SmartHealth Ascension

Ipilimumab

(Yervoy®) J9228 (1mg)(50mg/10ml & 200mg/40ml Vial)

Covered with prior authorization

Yervoy® (Ipilimumab) may be authorized when the following criteria are met:

Colorectal Cancer

- **Individual meets one of the following:**
  - Primary treatment used in combination with nivolumab (Opdivo) for unresectable metachronous metastases (deficient mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months; **OR**
  - Used in combination with nivolumab (Opdivo) as subsequent therapy for unresectable advanced or metastatic colorectal cancer with deficient mismatch repair (dMMR) or high microsatellite instability (MSIH) mutations that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, or irinotecan- based chemotherapy**; AND**
- Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC)

- Individual is using in combination with nivolumab (Opdivo); **AND**
- Individual is using as first-line treatment; **AND**
- Individual has a current ECOG performance status of 0-1; **AND**
- Individual has not received prior treatment with anti-PD-1, anti-PD-L1, any antibody or drug specifically targeting T-cell costimulation, or checkpoint pathways; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Hepatocellular Carcinoma

- Individual is using in combination with nivolumab (Opdivo); **AND**
- Individual is using as subsequent therapy; **AND**
- Individual has a current ECOG performance status of 0-2; **AND**

- Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant**.**

Unresectable Malignant Pleural or Peritoneal Mesothelioma

- Individual is using as first line therapy; **AND**
- Individual is using in combination with nivolumab (Opdivo); **AND**
- Individual has a ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Malignant Pleural Mesothelioma

- Individual is using in combination with nivolumab (Opdivo) for subsequent therapy; **AND**
- Individual has an ECOG performance status of 0-2; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Metastatic Melanoma with brain metastases

- Individual has a primary diagnosis of melanoma; **AND**
- Individual has asymptomatic brain metastases; **AND**
- Individual is using in combination with nivolumab (Opdivo); **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or anti-CTLA-4 agent; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Unresectable or Metastatic Melanoma (Cutaneous and Uveal)

- Individual has an ECOG performance status of 0-2; **AND**
- Yervoy® (Ipilimumab) is used in combination with nivolumab (Opdivo) as either:
  - First-line therapy, **OR**
  - Second-line or subsequent therapy for disease progression if nivolumab (Opdivo) was not previously used.

OR

- Yervoy® (Ipilimumab) is used as a single agent for **ONE** of the following:
  - First line therapy as a single course of 4 treatments; **OR**
  - Second-line or subsequent lines of therapy as a single course of 4 treatments; **OR**
  - Retreatment, consisting of a 4-dose limit, for an individual who had no significant systemic toxicity during prior Yervoy therapy, and whose disease progressed after being stable for greater than 3 months following completion of a prior course of Yervoy, and for whom no intervening therapy has been administered.

Adjuvant treatment of Melanoma (Cutaneous and Uveal)

- Individual has pathologic involvement of regional lymph nodes of more than 1 mm and has undergone complete resection, including lymphadenectomy

Recurrent, advanced, or metastatic Non-Small Cell Lung Cancer (NSCLC)

- Individual is using for first line treatment; **AND**
- Individual is using in combination with Nivolumab (Opdivo); **AND**
- Current ECOG performance status of 0-2; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Recurrent or metastatic Non-Small Cell Lung Cancer

- Individual is using for first line treatment; **AND**
- Individual is using in combination with nivolumab and 2 (two) cycles of platinum-doublet chemotherapy (e.g., platinum based chemotherapy with pemetrexed, or carboplatin with paclitaxel); **AND**
- Individual does not have presence of actionable molecular markers; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.
    - ***NOTE:*** *Actionable molecular markers include EGFR, ALK, ROS1, BRAF, NTRK, MET and RET mutations. The NCCN panel recommends testing prior to initiating therapy to help guide appropriate treatment. If there is insufficient tissue to allow testing for all of these markers, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Intermediate- or poor-risk advanced Renal Cell Carcinoma (RCC)

- Yervoy® is used in combination with nivolumab (Opdivo) for four cycles followed by single agent nivolumab (Opdivo), as first-line therapy for previously untreated RCC;
  OR
- Yervoy® is used in subsequent therapy with nivolumab (Opdivo) for four cycles followed by single agent nivolumab (Opdivo), if no checkpoint blockade (PD-1, PD-L1, or CTLA-4) antibody treatment has been previously administered; **AND**
- Histologic confirmation of RCC with clear-cell component; **AND**
- Individual has an ECOG performance status 0-2; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Small Bowel Adenocarcinoma (SBA)—Advanced ampullary cancer

- Individual has advanced or metastatic disease (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only); **AND**

- Individual is using as initial or subsequent therapy in combination with nivolumab; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria
Yervoy® (Ipilimumab) is considered medically necessary for continued use when initial criteria are met **AND** the patient has experienced clinical benefit to therapy **AND** has not experienced an unacceptable toxicity.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Yervoy® (Ipilimumab) is a human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody indicated for:

Melanoma

- Treatment of unresectable or metastatic melanoma in adults and pediatric patients 12 years and older.
- Treatment of adult patients with unresectable or metastatic melanoma, in combination with nivolumab.
- 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.

Renal Cell Carcinoma (RCC)

- Treatment of patients with intermediate or poor risk advanced renal cell carcinoma, as first-line treatment in combination with nivolumab.

Colorectal Cancer

- 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.

Hepatocellular Carcinoma

- Treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib, in combination with nivolumab.

Non-Small Cell Lung Cancer (NSCLC)

- 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.
- 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.

Malignant Pleural Mesothelioma

- Treatment of adult patients with unresectable malignant pleural mesothelioma, as first-line treatment in combination with nivolumab.

Esophageal Cancer

- Treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma, as first line treatment in combination with nivolumab.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022.
3. Long GV, Atkinson V, Menzies AM, et al. A randomized phase II study of nivolumab or nivolumab combined with ipilimumab in patients with melanoma brain metastases: the Anti-PD1 Brain Collaboration. J Clin Oncol. 2017;35:9508[abstract]. Available at: https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.9508.
4. Long GV, Atkinson V, Lo S, et al. Combination nivolumab and ipilimumab or nivolumab alone in melanoma brain metastases: a multicenter randomized phase 2 study. Lancet Oncol. 2018;19:672-81.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.Tawbi HA, Forsyth AJ, Algazi AP, et al. Efficacy and safety of nivolumab (NIVO) plus ipilimumab (IPI) in patients with melanoma (MEL) metastatic to the brain: results of the phase II study CheckMate 204. J Clin Oncol. 2017;35:9507-9507[abstract]. Available at: https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.9507.
6. Yervoy [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; 2022.

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.