PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Yervoy® (ipilimumab injection for intravenous use – Bristol-Myers Squibb)

APPROVAL DATE: 09/25/2019

OVERVIEW

Yervoy, a human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody, is indicated for the following conditions:

1) Unresectable or metastatic melanoma in adults and pediatric patients (≥ 12 years).
2) Adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of > 1 mm who have undergone complete resection, including total lymphadenectomy.
3) In combination with Opdivo® (nivolumab for intravenous injection) for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma (RCC).
4) In combination with Opdivo for the treatment of adult and pediatric patients ≥ 12 years of age with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium recommends Yervoy for the following indications: melanoma (uveal, cutaneous, and brain metastases), small bowel adenocarcinoma, kidney cancer, small cell lung cancer, malignant pleural mesothelioma, colon and rectal cancer, and non-small cell lung cancer (NSCLC).[2] The indication for NSCLC is not addressed below since it is for activity against tumor mutational burden (TMB) in combination with Opdivo. The NCCN NSCLC guidelines note TMB as an evolving biomarker that may be helpful in selecting patients for immunotherapy.[3] There is no consensus on how to measure TMB.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Yervoy. Because of the specialized skills required for evaluation and diagnosis of patients treated with Yervoy as well as the monitoring required for adverse events and long-term efficacy, approval requires the medication to be prescribed by or in consultation with a prescriber who specializes in the condition being treated. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Yervoy is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Colon or Rectal Cancer, Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR).** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** The patient is 12 years of age or greater; AND
   - **B)** The patient meets ONE of the following criteria (i or ii):
     - **i.** The patient has tried chemotherapy.
       Note: Examples of chemotherapy are fluoropyrimidine such as 5-fluorouracil [5-FU], capecitabine~~,~~ oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX [5-FU, leucovorin, and oxaliplatin] or CapeOX [capecitabine and oxaliplatin]); OR
     - **ii.** The patient has unresectable or metastatic disease and is not a candidate for intensive therapy, according to the prescriber; AND
   - **C)** The medication will be used in combination with Opdivo (nivolumab intravenous injection); AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

2. **Melanoma** [Note: This includes cutaneous melanoma, brain metastases due to melanoma, and uveal melanoma]. Approve if the patient meets ALL of the following (A, B, and C):
   - **A)** The patient is 12 years of age or greater; AND
   - **B)** The patient meets ONE of the following (i or ii):
     - **i.** Approve for 4 months if the patient has unresectable or metastatic melanoma; OR
     - **ii.** Approve for 1 year if Yervoy will be used as adjuvant treatment.
       Note: For example, in patients with cutaneous melanoma who have undergone complete resection, including total lymphadenectomy; AND
   - **C**) The medication is prescribed by or in consultation with an oncologist.

3. **Renal Cell Carcinoma.** Approve for 4 months if the patient meets the following criteria (A, B, and C):
   - **A)** The patient has advanced (e.g., relapsed, Stage IV, metastatic) disease; AND
   - **B)** The medication will be used in combination with Opdivo (nivolumab for intravenous injection); AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

4. **Small Cell Lung Cancer.** Approve for 1 year if the patient meets all of the following (A, B, and C):
   - **A)** The patient has tried at least one other systemic chemotherapy regimen within the past 6 months.
     Note: Examples of chemotherapy are cisplatin and etoposide, carboplatin and etoposide; AND
   - **B)** The medication will be used in combination with Opdivo (nivolumab for intravenous injection); AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

5. **Malignant Pleural Mesothelioma.** Approve for 1 year if the patient meets the following (A, B, and C):
   A) The patient has tried at least one other chemotherapy regimen.
   Note: Examples of chemotherapy are cisplatin, gemcitabine, Alimta (pemetrexed for injection), carboplatin, bevacizumab; AND
   B) The medication will be used in combination with Opdivo (nivolumab for intravenous injection); AND
   C) The medication is prescribed by or in consultation with an oncologist.

6. **Small Bowel Adenocarcinoma, Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR).** Approve for 1 year if the patient meets the following (A, B, and C):
   A) The patient has advanced or metastatic disease; AND
   B) The medication will be used in combination with Opdivo (nivolumab for intravenous injection); AND
   C) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Yervoy has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Yervoy® Intravenous Infusion [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; May 2019.
2. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 20, 2019. Search term: ipilimumab.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 7.2019). 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 23, 2019.