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, recurrent, or metastatic disease

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.

(7) Policy Update

Date of last revision: 1Q2023
Date of next review: 3Q2023
Changes from previous policy version:

- Section (2): Non-small cell lung cancer –

- Added coverage for use in combination with chemotherapy for first-line, continuation maintenance, and subsequent treatment

  Rationale: In November 2022, FDA approved Libtayo in combination with platinum-based chemotherapy for the first-line treatment of adults with NSCLC with no EGFR, ALK or ROS1 aberrations in patients with: 1) locally advanced where patients are not candidates for surgical resection or definitive chemoradiation; or 2) metastatic disease; NCCN category 1 and 2A support
- Expanded coverage of NSCLC to include recurrent disease

  Rationale: NCCN category 1 and 2A support
- Removed requirement for first-line treatment

  Rationale: NCCN category 1 and 2A support
- Remove requirement for TPS for coverage of single agent use

  Rationale: NCCN category 1 and 2A support

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee