Reference number(s)
1796-A

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 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 when Yervoy is used as first-line therapy in combination with nivolumab (Opdivo).
2. Authorization of 12 months may be granted as a single agent or in combination thereapy with nivolumab (Opdivo) for second-line therapy following Eastern Cooperative Oncology (ECOG) performance status of 0-2 for individuals who are treatment nive to PD-1 agents (e.g. Keytruda (pembrolizumab))
3. Authorization of 12 months may be granted for the adjuvant treatment of melanoma when ALL of the following criteria are met:
    a. Yervoy will be used as adjuvant therapy following complete resection, including total lymphadenectomy
    b. The disease has pathologic involvement of regional lymph nodes of more than 1 millimeter

B. CNS Metastases
Authorization of 12 months may be granted for the treatment of CNS metastases in members with a diagnosis of melanoma when ALL of the following criteria are met:
1. Yervoy was active against the primary tumor (melanoma)
2. Member has recurrent disease
3. Yervoy will be used as a single agent

Authorization of 12 months may be granted for the treatment of CNS metastases in members with a diagnosis of melanoma when ALL of the following criteria are met:

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

F. Colorectal cancer
Authorization of 12 months may be granted for treatment of colorectal cancer with defective mismatch repair or high microsatellite instability 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 when all of the following criteria are met:
    a. Yervoy is used as a single agent or in combination with nivolumab (Opdivo)
    b. Member had disease progression on Yervoy after stable disease of at least three months duration OR member relapsed after initial clinical response to Yervoy therapy
2. Authorization of 12 months may be granted for the adjuvant treatment of melanoma when the member meets ALL initial authorization criteria.

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

B. 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

C. 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

D. 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.

E. Colorectal cancer

Authorization of 12 months may be granted for the treatment of colorectal cancer 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® © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 4, 2017.