

Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: [LA.PHAR.397](#)

Effective Date: 10.16.18

Last Review Date: 06.23

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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.*
- [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.](#)
- For the first-line treatment of patients with ~~non-small cell lung cancer (NSCLC)~~ whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) \geq 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.

*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

~~Prior authorization is required.~~ 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 Louisiana Healthcare Connections 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;
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. 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Basal Cell Carcinoma (must meet all):

1. Diagnosis of BCC;
2. Disease is metastatic or locally advanced;
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®, 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

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

1. Diagnosis of NSCLC;
2. Disease is metastatic or locally advanced where members are not candidates for surgical resection or definitive chemoradiation;
3. Prescribed by or in consultation with an oncologist;
4. Age \geq 18 years;
5. Disease is EGFR wild-type, ALK negative, and ROS1 negative;
6. 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 \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;
- ~~6. Tumor has high PD-L1 expression (TPS \geq 50%);~~
- 7. Request meets one of the following (a or b):*
 - a. Dose does not exceed both of the following (i or 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

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

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255~~one of the following policies (a or b)~~
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy- LA.PMN.53
- ~~1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):~~
 - ~~a. For drugs on the PDL (Medicaid), the no coverage criteria policy for Medicaid: LA.PMN.255; or~~
 - ~~b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for Medicaid: LA.PMN.16; or~~
- ~~2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: LA.PMN.53 for Medicaid.~~

II. Continued Therapy

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

- 1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Libtayo for a covered indication and has received this medication for at least 30 days;
- 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

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

3. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
4. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy- LA.PMN.53
- ~~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); LA.PMN.53 for Medicaid.~~

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 policies – LA.PMN.53 for Medicaid, 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

TPS: tumor proportion score

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 2024~~November 2022. Available at: <https://www.libtayohcp.com>. Accessed- ~~November 30~~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~~December 12, 2022.

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. Accessed December 12, 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	LDH Approval Date
Converted corporate to local policy	02.23	03.16.23
<u>Updated criteria for other diagnoses/indications.</u> <u>Added new indication for NSCLC in combination with platinum-based chemotherapy; updated criteria per NCCN NSCLC guidelines.</u> <u>References reviewed and updated.</u>	<u>06.25.23</u>	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the

requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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