Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: PA.CP.PHAR.397
Effective Date: 01/2019
Last Review Date: 10/2024

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) ≥ 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. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Disease is metastatic, recurrent, or locally advanced where members are not a candidate for curative surgery or curative radiation;
   b. Prescribed as neoadjuvant treatment;
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: 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 ≥ 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: 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 ≥ 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 ≥ 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. NCCN Recommended Uses (off-label) (must meet all):

1. Diagnosis of one of the following (a, b, c, d or e):

a. Cervical cancer;
b. Vaginal cancer;
c. Vulvar cancer;
d. Small Bowel Adenocarcinoma;
e. Anal Carcinoma;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
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: 6 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. 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.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
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 until disease progression, unacceptable toxicity, or up to 24 months	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 2024. Available at: https://www.libtayohcp.com/. Accessed July 16, 2024.
2. Cemiplimab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 1, 2024.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer, Version 7.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed August 1, 2024.
4. National Comprehensive Cancer Network. Basal Cell Skin Cancer, Version 3.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed August 1, 2024.
5. National Comprehensive Cancer Network. Squamous Cell Skin Cancer, Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf. Accessed August 1, 2024.

6. National Comprehensive Cancer Network. Cervical Cancer, Version 3.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed August 1, 2024.
7. National Comprehensive Cancer Network. Vulvar Cancer, Version 4.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/vulvar.pdf. Accessed August 1, 2024.
8. National Comprehensive Cancer Network. Vaginal Cancer, Version 4.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/vaginal.pdf. Accessed August 1, 2024.

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
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