial Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer[1,2]

Authorization of 6 months may be granted:

- As a single agent for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma, or malignant germ cell tumors for recurrent or persistent microsatellite instability-high or mismatch repair deficient tumors or tumor mutational burden-high (TMB-H) (tumors ≥10 mutations/megabase [mut/Mb]).

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- In combination with oral cyclophosphamide and bevacizumab for treatment of recurrent or persistent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma.
- As subsequent treatment for platinum-resistant or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), mucinous neoplasms of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma, when the requested agent is used in combination with paclitaxel, with or without bevacizumab and the tumor is PD-L1 positive (CPS ≥1)
- As a single agent for progressive or recurrent small cell carcinoma of the ovary (hypercalcemic type)

Uveal Melanoma[2]

Authorization of 6 months may be granted as a single agent for treatment of unresectable or metastatic uveal melanoma.

Endometrial Carcinoma[1,2,3]

Authorization of 6 months may be granted:

- In combination with lenvatinib for treatment of advanced, metastatic or recurrent endometrial carcinoma when either of the following criteria are met:
  - The disease is mismatch repair proficient (pMMR)
  - The disease is mismatch repair deficient (dMMR) and has progressed following prior platinum-based chemotherapy
- As a single agent for treatment of endometrial carcinoma in members with recurrent unresectable or metastatic microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb] tumors.
- For treatment of endometrial carcinoma in combination with carboplatin and paclitaxel and continued as single agent maintenance therapy (for up to 20 cycles total) in members with stage III-IV or recurrent disease.

Anal Carcinoma[2]

Authorization of 6 months may be granted for the treatment of anal carcinoma when the requested medication will be used in either of the following settings:

- In combination with paclitaxel and carboplatin for treatment of recurrent or metastatic disease.
- As a single agent for subsequent treatment of metastatic disease.

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CNS Brain Metastases[2]

Authorization of 6 months may be granted as a single agent for treatment of CNS brain metastases in members with BRAF non-specific melanoma or PD-L1 positive non-small cell lung cancer.

Primary Mediastinal Large B-Cell Lymphoma[1,2]

Authorization of 6 months may be granted as a single agent or in combination with brentuximab vedotin for treatment of primary mediastinal large B-cell lymphoma in members with relapsed or refractory disease.

Pancreatic Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of recurrent, locally advanced or metastatic pancreatic adenocarcinoma in members with microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb] tumors.

Biliary Tract Cancers[1,2]

Authorization of 6 months may be granted:

- In combination with gemcitabine and cisplatin or carboplatin for unresectable, gross residual (R2) disease or metastatic biliary tract cancers.
- As a single agent for unresectable, gross residual (R2) disease, or metastatic biliary tract cancers, including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer that is microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb].
- For neoadjuvant treatment of resectable locoregionally advanced gallbladder cancer when either of the following criteria are met:
    - The requested medication will be used in combination with cisplatin or carboplatin and gemcitabine.
    - The requested medication will be used as a single agent and member has microsatellite instability-high (MSI-H) and/or mismatch repair deficient (dMMR) tumors.

Hepatocellular Carcinoma[1,2]

Authorization of 6 months may be granted for treatment of hepatocellular carcinoma when any of the following criteria is met:

- The member has disease secondary to hepatitis B and has received prior systemic therapy other than a PD-1/PD-L1- containing regimen and will use the requested medication as a single agent.
- The requested medication will be used as single agent subsequent therapy.

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Vulvar Cancer[2]

Authorization of 6 months may be granted for treatment of advanced, recurrent or metastatic vulvar cancer when any of the following criteria is met:

- The requested medication will be used as single agent subsequent therapy
- The requested medication will be used in combination with chemotherapy with or without bevacizumab.

Renal Cell Carcinoma[1,2,4]

Authorization of 6 months may be granted for treatment of renal cell carcinoma (RCC) when any of the following criteria are met:

- The requested medication will be used as first-line treatment as a single agent or in combination with axitinib for advanced, relapsed or stage IV disease.
- The requested medication will be used as subsequent therapy in combination with axitinib for relapsed or stage IV disease with clear cell histology.
- The requested medication will be used in combination with lenvatinib for advanced, relapsed or stage IV disease
- The requested medication will be used as a single agent for relapsed or stage IV disease with non-clear cell histology.
- The requested medication will be used as a single agent for the adjuvant treatment of members with RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Thymic Carcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of thymic carcinoma for recurrent, unresectable, advanced, or metastatic disease, or as postoperative therapy in members who cannot tolerate first-line combination regimens.

Primary Cutaneous Lymphomas[2]

Authorization of 6 months may be granted for treatment of primary cutaneous lymphomas when either of the following is met:

- Member has a diagnosis of mycosis fungoides/Sezary syndrome.
- Member has a diagnosis of relapsed or refractory anaplastic large cell lymphoma (ALCL) and the requested medication will be used as a single agent.

Extranodal NK/T-cell Lymphoma[2]

Authorization of 6 months may be granted for treatment of extranodal NK/T-cell lymphoma, in members with relapsed or refractory disease.

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Gestational Trophoblastic Neoplasia[2]

Authorization of 6 months may be granted as a single agent for treatment of gestational trophoblastic neoplasia for multi-agent chemotherapy-resistant disease when either of the following criteria is met:

- Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor).
- Member has high-risk disease.

Neuroendocrine and Adrenal Tumors[2]

Authorization of 6 months may be granted for treatment of unresectable, locally advanced or metastatic neuroendocrine and adrenal tumors.

Cutaneous Squamous Cell Skin Carcinoma[1,2]

Authorization of 6 months may be granted as a single agent for treatment of cutaneous squamous cell carcinoma when both of the following criteria are met:

- Disease is locally advanced, recurrent, metastatic, or with satellitosis/in-transit metastasis.
- Curative radiation therapy or surgery is not feasible.

Soft Tissue Sarcoma[2]

Authorization of 6 months may be granted for treatment of the following types of soft tissue sarcoma when any of the following criteria is met:

- The requested medication will be used as a single agent or in combination with axitinib (Inlyta) for the treatment of alveolar soft part sarcoma (ASPS).
- The requested medication will be used as a single agent for the treatment of cutaneous angiosarcoma or dedifferentiated liposarcoma.
- The requested medication will be used as a single agent for the subsequent treatment of advanced/metastatic extremity/body wall sarcoma, head/neck sarcoma, or pleomorphic rhabdomyosarcoma.
- The requested medication will be used as a single agent for the subsequent treatment of unresectable, progressive, or stage IV retroperitoneal/intra-abdominal sarcoma.
- The requested medication will be used as neoadjuvant therapy in combination with radiation therapy, followed by single agent adjuvant therapy, for undifferentiated pleomorphic sarcoma (UPS) related sarcomas.

Occult Primary Cancer[2]

Authorization of 6 months may be granted as a single agent for treatment of occult primary cancer in members with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase (mut/Mb) tumors).

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Breast Cancer[1,2]

- Authorization of 6 months may be granted for treatment in members with no response to preoperative systemic therapy or for recurrent unresectable or metastatic triple-negative breast cancer (TNBC) when all of the following criteria are met:
    - The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
        - Human epidermal growth factor receptor 2 (HER-2)
        - Estrogen
        - Progesterone
    - Tumor must express PD-L1 (CPS ≥10).
    - The requested medication will be used in combination with sacituzumab govitecan-hziy (Trodelvy) or chemotherapy.
- Authorization of 6 months may be granted for treatment of locally advanced or high-risk triple-negative breast cancer (TNBC) when all of the following criteria are met:
    - The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
        - Human epidermal growth factor receptor 2 (HER-2)
        - Estrogen
        - Progesterone
    - The requested medication will be used as either:
        - Neoadjuvant treatment in combination with chemotherapy; or
        - Continued adjuvant treatment after surgery, as a single agent.
- Authorization of 6 months may be granted for treatment as a single agent in members with no response to preoperative systemic therapy or for recurrent unresectable or metastatic breast cancer when both of the following criteria are met:
    - Disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H ≥ 10 mut/Mb) tumors.
    - The requested medication will be used as either:
        - subsequent therapy for hormone receptor positive and human epidermal growth factor receptor 2 (HER2)-negative disease and both of the following are met:
            - member has experienced a visceral crisis or is endocrine therapy refractory
            - member is not a candidate for fam-trastuzumab deruxtecan-nxki (Enhertu)
        - fourth-line or beyond for HER2-positive disease

Prostate Cancer[2]

Authorization of 6 months may be granted as a single agent for treatment of castration-resistant distant metastatic prostate cancer in members with tumor mutational burden (TMB) ≥10 mutations/megabase tumors.

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Small Cell Lung Cancer[2]

Authorization of 6 months may be granted as a single agent for subsequent therapy of relapsed or progressive small cell lung cancer.

Pediatric Diffuse High-Grade Gliomas[2]

Authorization of 6 months may be granted as adjuvant treatment for hypermutant tumor pediatric diffuse high-grade glioma or for recurrent or progressive disease.

Ampullary Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H ≥ 10 mut/Mb) ampullary adenocarcinoma.

Kaposi Sarcoma[2]

Authorization of 6 months may be granted as a single agent for subsequent treatment of relapsed/refractory advanced Kaposi Sarcoma.

Vaginal Cancer[2]

Authorization of 6 months may be granted for treatment of vaginal cancer when any of the following criteria is met:

- The requested medication will be used in combination with cisplatin or carboplatin, paclitaxel, and with or without bevacizumab for recurrent or metastatic PD-L1 positive (CPS ≥1) disease.
- The requested medication will be used as single agent subsequent treatment for recurrent or metastatic disease that is PD-L1 positive or disease with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) tumors.

Pleural or Peritoneal Mesothelioma[1,2]

Authorization of 6 months may be granted for first-line treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, when used in combination with pemetrexed and platinum chemotherapy.

Histologic (Richter) Transformation to Diffuse Large B-Cell Lymphoma[2]

Authorization of 6 months may be granted for treatment of Histologic (Richter) transformation to diffuse large B-cell lymphoma as a single agent or in combination with ibrutinib.

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Penile Cancer[2]

Authorization of 6 months may be granted for the treatment of penile cancer when either of the following criteria are met:

- The requested medication will be used as first-line therapy in combination with fluorouracil and either cisplatin or carboplatin followed by single agent maintenance therapy for recurrent or metastatic disease.
- The requested medication will be used as single agent subsequent therapy for unresectable or metastatic disease with microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H ≥ 10 mut/Mb) tumors.

Chordoma[2]

Authorization of 6 months may be granted for the treatment of recurrent conventional chordoma as a single agent.

Malignant Histiocytic Neoplasms[2]

Authorization of 6 months may be granted for the treatment of malignant histiocytic neoplasms as a single agent.

Continuation of Therapy

Adjuvant Treatment of Melanoma, HNSCC, TNBC, RCC, or NSCLC

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for adjuvant treatment of cutaneous melanoma, HNSCC, TNBC, RCC or NSCLC who have not experienced disease recurrence or an unacceptable toxicity.

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NSCLC, HNSCC, cHL, PMBCL, MSI-H or dMMR Cancers, Gastric Cancer, Esophageal Cancer and Esophagogastric Junction (EGJ) Cancer, Cervical Cancer, HCC, MCC, RCC, Endometrial Carcinoma, cSCC, TNBC, TMB-H Cancer, Biliary Tract Cancer, Pleural or Peritoneal Mesothelioma, Histologic (Richter) Transformation to Diffuse Large B-Cell Lymphoma, Penile Cancer, Chordoma, Anaplastic, Follicular, Oncocytic (Hürthle Cell), or Papillary Thyroid Carcinoma, Neuroendocrine or Adrenal Tumors, Uveal Melanoma, Vaginal Cancer, CNS Brain Metastases, Vulvar Cancer, Thymic Carcinoma, Primary Cutaneous Lymphomas, Extranodal NK/T-cell Lymphoma, Gestational Trophoblastic Neoplasia, Small Cell Lung Cancer or Anal Carcinoma

Authorization of 6 months may be granted (up to 24 months of continuous use) for continued treatment in members requesting reauthorization for NSCLC, HNSCC, cHL, PMBCL, MSI-H or dMMR cancers, gastric cancer, esophageal cancer and esophagogastric junction (EGJ) cancer, cervical cancer, HCC, MCC, RCC, endometrial carcinoma, cSCC, TNBC,TMB-H cancer, biliary tract cancers, pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma subtypes, Histologic (Richter) transformation to diffuse large B-cell lymphoma, penile cancer, chordoma, anaplastic follicular, oncocytic (Hürthle Cell), or papillary thyroid carcinoma, neuroendocrine or adrenal tumors, uveal melanoma, vaginal cancer, CNS brain metastases, vulvar cancer, thymic carcinoma, primary cutaneous lymphomas, extranodal NK/T-cell lymphoma, small cell lung and anal carcinoma cancer who have not experienced disease progression or unacceptable toxicity.

Kaposi Sarcoma

Authorization of 6 months may be granted (up to 6 months total) for continued treatment in members requesting reauthorization for adjuvant treatment of Kaposi sarcoma who have not experienced disease recurrence or an unacceptable toxicity.

Soft Tissue Sarcoma

Authorization of 6 months may be granted:

- For continued treatment in members requesting reauthorization for alveolar soft part sarcoma (ASPS) in combination with axitinib (Inlyta), for up to 26 months total who have not experienced disease progression or an unacceptable toxicity.
- For continued treatment in members requesting reauthorization for soft tissue sarcoma as a single agent for up to 24 months total who have not experienced disease progression or an unacceptable toxicity.

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Cutaneous Melanoma

Authorization of 6 months may be granted:

- Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for adjuvant treatment of cutaneous melanoma who have not experienced disease recurrence or unacceptable toxicity.
- For continued treatment in members requesting reauthorization for metastatic or unresectable cutaneous melanoma when the requested medication will be used in combination with lenvatinib who have not experienced disease progression or an unacceptable toxicity.
- Up to 24 months of continuous use, for continued treatment in members requesting reauthorization for cutaneous melanoma when the member has not experienced disease progression or unacceptable toxicity.

Urothelial Carcinoma

Authorization of 6 months may be granted:

- Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for adjuvant treatment of urothelial carcinoma who have not experienced disease recurrence or unacceptable toxicity.
- For continued treatment in members requesting reauthorization for urothelial carcinoma when the requested medication is used in combination with enfortumab vedotin-ejfv who have not experienced disease progression or an unacceptable toxicity.
- Up to 24 months of continuous use, for continued treatment in members requesting reauthorization for urothelial carcinoma when the member has not experienced disease progression or unacceptable toxicity.

All Other Indications

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who have not experienced disease progression or an unacceptable toxicity.

References

1. Keytruda [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2026.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed May 15, 2026.
3. Makker V, Colombo N, Casado Herraez A, et al: Lenvatinib plus Pembrolizumab for Advanced Endometrial Cancer. N Engl J Med 2022; 386(5):437-448.
4. Pembrolizumab. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. https://online.lexi.com. Accessed May 15, 2026.

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