

## Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: PA.CP.PHAR.397

Effective Date: 01/2019

Last Review Date: 10/2023

[Revision Log](#)

### Description

Cemiplimab-rwlc (Libtayo®) is a programmed death receptor-1 (PD-1) blocking antibody.

### FDA Approved Indication(s)

Libtayo is indicated:

- For the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.
- For the treatment of patients with locally advanced or metastatic basal cell carcinoma (BCC)(laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- In combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or ROS1 aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.
- As a single agent for the first-line treatment of adult patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS)  $\geq 50\%$ ] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Libtayo is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Cutaneous Squamous Cell Carcinoma (must meet all):

1. Diagnosis of CSCC;
2. Disease is metastatic, locally advanced, recurrent, unresectable, very-high risk, or regional (e.g., inoperable or borderline resectable);;
3. Prescribed by or in consultation with an oncologist;
4. Age  $\geq 18$  years;
5. Member is not a candidate for curative surgery or curative radiation;
6. Prescribed as a single agent;
7. Request meets one of the following (a or b):
  - a. Dose does not exceed both of the following (i and ii):

- i. 350 mg every 3 weeks;
  - ii. 1 vial every 3 weeks;
- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**B. Basal Cell Carcinoma** (must meet all):

1. Diagnosis of BCC;
2. Disease is metastatic, locally advanced, local recurrence or nodal disease;
3. Prescribed by or in consultation with an oncologist;
4. Age  $\geq 18$  years;
5. Previous treatment with a hedgehog pathway inhibitor (e.g., Erivedge<sup>®</sup>, Odomzo<sup>®</sup>), unless clinically significant adverse effects are experienced, all are contraindicated, or medical justification indicates that hedgehog pathway inhibitor therapy is not appropriate;
6. Prescribed as a single agent;
7. Request meets one of the following (a, or b):
  - a. Dose does not exceed both of the following (i and ii):
    - i. 350 mg every 3 weeks;
    - ii. 1 vial every 3 weeks;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

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

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq 18$  years;
4. Disease is EGFR negative, ALK negative, and ROS1 negative;
5. Prescribed in one of the following ways (a, b, c or d):
  - a. As a single agent, and one of the following (i or ii):
    - i. Tumor has high PD-L1 expression (TPS  $\geq 50\%$ );
    - ii. Tumor has PD-L1 expression  $< 50\%$ , and therapy is prescribed following first-line therapy with Libtayo combination therapy (e.g., cemiplimab-rwlc, [pemetrexed or paclitaxel], and [carboplatin or cisplatin]);
  - b. In combination with platinum-based chemotherapy (e.g., cisplatin, carboplatin);
  - c. In combination with pemetrexed as continuation maintenance therapy following first-line therapy with Libtayo combination therapy for nonsquamous cell tumors;
  - d. Other NCCN category 1, 2A, and 2B recommended use;
6. Request meets one of the following (a or b):
  - a. Dose does not exceed both of the following (i and ii):
    - iii. 350 mg every 3 weeks;
    - iv. 1 vial every 3 weeks;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**D. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

**II. Continued Therapy**

**A. All indications in Section I (must meet all):**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. For BCC or CSCC requests, member has not received more than 24 months of Libtayo therapy;
4. If request is for a dose increase, request meets one of the following (a, or b):
  - a. New dose does not exceed both of the following (i or ii):
    - i. 350 mg every 3 weeks;
    - ii. 1 vial every 3 weeks;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months (up to a total treatment duration of 24 months for BCC or CSCC)**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ALK: anaplastic lymphoma kinase

BCC: basal cell carcinoma

CSCC: cutaneous squamous cell carcinoma

EGFR: epidermal growth factor receptor

FDA: Food and Drug Administration

la: locally advanced

m: metastatic

NSCLC: non-small cell lung cancer

PD-1: programmed death receptor-1

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
BCC, CSCC	350 mg IV over 30 minutes every 3 weeks	See dosing regimen
NSCLC	350 mg IV over 30 minutes every 3 weeks until disease progression or unacceptable toxicity	See dosing regimen

**VI. Product Availability**

Single-dose vial for injection: 350 mg/7 mL (50 mg/mL) solution

**VII. References**

1. Libtayo Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2023. Available at: <https://www.libtayohcp.com/>. Accessed June, 30, 2023.
2. Cemiplimab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed July 11, 2023.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer, Version 6.2022. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed July 11, 2023.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9119	Injection, cemiplimab-rwlc, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2019	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: Added age limit and references reviewed and updated.	08/2020	
Added new indications for BCC and NSCLC	04/2021	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022	
4Q 2023 annual review: for BCC and CSCC, added prescribed as a single agent per NCCN and added total treatment duration up to 24 months per PI; updated language in FDA Approved Indications; for NSCLC updated verbiage from wild-type to negative; references reviewed and updated. RT4: FDA approved indication for mBCC converted from accelerated approval to traditional approval; Section V updated per PI.	10/2023	