Clinical Policy Title:	ipilimumab
Policy Number:	RxA.322
Drug(s) Applied:	Yervoy®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Melanoma

- Treatment of unresectable or metastatic melanoma in adults and pediatric patients (12 years and older)
- 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, previously untreated advanced renal cell carcinoma, in combination with nivolumab.

Colorectal Cancer (CRC)

- Treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, in combination with nivolumab.

Hepatocellular Carcinoma (HCC)

- 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 NSCLC expressing PD-L1 ($\geq$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 NSCLC 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 (MPM)

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

Dosing Information			
Drug Name	**Indication**	**Dosing Regimen**	**Maximum Dose**
ipilimumab (Yervoy®)	Cutaneous Melanoma	Adjuvant therapy: 10 mg/kg IV every 3 weeks for 4 doses, followed by 10 mg/kg every 12 weeks for up to 3 years. *Off-label dosing:* 3 mg/kg IV once every 3 weeks for 4 doses (induction), followed by 3 mg/kg IV once every 12 weeks for up to 4 additional doses (maintenance) or until disease progression or unacceptable toxicity for up to a maximum of 60 weeks.	10 mg/kg/dose
	Unresectable or Metastatic Melanoma	3 mg/kg IV every 3 weeks for a total of 4 doses	3 mg/kg/dose
	Advanced RCC	Combo therapy: 1 mg/kg immediately following nivolumab 3 mg/kg on the same day, every 3 weeks for 4 doses. After completing 4 doses of the combination, administer nivolumab as a single agent as recommended at 240 mg IV every 2 weeks or 480 mg IV every 4 weeks.	1 mg/kg/dose
	Metastatic CRC	Combo therapy: 1 mg/kg IV over 30 minutes immediately following nivolumab 3 mg/kg IV over 30 minutes on the same day, every 3 weeks for 4 doses. After completing 4 doses of the combination, administer nivolumab as a single agent as recommended at 240 mg IV every 2 weeks or 480 mg IV every 4 weeks.	1 mg/kg/dose
	HCC	Combo therapy: 3 mg/kg IV over 30 minutes immediately following nivolumab 1 mg/kg IV over 30 minutes on the same day, every 3 weeks for 4 doses. After completing 4 doses of the combination, administer nivolumab as a single agent as recommended at 240 mg IV every 2 weeks or 480 mg IV every 4 weeks.	3 mg/kg/dose
	NSCLC	Combo therapy: 1 mg/kg IV every 6 weeks with nivolumab IV 3 mg/kg every 2 weeks OR Combo therapy: 1 mg/kg IV every 6 weeks with nivolumab 360 mg IV every 3 weeks and 2 cycles of platinum-doublet chemotherapy	1 mg/kg/dose
	MPM	1 mg/kg IV every 6 weeks with nivolumab 360 mg every 3 weeks	1 mg/kg/dose

Dosage Forms

- Single-use vials: 50 mg/10 mL (5 mg/mL), 200 mg/40 mL (5 mg/mL)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Cutaneous Melanoma (must meet all)**:**

1. Diagnosis of cutaneous melanoma with pathologic involvement of regional lymph nodes;
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Member has undergone complete resection including total lymphadenectomy;
5. Prescribed as adjuvant single agent;
6. Request meets one of the following (a or b): *
   a. Dose does not exceed 10 mg/kg per dose;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

B. Unresectable or Metastatic Melanoma (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Unresectable or metastatic melanoma:
   b. Brain metastasis from melanoma as primary tumor (off-label);
2. Prescribed by or in consultation with an oncologist:
3. Age 12 years or older;
4. Prescribed as a single agent or in combination with nivolumab (Opdivo®);
5. Request meets one of the following (a or b):
   a. Dose does not exceed 3 mg/kg per dose for a maximum of 4 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant of-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 3 months (maximum of 4 doses)
Medicaid: 3 months (maximum of 4 doses)

C. Colorectal Cancer (must meet all)**:**

1. Diagnosis of colorectal cancer (dMMR/MSI-H only);
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Disease is unresectable or metastatic;
5. Prescribed in combination with nivolumab (Opdivo®);
6. Member has failed fluoropyrimidine, oxaliplatin, and irinotecan treatment within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 1 mg/kg IV every 3 weeks for a maximum of 4 doses;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant of-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 3 months (maximum of 4 doses)
Medicaid: 3 months (maximum of 4 doses)

D. Hepatocellular Carcinoma (must meet all)**:**

1. Diagnosis of hepatocellular carcinoma (Child-Pugh A only) with one of the following (a, b or c):
   a. Unresectable disease and patient is not a transplant candidate;
   b. Inoperable by performance status or comorbidity, or have local disease or local disease with minimal extrahepatic disease only;
   c. Metastatic disease or extensive liver tumor burden;
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Prescribed in combination with nivolumab (Opdivo®);
5. Request meets one of the following (a or b): *
   a. Dose does not exceed 3 mg/kg IV every 3 weeks for a maximum of 4 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant of-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 3 months (maximum of 4 doses)
Medicaid: 3 months (maximum of 4 doses)

E. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of recurrent, advanced or metastatic NSCLC with no EGFR or ALK genomic tumor aberrations;
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Prescribed in combination with (a, b or c):
   a. nivolumab (Opdivo®) for PD-L1 positive NSCLC;
   b. nivolumab (Opdivo®), pemetrexed and either carboplatin or cisplatin (for nonsquamous cell histology);
   c. nivolumab (Opdivo®), paclitaxel and carboplatin (for squamous cell histology);
5. Request meets one of the following (a or b): *
   a. Dose does not exceed 1 mg/kg IV every 6 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant of-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

F. Renal Cell Carcinoma (must meet all)**:**

1. Diagnosis of advanced RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Prescribed in combination with nivolumab (Opdivo®);
5. Request meets one of the following (a or b): *

a. Dose does not exceed 1 mg/kg IV every 3 weeks for a maximum of 4 doses;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant of-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 3 months (maximum of 4 doses)
Medicaid: 3 months (maximum of 4 doses)

G. Malignant Pleural Mesothelioma (must meet all):
1. Diagnosis of malignant pleural mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Prescribed in combination with nivolumab (Opdivo®);
5. Request meets one of the following (a or b): *
   a. Dose does not exceed 1 mg/kg/dose;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

H. Neuroendocrine and Adrenal Tumors (off-label) (must meet all):
1. Diagnosis of non-pancreatic, poorly differentiated (high grade) neuroendocrine carcinoma (large or small cell);
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Disease progressed after first-line therapy;
5. Prescribed in combination with nivolumab (Opdivo®);
6. Request meets one of the following (a or b): *
   a. Dose does not exceed 1 mg/kg/dose;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

I. Small Bowel Cancer (off-label) (must meet all):
1. Diagnosis of advanced or metastatic small bowel cancer (dMMR/MSI-H only);
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Disease has progressed following previous oxaliplatin-based therapy;
5. Prescribed in combination with nivolumab (Opdivo®)
6. Request meets one of the following (a or b): *
   a. Dose does not exceed 1 mg/kg/dose every 3 weeks for a maximum of 4 doses;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 3 months (maximum of 4 doses)
Medicaid: 3 months (maximum of 4 doses)

J. Uveal Melanoma (off-label) (must meet all):
1. Diagnosis of distant, metastatic uveal melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age 12 years or older;
4. Prescribed as a single agent or in combination with nivolumab (Opdivo®);
5. Request meets one of the following (a or b): *
   a. Dose does not exceed 1 mg/kg/dose;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Cutaneous Melanoma (must meet all)**:**
1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member has received this medication for at least 30 days;
3. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
4. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 10 mg/kg per dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 12 months, up to a total of 3 years of therapy
Medicaid: 12 months, up to a total of 3 years of therapy

B. Unresectable or Metastatic Melanoma (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member has received this medication for at least 30 days;
3. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
4. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 3 mg/kg per dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Unresectable or Metastatic Melanoma

Reauthorization beyond 3 months is not permitted. Members must meet the initial approval criteria, at a minimum of 3 months since initial treatment discontinuation.

Brain metastasis from melanoma as primary tumor (off-label)
Commercial: 12 months, up to a total of 2 years of therapy
Medicaid: 12 months, up to a total of 2 years of therapy

C. Colorectal Cancer
Reauthorization beyond 3 months is not permitted. Members must meet the initial approval criteria, at a minimum of 3 months since initial treatment discontinuation.

D. Hepatocellular Carcinoma
Reauthorization beyond 3 months is not permitted. Members must meet the initial approval criteria, at a minimum of 3 months since initial treatment discontinuation.

E. Non-Small Cell Lung Cancer (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member has received this medication for at least 30 days;
3. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
4. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 1 mg/kg per dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 12 months, up to a total of 2 years of therapy
Medicaid: 12 months, up to a total of 2 years of therapy

F. Renal Cell Carcinoma
Reauthorization beyond 3 months is not permitted. Members must meet the initial approval criteria, at a minimum of 3 months since initial treatment discontinuation.

G. Malignant Pleural Mesothelioma (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member has received this medication for at least 30 days;
3. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
4. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 1 mg/kg per dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

H. Neuroendocrine and Adrenal Tumors (off-label) (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member has received this medication for at least 30 days;
3. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
4. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 1 mg/kg per dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

I. Small Bowel Cancer

Reauthorization beyond 16 weeks is not permitted. Members must meet the initial approval criteria, at a minimum of 3 months since initial treatment discontinuation.

J. Uveal Melanoma (off-label) (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member has received this medication for at least 30 days;
3. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
4. If request is for a dose increase, request meets one of the following (a or b): *
   a. New dose does not exceed 1 mg/kg per dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

CRC: colorectal cancer
CTLA-4: cytotoxic T-lymphocyte antigen 4
FDA: Food and Drug Administration
IV: intravenous
RCC: renal cell carcinoma
MPM: malignant pleural mesothelioma
NSCLC: non-small cell lung cancer
dMMR: mismatch repair deficient
MSI-H: microsatellite instability-high
NCCN: National Cancer Center Network
EGFR: epidermal growth factor receptor

ALK: anaplastic large-cell lymphoma kinase
PD-L1: programmed death-ligand 1

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
Cutaneous Melanoma *Examples of first-line, second-line and subsequent therapies:* pembrolizumab nivolumab nivolumab + ipilimumab trastuzumab + pertuzumab trastuzumab + lapatinib encorafenib + cetuximab encorafenib + panitumumab larotrectinib entrectinib	Varies	Varies
Unresectable or Metastatic Melanoma *Examples of first-line, second-line and subsequent therapies:* ipilimumab ipilimumab + nivolumab nivolumab pembrolizumab	Varies	Varies
Colorectal Cancer *Examples of first-line, second-line and subsequent therapies:* capecitabine ± bevacizumab CAPEOX ± bevacizumab FOLFOX ± bevacizumab FOLFOX + cetuximab or panitumumab FOLFIRI ± bevacizumab FOLFIRI + cetuximab or panitumumab FOLFOXIRI ± bevacizumab nivolumab nivolumab + ipilimumab pembrolizumab trastuzumab + pertuzumab or lapatinib	Varies	Varies
Hepatocellular Carcinoma *Examples of first-line, second-line and subsequent therapies:* cabozantinib lenvatinib nivolumab nivolumab + ipilimumab	Varies	Varies

pembrolizumab ramucirumab regorafenib sorafenib		
Non-Small Cell Lung Cancer *Examples of first-line, second-line and subsequent therapies:* carboplatin + paclitaxel + bevacizumab + atezolizumab nivolumab + ipilimumab nivolumab + ipilimumab + paclitaxel + carboplatin nivolumab + ipilimumab + pemetrexed + carboplatin or cisplatin pembrolizumab pembrolizumab + pemetrexed + carboplatin or cisplatin	Varies	Varies
Renal Cell Carcinoma *Examples of first-line, second-line and subsequent therapies:* axitinib axitinib + avelumab axitinib + pembrolizumab bevacizumab cabozantinib everolimus ipilimumab + nivolumab nivolumab pazopanib sunitinib	Varies	Varies
Malignant Pleural Mesothelioma *Examples of first-line, second-line and subsequent therapies:* gemcitabine + cisplatin nivolumab + ipilimumab pembrolizumab pemetrexed + carboplatin pemetrexed + cisplatin pemetrexed + cisplatin + bevacizumab vinorelbine	Varies	Varies
Neuroendocrine and Adrenal Tumors *Examples of first-line, second-line and subsequent therapies:* carboplatin + etoposide cisplatin + etoposide FOLFOX FOLFIRI nivolumab + ipilimumab temozolomide ± capecitabine	Varies	Varies

Small Cell Lung Cancer *Examples of first-line, second-line and subsequent therapies:* docetaxel etoposide gemcitabine irinotecan lurbinectedin nivolumab + ipilimumab paclitaxel temozolomide topotecan vinorelbine	Varies	Varies
Small Bowel Cancer *Examples of first-line, second-line and subsequent therapies:* 5-fluorouracil + leucovorin capecitabine docetaxel FOLFIRI gemcitabine gemcitabine + docetaxel irinotecan nivolumab nivolumab + ipilimumab paclitaxel pembrolizumab	Varies	Varies
Uveal Melanoma *Examples of first-line, second-line and subsequent therapies:* dacarbazine ipilimumab nivolumab nivolumab + ipilimumab pembrolizumab temozolomide trametinib	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications and Boxed Warnings

- Contraindication(s): None.

- Boxed warning(s): None.

APPENDIX D: General Information

NCCN lists ipilimumab as a category 2A recommendation for:

- Extensive brain metastases in patients with melanoma (in combination with nivolumab)
- Malignant pleural mesothelioma (in combination with nivolumab)
- Rectal cancer (in combination with nivolumab)
- Advanced or metastatic small bowel cancer, deficient mismatch repair/microsatellite instability-high only (in combination with nivolumab)
- Small Cell Lung Cancer (in combination with nivolumab)
- Uveal Melanoma, as single agent therapy or in combination with nivolumab

NCCN lists ipilimumab as a category 2A recommendation for:

- non-pancreatic, poorly differentiated neuroendocrine carcinoma (large or small cell);

References

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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	02/07/2020
Policy updated. 1. Formatting updated. 2. Policy Title updated. 3. Clinical information updated. 4. Criteria for approval and continued approval updated. 5. Approval duration updated. 6. Reference updated.	07/28/2020	09/14/2020
Policy was reviewed: 1. Policy title table was updated. 2. Clinical policy section standard verbiage was updated to include "The provision of prescriber samples…". 3. Dosing information table updated: a. For clarity. b. To add off-label dosing for indication cutaneous melanoma. 4. Dosage forms section updated to add vial strength, 5 mg/mL. 5. Age criteria language for all indications updated for simplification. 6. Dosing criteria updated to add verbiage "*Prescribed regimen must be FDA-approved or recommended by NCCN." 7. Initial approval criteria I.A.4 was added and I.A.5 updated based on updated guidelines. 8. Initial approval criteria I.C.6 added for consistency with indication. 9. Initial approval criteria for small cell lung cancer removed based on updated guidelines. 10. Continuation therapy criteria II.A.1., B.1., E.1., G.1., H.1., K.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 11. All approval durations with 3-week doses with 4-dose maximum updated from 112 days to 3 months for accuracy. 12. Appendix A for abbreviations was updated for accuracy. 13. Appendix B for therapeutic alternatives standard verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance...". 14. Appendix C for boxed warnings was updated	05/17/2021	06/10/2021

to remove boxed warning. 15. References were updated.		