Utilization Review Policy 172

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Libtayo Utilization Management Medical Policy

- Libtayo® (cemiplimab-rwlc intravenous infusion – Regeneron/Sanofi-Genzyme)

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 01/14/2026

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Libtayo, a programmed death receptor-1 (PD-1) blocking antibody, is indicated for the treatment of the following conditions:[1]

- **Basal Cell Carcinoma**, for treatment of locally advanced or metastatic disease in patients previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- **Cutaneous Squamous Cell Carcinoma**, in adults:
  - For the treatment of metastatic or locally advanced disease in patients who are not candidates for curative surgery or curative radiation.
  - As adjuvant treatment of disease at a high risk of recurrence after surgery and radiation.
- **Non-Small Cell Lung Cancer (NSCLC)**, in adults:
  - For first-line treatment, as a single agent, in tumors that have high programmed death-ligand 1 (PD-L1) expression (tumor proportion score [TPS] ≥ 50%), as determined by an FDA-approved test, with no epidermal growth factor receptor (*EGFR*), anaplastic lymphoma kinase (*ALK*) or *ROS1* aberrations. The disease can be locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or for metastatic disease.
  - For first-line treatment, in combination with platinum-based chemotherapy, in NSCLC without *EGFR*, *ALK*, or *ROS1* aberrations and with disease that is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or for metastatic disease.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Libtayo. Approval is recommended for those who meet the conditions of coverage in **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Due to the specialized skills required for evaluation and diagnosis of patients treated with Libtayo, as well as the monitoring required for adverse events and long-term efficacy, approval requires Libtayo to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Libtayo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Basal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced, nodal, or metastatic disease; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

2. **Cutaneous Squamous Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - a. Patient meets BOTH of the following (a and b):
       - i. Patient has locally advanced, recurrent, or metastatic disease; AND
       - ii. Patient is not a candidate for curative surgery or curative radiation; OR
     - b. Patient meets BOTH of the following (a and b):
       - i. Patient has very-high risk, locally advanced, unresectable, in-transit metastasis, or regional disease; AND
       - ii. The medication will be used as neoadjuvant therapy; OR
     - c. Patient meets BOTH of the following (a and b):
       - i. Patient has disease that is at a high or very-high risk for recurrence; AND
         Note: High or very-high risk for disease recurrence is defined as nodal features (extracapsular extension with largest node ≥ 20 mm in diameter or ≥ 3 involved nodes) or non-nodal features (in-transit metastases, T4 lesion [with bone invasion], perineural invasion, or locally recurrent tumor with ≥ 1 addition risk feature).
       - ii. The medication will be used as adjuvant therapy; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

3. **Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (*EGFR) exon 19* deletion or *exon 21 L858R*, anaplastic lymphoma kinase (*ALK), RET*, and *ROS1*; AND
   - **C)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient meets BOTH of the following (a and b):
       - i. The medication will be used first-line; AND
       - **b)** The tumor is positive for ONE of the following [(1), (2), or (3)]:
         - **(1)** *EGFR exon 20* mutation; OR
         - **(2)** *ERBB2 (HER2)* mutation; OR
         - **(3)** *NRG1* gene fusion; OR
     - **iii.** Patient meets BOTH of the following (a and b):

a) The medication will be used as first-line or subsequent therapy; AND
b) The tumor is positive for ONE of the following [(1), (2), or (3)]:
(1) *BRAF V600E* mutation; OR
(2) *NTRK1/2/3* gene fusion; OR
(3) *MET exon 14* skipping mutation; OR

iv. Patient meets BOTH of the following (a and b):
a) The medication will be used as subsequent therapy; AND
b) The tumor is positive for *EGFR S768I, L861Q*, and/or *G719X* mutation; OR

iv. Patient meets BOTH of the following (a and b):
a) The medication is used for first-line or continuation maintenance therapy; AND
b) The tumor has no actionable mutations; AND
Note: The tumor does NOT have the following mutations: *EGFR exon 19* deletion, *EGFR exon 21 L858R. EGFR S768I, EGFR L861Q, EGFR G719X, EGFR exon 20* insertion, *ALK* rearrangement, *ROS1* rearrangement, *BRAF V600E, NTRK 1/2/3* gene fusion, *METex14* skipping, *RET* rearrangement, *ERBB2 (HER2)*, and *NRG1* gene fusion.

D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

Other Uses with Supportive Evidence

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4. Anal Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has locally recurrent, metastatic, or progressive disease; AND
C) Patient meets ONE of the following (i or ii):
i. The medication is administered before proceeding to abdominoperineal resection; OR
ii. The medication is used as subsequent therapy; AND
D) The medication is used as a single agent; AND
E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

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5. Cervical Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. Patient has local or regional recurrence; OR
ii. Patient has distant metastatic disease; AND
C) The medication is used as subsequent therapy; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

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6. Colon, Rectal, and Appendiceal Cancer. Approve for duration noted if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); OR
  ii. Disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutational burden > 50 mutations/megabase); AND
C) Patient meets ONE of the following (i or ii):
  i. Approve for 1 year of the patient has locally unresectable, advanced, recurrent, metastatic, or medically inoperable disease; OR
  ii. Approve for 6 months if the medication is used for neoadjuvant therapy; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

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7. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); OR
  ii. Disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutational burden > 50 mutations/megabase); AND
C) Patients meets ONE of the following (i or ii):
  i. Patient has locally unresectable or medically inoperable disease; OR
  ii. Patient has advanced or metastatic disease; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

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8. Vaginal Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Patient has local or regional recurrence; OR
  ii. Patient has distant metastatic disease; AND
C) The medication is used as subsequent therapy; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

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9. Vulvar Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has advanced, recurrent, or metastatic disease; AND
C) The medication is used as subsequent therapy; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 350 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Libtayo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Libtayo® intravenous infusion [prescribing information]. Tarrytown, NY and Bridgewater, NJ: Regeneron/Sanofi-Genzyme; October 2025.
2. The NCCN Basal Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – September 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
3. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – September 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2026 – December 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
5. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 6, 2026. Search term: cemiplimab.
6. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – November 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
7. The NCCN Vulvar Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – November 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
8. The NCCN Vaginal Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – December 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
9. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 5.2025 – October 30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
10. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 4.2025 – October 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
11. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 5.2025 – October 31, 2025). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
12. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – October 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.
13. The NCCN Appendiceal Neoplasms and Cancers Clinical Practice Guidelines in Oncology (version 1.2026 – October 30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 6, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Cutaneous Squamous Cell Carcinoma:** The descriptor "recurrent" was added to the requirement that the patient has advanced, recurrent, or metastatic disease. **Non-Small Cell Lung Cancer:** A requirement was added that in patients with total proportion score of ≥ 50%, Libtayo will be used as a single agent. Use of Libtayo in combination with platinum-based chemotherapy was added as an option for approval.	11/30/2022
Annual Revision	**Basal Cell Carcinoma:** Added descriptor "nodal" to requirement that the patient has locally advanced, nodal, or metastatic disease. Removed requirement that the patient has previously received a hedgehog pathway inhibitor OR hedgehog inhibitor therapy is not appropriate. **Cutaneous Squamous Cell Carcinoma:** Added option of approval for patients with very-high risk, locally advanced, unresectable, or regional disease AND medication will be used as neoadjuvant therapy. **Non-Small Cell Lung Cancer:** Revised requirement that the patient has locally advanced disease and is not eligible for surgical resection or chemotherapy or has metastatic disease to: Patient has recurrent, advanced, or metastatic disease. Added options for approval Libtayo use as first-line or continuation maintenance therapy, as	12/13/2023

	first-line therapy, as first-line or subsequent therapy, and as subsequent therapy. Removed option for approval that the tumor has a tumor proportion score ≥ 50% and Libtayo will be used as a single agent. Removed option for approval that Libtayo will be used in combination with chemotherapy and the tumor is negative for actionable mutations. **Cervical Cancer:** Added new condition of approval. **Vulvar Cancer:** Added new condition of approval.	
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	**Non-Small Cell Lung Cancer:** Added tumor may be *KRAS G12C* mutation positive to Note. Removed *KRAS G12C* mutation as an option for approval for first-line use of Libtayo. **Vaginal Cancer**: Added new condition of approval.	12/11/2024
Early Annual Revision	**Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease:** Indication was changed to as listed. Previously, all non-small cell lung cancer (NSCLC) was addressed more generally under NSCLC. Added a requirement that the "the tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGRF) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1". Added "the tumor has no actionable mutations; Note: The tumor does NOT have the following mutations: EFGR exon 19 deletion, EFGR exon 21 L858R, EFGR S768I, EGFR L861Q, EGFR G719X, EGFR exon 20 insertion, ALK rearrangement, ROS1 rearrangement, BRAF V600E, NTRK 1/2/3 gene fusion, METex14 skipping, RET rearrangement, ERBB2 (HER2), and NRG1 gene fusion." as a condition for approval, if the medication is used as first-line therapy or as continuation maintenance therapy. Added "NRG1 gene fusion positive" as an approval condition for first-line therapy. Removed "RET rearrangement positive" as an approvable mutation, if used as first-line or subsequent therapy. For subsequent therapy, removed "EGFR exon 19 deletion or exon 21 L858R mutation positive, ALK rearrangement positive, or ROS1 rearrangement" and the requirement that "the patient has received targeted drug therapy for the specific mutation" was removed as approval option. **Anal Carcinoma:** Added new condition of approval. **Colon or Rectal Cancer:** Added new condition of approval. **Small Bowel Adenocarcinoma:** Added new condition of approval.	07/02/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025
Selected Revision	**Cutaneous Squamous Cell Carcinoma:** The option that the patient has very-high risk, locally advanced, unresectable, or regional disease was modified to the patient has very-high risk, locally advanced, unresectable, in-transit metastasis, or regional disease. When the patient has disease that is at a high or very-high risk for recurrence and the medication will be used as adjuvant therapy was added as an option for approval. The note "high or very-high risk for disease recurrence is defined as nodal features (extracapsular extension with largest node ≥ 20 mm in diameter or ≥ 3 involved nodes) or non-nodal features (in-transit metastases, T4 lesion [with bone invasion], perineural invasion, or locally recurrent tumor with ≥ 1 addition risk feature)" was added. **Colon, Rectal, and Appendiceal Cancer:** Indication was changed to as listed. Previously, listed as Colon and Rectal Cancer.	10/22/2025
Early Annual Revision	Anal Carcinoma: The requirement that the medication is used as subsequent therapy and the patient has NOT received prior immunotherapy was modified to the medication is used as subsequent therapy. The corresponding Note with examples of immunotherapy was removed. Colon, Rectal, and Appendiceal Cancer: The option for approval that the patient has NOT received prior checkpoint inhibitors and the corresponding Note was removed if the patient has locally unresectable, advanced, recurrent, metastatic, or medically inoperable disease. Small Bowel Adenocarcinoma: The option of approval that the patient has advanced or metastatic disease and has NOT received prior checkpoint inhibitors was modified to the patient has advanced or metastatic disease. The corresponding Note with examples of checkpoint inhibitors was removed.	01/14/2026