POLICY Document for LIBTAYO (cemiplimab)

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
Libtayo

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
Libtayo	cemiplimab-rwlc

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.

CVS/caremark

FDA-Approved Indications[1]

Cutaneous Squamous Cell Carcinoma (CSCC)

Libtayo is indicated for the treatment of patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

Basal Cell Carcinoma (BCC)

Libtayo is indicated for the treatment of patients with locally advanced or metastatic BCC who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.

Non-Small Cell Lung Cancer (NSCLC)

Libtayo, as a single agent, is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is:

- locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
- metastatic

Libtayo, in combination with platinum-based chemotherapy, is indicated for the first-line treatment of adult patients with NSCLC with no EGFR, ALK, or ROS1 aberrations and is:

- locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
- metastatic

Compendial Uses[2]

Squamous cell skin cancer
Basal cell skin cancer
Non-small cell lung cancer
Vulvar Cancer
Cervical Cancer
Vaginal Cancer
Anal carcinoma
Small bowel adenocarcinoma
Colon adenocarcinoma
Appendiceal adenocarcinoma
Rectal adenocarcinoma

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

Exclusions

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy.

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 molecular testing for EGFR, ALK, ROS1, BRAF, NTRK, MET, or RET genomic tumor aberrations, where applicable.
Documentation of laboratory report confirming MSI-H, mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.

Coverage Criteria

Cutaneous Squamous Cell Carcinoma (CSCC) [1,2]

Authorization of 6 months may be granted as single-agent neoadjuvant treatment of very high risk, locally advanced, unresectable, or regional cutaneous squamous cell carcinoma.

Authorization of 6 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:

The disease is one of the following:
- Metastatic
- Locally advanced
- Recurrent

The member is not a candidate for curative surgery or curative radiation
The requested medication will be used as a single agent

Basal Cell Carcinoma (BCC) [1,2]

Authorization of 6 months may be granted for single-agent treatment of basal cell carcinoma in members who have received a hedgehog pathway inhibitor (e.g., vismodegib [Erivedge], sonidegib [Odomzo]) or for whom a hedgehog pathway inhibitor is not appropriate and when any of the following criteria are met:

Member has locally advanced disease
Member has nodal disease and surgery is not feasible
Member has metastatic disease

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

Authorization of 6 months may be granted for treatment of recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) when any of the following criteria are met:

- The requested medication will be used as first-line therapy and the tumor does not have EGFR exon 19 deletions or L858R mutations, ALK rearrangements, or ROS1 aberrations (unless testing is not feasible due to insufficient tissue) as either:
  - A single agent for tumors with a high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%], or
  - In combination with platinum-based chemotherapy
- The requested medication will be used as maintenance therapy following first-line cemiplimab-rwlc therapy and the tumor does not have EGFR exon 19 deletions or L858R mutations, ALK rearrangements, or ROS1 aberrations (unless testing is not feasible due to insufficient tissue) as either:
  - A single agent, or
  - In combination with pemetrexed
- The requested medication will be used as subsequent therapy in combination with platinum-based chemotherapy.

Vulvar Cancer[2]

Authorization of 6 months may be granted as subsequent therapy for advanced or recurrent/metastatic vulvar cancer when the requested medication will be used as a single agent.

Cervical Cancer[2]

Authorization of 6 months may be granted as subsequent therapy for recurrent or metastatic cervical cancer when the requested medication will be used as a single agent.

Vaginal Cancer[2]

Authorization of 6 months may be granted as subsequent therapy for recurrent or metastatic vaginal cancer when the requested medication will be used as a single agent.

Anal Carcinoma[2]

Authorization of 6 months may be granted as subsequent therapy for metastatic anal carcinoma when the requested medication will be used as a single agent.

Small Bowel Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of either of the following:

- Advanced or metastatic small bowel adenocarcinoma with microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors

- Locally unresectable or medically inoperable small bowel adenocarcinoma with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors

Colon Cancer[2]

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

Appendiceal Cancer[2]

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

Rectal Cancer[2]

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

Continuation of Therapy

Basal Cell Carcinoma or Cutaneous Squamous Cell Carcinoma

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for treatment of basal cell carcinoma or cutaneous squamous cell carcinoma who have not experienced disease progression or an unacceptable toxicity.

All other indications

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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.

REFERENCES:

SECTION 1

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12. Tevimbra [prescribing information]. San Mateo, CA: BeiGene USA, Inc.; March 2025.
13. Unloxcyt [prescribing information]. Waltham, MA: Checkpoint Therapeutics, Inc; December 2024.

SECTION 2

1. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2024.
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SECTION 3

1. National Comprehensive Cancer Network. About NCCN website. https://www.nccn.org/home/about, accessed September 9, 2024.
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5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. https://www.nccn.org/compendia-templates/nccn-templates-main/browse-by-cancer-type, accessed September 9, 2024. (Note: A subscription may be required.)