Reference number(s)
2437-A

STANDARD MEDICARE PART B 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.
5. Yervoy is indicated for the treatment of hepatocellular carcinoma in patients who have been previously treated with sorafenib, in combination with nivolumab.
6. Yervoy is indicated for the treatment of adult patients with metastatic non-small cell lung cancer expressing PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with nivolumab.
7. Yervoy is indicated for the treatment of adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy.
8. Yervoy, in combination with nivolumab, is indicated for the treatment of adult patients with unresectable malignant pleural mesothelioma, as first-line treatment.

B. Compendial Uses
1. Cutaneous melanoma
2. Uveal Melanoma
3. CNS brain metastases with melanoma as a single agent or in combination with nivolumab
4. Colorectal cancer
5. Hepatocellular carcinoma
6. Renal cell carcinoma
7. Non-small cell lung cancer
8. Malignant pleural mesothelioma subsequent
9. Small bowel adenocarcinoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: documentation of laboratory report confirming MSI-H or mismatch repair deficient (dMMR) tumor status, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Cutaneous Melanoma

1. Authorization of 12 months may be granted for treatment of unresectable or metastatic melanoma.
2. Authorization of 12 months may be granted for adjuvant treatment of stage III or IV disease following complete resection or no evidence of disease.

B. Central Nervous System Brain Metastases

Authorization of 12 months may be granted for treatment of brain metastases with a diagnosis of melanoma.

C. Malignant Pleural Mesothelioma

Authorization of 12 months may be granted for treatment of malignant pleural mesothelioma in combination with nivolumab.

D. Renal Cell Carcinoma

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

E. Colorectal Cancer

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

F. Non-Small Cell Lung Cancer

Authorization of 12 months may be granted for treatment of non-small cell lung cancer in combination with nivolumab with or without 2 cycles of platinum-doublet chemotherapy.

G. Uveal Melanoma

Authorization of 12 months may be granted for treatment of uveal melanoma for distant metastatic disease.

H. Hepatocellular Carcinoma

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma as subsequent therapy in combination with nivolumab.

I. Small Bowel Adenocarcinoma

Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma for microsatellite-instability high or mismatch repair deficient tumors.

IV. CONTINUATION OF THERAPY

A. Adjuvant Treatment of Melanoma

Authorization for 12 months (up to 3 years) may be granted for all members (including new members) who are continuing with Yervoy therapy when all of the following criteria are met:

1. The member is currently receiving therapy with Yervoy.
2. Yervoy is being used as adjuvant treatment for a member with melanoma.
3. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen or
   ii. No evidence of disease progression while on the current regimen.

B. Cutaneous Melanoma, Renal Cell Carcinoma, Hepatocellular Carcinoma, Colorectal Cancer

Authorization for 12 months (up to 4 doses maximum, if member has not already received 4 doses) may be granted for all members (including new members) who are continuing with Yervoy therapy when all of the following criteria are met:

1. The member is currently receiving therapy with Yervoy.
2. Yervoy is being used to treat cutaneous melanoma, renal cell carcinoma, hepatocellular carcinoma, and colorectal cancer.
3. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen or
   ii. No evidence of disease progression while on the current regimen.

C. Non-Small Cell Lung Cancer or Malignant Pleural Mesothelioma

Authorization of 12 months may be granted (up to 24 months total) may be granted for all members (including new members) who are continuing with Yervoy therapy when all of the following criteria are met:

1. The member is currently receiving therapy with Yervoy.
2. Yervoy is being used to treat non-small cell lung cancer or malignant pleural mesothelioma.
3. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen or
   ii. No evidence of disease progression while on the current regimen.

D. All Other Indications

Authorization of 12 months may be granted for all members (including new members) who are continuing with Yervoy therapy when all of the following criteria are met:

1. The member is currently receiving therapy with Yervoy.
2. Yervoy is being used to treat any other diagnosis or condition enumerated in Section III.
3. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen or
   ii. No evidence of disease progression while on the current regimen.

V. REFERENCES

1. Yervoy [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2020.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 10, 2020.