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LIBTAYO product information



Advanced NSCLC

LIBTAYO in combination with platinum-based chemotherapy

LIBTAYO in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with no EGFR, ALK or ROS1 aberrations and is¹:

- Locally advanced where patients are not candidates for surgical resection or definitive chemoradiation OR
- Metastatic

LIBTAYO as a single agent

LIBTAYO as a single agent is indicated 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 is¹:

- Locally advanced where patients are not candidates for surgical resection or definitive chemoradiation OR
- Metastatic



Advanced CSCC

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.¹



Advanced BCC

LIBTAYO is indicated for the treatment of patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.¹

ALK=anaplastic lymphoma kinase; EGFR=epidermal growth factor receptor; FDA=Food and Drug Administration; PD-L1=programmed death ligand 1; ROS1=ROS proto-oncogene 1, receptor tyrosine kinase.

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue at any time after starting treatment. While immune-mediated adverse reactions usually occur during treatment, they can also occur after discontinuation. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. Early identification and management are essential to ensuring safe use of PD-1/PD-L1-blocking antibodies. The definition of immune-mediated adverse reactions included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#).

Storage and handling¹

LIBTAYO (cemiplimab-rwlc) injection is a clear to slightly opalescent, colorless to pale yellow solution that may contain trace amounts of translucent to white particles.

Store in a refrigerator at 2°C to 8°C (36°F to 46°F) for no more than 10 days in the original carton. Protect from light. Do not freeze or shake.

Reimbursement and customer support

LIBTAYOhcp.com or **1.877.LIBTAYO (1.877.542.8296), option 1**

Product information

How supplied	350 mg/7 mL (50 mg/mL) solution in a single-dose vial
Quantity and units per case	1 vial per carton/24 cartons per case
NDC	61755-008-01 (350 mg/7 mL)
HCPCS codes	J9119 – Injection, cemiplimab-rwlc, 1 mg
GTIN	00361755008013 (350-mg/7-mL case) 00361755008018 (350-mg/7-mL carton)
UPC	361755008018 (350 mg/7 mL)

Authorized specialty distributors

ASD Healthcare

1.800.746.6273
asdhealthcare.com

LIBTAYO 350-mg/7-mL item 52512

Oncology Supply

1.800.633.7555
oncologysupply.com

LIBTAYO 350-mg/7-mL item 52512

Cardinal Health Specialty Distribution

1.866.677.4844
specialtyonline.cardinalhealth.com

LIBTAYO 350-mg/7-mL item 5436464

McKesson Plasma and Biologics

1.877.625.2566
connect.mckesson.com

LIBTAYO 350-mg/7-mL item 2580579

McKesson Specialty Health

1.800.482.6700
oncology.mckessonspecialtyhealth.com

LIBTAYO 350-mg/7-mL item 5008480

BioCareSD

1.800.304.3064
biocaresd.com

LIBTAYO 350-mg/7-mL item 1000870

Contracted specialty pharmacy

Onco360

1.877.662.6633
onco360.com

Regeneron does not recommend the use of any particular distributor or specialty pharmacy.

To learn more about LIBTAYO:

- Visit LIBTAYOhcp.com
- Call 1.877.LIBTAYO (1.877.542.8296), option 1
- Contact a LIBTAYO field representative



Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Withhold or permanently discontinue LIBTAYO depending on severity of the adverse reaction (see Section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if LIBTAYO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids. Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

The incidence and severity of immune-mediated adverse reactions were similar when LIBTAYO was administered as a single agent or in combination with chemotherapy.



Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#).

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated pneumonitis: LIBTAYO can cause immune-mediated pneumonitis. In patients treated with other PD-1/PD-L1-blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 2.6% (33/1281) of patients receiving LIBTAYO, including Grade 4 (0.3%), Grade 3 (0.6%), and Grade 2 (1.6%). Pneumonitis led to permanent discontinuation in 1.3% of patients and withholding of LIBTAYO in 1.4% of patients. Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 61% of the 33 patients. Of the 18 patients in whom LIBTAYO was withheld, 10 reinitiated after symptom improvement; of these, 4/10 (40%) had recurrence of pneumonitis.

Immune-mediated colitis: LIBTAYO can cause immune-mediated colitis. The primary component of immune-mediated colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1-blocking antibodies. In cases of corticosteroid-refractory immune-mediated colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 2% (25/1281) of patients receiving LIBTAYO, including Grade 3 (0.8%) and Grade 2 (0.9%). Colitis led to permanent discontinuation in 0.4% of patients and withholding of LIBTAYO in 1.2% of patients. Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 56% of the 25 patients. Of the 16 patients in whom LIBTAYO was withheld, 6 reinitiated LIBTAYO after symptom improvement; of these, 4/6 (67%) had recurrence

Immune-mediated hepatitis: LIBTAYO can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2.4% (31/1281) of patients receiving LIBTAYO, including fatal (<0.1%), Grade 4 (0.3%), Grade 3 (1.6%), and Grade 2 (0.2%). Hepatitis led to permanent discontinuation of LIBTAYO in 1.4% of patients and withholding of LIBTAYO in 0.7% of patients. Systemic corticosteroids were required in all patients with hepatitis. Additional immunosuppression with mycophenolate was required in 13% (4/31) of these patients. Hepatitis resolved in 39% of the 31 patients. Of the 9 patients in whom LIBTAYO was withheld, 5 reinitiated LIBTAYO after symptom improvement; of these, 1/5 (20%) had recurrence.

Immune-mediated endocrinopathies:

- **Adrenal insufficiency:** LIBTAYO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold LIBTAYO depending on severity. Adrenal insufficiency occurred in 0.5% (6/1281) of patients receiving LIBTAYO, including Grade 3 (0.5%). Adrenal insufficiency led to permanent discontinuation of LIBTAYO in 1 (<0.1%) patient. LIBTAYO was withheld in 1 (<0.1%) patient due to adrenal insufficiency and not reinitiated. Systemic corticosteroids were required in 83% (5/6) patients with adrenal insufficiency; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency had resolved in 17% of the 6 patients
- **Hypophysitis:** LIBTAYO can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue depending on severity. Hypophysitis occurred in 0.5% (7/1281) of patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.3%) adverse reactions. Hypophysitis led to permanent discontinuation of LIBTAYO in 1 (<0.1%) patient and withholding of LIBTAYO in 2 (0.2%) patients. Systemic corticosteroids were required in 86% (6/7) of patients with hypophysitis. Hypophysitis resolved in 14% of the 7 patients. Of the 2 patients in whom LIBTAYO was withheld for hypophysitis, none of the patients reinitiated
- **Thyroid disorders:** LIBTAYO can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue LIBTAYO depending on severity
- **Thyroiditis:** Thyroiditis occurred in 0.6% (8/1281) of patients receiving LIBTAYO, including Grade 2 (0.3%) adverse reactions. No patient discontinued LIBTAYO due to thyroiditis. Thyroiditis led to withholding of LIBTAYO in 1 (<0.1%) patient. Systemic corticosteroids were not required in any patient with thyroiditis. Thyroiditis resolved in 13% of the 8 patients. Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported



Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#).

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Immune-mediated endocrinopathies (continued):

- **Hyperthyroidism:** Hyperthyroidism occurred in 3% (39/1281) of patients receiving LIBTAYO, including Grade 3 (<0.1%) and Grade 2 (0.9%). No patient discontinued treatment and LIBTAYO was withheld in 7 (0.5%) patients due to hyperthyroidism. Systemic corticosteroids were required in 8% (3/39) of patients. Hyperthyroidism resolved in 56% of 39 patients. Of the 7 patients in whom LIBTAYO was withheld for hyperthyroidism, 2 patients reinitiated LIBTAYO after symptom improvement; of these, none had recurrence of hyperthyroidism.
- **Hypothyroidism:** Hypothyroidism occurred in 7% (87/1281) of patients receiving LIBTAYO, including Grade 3 (<0.1%) and Grade 2 (6%). Hypothyroidism led to permanent discontinuation of LIBTAYO in 3 (0.2%) patients. Hypothyroidism led to withholding of LIBTAYO in 9 (0.7%) patients. Systemic corticosteroids were required in 1.1% (1/87) of patients with hypothyroidism. Hypothyroidism resolved in 6% of the 87 patients. Majority of the patients with hypothyroidism required long-term thyroid hormone replacement. Of the 9 patients in whom LIBTAYO was withheld for hypothyroidism, 1 reinitiated LIBTAYO after symptom improvement and did not have recurrence of hypothyroidism.
- **Type 1 diabetes mellitus, which can present with diabetic ketoacidosis:** Monitor for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold LIBTAYO depending on severity. Type 1 diabetes mellitus occurred in <0.1% (1/1281) of patients (Grade 4). No patient discontinued treatment due to Type 1 diabetes mellitus. Type 1 diabetes mellitus led to withholding of LIBTAYO in 0.1% of patients, treatment was reinitiated after symptom improvement. Patient received long-term insulin therapy.

Immune-mediated nephritis with renal dysfunction: LIBTAYO can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.7% (9/1281) of patients receiving LIBTAYO, including fatal (<0.1%), Grade 3 (<0.1%), and Grade 2 (0.5%). Nephritis led to permanent discontinuation in 0.2% of patients and withholding of LIBTAYO in 0.4% of patients. Systemic corticosteroids were required in all patients with nephritis. Nephritis resolved in 78% of the 9 patients. Of the 5 patients in whom LIBTAYO was withheld, 4 reinitiated LIBTAYO after symptom improvement; of these, 1/4 (25%) had recurrence.

Immune-mediated dermatologic adverse reactions: LIBTAYO can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) has occurred with PD-1/PD-L1-blocking antibodies. Immune-mediated dermatologic adverse reactions occurred in 1.9% (24/1281) of patients receiving LIBTAYO, including Grade 3 (0.9%) and Grade 2 (0.8%). Immune-mediated dermatologic adverse reactions led to permanent discontinuation in 0.2% of patients and withholding of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 71% of the 24 patients. Of the 17 patients in whom LIBTAYO was withheld for dermatologic adverse reaction, 13 reinitiated LIBTAYO after symptom improvement; of these, 5/13 (38%) had recurrence of the dermatologic adverse reaction. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 1281 patients who received LIBTAYO or were reported with the use of other PD-1/PD-L1-blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

- **Cardiac/vascular:** Myocarditis, pericarditis, and vasculitis. Permanently discontinue for Grades 2, 3, or 4 myocarditis.
- **Nervous system:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy.



Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#).

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

Other immune-mediated adverse reactions (continued):

- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis, stomatitis
- **Musculoskeletal and connective tissue:** Myositis/polymyositis/dermatomyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
- **Endocrine:** Hypoparathyroidism
- **Other (hematologic/immune):** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis (HLH), systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection

Infusion-Related Reactions

Severe or life-threatening infusion-related reactions occurred in 0.2% of patients receiving LIBTAYO as a single agent. Monitor patients for signs and symptoms of infusion-related reactions. Common symptoms of infusion-related reaction include nausea, pyrexia, and vomiting. Interrupt or slow the rate of infusion or permanently discontinue LIBTAYO based on severity of reaction.

Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1-blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1-blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.



Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#).

Important Safety Information (continued)

Adverse Reactions

LIBTAYO as a single agent: the most common adverse reactions ($\geq 15\%$) are fatigue, musculoskeletal pain, rash, diarrhea, and anemia

LIBTAYO in combination with platinum-based chemotherapy: the most common adverse reactions ($\geq 15\%$) are alopecia, musculoskeletal pain, nausea, fatigue, peripheral neuropathy, and decreased appetite

Use in Specific Populations

- **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO

Please see accompanying full [Prescribing Information](#).

Indications and Usage

LIBTAYO in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (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.

LIBTAYO as a single agent is indicated 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.

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

LIBTAYO is indicated for the treatment of patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.



To learn more about LIBTAYO,
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 **LIBTAYO**[®]
(cemiplimab-rwlc)
Injection 350 mg