

## Cemiplimab-rwlc (Libtayo®)

### Place of Service

Office Administration  
Infusion Center Administration  
Outpatient Facility Administration

HCPCS: J9119 per 1 mg

### **Condition listed in policy (see criteria for details)**

- [Basal cell carcinoma](#)
- [Cutaneous squamous cell carcinoma](#)
- [Non-small lung cancer](#)

**AHFS therapeutic class:** Antineoplastic agent

**Mechanism of action:** Programmed death receptor-1 (PD-1) blocking antibody

### **(1) Special Instructions and pertinent information**

**Covered under the medical benefit**, please submit clinical information for prior authorization review via fax.

### **(2) Prior Authorization/Medical Review is required for the following condition(s)**

**All requests for cemiplimab-rwlc (Libtayo®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

#### **Basal cell carcinoma**

1. Locally advanced, metastatic, or recurrent disease, **AND**
2. Being used as a single agent, **AND**
3. Previously treated with a hedgehog pathway inhibitor, or treatment with a hedgehog pathway inhibitor is not appropriate

#### **Covered Dose**

Up to 350 mg IV every 3 weeks

#### **Coverage Period**

Indefinite

#### **ICD-10:**

C44.01, C44.111, C44.1121, C44.1122, C44.1191, C44.1192, C44.211, C44.212, C44.219, C44.310, C44.311, C44.319, C44.41, C44.510, C44.511, C44.519, C44.611, C44.612, C44.619, C44.711, C44.712, C44.719, C44.81, C44.91, Q87.89

#### **Cutaneous squamous cell carcinoma (CSCC)**

1. Recurrent, locally advanced, inoperable, unresectable, or metastatic disease, **AND**
2. Being used as a single agent

#### **Covered Dose**

Up to 350 mg IV every 3 weeks

#### **Coverage Period**

Indefinite

**ICD-10:**

C44.02, C44.121, C44.1221, C44.1222, C44.1291, C44.1292, C44.221, C44.222, C44.229, C44.320, C44.321, C44.329, C44.42, C44.520, C44.521, C44.529, C44.621, C44.622, C44.629, C44.721, C44.722, C44.729, C44.82, C44.92

**Non-small lung cancer**

1. Locally advanced, unresectable, or metastatic disease, **AND**
2. Being used for first-line treatment, **AND**
3. Being used as a single agent, **AND**
4. Tumor Proportion Score (TPS) at least 50% as determined by an FDA-approved test, **AND**
5. Provider attestation that patient does not have EGFR, ALK, or ROS1 aberrations

**Covered Dose**

Up to 350 mg IV every 3 weeks

**Coverage Period**

Indefinite

**ICD-10:**

C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

**All requests for cemiplimab-rwlc (Libtayo®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

350 mg/7 mL (single-dose vial)

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Libtayo® (cemiplimab-rwlc) [Prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2/2021.
- National Comprehensive Cancer Network. Squamous Cell Skin Cancer (Version 1.2021). Available at: [www.nccn.org](http://www.nccn.org).

**(7) Policy Update**

Date of last review: 3Q2021

Date of next review: 3Q2022

Changes from previous policy version:

- Section (2): Cutaneous squamous cell carcinoma – Expanded coverage to include inoperable or unresectable disease

*Rationale: NCCN category 2A support*