| Reference number(s) |
| --- |
| 2437-A |

# Standard Medicare Part B Management Yervoy

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Yervoy | ipilimumab |

## 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.

### FDA-Approved Indications[1]

#### Unresectable or Metastatic Melanoma

Yervoy is indicated as a single agent or in combination with nivolumab for the treatment of unresectable or metastatic melanoma in adult and pediatric patients 12 years and older.

#### Adjuvant Treatment of Melanoma

Yervoy is indicated for the adjuvant treatment of adult patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy.

#### Advanced Renal Cell Carcinoma

Yervoy, in combination with nivolumab, is indicated for the first-line treatment of adult patients with intermediate or poor risk advanced renal cell carcinoma (RCC).


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### Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer

Yervoy, in combination with nivolumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC).

### Hepatocellular Carcinoma

- Yervoy, in combination with nivolumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC).
- Yervoy, in combination with nivolumab, is indicated for the treatment of adult patients with unresectable or metastatic HCC who have been previously treated with sorafenib.

### Metastatic Non-Small Cell Lung Cancer

- Yervoy, in combination with nivolumab, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
- Yervoy, in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations.

### Malignant Pleural Mesothelioma

Yervoy, in combination with nivolumab, is indicated for first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

### Esophageal Cancer

Yervoy, in combination with nivolumab, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).

## Compendial Uses[2]

- Ampullary adenocarcinoma
- Appendiceal neoplasms and cancers
- Biliary Tract Cancers
  - Cholangiocarcinoma
  - Gallbladder Cancer
- Bone Cancer
- Central nervous system (CNS) brain metastases
- Cervical Cancer
- Colorectal cancer, including anal adenocarcinoma
- Cutaneous melanoma
- Esophageal/Esophagogastric Junction Cancers
- Gastric Cancer


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- Gestational trophoblastic neoplasia
- Head and neck cancer
- Hepatocellular carcinoma
- Kaposi Sarcoma
- Merkel Cell Carcinoma
- Neuroendocrine and adrenal tumors
    - Adrenal gland tumors
    - Extrapulmonary poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma/mixed neuroendocrine-non-neuroendocrine neoplasm poorly differentiated neuroendocrine carcinoma/large or small cell
    - Well-differentiated grade 3 neuroendocrine tumors
- Non-small cell lung cancer
- Pancreatic Adenocarcinoma
- Peritoneal mesothelioma
- Pleural mesothelioma
- Renal cell carcinoma
- Small bowel adenocarcinoma
- Soft Tissue Sarcoma
    - Angiosarcoma
    - Dedifferentiated liposarcoma
    - Epithelioid hemangioendothelioma
    - Extremity/body wall sarcoma
    - Head/neck sarcoma
    - Retroperitoneal/intra-abdominal sarcoma
    - Rhabdomyosarcoma
- Uterine Neoplasms
    - Endometrial Carcinoma
    - Uterine Sarcoma
- Uveal Melanoma
- Vaginal Cancer
- Vulvar Cancer

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

# Documentation

The following documentation must be available, upon request, for all submissions:

- Documentation of laboratory report confirming microsatellite instability-high MSI-H, mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.


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- Documentation of the absence of EGFR exon 19 deletion and exon 21 L858R mutations, ALK, RET, and ROS1 gene fusions, where applicable.

# Coverage Criteria

## Ampullary Adenocarcinoma[2]

Authorization of 12 months may be granted in combination with nivolumab (for 4 doses followed by nivolumab as a single agent) for treatment of progressive or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) ampullary adenocarcinoma.

## Appendiceal Neoplasms and Cancers[2,6]

Authorization of 12 months may be granted for treatment of appendiceal neoplasms and appendiceal cancers (including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified) for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb) when used in combination with nivolumab (for 4 doses followed by nivolumab as a single agent).

## Biliary Tract Cancer (Cholangiocarcinoma and Gallbladder Cancer)[2]

Authorization of 12 months may be granted in combination with nivolumab, for treatment of unresectable or gross residual (R2), or metastatic extrahepatic or intrahepatic cholangiocarcinoma or gallbladder cancer that is tumor mutational burden-high (TMB-H).

Authorization of 12 months may be granted in combination with nivolumab for neoadjuvant treatment of resectable locoregionally advanced gallbladder cancer that is tumor mutational burden-high (TMB-H).

## Bone Cancer[2]

Authorization of 12 months may be granted in combination with nivolumab for unresectable or metastatic disease when both of the following criteria are met:

- Disease has tumor mutational burden-high (TMB-H) [≥10 mut/Mb] tumors.
- Disease has progressed following prior treatment and has no satisfactory alternative treatment options.

## Central Nervous System Brain Metastases[2]

Authorization of 12 months may be granted as a single agent or in combination with nivolumab (for 4 doses followed by nivolumab as a single agent) for treatment of CNS brain metastases in members with BRAF non-specific melanoma.


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## Cervical Cancer[2]

Authorization of 12 months may be granted in combination with nivolumab for subsequent treatment of cervical cancer when either of the following criteria is met:

- Disease is recurrent or metastatic.
- Disease is persistent small cell neuroendocrine carcinoma of the cervix (NECC).

## Colorectal Cancer[1-3]

Authorization of 12 months may be granted for treatment of microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb) colorectal cancer, including anal adenocarcinoma, in combination with nivolumab (for 4 doses followed by nivolumab as a single agent).

## Cutaneous Melanoma[1,2]

Authorization of 12 months may be granted for treatment of unresectable or metastatic disease.

Authorization of 12 months may be granted for adjuvant treatment following complete resection or no evidence of disease.

Authorization of 12 months may be granted as a single agent for treatment of resectable disease after prior anti-PD-1 therapy.

Authorization of 12 months may be granted for neoadjuvant treatment of resectable disease.

## Esophageal and Esophagogastric Junction Cancers[1,2]

Authorization of 12 months may be granted in combination with nivolumab for the treatment of esophageal or esophagogastric junction cancer in members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease for either of the following:

- First-line therapy when PD-L1 ≥ 1.
- Subsequent therapy.

Authorization of 12 months may be granted in combination with nivolumab for treatment of esophageal or esophagogastric junction cancer if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Authorization of 12 months may be granted for induction therapy for relieving dysphagia in combination with nivolumab for members with esophageal or esophagogastric junction squamous cell carcinoma with PD-L1 ≥ 1 planned for esophagectomy.

## Gastric Cancer[2,5]

Authorization of 12 months may be granted in combination with nivolumab for treatment of gastric adenocarcinoma if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).


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## Gestational Trophoblastic Neoplasia[2]

Authorization of 12 months may be granted in combination with nivolumab for treatment of gestational trophoblastic neoplasia for multiagent chemotherapy-resistant disease when either of the following criteria is met:

- Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor).
- Member has high-risk disease.

## Head and Neck Cancer[2]

Authorization of 12 months may be granted in combination with nivolumab for unresectable, recurrent, persistent, or metastatic non-nasopharyngeal cancer.

## Hepatocellular Carcinoma[1,2]

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma in combination with nivolumab (for 4 doses followed by nivolumab as a single agent).

## Kaposi Sarcoma[2]

Authorization of 12 months may be granted in combination with nivolumab for subsequent treatment of relapsed/refractory advanced Kaposi Sarcoma.

## Merkel Cell Carcinoma[2,4]

Authorization of 12 months may be granted as a single agent or in combination with nivolumab for treatment of regional, in-transit, unresectable, recurrent, or stage IV Merkel cell carcinoma.

## Neuroendocrine Tumors[2]

Authorization of 12 months may be granted for subsequent treatment of metastatic extrapulmonary poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma/mixed neuroendocrine-non-neuroendocrine neoplasm in combination with nivolumab.

Authorization of 12 months may be granted for treatment of locally advanced/metastatic well-differentiated grade 3 neuroendocrine tumors with unfavorable biology (e.g., relatively high Ki-67 [≥55%], rapid growth rate, negative somatostatin receptor (SSTR)-based positron emission tomography (PET) imaging) in combination with nivolumab.

Authorization of 12 months may be granted in combination with nivolumab for treatment of unresectable or metastatic adrenocortical carcinoma.


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## Non-Small Cell Lung Cancer[1,2]

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic non-small cell lung cancer if there are no EGFR exon 19 deletions, exon 21 L858R mutations, or ALK, RET, or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue) and the requested medication will be used in a regimen containing nivolumab.

## Pancreatic Adenocarcinoma[2]

Authorization of 12 months may be granted in combination with nivolumab for treatment of locally advanced, metastatic, or recurrent pancreatic adenocarcinoma with tumor mutational burden-high (TMB-H) [≥10 mut/Mb] tumors.

## Pleural or Peritoneal Mesothelioma[1,2]

Authorization of 12 months may be granted for treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, in combination with nivolumab.

## Renal Cell Carcinoma[1,2]

Authorization of 12 months may be granted for treatment of renal cell carcinoma in combination with nivolumab (for 4 doses followed by nivolumab as a single agent).

## Small Bowel Adenocarcinoma[2]

Authorization of 12 months may be granted for treatment of unresectable, medically inoperable, advanced, or metastatic small bowel adenocarcinoma for microsatellite-instability high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb), in combination with nivolumab (for 4 doses followed by nivolumab as a single agent).

## Soft Tissue Sarcoma[2]

Authorization of 12 months may be granted in combination with nivolumab for treatment of extremity/body wall sarcomas, head/neck sarcomas, retroperitoneal/intra-abdominal sarcomas, rhabdomyosarcoma, angiosarcoma, dedifferentiated liposarcoma, and epithelioid hemangioendothelioma.

## Uterine Neoplasms[2]

Authorization of 12 months may be granted in combination with nivolumab for subsequent treatment of recurrent unresectable or metastatic endometrial carcinoma that is tumor mutational burden-high (TMB-H) [≥10 mut/Mb] and has no satisfactory alternative treatment options.


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Authorization of 12 months may be granted in combination with nivolumab for subsequent treatment of unresectable or metastatic uterine sarcoma that is tumor mutational burden-high (TMB-H) [≥10 mut/Mb] and has no satisfactory alternative treatment options.

### Uveal Melanoma[2]

Authorization of 12 months may be granted as a single agent or in combination with nivolumab (for 4 doses followed by nivolumab as a single agent) for treatment of uveal melanoma for unresectable or metastatic disease.

### Vaginal Cancer[2]

Authorization of 12 months may be granted as subsequent therapy for recurrent or metastatic vaginal cancer when used in combination with nivolumab.

### Vulvar Cancer[2]

Authorization of 12 months may be granted as subsequent therapy for advanced or recurrent/metastatic vulvar cancer when used in combination with nivolumab.

## Continuation of Therapy

### Cutaneous Melanoma, Colorectal Cancer,Hepatocellular Carcinoma, Renal Cell Carcinoma

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 the requested therapy when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat cutaneous melanoma, colorectal cancer, hepatocellular carcinoma, or renal cell carcinoma.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

### Cervical Cancer, Esophageal/Esophagogastric Junction Cancers, Non-Small Cell Lung Cancer, or Pleural or Peritoneal Mesothelioma

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


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- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat cervical cancer, esophageal/esophagogastric junction cancer, non-small cell lung cancer, or pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma subtypes.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

## Biliary Tract Cancer

Authorization for 12 months may be granted (for 2 to 6 months total for neoadjuvant treatment, and for up to 24 months total for other clinical settings) for all members (including new members) who are continuing with the requested therapy when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat biliary tract cancer.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

## All Other Indications

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

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat any other indication listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

# Summary of Evidence

The contents of this document were created after examining the following resources:

- The prescribing information for Yervoy.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Neuroendocrine and adrenal tumors


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- NCCN Guideline: Small bowel adenocarcinoma
- NCCN Guideline: Peritoneal mesothelioma
- NCCN Guideline: Pleural mesothelioma
- NCCN Guideline: Cutaneous melanoma
- NCCN Guideline: Non-small cell lung cancer
- NCCN Guideline: Hepatocellular carcinoma
- NCCN Guideline: Uveal melanoma
- NCCN Guideline: Gestational trophoblastic neoplasia
- NCCN Guideline: Central nervous system cancers
- NCCN Guideline: Ampullary adenocarcinoma
- NCCN Guideline: Colon cancer
- NCCN Guideline: Rectal cancer
- NCCN Guideline: Kidney cancer
- NCCN Guideline: Kaposi sarcoma
- NCCN Guideline: Biliary tract cancers
- NCCN Guideline: Soft tissue sarcoma
- NCCN Guideline: Merkel cell carcinoma
- NCCN Guideline: Head and neck cancers
- NCCN Guideline: Esophageal/esophagogastric junction cancers
- NCCN Guideline: Gastric cancer
- NCCN Guideline: Pancreatic Adenocarcinoma
- NCCN Guideline: Anal Carcinoma
- NCCN Guideline: Vulvar cancer
- NCCN Guideline: Cervical cancer
- NCCN Guideline: Vaginal cancer
- NCCN Guideline: Appendiceal neoplasms and cancers
- NCCN Guideline: Uterine neoplasms

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Yervoy are covered in addition to the following:

- Ampullary adenocarcinoma
- Appendiceal neoplasms and cancers
- Biliary Tract Cancers
  - Cholangiocarcinoma
  - Gallbladder Cancer
- Bone Cancer
- Central nervous system (CNS) brain metastases
- Cervical Cancer
- Colorectal cancer, including anal adenocarcinoma
- Cutaneous melanoma
- Esophageal/Esophagogastric Junction Cancers
- Gastric Cancer
- Gestational trophoblastic neoplasia
- Head and neck cancer


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- Hepatocellular carcinoma
- Kaposi Sarcoma
- Merkel Cell Carcinoma
- Neuroendocrine and adrenal tumors
    - Adrenal gland tumors
    - Extrapulmonary poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma/mixed neuroendocrine-non-neuroendocrine neoplasm Poorly differentiated neuroendocrine carcinoma/large or small cell well-differentiated grade 3 neuroendocrine tumors
- Non-small cell lung cancer
- Pancreatic Adenocarcinoma
- Peritoneal mesothelioma
- Pleural mesothelioma
- Renal cell carcinoma
- Small bowel adenocarcinoma
- Soft Tissue Sarcoma
    - Angiosarcoma
    - Dedifferentiated liposarcoma
    - Epithelioid hemangioendothelioma
    - Extremity/body wall sarcoma
    - Head/neck sarcoma
    - Retroperitoneal/intra-abdominal sarcoma
    - Rhabdomyosarcoma
- Uterine Neoplasms
    - Endometrial Carcinoma
    - Uterine Sarcoma
- Uveal Melanoma
- Vaginal Cancer
- Vulvar Cancer

# Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for the following indications can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

- Ampullary adenocarcinoma
- Appendiceal neoplasms and cancers
- Biliary Tract Cancers
    - Cholangiocarcinoma


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  - Gallbladder Cancer
- Bone Cancer
- Central nervous system (CNS) brain metastases
- Cervical Cancer
- Colorectal cancer, including anal adenocarcinoma
- Cutaneous melanoma
- Esophageal/Esophagogastric Junction Cancers
- Gastric Cancer
- Gestational trophoblastic neoplasia
- Head and neck cancer
- Hepatocellular carcinoma
- Kaposi Sarcoma
- Merkel Cell Carcinoma
- Neuroendocrine and adrenal tumors
  - Adrenal gland tumors
  - Extrapulmonary poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma/mixed neuroendocrine-non-neuroendocrine neoplasm Poorly differentiated neuroendocrine carcinoma/large or small cell well-differentiated grade 3 neuroendocrine tumors
- Non-small cell lung cancer
- Pancreatic Adenocarcinoma
- Peritoneal mesothelioma
- Pleural mesothelioma
- Renal cell carcinoma
- Small bowel adenocarcinoma
- Soft Tissue Sarcoma
  - Angiosarcoma
  - Dedifferentiated liposarcoma
  - Epithelioid hemangioendothelioma
  - Extremity/body wall sarcoma
  - Head/neck sarcoma
  - Retroperitoneal/intra-abdominal sarcoma
  - Rhabdomyosarcoma
- Uterine Neoplasms
  - Endometrial Carcinoma
  - Uterine Sarcoma
- Uveal Melanoma
- Vaginal Cancer
- Vulvar Cancer

Support for using Yervoy to treat Merkel cell carcinoma can be found in the Lexi-Drugs database. Use of information in the Lexi-Drugs database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).


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# References

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3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 5.2025. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf Accessed December 2, 2025.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025 http://online.lexi.com. Accessed December 2, 2025.
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6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Appendiceal Neoplasms and Cancers Version 1.2026. https://www.nccn.org/professionals/physician_gls/pdf/appendiceal.pdf Accessed December 30, 2025.


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