

Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: LA.PHAR.397

Effective Date: 10.16.18

Last Review Date: ~~12.19.2501.15.25~~

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) ~~(mCSCC)~~ (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 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. Prescribed by or in consultation with an oncologist;

3. Age ≥ 18 years;
4. Member meets one of the following (a, b, or c):
 - a. Disease is metastatic, recurrent, ~~or~~ locally advanced or satellitosis/in-transit metastasis that is unresectable or incompletely resected, where ~~members~~ are 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);
 - ~~b,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 ~~or~~ b, or c):*
 - ~~a.~~ Metastatic and locally advanced CSCC: Dose does not exceed both of the following (i and ii):
 - ~~i.~~ 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):
 - ~~ii.~~ 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;
 - ~~b,c.~~ 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. 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 (1 vial) every 3 weeks;
 - ii. 1 vial every 3 weeks;
 - ~~a.~~ Dose is supported by practice guidelines or peer-reviewed literature for a maximum of 24 months;
 - 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

~~b,c.~~ **Approval duration:** the relevant off-label use (prescriber must submit supporting evidence).

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

Approval duration: 6-12 months

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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 $\geq$ 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 $\geq$ 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;
7. Request meets one of the following (a or b):*

~~a.~~ Dose does not exceed ~~both of the following (i and ii):~~

~~i.a.~~ 350 mg (1 vial) every 3 weeks;

~~ii.a.~~ 1 vial every 3 weeks;

~~b.a.~~ 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.~~ 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

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

1. Diagnosis of one of the following (a, b, c, d, or ~~ee~~):
 - a. Cervical cancer, as second-line or subsequent therapy;
 - b. Vaginal cancer, as second-line or subsequent therapy;
 - ~~c. Vulvar cancer;~~
 - c. Advanced, recurrent, or metastatic vulvar cancer, as second-line or subsequent therapy;
 - d. Locally recurrent, progressive, or metastatic anal carcinoma;
 - 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 or 2):
 - 1) As primary treatment for locally unresectable or medically inoperable disease;

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2) For advanced or metastatic disease with no previous treatment with a checkpoint inhibitor (e.g. Keytruda®, Opdivo®);

ii. Rectal cancer;

iii. Colon 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:~~ 12 months

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

1.a. 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

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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 NOT received more than 24 months the maximum duration of Libtayo 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;

3-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 ~~both one~~ of the following (i ~~and~~ ii):

i. 350 mg (1 vial) every 3 weeks;

ii. Adjuvant treatment of CSSS: 350 mg (1 vial) every 3 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).

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

Approval duration: 12 months ~~12 months (up to a total treatment duration of 24 months for BCC or CSCC)~~

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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 policy ~~yes~~ 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
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

Not applicable

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/Maximum Dose</u>
<u>Cervical Cancer – examples of 1st line therapies</u> <u>Pembrolizumab (Keytruda®) + cisplatin or carboplatin/paclitaxel ± bevacizumab</u> <u>Cisplatin or carboplatin /paclitaxel/bevacizumab</u> <u>Atezolizumab + cisplatin or carboplatin/paclitaxel + bevacizumab</u> <u>Cisplatin or carboplatin/paclitaxel</u> <u>Topotecan/paclitaxel ± bevacizumab</u> <u>Cisplatin + topotecan</u> <u>Cisplatin or carboplatin</u> <u>_____</u> <u>Vaginal Cancer – examples of 1st line therapies</u> <u>Pembrolizumab (Keytruda®) + cisplatin or carboplatin/paclitaxel ± bevacizumab</u> <u>Cisplatin or carboplatin /paclitaxel/bevacizumab</u> <u>Cisplatin or carboplatin/paclitaxel</u> <u>Topotecan/paclitaxel ± bevacizumab</u>	<u>Varies</u>	<u>Varies</u>

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
- Cisplatin + topotecan - Cisplatin or carboplatin Vulvar Cancer – examples of 1st line therapies - Cisplatin or carboplatin/paclitaxel ± bevacizumab - Pembrolizumab (Keytruda®) + cisplatin or carboplatin/paclitaxel ± bevacizumab - Cisplatin or carboplatin		

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 ≥ 1 additional risk feature*
 - *Additional risk features for recurrent lesion: ≥ N2b, ≥ T3, poorly differentiated histology and recurrent lesion ≥ 20 mm diameter
- NCCN Squamous Cell Skin Cancer Version 1.2026 risk group stratification

	Low risk	High risk	Very high risk
H&P			
Location/diameter (cm)	Trunk, extremities < 2 cm	Trunk, extremities 2 cm - < 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	(-)	(+)	
Pathology			
Degree of differentiation	Well or moderately differentiated		Poorly differentiated

	Low risk	High risk	Very high risk
<u>Histologic subtype</u>	<u>(-)</u>	<u>(+)</u>	
<u>Depth: thickness of level of invasion</u>	<u>< 2 mm thick and no invasion beyond subcutaneous fat</u>	<u>2-6 mm depth and no invasion beyond subcutaneous fat</u>	<u>> 6 mm or invasion beyond subcutaneous fat</u>
<u>Perineural involvement</u>	<u>(-)</u>	<u>(+)</u>	<u>Tumor cells within the nerve sheath of a nerve lying deeper than the dermis or measuring > 0.1 mm</u>
<u>Lymphatic or vascular involvement</u>	<u>(-)</u>	<u>(-)</u>	<u>(+)</u>

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
<u>BCC, CSCC (metastatic and locally advanced)</u>	<u>350 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months</u>	<u>See dosing regimen</u>
<u>BCC, CSCC (adjuvant treatment)</u>	<u>350 mg IV over 30 minutes every 3 weeks for 12 weeks followed by 700 mg IV every 6 weeks until disease progressionrecurrence, unacceptable toxicity, or up to 24 months48 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</u>	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~~October 2025. Available at: <https://www.libtayahcp.com>. Accessed ~~July 16, 2024~~October 15, 2025.
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-SmallSquamous~~ Cell ~~LungSkin~~ Cancer; Version ~~7.2024~~1.2026. Available at:

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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.
 - 8.4. 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.
- 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	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 accelerated approval to traditional approval; Section V updated per PI; references reviews and updated	05.21.24	07.29.24
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	01.15.25	<u>04.07.25</u>

Reviews, Revisions, and Approvals	Date	LDH Approval Date
NCCN supported recommended uses (off-label) section to include: cervical cancer, vaginal, vulvar cancer; references reviewed and updated		
<u>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. 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</u>	<u>12.19.25</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.

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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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