POLICY Document for KEYTRUDA (pembrolizumab)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 3: Oncology Clinical Policy
- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Site of Care

Site of Care Criteria
Checkpoint Inhibitors

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.

Brand Name	Generic Name	Dosage Form
Bavencio	avelumab	intravenous
Imfinzi	durvalumab	intravenous
Jemperli	dostarlimab-gxly	intravenous
Keytruda	pembrolizumab	intravenous
Libtayo	cemiplimab	intravenous
Loqtorzi	toripalimab-tpzi	intravenous
Opdivo	nivolumab	intravenous
Opdualag	nivolumab and relatlimab-rmbw	intravenous
Tecentriq	atezolizumab	intravenous
	penpulimab-kcqx	intravenous
Tevimbra	tislelizumab	intravenous

Brand Name	Generic Name	Dosage Form
Unloxcyt	cosibelimab-ipdl	intravenous
Yervoy	ipilimumab	intravenous
Zynyz	retifanlimab-dlwr	intravenous

Criteria For Approval For Administration In Outpatient Hospital Setting

This policy provides coverage for administration of a checkpoint inhibitor in an outpatient hospital setting for the initial 6 months approval and up to 45 days for renewal of therapy.

This policy provides coverage for administration of tocilizumab in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion or has experienced severe toxicity requiring continuous monitoring (e.g. Grade 2-4 bullous dermatitis, transaminitis, pneumonitis, Stevens-Johnson syndrome, acute pancreatitis, primary adrenal insufficiency aseptic meningitis, encephalitis, transverse myelitis, myocarditis, pericarditis, arrhythmias, impaired ventricular function, conduction abnormalities).
- The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
- The member has severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting.
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- The member is receiving provider administered combination chemotherapy.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of a checkpoint inhibitor does not meet the criteria for outpatient hospital infusion, coverage for a checkpoint inhibitor is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion or a severe toxicity requiring continuous monitoring
- Medical records supporting the member is medically unstable
- Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Medical records supporting the member is receiving provider administered combination therapy.
- Records supporting alternative infusion sites are greater than 30 miles from the member's home.
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

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.

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, 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.

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, 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, 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.

Keytruda, in combination with enfortumab vedotin, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer.

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 HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma.

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, 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.

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 patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-

approved test or not MSI-H, 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, 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.

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.

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.

Compendial Uses[2]

Cutaneous melanoma
Non-small cell lung cancer
Head and neck squamous cell 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
Medullary 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
Testicular cancer
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
Thymomas and 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

- 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

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

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:

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, 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 are negative for the following receptors, where applicable:
- human epidermal growth factor receptor 2 (HER-2)
- estrogen
- progesterone

Documentation of the presence of EGFR exon 19 deletions or L858R mutations or ALK rearrangements, 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 as second-line or subsequent therapy for

metastatic or unresectable melanoma in combination with ipilimumab following progression on single agent anti-PD-1 immunotherapy).

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, recurrent, or metastatic disease as a single agent.
- As subsequent therapy for disease progression of metastatic or unresectable tumors, as a single agent or in combination with ipilimumab or lenvatinib.
- 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.

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 L858R mutations or ALK rearrangements (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 first-line therapy for PDL1 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.
    - The requested medication will be used as single agent subsequent treatment of PDL1 positive disease.
- As neoadjuvant treatment when used in combination with platinum containing chemotherapy for resectable (tumors ≥4 cm or node positive) NSCLC, and then continued as single agent adjuvant therapy after surgery.
- As a single agent for adjuvant treatment following resection and platinum-based chemotherapy for stage IB (T2a ≥4 cm), II, or III NSCLC.

Head and Neck Squamous Cell Cancer[1,2]

Authorization of 6 months may be granted for treatment of members with very advanced head and neck squamous cell carcinoma with 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.

Classical Hodgkin Lymphoma[1,2,4]

Authorization of 6 months may be granted as a single agent or in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin) or ICE (ifosfamide, carboplatin, etoposide) for treatment of relapsed, refractory or progressive classical Hodgkin lymphoma.

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, locally advanced or metastatic disease in members who are not eligible for any platinum containing chemotherapy.
  - Subsequent 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 with locally advanced, recurrent or metastatic disease post-platinum or other chemotherapy or for members who are not eligible for any platinum-containing chemotherapy.
- Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate with metastatic disease post-platinum or other chemotherapy or for members who are not eligible for any platinum-containing chemotherapy.

For the treatment of stage II, recurrent, locally advanced or metastatic urothelial carcinoma in combination with enfortumab vedotin-ejfv.

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.

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 for treatment of metastatic anaplastic thyroid carcinoma for tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) tumors.
- 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 unresectable or metastatic follicular, oncocytic (hürthle cell), or papillary thyroid carcinoma for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) (TMB-H) tumors not amenable to radioactive iodine therapy.

Medullary Thyroid Carcinoma[2]

Authorization of 6 months may be granted for treatment of unresectable, recurrent, or metastatic medullary thyroid carcinoma for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) tumors.

Colorectal Cancer[1,2]

Authorization of 6 months may be granted as a single agent for the treatment of inoperable, advanced, or metastatic colorectal cancer, including appendiceal carcinoma, for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors.

Small Bowel Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of unresectable, medically inoperable, advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors.

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, recurrent or metastatic disease.

Gastric Cancer[1,2]

Authorization of 6 months may be granted:

- For treatment of gastric cancer in members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease when any of the following criteria are 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 in combination with trastuzumab and chemotherapy for HER2 overexpression positive adenocarcinoma.
- The requested medication will be used in combination with chemotherapy for the first-line treatment of HER2-negative adenocarcinoma.

- For treatment of gastric cancer in members who are surgical candidates 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 in combination with trastuzumab and chemotherapy to treat early stage or surgically unresectable locoregional disease that is HER2 overexpression positive.
  - The requested medication will be used in combination with chemotherapy to treat early stage or surgically unresectable locoregional disease that is HER2 overexpression negative with PD-L1 tumor expression by CPS ≥10.

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

Authorization of 6 months 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 ≥ 10 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 requested medication will be used to treat microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.

In combination with platinum and fluoropyrimidine-based chemotherapy and trastuzumab for treatment of esophageal and EGJ cancer in members who are surgical candidates and have HER2 overexpression positive adenocarcinoma.

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 are 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 in combination with platinum and fluoropyrimidine-based chemotherapy for squamous cell carcinoma or HER2 overexpression negative adenocarcinoma with PD-L1 tumor expression by CPS ≥10.
- The requested medication will be used in combination with trastuzumab and platinum and fluoropyrimidine-based chemotherapy for HER2 overexpression positive adenocarcinoma.

Cervical Cancer[1,2]

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

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 subsequent therapy in members whose tumors express PD-L1 (CPS ≥1) or are microsatellite instability-high or mismatch repair deficient.

Recurrent or metastatic disease and the member has experienced disease progression on or after chemotherapy for tumors that express PD-L1 (CPS ≥ 1), as a single agent.

FIGO stage III-IVA disease in combination with chemoradiotherapy (CRT).

Epithelial Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer[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 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]).

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.

Uveal Melanoma[2]

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

Testicular Cancer[2]

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

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 as a single agent for subsequent treatment of metastatic anal carcinoma.

CNS Brain Metastases[2]

Authorization of 6 months may be granted as a single agent for treatment of CNS brain metastases in members with 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 for unresectable, resected gross residual (R2) disease or metastatic biliary tract cancers.

As a single agent for unresectable, resected 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 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 are 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 member has unresectable or metastatic disease and will use the requested medication as a single agent.

Vulvar Cancer[2]

Authorization of 6 months may be granted as a single agent for subsequent treatment of advanced, recurrent or metastatic disease in members with vulvar cancer when either of the following criteria is met:

Member has microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [≥ 10 mut/Mb] tumors.

Member has experienced disease progression on or after chemotherapy and whose tumor expresses PD-L1 (CPS ≥ 1).

Renal Cell Carcinoma[1,2]

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

The requested medication will be used as first-line treatment in combination with axitinib or lenvatinib for advanced, relapsed or stage IV disease.

The requested medication will be used as subsequent therapy in combination with axitinib or lenvatinib for relapsed or stage IV disease with clear cell histology.

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.

Thymomas and Thymic Carcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of thymomas and thymic carcinoma for recurrent, unresectable, locally advanced, or metastatic disease, or as pre or postoperative therapy for residual tumor 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.

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 are 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 locally advanced, recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation.

Soft Tissue Sarcoma[2]

Authorization of 6 months may be granted for treatment of the following types of soft tissue sarcoma when either of the following criteria are 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.

The requested medication will be used as a single agent for the subsequent treatment of extremity/body wall sarcoma, head/neck sarcoma, retroperitoneal/intra-abdominal sarcoma, and rhabdomyosarcoma.

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).

Breast Cancer[1,2]

- Authorization of 6 months may be granted as a single agent in members who have recurrent unresectable or metastatic HER2-positive breast cancer when the requested medication will be used as therapy in the fourth line and beyond.
- 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.
    - The requested medication will be used as a single agent or in combination with chemotherapy.
- Authorization of 6 months may be granted for treatment of high-risk early-stage 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.

Prostate Cancer[2]

Authorization of 6 months may be granted as single agent subsequent therapy for treatment of castration-resistant distant metastatic prostate cancer in members with microsatellite instability-high, mismatch repair deficient, or tumor mutational burden (TMB) ≥10 mutations/megabase tumors.

Small Cell Lung Cancer[2]

Authorization of 6 months may be granted as a single agent for subsequent therapy of relapsed or progressive disease.

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 endemic or classic Kaposi Sarcoma.

Vaginal Cancer[2]

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

- The requested medication will be used in combination with cisplatin or carboplatin, paclitaxel, and with or without bevacizumab for recurrent or metastatic 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) tumors.
- The requested medication will be used as subsequent treatment for unresectable or metastatic tumor mutational burden-high (TMB-H ≥ 10 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.

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 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 a single agent for unresectable or metastaic disease with microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H ≥ 10 mut/Mb) tumors.

Continuation of Therapy

Adjuvant treatment of melanoma, high-risk early-stage 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, high-risk early-stage TNBC, RCC or NSCLC who have not experienced disease recurrence or an unacceptable toxicity.

NSCLC, HNSCC, cHL, PMBCL, MSI-H or dMMR Cancers, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, RCC, Endometrial carcinoma, cSCC, recurrent unresectable or metastatic TNBC, TMB-H Cancer, Biliary Tract Cancer, pleural or peritoneal mesothelioma, Histologic (Richter) transformation to diffuse large B-cell lymphoma, penile cancer

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, cervical cancer, HCC, MCC, RCC, endometrial carcinoma, cSCC, recurrent unresectable or metastatic TNBC,TMB-H, 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, and penile cancer who have not experienced disease progression or unacceptable toxicity.

Urothelial Carcinoma

Authorization of 6 months may be granted:

- 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 both of the following criteria are met:

  Member has not experienced disease progression or unacceptable toxicity.
  For high-risk BCG-unresponsive non-muscle invasive bladder cancer only: disease is not persistent or recurrent.

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.

Section 3: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

PROGRAM DESCRIPTION

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness, and efficiency of cancer care so patients can live better lives.[1] It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN Templates® are based on NCCN Guidelines® and NCCN Compendium®. The NCCN Compendium lists the appropriate drugs and biologics as treatment options for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus[2]

• Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
• Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
• Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
• Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

POLICY

Policy for Regimen Prior Authorization
A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

PROCEDURE

This policy provides coverage of a regimen review when all of the following criteria are met:
1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
- If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.

2. The prior authorization review is requested for an oncology drug or biologic.
3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:
- Ampullary Adenocarcinoma
- Anal Carcinoma
- B-Cell Lymphomas
- Basal Cell Skin Cancer
- Biliary Tract Cancers
- Bone Cancer
- Breast Cancer
- Bladder Cancer
- Central Nervous System Cancers
- Cervical Cancer
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
- Chronic Myeloid leukemia
- Colon Cancer
- Dermatofibrosarcoma Protuberans
- Esophageal Cancer
- Gastric Cancer

- Gastrointestinal Stromal Tumors
- Gestational Trophoblastic Neoplasms
- Hairy Cell Leukemia
- Head and Neck Cancers
- Histiocytic Neoplasms
- Hodgkin Lymphoma
- Hepatocellular Carcinoma
- Kaposi Sarcoma
- Kidney Cancer
- Melanoma: Cutaneous
- Melanoma: Uveal
- Merkel Cell Carcinoma
- Mesothelioma: Peritoneal
- Mesothelioma: Pleural
- Multiple Myeloma
- Myelodysplastic Syndromes
- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- Myeloproliferative Neoplasms
- Neuroendocrine and Adrenal Tumors
- Non-Small Cell Lung Cancer
- Occult Primary
- Ovarian Cancer
- Pancreatic Cancer
- Penile Cancer
- Primary Cutaneous Lymphomas
- Prostate Cancer
- Rectal Cancer
- Small Bowl Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Squamous Cell Skin Cancer
- Systemic Mastocytosis
- Systemic Light Chain Amyloidosis
- T-Cell Lymphomas
- Testicular Cancer
- Thymomas and Thymic Carcinomas
- Thyroid Carcinoma
- Uterine Neoplasms
- Vaginal Cancer
- Vulvar Cancer
- Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- Wilms Tumor (Nephroblastoma)

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Further review may be indicated when the above criteria are not met.

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy
Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

Continuation of Therapy
To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

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