BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.118

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 12, 2018
Subject:	Libtayo	**Page:**	1 of 6

Last Review Date: December 12, 2025

Libtayo

Description

Libtayo (cemiplimab-rwlc)

Background
Libtayo (cemiplimab-rwlc) is a recombinant human immunoglobulin G4 (IgG4) monoclonal antibody that binds to programmed death receptor-1 (PD-1) and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth (1).

Regulatory Status
FDA-approved indications: Libtayo is a programmed death receptor-1 (PD-1) blocking antibody indicated: (1)

- Cutaneous Squamous Cell Carcinoma (CSCC)
  - for the treatment of adult patients with metastatic cutaneous squamous cell carcinoma (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
- Basal Cell Carcinoma (BCC)
  - for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate

    - for the treatment of adult patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate
- Non-Small Cell Lung Cancer (NSCLC)
    - in combination with platinum-based chemotherapy for the first-line treatment of adult patients with NSCLC with no EGFR, 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

Libtayo can cause severe and fatal immune-mediated adverse reactions. These can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, and immune-mediated nephritis and renal dysfunction. Patients should be monitored for signs and symptoms of immune-mediated adverse reactions. Evaluate chemical chemistries, including liver and thyroid function, at baseline and periodically during treatment. Libtayo should be withheld or permanently discontinued, and corticosteroids should be administered based on the severity of the reaction (1).

Severe infusion-related reactions may occur during Libtayo treatment. Patients should be monitored for signs and symptoms of infusion-related reactions and the rate of infusion should be interrupted, slowed, or permanently discontinued based on severity of reaction (1).

Libtayo can cause fetal harm when administered to a pregnant woman. The mechanism of action of Libtayo has been shown to lead to increased risk of immune-mediated rejection of a developing fetus resulting in fetal death. Females of reproductive potential should use effective contraception during treatment with Libtayo and for at least 4 months after the last dose (1).

The safety and effectiveness of Libtayo in pediatric patients have not been established (1).

Related policies

Keytruda, Opdivo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Libtayo may be considered **medically necessary** if the conditions indicated below are met.

Libtayo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Cutaneous squamous cell carcinoma (CSCC) with **ONE** of the following:
    a. Metastatic or locally advanced CSCC
        i. Patient is not a candidate for curative surgery or curative radiation
    b. Patient is at high risk of recurrence after surgery and radiation
        i. Used as adjuvant treatment
2. Metastatic or locally advanced basal cell carcinoma (BCC)
    a. Patient has previously been treated with a hedgehog pathway inhibitor (e.g., vismodegib) **OR** a hedgehog pathway inhibitor is not appropriate
3. Metastatic or locally advanced non-small cell lung cancer (NSCLC)
    a. Used as first-line treatment
    b. Patient has **ONE** of the following:
        i. Used as a single agent for tumors that have high PD-L1 expression as determined by an FDA-approved test
        ii. Used in combination with platinum-based chemotherapy
    c. **NO** EGFR, ALK, or ROS1 aberrations
    d. Locally advanced NSCLC **only:** patient is not a candidate for surgical resection or definitive chemoradiation

AND ALL of the following:

1. Prescriber agrees to monitor for immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, and nephritis
2. Females of reproductive potential **only:** patient will be advised to use effective contraception during treatment and for at least 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Cutaneous squamous cell carcinoma (CSCC)
2. Metastatic or locally advanced basal cell carcinoma (BCC)
3. Metastatic or locally advanced non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, and nephritis
3. Females of reproductive potential **only:** patient will be advised to use effective contraception during treatment and for at least 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 vials every 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Libtayo (cemiplimab-rwlc) is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of cutaneous squamous cell carcinoma, metastatic or locally advanced basal cell carcinoma, or metastatic or locally advanced non-small cell lung cancer. Libtayo has warnings for immune-mediated adverse reactions, infusion-related reactions, complications of allogenic hematopoietic stem cell transplantation (HSCT) and embryo-fetal toxicity. The safety and effectiveness of Libtayo in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Libtayo while maintaining optimal therapeutic outcomes.

References

1. Libtayo [package insert]. Tarrytown, NJ: Regeneron Pharmaceuticals, Inc.; October 2025.
2. NCCN Drugs & Biologics Compendium® Cemiplimab-rwlc 2025. National Comprehensive Cancer Network, Inc. Accessed on October 28, 2025.

Policy History

Date	Action
October 2018	Addition to PA
November 2018	Annual review. Addition of requirement for females of reproductive potential to use contraception during therapy and for at least 4 months after the last dose per SME
June 2019	Annual review and reference update
June 2020	Annual review
March 2021	Addition of indication: basal cell carcinoma (BCC). Addition of indication: non-small cell lung cancer (NSCLC)
June 2021	Annual editorial review and reference update
September 2021	Annual review and reference update
June 2022	Annual review and reference update
September 2022	Annual review and reference update
November 2022	Per PI update, added indication of NSCLC with platinum-based chemotherapy and revised indication for NSCLC as a single agent for tumors with high PD-L1 expression
March 2023	Annual review and reference update
September 2023	Annual review and reference update

March 2024	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update
March 2025	Annual review and reference update
June 2025	Annual review and reference update
November 2025	Per PI update, added indication of adjuvant treatment of CSCC with high risk of recurrence after surgery and radiation
December 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.