

POLICY Document for IMFINZI (durvalumab)

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 Imfinzi

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
Imfinzi	durvalumab

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 Indications¹

Imfinzi, as a single agent, is indicated for the treatment of adult patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Imfinzi, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

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

Imfinzi, in combination with tremelimumab-actl, is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).

Imfinzi, in combination with tremelimumab-actl and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Imfinzi, in combination with carboplatin and paclitaxel followed by Imfinzi as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

Imfinzi, in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, is indicated for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

Imfinzi, as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Compendial Uses²⁻⁶

Cervical Cancer

Non-Small Cell Lung Cancer

Small Cell Lung Cancer

Ampullary Adenocarcinoma

Pleural Mesothelioma

Hepatocellular Carcinoma

Esophageal and Esophagogastric Junction Cancer

Gastric Cancer

Biliary Tract Cancer

 Intrahepatic Cholangiocarcinoma

 Extrahepatic Cholangiocarcinoma

 Gallbladder Cancer

Bladder Cancer

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 the absence of EGFR exon 19 deletion and exon 21 L858R mutations and ALK rearrangements, where applicable (unless testing is not feasible due to insufficient tissue).

Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumor status, where applicable.

Exclusions

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

Coverage Criteria

Non-small cell lung cancer (NSCLC)^{1,2}

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

The member has unresectable stage II or III NSCLC that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

The member has recurrent, advanced or metastatic NSCLC and meets all of the following criteria:

The requested medication will be used in combination with tremelimumab-actl (Imjudo) and platinum-based chemotherapy

The tumor is negative for EGFR exon 19 deletion and exon 21 L858R mutations and ALK rearrangements.

The member has resectable NSCLC and meets all of the following criteria:

The requested medication will be used as neoadjuvant treatment in combination with platinum-containing chemotherapy and continued as adjuvant treatment after surgery as a single agent

The tumor is negative for EGFR exon 19 deletion and exon 21 L858R mutations and ALK rearrangements

Small cell lung cancer (SCLC)^{1-2,5}

Authorization of 6 months may be granted for treatment of small cell lung cancer when either of the following criteria is met:

- The requested medication will be used for first-line treatment of extensive-stage small cell lung cancer in combination with etoposide and either carboplatin or cisplatin followed by single agent maintenance.
- The requested medication will be used for adjuvant consolidation therapy as a single agent for treatment of limited stage small cell lung cancer and the member did not experience disease progression after systemic therapy with concurrent radiation therapy.

Cervical Cancer²

Authorization of 6 months may be granted for treatment of persistent, recurrent or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) when used in combination with etoposide and either cisplatin or carboplatin and continued as single agent maintenance therapy.

Ampullary Adenocarcinoma²

Authorization of 6 months may be granted for first-line treatment of unresectable or metastatic ampullary adenocarcinoma when both of the following criteria are met:

The disease is pancreatobiliary or mixed type

The requested medication will be used in combination with cisplatin and gemcitabine

Pleural Mesothelioma³

Authorization of 6 months may be granted for first-line treatment of unresectable pleural mesothelioma when used in combination with pemetrexed and either cisplatin or carboplatin.

Hepatocellular Carcinoma^{1,2}

Authorization of 6 months may be granted for first-line treatment of hepatocellular carcinoma as a single agent or in combination with tremelimumab-actl (Imjudo) when both of the following criteria are met:

The disease is unresectable or extrahepatic/metastatic

The member is ineligible for transplant

Esophageal, Esophagogastric Junction and Gastric Cancer^{2,4}

Authorization of 3 months for a total of 3 doses may be granted for treatment of esophageal, esophagogastric junction or gastric cancer when all of the following criteria are met:

The requested medication will be used in combination with tremelimumab (Imjudo) for neoadjuvant treatment

The tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR)

The member is medically fit for surgery

Endometrial Cancer¹

Authorization of 6 months may be granted for treatment of advanced or recurrent endometrial cancer when all of the following criteria are met:

The requested medication will be used in combination with carboplatin and paclitaxel followed by use as a single agent.

The tumor is deficient mismatch repair (dMMR)

Biliary Tract Cancer^{1,2}

Authorization of 6 months may be granted for treatment of biliary tract cancer when the requested medication will be used in combination with cisplatin and gemcitabine to treat locally advanced, locoregionally advanced, unresectable or resected gross residual (R2) disease, or metastatic biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer) or for disease recurrence after surgery and adjuvant therapy.

Bladder Cancer^{2,6}

Authorization of 6 months may be granted for perioperative/sandwich treatment of stage II or IIIA bladder cancer when used in combination with gemcitabine and cisplatin prior to cystectomy followed by durvalumab after surgery.

Continuation of Therapy

NSCLC

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for NSCLC when any of the following criteria are met:

The member has unresectable stage II or III NSCLC and there is no evidence of unacceptable toxicity or disease progression while on the current regimen. (up to 12 months total)

The member has recurrent, advanced or metastatic NSCLC and there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

The member has resectable NSCLC and there is no evidence of unacceptable toxicity or disease progression while on the current regimen (up to 12 cycles after surgery).

Limited Stage SCLC

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for limited stage SCLC when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. (up to 24 months total).

Esophageal, Esophagogastric Junction and Gastric Cancer

Authorization of 3 months for a total of 3 doses may be granted for treatment of esophageal, esophagogastric junction or gastric cancer. Reauthorization may be granted only when the member did not receive a total of 3 doses from the initial approval.

Bladder Cancer

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for bladder cancer when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. (Up to 12 cycles)

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 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 Consensus²

- 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:
 - o Ampullary Adenocarcinoma
 - o Anal Carcinoma
 - o B-Cell Lymphomas
 - o Basal Cell Skin Cancer
 - o Biliary Tract Cancers
 - o Bone Cancer
 - o Breast Cancer
 - o Bladder Cancer
 - o Central Nervous System Cancers
 - o Cervical Cancer
 - o Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
 - o Chronic Myeloid leukemia
 - o Colon Cancer
 - o Dermatofibrosarcoma Protuberans
 - o Esophageal Cancer
 - o Gastric Cancer
 - o Gastrointestinal Stromal Tumors
 - o Gestational Trophoblastic Neoplasms
 - o Hairy Cell Leukemia
 - o Head and Neck Cancers
 - o Histiocytic Neoplasms
 - o Hodgkin Lymphoma
 - o Hepatocellular Carcinoma
 - o Kaposi Sarcoma
 - o Kidney Cancer

- o Melanoma: Cutaneous
- o Melanoma: Uveal
- o Merkel Cell Carcinoma
- o Mesothelioma: Peritoneal
- o Mesothelioma: Pleural
- o Multiple Myeloma
- o Myelodysplastic Syndromes
- o Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- o Myeloproliferative Neoplasms
- o Neuroendocrine and Adrenal Tumors
- o Non-Small Cell Lung Cancer
- o Occult Primary
- o Ovarian Cancer
- o Pancreatic Cancer
- o Penile Cancer
- o Primary Cutaneous Lymphomas
- o Prostate Cancer
- o Rectal Cancer
- o Small Bowel Adenocarcinoma
- o Small Cell Lung Cancer
- o Soft Tissue Sarcoma
- o Squamous Cell Skin Cancer
- o Systemic Mastocytosis
- o Systemic Light Chain Amyloidosis
- o T-Cell Lymphomas
- o Testicular Cancer
- o Thymomas and Thymic Carcinomas
- o Thyroid Carcinoma
- o Uterine Neoplasms
- o Vaginal Cancer
- o Vulvar Cancer
- o Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- o 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

Checkpoint Inhibitors_5374-A_CVSH_SOC_P2025F_R.docx
Imfinzi SGM 1820-A P2025a.docx
Novologix LLC_NCCN Oncology Clinical Policy_9.2024

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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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SECTION 2

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SECTION 3

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