

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.

Reference number(s)
1796-A

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

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.
3. 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.

IV. REFERENCES

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.