Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: LA.PHAR.397
Effective Date: 10.16.18
Last Review Date: 01.15.25 ~~05.21.24~~ Coding Implications
Line of Business: Medicaid 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)(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 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.~~2. Prescribed by or in consultation with an oncologist;
~~4.~~3. Age ≥ 18 years;

4. Member ~~is~~meets one of the following (a or b):
   ~~5.~~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;
~~6.~~5. Prescribed as a single agent;
~~7.~~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 ≥ 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.~~5. Prescribed as a single agent;
~~7.~~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, recurrent, 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 ≥ 18 years;
5. Disease is EGFR negative, 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 ≥ 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);

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c. In combination with pemetrexed as continuation maintenance therapy following first-line therapy with Libtayo combination therapy for nonsquamous cell tumors;

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*).

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

Approval duration: 6 months

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

1. Diagnosis of one of the following (a, b, or c):
   a. Cervical cancer;
   b. Vaginal cancer;
   c. Vulvar cancer;
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*).*

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

Approval duration: 6 months

~~D.~~ **E. 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
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

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. 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 and ii):
      i. 350 mg every 3 weeks;
      ii. 1 vial every 3 weeks;

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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 (up to a total treatment duration of 24 months for BCC or CSCC)

B. 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
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

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
la: locally advanced
m: metastatic
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	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

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VII. References

1. Libtayo Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April ~~2023~~2024. Available at: https://www.libtayohcp.com. Accessed ~~June 30, 2023~~July 16, 2024.
2. Cemiplimab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed ~~July 11, 2023~~August 1, 2024.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer, Version ~~6.2022~~7.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed ~~July 11, 2023~~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.
~~3.~~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	LDH Approval Date
Converted corporate to local policy	02.23	03.16.23
Updated criteria for other diagnoses/indications. Added new indication for NSCLC in combination with platinum-based chemotherapy; updated criteria per NCCN NSCLC guidelines. References reviewed and updated.	06.25.23	10.05.23
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; for NSCLC updated verbiage from wild-type to negative; FDA approved indication for mBCC converted from	05.21.24	07.29.24

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
accelerated approval to traditional approval; Section V updated per PI; references reviews and updated		
Aannual 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; references reviewed and updated	01.15.25	

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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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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