Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: PA.CP.PHAR.397
Effective Date: 01/2019
Last Review Date: 10/2022

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) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.
- For the treatment of patients with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- For the treatment of patients with metastatic BCC previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.*
- For the first-line treatment of patients with non-small cell lung cancer (NSCLC) as a single agent whose tumors have high 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, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.
- For the first-line treatment of patients with non-small cell lung cancer (NSCLC) in combination with platinum-based chemotherapy with no epidermal growth factor receptor (EGFR), ALK or ROS1 aberrations, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.

*The metastatic BCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for metastatic BCC may be contingent upon verification and description of clinical benefit.

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 or locally advanced, local and regional recurrence, unresectable disease, inoperable or incompletely resected regional disease, or new regional disease;
3. Prescribed by or in consultation with an oncologist;

4. Age ≥ 18 years;
5. Member is not a candidate for curative surgery or curative radiation;
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 or locally advanced or local recurrence;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Previous treatment with a hedgehog pathway inhibitor (e.g., Erivedge®, Odomzo®), unless clinically significant adverse effects are experienced, all are contraindicated, or medical justification indicates that hedgehog pathway inhibitor therapy is not appropriate;
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 wild-type, ALK negative, and ROS1 negative;
5. Prescribed in one of the following ways (a, b, or c):
   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;
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. 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

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
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, NSCLC	350 mg IV over 30 minutes every 3 weeks	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.; February 2021. Available at: https://www.libtayohcp.com/. Accessed July 7, 2022.
2. Cemiplimab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 7, 2022.

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	01.19	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
4Q 2020 annual review: Added age limit and references reviewed and updated.	08/20	11/20
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	