Clinical Policy Title:	ipilimumab
Policy Number:	RxA.322
Drug(s) Applied:	Yervoy®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of unresectable, metastatic, or lymph node positive melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Prescribed in one of the following way (a, b, c or d):
   a. As a single agent;
   b. In combination with Opdivo®*
   c. In combination with Keytruda®, or Imlygic®* and both of the following (i and ii):
      i. Member has unresectable or metastatic melanoma;
      ii. Age ≥ 18 years;
   d. As adjuvant treatment and member meets all of the following (i, ii and iii):
      i. Member has cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm;
      ii. Age ≥ 18 years;
      iii. Member had undergone complete resection, including total lymphadenectomy.

   *Prior authorization may be required for Opdivo, Keytruda, and Imlygic
5. Request meets one of the following (a, b, or c):*
   a. Unresectable or metastatic disease: Dose does not exceed 3 mg per kg every 3 weeks for a maximum of 4 doses;
   b. Adjuvant treatment: Dose does not exceed 10 mg/kg every 3 weeks for 4 doses, followed by 10 mg/kg every 12 weeks for up to 3 years;
   c. 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. 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;
4. Disease is unresectable or metastatic;
5. Prescribed in combination with Opdivo®;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 1 mg/kg intravenously 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)

C. Hepatocellular Carcinoma (must meet all)**:**
1. Diagnosis of hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Opdivo®;
5. Member has previously received Nexavar®, Lenvima®, or Tecentriq® + bevacizumab or Imfinzi®;
   *Prior authorization may be required for Nexavar®, Lenvima®, Tecentriq®, bevacizumab and Imfinzi®
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 3 mg/kg intravenously 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. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Opdivo®;
5. Request meets one of the following (a, b, c, or d):
   a. Disease mutation status is negative for actionable biomarkers (EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET), and member has not received prior systemic therapy for advanced disease;
   b. Disease mutation status is positive for EGFR S768I, L861Q, and/or G719X, and member has received prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib;
   c. Disease mutation status is positive for ROS1 rearrangement, and member has received prior crizotinib, entrectinib, or ceritinib;
   d. Disease mutation status is positive for EGFR exon 20, KRAS G12C, NRTK1/2/3, BRAF V600E, MET exon 14 skipping, or RET rearrangement;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg intravenously every 6 weeks in combination with Opdivo®;
   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

E. Renal Cell Carcinoma (must meet all)**:**
1. Diagnosis of advanced RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Opdivo®;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg intravenously 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)

F. Malignant Pleural Mesothelioma (must meet all):
1. Diagnosis of malignant pleural mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Opdivo®;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg/dose intravenous every 6 weeks in combination with Opdivo®;
   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

G. 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;
4. Disease has progressed following previous oxaliplatin-based therapy;
5. Prescribed in combination with 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)

I. 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;
4. Prescribed as a single agent or in combination with 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

J. Esophageal Cancer (must meet all):
1. Diagnosis of unresectable advanced or metastatic ESCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Opdivo®;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg/kg intravenous every 6 weeks in combination with Opdivo®;
   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

K. Ampullary Adenocarcinoma (off-label) (must meet all):
1. Diagnosis of ampullary adenocarcinoma (dMMR/MSI-H only);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member meets one of the following when used in combination with Opdivo® (a or b):
   a. First-line therapy for unresectable or metastatic intestinal type disease;
   b. Subsequent therapy for disease progression;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 3 mg/kg intravenous every 3 weeks for four total cycles;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

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

Approval duration
Commercial: 6 months
Medicaid: 6 months

L. Bone cancer (off-label) (must meet all):
1. Diagnosis of one of the following (a, b, c or d):
   a. Chondrosarcoma;
   b. Osteosarcoma;
   c. Chordoma;

d. Ewing Sarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has tumor mutation burden-high (TMB-H) tumors [≥ 10 mutations/megabase (mut/Mb)] as determined by an FDA-approved or CLIA-compliant test;
5. Prescribed in combination with nivolumab;
6. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
*Prescriber regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months

M. Malignant Peritoneal Mesothelioma (off-label) (must meet all):
1. Diagnosis of malignant peritoneal mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as subsequent therapy (if not administered first-line);
5. Member meets one of the following if used as first line therapy (a or b):
   a. Unresectable diffuse disease;
   b. Unresectable recurrent benign multicystic or well-differentiated papillary disease;
6. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
*Prescriber regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Melanoma (must meet all)**:**
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has 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 does not exceed 10 mg/kg per dose;
   c. 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

<u>Unresectable or Metastatic Melanoma</u>
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

B. 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.

C. 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.

D. Non-Small Cell Lung Cancer (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has 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

E. 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.

F. Malignant Pleural Mesothelioma (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has 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

G. 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.

H. Uveal Melanoma (off-label) (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has 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. Esophageal Cancer (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
3. 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 intravenous every 6 weeks in combination with Opdivo®;
   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

J. Ampullary Adenocarcinoma (off-label) (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. 3 mg/kg intravenous every 3 weeks for four total cycles;
   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

K. Bone cancer (off-label) (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
3. 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

L. Malignant Peritoneal Mesothelioma (off-label) (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (i.e. no evidence of unacceptable toxicity or disease progression);
3. 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

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. Age criteria language for all indications updated for simplification. 3. Initial approval criteria I.A.4 was added and I.A.5 updated based on updated guidelines. 4. Initial approval criteria I.C.6 added for consistency with indication. 5. Initial approval criteria for small cell lung cancer removed based on updated guidelines. 6. 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…". 7. All approval durations with 3-week doses with 4-dose maximum updated from 112 days to 3 months for accuracy. 8. References were updated.	05/17/2021	06/10/2021

Policy was reviewed: 1. Initial Approval Criteria, I.B.3: Updated age criteria from 12 years or older to having separate specific criteria for ages 12 and older and ages 18 and older (a and b). 2. Initial Approval Criteria I.C.6: Updated to include trial and failure of fluoropyrimidine, oxaliplatin, and irinotecan. 3. Initial Approval Criteria, I.D.5: Updated to include requirement that member try Nexavar or Lenvima. 4. Initial Approval Criteria, I.E.3, I.G.3: Updated age from 12 and older to 18 and older. 5. Continued Therapy Approval Criteria II.A.1, II.B.1, II.E.1, II.G.1, II.H.1 & II.J.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. References were reviewed and updated.	01/31/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A and I.B: Updated to merge from two separate approval criteria to one approval criteria as "Melanoma". 2. Initial Approval Criteria, I.A.4: Updated prescribing criteria from Prescribed in one of the following ways (a or b): a. As a single agent; b. In combination with Opdivo®, Keytruda®, or Imlygic®,* and both of the following (i and ii): i. Member has unresectable or metastatic melanoma; ii. Age ≥ 18 years; *Prior authorization may be required for Opdivo, Keytruda, and Imlygic to Prescribed in one of the following way (a, b or c): a. As a single agent; b. In combination with Opdivo®* c. In combination with Keytruda®, or Imlygic®* and both of the following (i and ii): i. Member has unresectable or metastatic melanoma; ii. Age ≥ 18 years;	03/23/2023	04/13/2023

d. As adjuvant treatment and member meets all of the following (i, ii and iii): i. Member has cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm; ii. Age ≥ 18 years; iii. Member had undergone complete resection, including total lymphadenectomy. 3. Initial Approval Criteria, I.B.5, I.C.4, I.E.4, I.F.4, I.G.5 and I.I.4: Updated to remove generic "nivolumab". 4. Initial Approval Criteria, I.B.6: Updated to remove prior trial and failure criteria "Member has failed fluoropyrimidine, oxaliplatin, and irinotecan treatment within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced." 5. Initial Approval Criteria, I.C.1: Updated diagnostic criteria to remove "(Child-Pugh A only) with one of the following (a, b or c): a. Unresectable disease and the 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 6. Initial Approval Criteria, I.D.1: Updated diagnostic criteria to remove "with no EGFR or ALK genomic tumor aberrations." 7. Initial Approval Criteria, I.D.3: Updated age criteria from Age ≥ 12 years to Age ≥ 18 years. 8. Initial Approval Criteria, I.D.4: Upadated combination criteria from "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 nonsquamousnon-squamous cell histology); c. nivolumab (Opdivo®), paclitaxel and carboplatin (for squamous cell histology); to Prescribed in combination with Opdivo®. 9. Initial Approval Criteria, I.D.5: Updated previously received drug criteria from Member has previously received Nexavar® or Lenvima®; *Prior authorization may be required for Nexavar and Lenvima to Member has previously received Nexavar®, Lenvima®, or Tecentriq® + bevacizumab or Imfinzi®. *Prior authorization may be required for Nexavar®, Lenvima®, Tecentriq®, bevacizumab and Imfinzi®. 10. Initial Approval Criteria, I.E.5: Updated to include new diagnostic criteria Request meets one of the following (a, b, c, or d): a. Disease mutation status is negative for actionable biomarkers (EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET), and member has not received prior systemic therapy for advanced disease; b. Disease mutation status is positive for EGFR S768I, L861Q, and/or G719X, and member has received prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib; c. Disease mutation status is positive for ROS1 rearrangement, and member has received prior crizotinib, entrectinib, or ceritinib; d. Disease mutation status is positive for EGFR exon 20, KRAS G12C, NRTK1/2/3, BRAF V600E, MET exon 14 skipping, or RET rearrangement. 11. Initial Approval Criteria, I.F.3: Updated age criteria from Age ≥ 12 years to Age ≥ 18 years. 12. Initial Approval Criteria, I.H: Updated to remove approval criteria for "Neuroendocrine and Adrenal Tumors (off-label)".		

13. Initial Approval Criteria, I.J: Updated to include approval criteria for Esophageal Cancer. 14. Initial Approval Criteria, I.K: Updated to include approval criteria for Ampullary Adenocarcinoma (off-label). 15. Initial Approval Criteria, I.L: Updated to include approval criteria for Bone cancer (off-label). 16. Initial Approval Criteria, I.M: Updated to include approval criteria for Malignant Peritoneal Mesothelioma (off-label). 17. Continued Therapy Approval, II.B: Merged into II.A as “Melanoma”. 18. Continued Therapy Approval, II.H: Updated to remove approval criteria for "Neuroendocrine and Adrenal Tumors (off-label)". 19. Continued Therapy Approval, II.J: Updated to include approval criteria for Esophageal Cancer. 20. Continued Therapy Approval, II.K: Updated to include approval criteria for Ampullary Adenocarcinoma (off-label). 21. Continued Therapy Approval, II.L: Updated to include approval criteria for Bone cancer (off-label). 22. Continued Therapy Approval, II.M: Updated to include approval criteria for Malignant Peritoneal Mesothelioma (off-label). 23. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023