# POLICY Document for YERVOY (ipilimumab)

The overall objective of this policy is to support the appropriate and cost effective use of the medication. This document provides specific information to each section of the overall policy.

**Section 1: Clinical Criteria**
- Policy information specific to the clinical appropriateness for the medication

**Section 2: Oncology Clinical Policy**
- Policy information specific to regimen review per NCCN Guidelines.

# Section 1: Clinical Criteria

## SPECIALTY GUIDELINE MANAGEMENT
## YERVOY (ipilimumab)

**POLICY**

**I. 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.

A. FDA-Approved Indications
1. Yervoy is indicated for the treatment of unresectable or metastatic melanoma in adults and pediatric patients (12 years and older).
2. Yervoy is indicated for the adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy.
3. Yervoy is indicated for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with nivolumab.
4. Yervoy is indicated for the treatment of adult and pediatric patients (12 years and older) with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, in combination with nivolumab.

B. Compendial Uses
1. Retreatment of melanoma in patients who experience disease control but who relapse or progress greater than 3 months after treatment discontinuation
2. Treatment of metastatic or unresectable uveal melanoma as single-agent therapy or in combination with nivolumab
3. Treatment of previously untreated, unresectable or metastatic melanoma in combination with dacarbazine
4. Treatment of metastatic or unresectable cutaneous melanoma as a single agent or in combination with nivolumab
5. Treatment of brain metastases with melanoma as a single agent or in combination with nivolumab
6. Small cell lung cancer subsequent systemic therapy in combination with nivolumab

7. Non-small cell lung cancer in combination with nivolumab

All other indications are considered experimental/investigational and are not a covered benefit.

## II. CRITERIA FOR INITIAL APPROVAL

### A. Melanoma

1. Authorization of 12 months may be granted for the treatment of unresectable or metastatic melanoma.
2. Authorization of 12 months may be granted for the adjuvant treatment of melanoma.
3. Authorization of 12 months may be granted for the treatment of brain metastases with a diagnosis of melanoma.

### B. Small Cell Lung Cancer

Authorization of 12 months may be granted for the treatment of small cell lung cancer.

### C. Renal Cell Carcinoma

Authorization of 12 months may be granted for the treatment of renal cell carcinoma in combination with nivolumab.

### D. Colorectal Cancer

Authorization of 12 months may be granted for the treatment of microsatellite instability-high or mismatch repair deficient colorectal cancer in combination with nivolumab.

### E. Non-small Cell Lung Cancer

Authorization of 12 months may be granted for the treatment of non-small cell lung cancer.

## III. CONTINUATION OF THERAPY

### A. Melanoma

a. Authorization of 12 months may be granted for the treatment of unresectable or metastatic melanoma if the member had disease progression or relapse after stable disease of at least three months duration after their first course of Yervoy
b. Authorization of 12 months may be granted for the adjuvant treatment of melanoma when the member meets all initial authorization criteria.
c. Authorization of 12 months may be granted for the treatment of brain metastases with a diagnosis of melanoma when the member meets all initial authorization criteria.

### B. All Other Indications

Authorization of 12 months may be granted when the member meets all initial authorization criteria.

# Section 2: Oncology Clinical Policy

## Oncology Clinical Policy

**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 Clinical Practice Guidelines and NCCN Compendium. The NCCN Compendium lists the appropriate drugs and biologics 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 on high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based on lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

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.

This policy provides coverage of a regimen review when *all* of the following criteria are met:

a. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal: https://provider.carefirst.com/providers/home.page
b. 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 that requires prior authorization on the medical benefit.
3. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include breast, lung, colon and rectal cancer.
4. The member is eligible for regimen review.

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.

Authorizations may be granted for 12 months.
Further review may be indicated where the above criteria are not met.

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/or evidence-based practice guidelines.

## REFERENCES:

### SECTION 1


1. Yervoy [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2018.
2. The NCCN Drugs & Biologics Compendium 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 26, 2018.
3. Clinical Pharmacology powered by ClinicalKey [database online]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2018. http://www.clinicalpharmacology-ip.com/default.aspx. Accessed November 10, 2018.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 10, 2018.


### SECTION 2


1. National Comprehensive Cancer Network. About NCCN website. https://www.nccn.org/about/default.aspx, accessed September 16, 2019.
2. National Comprehensive Cancer Network. NCCN Categories of Evidence and Consensus website. https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx, accessed September 16, 2019.
3. National Comprehensive Cancer Network. NCCN Guidelines website. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp, accessed September 16, 2019. *(Note: An account may be required.)*
4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium® website. http://www.nccn.org/professionals/drug_compendium/content/contents.asp, accessed September 16, 2019. *(Note: A subscription may be required.)*
5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. https://www.nccn.org/professionals/OrderTemplates/Default.aspx, accessed September 16, 2019. *(Note: A subscription may be required.)*