

## Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: PA.CP.PHAR.397

Effective Date: 01/2019

Last Review Date: 10/2024

### Description

Cemiplimab-rwlc (Libtayo<sup>®</sup>) 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 adjuvant treatment of adult patients with CSCC at high risk of recurrence after surgery and 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<sup>®</sup> 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. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Member meets one of the following (a, b or c):
  - a. Disease is metastatic, recurrent, locally advanced or satellitosis/in-transit metastasis that is unresectable or incompletely resected, where member is not a candidate for curative surgery or curative radiation;

- b. Prescribed as adjuvant treatment for disease at high risk of recurrence after surgery and radiation (see *Appendix D*);
- c. Prescribed as neoadjuvant treatment, and disease is one of the following (i, ii, or iii):
  - i. Very-high-risk (see *Appendix D*);
  - ii. Locally advanced;
  - iii. Regional or satellitosis/in-transit metastatic;
5. Prescribed as a single agent;
6. Request meets one of the following (a, b or c):
  - a. Metastatic and locally advanced CSCC: Dose does not exceed 350 mg (1 vial) every 3 weeks for a maximum of 24 months;
  - b. Adjuvant treatment of CSCC, one of the following (i or ii):
    - i. Dose does not exceed 350 mg (1 vial) every 3 weeks for maximum of 48 weeks of total therapy;
    - ii. Dose does not exceed 350 mg (1 vial) every 3 weeks for 12 weeks followed by 700 mg (2 vials) every 6 weeks for a maximum of 48 weeks of total therapy;
  - c. 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**

**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. Prescribed as a single agent;
6. 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: 12 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, pemetrexed, carboplatin or cisplatin 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):
    - 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: 12 months**

**D. NCCN Recommended Uses (off-label) (must meet all):**

- 1. Diagnosis of one of the following (a-f):
  - a. Cervical cancer, as second-line or subsequent therapy;
  - b. Vaginal cancer, as second-line or subsequent therapy;
  - c. Advanced, recurrent, or metastatic vulvar cancer, as second-line or subsequent therapy;
  - d. Locally recurrent, progressive, metastatic anal carcinoma or inguinal node recurrence;
  - e. One of the following cancers with deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/mb) (i, ii, or iii):
    - i. Small bowel adenocarcinoma, one of the following (1, 2 or 3):
      - 1) As primary treatment for locally unresectable or medically inoperable disease;
      - 2) For advanced or metastatic disease with no previous treatment with a checkpoint inhibitor (e.g., Keytruda<sup>®</sup>, Opdivo<sup>®</sup>);
      - 3) For neoadjuvant therapy as a single agent for resectable disease;
    - ii. Rectal cancer;
    - iii. Colon cancer;
  - f. Other NCCN recommendations listed as category 1, 2A, or 2B;
- 2. Prescribed by or in consultation with an oncologist;
- 3. Age  $\geq$  18 years;
- 4. Prescribed as one of the following (a or b):
  - a. A single agent;
  - b. For anal carcinoma, in combination with paclitaxel and carboplatin;
- 5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*)

**Approval duration: 12 months**

**E. 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.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Member has NOT received the maximum duration of therapy as described below (a or b):
  - a. BCC: up to 24 months;
  - b. CSCC, one of the following (i or ii):
    - i. Adjuvant treatment: up to 48 weeks;
    - ii. Metastatic and locally advanced CSCC: up to 24 months;
4. If request is for a dose increase, request meets one of the following (a, or b):
  - a. New dose does not exceed one of the following (i or ii):
    - i. 350 mg (1 vial) every 3 weeks;
    - ii. Adjuvant treatment of CSSS: 350 mg (1 vial) every 3 weeks for 12 weeks, followed by 700 mg (2 vials) every 6 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.PHARM.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  
dMMR: deficient mismatch repair

EGFR: epidermal growth factor receptor  
 FDA: Food and Drug Administration  
 la: locally advanced  
 m: metastatic  
 MMI-H: microsatellite instability-high  
 NSCLC: non-small cell lung cancer

PD-1: programmed death receptor-1  
 POLE/POLD1: polymerase epsilon/delta  
 TMB: tumor mutational burden  
 TPS: tumor proportion score

*Appendix B: Therapeutic Alternatives*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<p><b>Cervical Cancer</b> – examples of 1<sup>st</sup> line therapies</p> <ul style="list-style-type: none"> <li>• Pembrolizumab (Keytruda<sup>®</sup>) + cisplatin or carboplatin/paclitaxel ± bevacizumab</li> <li>• Cisplatin or carboplatin /paclitaxel/bevacizumab</li> <li>• Atezolizumab + cisplatin or carboplatin/paclitaxel + bevacizumab</li> <li>• Cisplatin or carboplatin/paclitaxel</li> <li>• Topotecan/paclitaxel ± bevacizumab</li> <li>• Cisplatin + topotecan</li> <li>• Cisplatin or carboplatin</li> <li>•</li> </ul> <p><b>Vaginal Cancer</b> – examples of 1<sup>st</sup> line therapies</p> <ul style="list-style-type: none"> <li>• Pembrolizumab (Keytruda<sup>®</sup>) + cisplatin or carboplatin/paclitaxel ± bevacizumab</li> <li>• Cisplatin or carboplatin /paclitaxel/bevacizumab</li> <li>• Cisplatin or carboplatin/paclitaxel</li> <li>• Topotecan/paclitaxel ± bevacizumab</li> <li>• Cisplatin + topotecan</li> <li>• Cisplatin or carboplatin</li> </ul> <p><b>Vulvar Cancer</b> – examples of 1<sup>st</sup> line therapies</p> <ul style="list-style-type: none"> <li>• Cisplatin or carboplatin/paclitaxel ± bevacizumab</li> <li>• Pembrolizumab (Keytruda<sup>®</sup>) + cisplatin or carboplatin/paclitaxel ± bevacizumab</li> <li>• Cisplatin or carboplatin</li> </ul>	Varies	Varies

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: General Information*

- NCCN Squamous Cell Skin Cancer Version 1.2026 defines those with high-risk for recurrence CSCC due to:
  - Extremely high-risk nodal features: extracapsular extension with largest node ≥ 20 mm in diameter or ≥ 3 involved nodes

- Non-nodal features: in-transit metastases, T4 lesion [with bone invasion], perineural invasion, or locally recurrent tumor with  $\geq 1$  additional risk feature\*

\*Additional risk features for recurrent lesion:  $\geq$  N2b,  $\geq$  T3, poorly differentiated histology and recurrent lesion  $\geq 20$  mm diameter

- NCCN Squamous Cell Skin Cancer Version 1.2026 risk group stratification

	Low risk	High risk	Very high risk
<b>H&amp;P</b>			
Location/diameter (cm)	Trunk, extremities < 2 cm	Trunk, extremities 2 cm - $\leq$ 4 cm	> 4 cm (any location)
		Head, neck, hands, feet, pretibial, and anogenital area (any size)	
Clinical borders	Well-defined	Poorly-defined	
Primary vs. recurrent	Primary	Recurrent	
Immunosuppression	(-)	(+)	
Site of prior RT or chronic inflammation	(-)	(+)	
Rapid growth tumor	(-)	(+)	
Neurological symptoms	(-)	(+)	
<b>Pathology</b>			
Degree of differentiation	Well or moderately differentiated		Poorly differentiated
Histologic subtype	(-)	(+)	
Depth: thickness of level of invasion	< 2 mm thick and no invasion beyond subcutaneous fat	2-6 mm depth and no invasion beyond subcutaneous fat	> 6 mm or invasion beyond subcutaneous fat
Perineural involvement	(-)	(+)	Tumor cells within the nerve sheath of a nerve lying deeper than the dermis or measuring $\geq 0.1$ mm
Lymphatic or vascular involvement	(-)	(-)	(+)

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
BCC, CSCC (metastatic and locally advanced)	350 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months	See dosing regimen
CSCC (adjuvant treatment)	350 mg IV over 30 minutes every 3 weeks for 12 weeks followed by 700 mg IV every 6 weeks until disease recurrence, unacceptable toxicity, or up to 48 weeks of total therapy OR 350 mg IV over 30 minutes every 3 weeks until disease recurrence, unacceptable toxicity, or up to 48 weeks of total therapy	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.; October 2025. Available at: <https://www.libtayohcp.com/>. Accessed October 15, 2025.
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 August 1, 2024.
3. National Comprehensive Cancer Network. Squamous Cell Skin Cancer Version 1.2026. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/squamous.pdf](https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf). Accessed October 15, 2025.
4. Rischin D, Porceddu S, Day F, et al. Adjuvant cemiplimab or placebo in high-risk cutaneous squamous-cell carcinoma. N Engl J Med 2025;393:774-785.

**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
Policy created	01/2019
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019

Reviews, Revisions, and Approvals	Date
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
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 reviews and updated. RT4: FDA approved indication for mBCC converted from accelerated approval to traditional approval; Section V updated per PI.	10/2023
4Q 2024 annual review: for CSCC, added option for disease is recurrent and prescribed in neoadjuvant setting; NSCLC, added option for disease is recurrent; for BCC, removed criterion requiring previous treatment with a hedgehog pathway inhibitor per NCCN; added NCCN supported recommended uses (off-label) section to include: cervical cancer, vaginal, vulvar cancer, anal carcinoma, small bowel adenocarcinoma; references reviewed and updated.	10/2024
4Q 2025 annual review: for CSCC, added option for disease that is satellitosis/in-transit metastasis that is unresectable or incompletely resected per NCCN; for cervical, vaginal cancer and vulvar cancer, clarified usage as second-line or subsequent therapy per NCCN; added off-label indications for anal carcinoma and dMMR/MSI-H or POLE/POLD1 mutation with tumor cancers for: small bowel adenocarcinoma, and rectal and colon cancer per NCCN; initial approval durations changed from 6 to 12 months; references reviewed and updated. RT4: added new indication for adjuvant treatment of adult patients with CSCC at high risk of recurrence after surgery or curative radiation; added disease qualifiers for neoadjuvant use per NCCN.	10/2025