

# Libtayo (cemiplimab-rwlc)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Libtayo (cemiplimab-rwlc)

## **APPROVAL CRITERIA**

Requests for Libtayo (cemiplimab-rwlc) injection may be approved if the following criteria are met:

- I. Individual has a diagnosis of unresectable locally advanced, recurrent, or metastatic Basal Cell Carcinoma (BCC) (Label, NCCN 2A); **AND**
  - A. Individual is using as single agent for subsequent therapy; **AND**
  - B. Individual has confirmed disease progression on a hedgehog pathway inhibitor, or ineligible for treatment with a hedgehog pathway inhibitor;

**OR**

- II. Individual has a diagnosis of Cutaneous Squamous Cell Carcinoma CSCC (Label, NCCN 2A); **AND**
  - A. One of the following:
    1. Individual is diagnosed with metastatic disease; **OR**
    2. Individual is diagnosed with locally advanced or locally recurrent disease; **OR**
    3. Individual is diagnosed with regional new or regional recurrent disease;
  - AND**
  - B. Individual is using as single agent;

**OR**

- III. Individual has a diagnosis of recurrent, advanced, or metastatic disease NSCLC; **AND**
  - A. Individual is using in combination with pemetrexed (NCCN 1) or platinum-based chemotherapy (Label); **OR**
  - B. Individual is using as a single agent;

**OR**

- IV. Individual has a diagnosis of cervical or vulvar cancer (NCCN 2A); **AND**
  - A. Individual has advanced, recurrent, or metastatic disease; **AND**
  - B. Individual is using as second-line or subsequent therapy.

Requests for Libtayo (cemiplimab) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. Individual has received treatment with another anti-PD-1 or anti-PD-L1 agent; **OR**

III. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 19, 2024.
  - a. Basal Cell Skin Cancer. V3.2024. Revised March 1, 2024.
  - b. Cervical Cancer. V2.2024. Revised February 23, 2024.
  - c. Non-Small Cell Lung Cancer. V3.2024. Revised March 12, 2024.
  - d. Squamous Cell Skin Cancer. V1.2024. Revised November 9, 2023.
  - e. Vaginal Cancer. V1.2025. Revised March 26, 2024
  - f. Vulvar Cancer. V3.2024. Revised December 21, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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