

# 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.

##### B. Compendial Use

1. Retreatment of melanoma in patients who experience disease control but who relapse or progress greater than 3 months after treatment discontinuation
2. Central nervous system (CNS) metastases if active against primary tumor (melanoma) as a single agent or in combination with nivolumab
3. Small cell lung cancer in combination with nivolumab
4. Malignant pleural mesothelioma subsequent systemic therapy 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

##### B. **CNS Metastases**

Authorization of 12 months may be granted for the treatment of CNS metastases in members with a diagnosis of melanoma when Yervoy was active against the primary melanoma tumor

##### C. **Small Cell Lung Cancer**

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

##### D. **Malignant pleural mesothelioma**

Authorization of 12 months may be granted for the treatment of malignant pleural mesothelioma

##### E. **Renal Cell Carcinoma**

<b>Reference number(s)</b>
1796-A

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

### III. CONTINUATION OF THERAPY

#### A. Melanoma

1. 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
2. Authorization of 12 months may be granted for the adjuvant treatment of melanoma when the member meets ALL initial authorization criteria.

#### B. CNS Metastases

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

#### C. Small Cell Lung Cancer

Authorization of 12 months may be granted for the treatment of small cell lung cancer when the member meets all initial authorization criteria

#### D. Malignant pleural mesothelioma

Authorization of 12 months may be granted for the treatment of malignant pleural mesothelioma when the member meets all initial authorization criteria

#### E. Renal Cell Carcinoma

Authorization of 12 months may be granted for the treatment of renal cell carcinoma when the member meets all initial authorization criteria.

### IV. REFERENCES

1. Yervoy [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; April 2018.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed December 4, 2017.