

# Ipilimumab (YERVOY)

## Criteria for Use

June 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRAnet](#) site for further information.

### **Exclusion Criteria** *If the answer to ANY item below is met, the patient should NOT receive ipilimumab:*

- Active autoimmune disease (excluding diabetes and history of thyroid disease)
- Active or untreated brain metastases
- Primary ocular or mucosal melanoma
- Concomitant treatment with immunosuppressants including systemic corticosteroids (prednisone equivalent > 5mg/day)
- Child-Pugh Class B or C liver dysfunction
- Known pregnancy
- Lactating

### **Inclusion Criteria** *One of the following criteria must be met:*

- As monotherapy or in combination with nivolumab for treatment of unresectable or metastatic melanoma
- Adjuvant treatment of cutaneous melanoma with pathologic involvement of regional lymph nodes (> 1mm) after complete resection
- In combination with nivolumab as first-line treatment of intermediate or poor risk advanced renal cell carcinoma
- In combination with nivolumab in unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer
- In combination with nivolumab as first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) or in those previously treated with sorafenib
- In combination with nivolumab as first-line treatment of metastatic non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations and PD-L1 expression  $\geq$  1%
- In combination with nivolumab and 2 cycles of a platinum-doublet as first-line treatment of metastatic non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations
- In combination with nivolumab as first-line treatment of unresectable malignant pleural mesothelioma
- In combination with nivolumab as first-line treatment of unresectable advanced or metastatic esophageal squamous cell carcinoma

### **Additional Inclusion Criteria** *Select if applicable:*

- For females who can become pregnant: Pregnancy must be excluded prior to receiving ipilimumab.
- For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 3 months after stopping treatment.

### **Additional Inclusion Criteria** *All of the following must be met:*

- Care for the oncologic condition provided by VA or VA community care oncology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1

**Other Justification**

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