UTILIZATION MANAGEMENT MEDICAL POLICY

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

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

REVIEW DATE: 12/11/2024

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**, for metastatic or locally advanced disease in patients who are not candidates for curative surgery or curative radiation.
- **Non-Small Cell Lung Cancer (NSCLC)**, for first-line treatment, as a single agent, in adults with 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.
- **NSCLC**, for first-line treatment, in combination with platinum-based chemotherapy, for adults with 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.

Guidelines

Libtayo is addressed in National Comprehensive Cancer Network guidelines:

- **Basal Cell Carcinoma:** Guidelines (version 3.2024 – March 1, 2024) recommend Libtayo for locally advanced disease where surgery and/or radiation therapy may not result in a cure or would possibly produce a significant functional limitation, for nodal disease if surgery is not feasible, or metastatic disease (category 2A).[2,5]
- **Cervical Cancer:** Guidelines (version 4.2024 – September 24, 2024) recommend Libtayo for the subsequent treatment of local or regional recurrence, or stage IVB or recurrence with distant metastases, as a single agent (category 2A).[5,6]
- **Cutaneous Squamous Cell Carcinoma:** Guidelines (version 1.2024 – November 9, 2023) recommend Libtayo as a preferred therapy (category 2A) for locally advanced, recurrent, or metastatic disease in which curative surgery or curative radiotherapy is not feasible.[3,5] Libtayo is also recommended for the adjuvant treatment of very-high risk, locally advanced, unresectable, or regional disease.
- **Non-Small Cell Lung Cancer:** Guidelines (version 11.2024 – October 15, 2024) recommend Libtayo as a single agent for the first-line and continuation maintenance therapy, for advanced, recurrent, or metastatic disease with PD-L1 ≥ 50% and negative for actionable molecular markers.[4,5] Libtayo is also recommended as a single agent or in combination with chemotherapy, as first-line, continuation maintenance, and subsequent therapy in a variety of clinical situations.

- **Vaginal Cancer:** Guidelines (version 2.2025 – August 8, 2024) recommend Libtayo for the subsequent treatment of local or regional recurrence, or stage IVB or recurrence with distant metastases, as a single agent (category 2A).[5,8]
- **Vulvar Cancer:** Guidelines (version 4.2024 – May 1, 2024) recommend single agent Libtayo for the subsequent treatment of advanced, recurrent, or metastatic disease.[5,7]

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

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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.

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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 or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** Patient has locally advanced, recurrent, or metastatic disease; AND
    - **b)** Patient is not a candidate for curative surgery or curative radiation; OR
  - **ii.** Patient meets BOTH of the following (a and b):
    - **a)** Patient has very-high risk, locally advanced, unresectable, or regional disease; AND
    - **b)** Medication will be used as neoadjuvant 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. 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 recurrent, advanced, or metastatic disease; AND
- **C)** Patient meets ONE of the following (i, ii, iii, or iv):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** Medication is used for first-line or continuation maintenance therapy; AND
      Note: This is regardless of programmed death-ligand 1 (PD-L1) status.
    - **b)** The tumor is negative for actionable mutations; OR
      Note: Examples include sensitizing epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *RET* rearrangement, *MET* exon 14 skipping, *NTRK* gene fusion positive, *BRAF V600E* mutation-positive, and *ROS1* rearrangement positive. Tumor may be *KRAS G12C* mutation positive.
  - **ii.** Patient meets BOTH of the following (a and b):
    - **a)** Medication will be used first-line; AND
    - **b)** The tumor is positive for ONE of the following mutations [(1) or (2)]:
      - **(1)** EGFR exon 20 mutation; OR
      - **(2)** ERBB2 (HER2) mutation; OR
  - **iii.** Patient meets BOTH of the following (a and b):
    - **a)** Medication will be used as first-line or subsequent therapy; AND
      Note: This is regardless of the PD-L1 status.
    - **b)** The tumor is positive for ONE of the following mutations [(1), (2), (3), or (4)]:
      - **(1)** BRAF V600E mutation; OR
      - **(2)** NTRK1/2/3 gene fusion; OR
      - **(3)** MET exon 14 skipping mutation; OR
      - **(4)** RET rearrangement; OR
  - **iv.** Patient meets ALL of the following (a, b, and c):
    - **a)** Medication will be used as subsequent therapy; AND
    - **b)** The tumor is positive for ONE of the following mutations [(1), (2), (3), or (4)]:
      - **(1)** EGFR S768I, L861Q, and/or G719X mutation; OR
      - **(2)** EGFR exon 19 deletion or exon 21 L858R; OR
      - **(3)** ALK rearrangement; OR
      - **(4)** ROS1 rearrangement; AND
    - **c)** The patient has received targeted drug therapy for the specific mutation; OR
      Note: Examples of targeted drug therapy include Gilotrif (afatinib tablet), Tagrisso (osimertinib tablet), erlotinib, Iressa (gefitinib tablet), Vizimpro (dacomitinib tablet) Xalkori (crizotinib capsule), Rozlytrek (entrectinib capsule), Alecensa (alectinib capsule), or Zykadia (ceritinib tablet).
- **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

4. 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) 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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5. 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) 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. 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) 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; April 2024.
2. The NCCN Basal Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – March 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 4, 2024.
3. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – November 9, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 4, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 11.2024 – October 15, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 4, 2024.
5. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 4, 2024. Search term: cemiplimab.
6. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – September 24, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 4, 2024.
7. The NCCN Vulvar Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 4, 2024.

8. The NCCN Vaginal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – August 8, 2025). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 4, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
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 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.	12/13/2023
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