Clinical Policy: Cemiplimab-rwlc (Libtayo)

Reference Number: CP.PHAR.397
Effective Date: 10.16.18
Last Review Date: 11.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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, locally advanced or satellitosis/in-transit metastasis that is unresectable or incompletely resected, where member is 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*).

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

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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 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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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);

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. 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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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, as second-line or subsequent therapy;
   b. Vaginal cancer, as second-line or subsequent therapy;
   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;
         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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; 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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene 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;
   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:
Medicaid/HIM – 12 months (up to a total treatment duration of 24 months for BCC or CSCC)
Commercial – 6 months or to the member's renewal date, whichever is longer (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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; 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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace and CP.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

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Cisplatin or carboplatin/paclitaxel • Topotecan/paclitaxel ± bevacizumab • 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

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 09, 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.

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
4Q 2021 annual review: no significant changes; references reviewed and updated.	08.11.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications.	07.07.22	11.22
RT4: added new indication for NSCLC in combination with platinum-based chemotherapy; updated criteria per NCCN NSCLC guidelines; references reviewed and updated.	12.06.22	
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; 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.	06.30.23	11.23
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; references reviewed and updated.	07.16.24	11.24
4Q 2025 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 for Medicaid/HIM; references reviewed and updated.	07.09.25	11.25

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. The Health Plan 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. "Health Plan" means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.