



# LIBTAYO

# Quick reference coding guide

An understanding of the **codes needed for quick reimbursement** must be a core competency of your billing staff. Coding—descriptors that capture diagnoses, medical procedures, and products—enables payers to more easily recognize, process, and pay claims for LIBTAYO.

Additionally, understanding how to use and complete **common medical claims forms**, such as the CMS-1500 form and the UB-04 form, for billing purposes can help to streamline the claims process and may save your billing staff time.

CMS=Centers for Medicare & Medicaid Services.

## 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](#).**

# Quick reference coding guide provides you with key resources



## Lists of potential billing codes

- International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes
- Current Procedural Terminology (CPT®) codes
- Revenue codes
- Healthcare Common Procedure Coding System (HCPCS) level 2 codes
- Product information



## Annotated samples

### Annotated samples of the 2 most common CMS claim forms used to bill for drugs and services

- CMS 1500 (print) or 837P (electronic) forms for billing for physician office reimbursement
- CMS 1450 (print), also referred to as CMS UB-04, or 837I (electronic) forms for hospital outpatient reimbursement

## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

#### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

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.

**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.

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

## Billing codes for LIBTAYO

The coding information discussed in this document is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed herein may not apply to all patients or to all health plans. Conversely, additional codes not listed in this guide may apply to some patients. Providers should follow payer-specific coding requirements and exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.

## Advanced CSCC coding

### Indications and Usage

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.

### ICD-10-CM codes\*: Primary squamous cell carcinoma

C44.02	Squamous cell carcinoma of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus <sup>†</sup>
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal <sup>†</sup>
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face <sup>†</sup>
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder <sup>†</sup>
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip <sup>†</sup>
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified <sup>†</sup>

\*Be as specific as possible when selecting codes.

<sup>†</sup>Codes for "unspecified" sites should generally be avoided.

### Indications and Usage

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.

#### ICD-10-CM codes\*: Basal cell carcinoma

C44.01	Basal cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus†
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal†
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal
C44.310	Basal cell carcinoma of skin of unspecified parts of face†
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder†
C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip†
C44.712	Basal cell carcinoma of skin of right lower limb, including hip
C44.719	Basal cell carcinoma of skin of left lower limb, including hip
C44.81	Basal cell carcinoma of overlapping sites of skin
C44.91	Basal cell carcinoma of skin, unspecified†

\*Be as specific as possible when selecting codes.  
†Codes for "unspecified" sites should generally be avoided.

### 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] ≥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.

#### ICD-10-CM codes\*: Non-small cell lung cancer

C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus†
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung†
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung†
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung†
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung†
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung†
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung†

\*Be as specific as possible when selecting codes.  
†Codes for "unspecified" sites should generally be avoided.

### Important Safety Information (cont'd)

#### Warnings and Precautions (cont'd)

##### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**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.

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



CPT code

96413	Chemotherapy administration, intravenous (IV) infusion technique, up to 1 hour, single or initial substance/drug
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Example revenue codes for hospital-based infusions

Chemotherapy administration

0335	Chemotherapy administration, IV
0510	Clinic
0636	Drugs requiring detailed coding*
0761	Treatment room

\*Revenue code 0636 is customarily billed on hospital outpatient claims for care related to Medicare beneficiaries. Other payers may require different revenue codes, often from the O25X or O26X series. Please consult with your payer to determine the appropriate revenue code for your claim.

HCPCS level 2 codes

**J-codes:** J-codes are permanent codes that are used by hospitals, physicians, and other health professionals who bill Medicare and commercial payers for non-orally administered medication and chemotherapy drugs.

The following J-code can be used for administrative and billing purposes specific to LIBTAYO:

J9119	Injection, cemiplimab-rwlc, 1 mg
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**Note:** Effective July 1, 2023, CMS and most payers require prescribers to record drug wastage or lack thereof. A JW modifier may be required for reporting that there was discarded drug (ie, J9119-JW). A JZ modifier may be required for reporting there was no discarded drug (ie, J9119-JZ).

Product information

How supplied	350-mg/7-mL solution in a single-dose vial
Quantity and units per case	1 vial per carton/24 cartons per case
NDC	61755-0008-01 (350 mg/7 mL)
GTINs	00361755008013 (350-mg/7-mL case) 00361755008018 (350-mg/7-mL carton)
UPC	361755008018 (350 mg/7 mL)

**Note:** The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets general billing standards. The zero-fill location is indicated in bold above.

GTIN=Global Trade Item Number; NDC=National Drug Code; UPC=Universal Product Code.

The Centers for Medicare & Medicaid Services assigned a 1-mg billing unit for LIBTAYO (1 mg of LIBTAYO=1 unit). Please note that the recommended dosage of LIBTAYO is 350 mg every 3 weeks. Therefore 350 units should be billed for each claim. Coding requirements may vary by payer; please verify coding requirements before submitting claims.

Sample annotated CMS-1500 form<sup>1\*</sup>

The CMS-1500 form is commonly used for billing for LIBTAYO when it is administered in physician offices. The annotations in the sample form below are designed to provide you with information about how to populate some critical fields that health plans may require for LIBTAYO reimbursement.

This sample claim form is intended for informational purposes only. The information provided is subject to change and should not be construed as billing advice. Use of the information provided does not guarantee reimbursement. Providers are responsible for ensuring the accuracy of all claims submitted. Please confirm the accuracy of the codes you use to bill for LIBTAYO with each payer.

**21** Indicate appropriate diagnosis using ICD-10-CM codes

**24A** Enter a 6-digit or 8-digit (month-date-year) date for each procedure, service, or supply. Include NDC information, if required, in the shaded red areas above each date

**24B** Enter the appropriate place of service code(s)

**24D** Add the appropriate, specific CPT (96413) and HCPCS (J9119) level 2 codes and modifiers for procedures, services, and supplies. Enter the specific procedure code without a narrative description. In addition, Medicare and most payers require waste to be reported. Enter HCPCS code J9119 and use modifier JZ to indicate no wastage<sup>1,2</sup>

**24E** Enter the diagnosis code reference number or letter (as appropriate, per form version) as shown in item 21 to relate the date of service and the procedures performed to the primary diagnosis. Enter only 1 reference number/letter per line item. If multiple services were performed, enter the primary reference number/letter for each service

**24G** Enter the number of units of LIBTAYO administered

\*CMS 837P (not shown) is the electronic equivalent of CMS-1500. It should be used if you submit your claims electronically.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.



Sample annotated CMS UB-04 form<sup>3\*</sup>

The CMS UB-04 form is commonly used for billing for LIBTAYO when it is administered in hospital outpatient settings. The annotations in the sample form below are designed to provide you with information about how to populate some critical fields that health plans may require for LIBTAYO reimbursement.

This sample claim form is intended for informational purposes only. The information provided is subject to change and should not be construed as billing advice. Use of the information provided does not guarantee reimbursement. Providers are responsible for ensuring the accuracy of all claims submitted. Please confirm the accuracy of the codes you use to bill for LIBTAYO with each payer.

**42** List revenue codes in ascending order. Be sure to enter the appropriate numeric revenue code on the adjacent line in box 42 to explain each charge in box 47

**43** Provide a narrative description or standard abbreviation for each revenue code shown in box 42 on the adjacent line in box 43. Enter an 11-digit NDC if required. Some payers require the qualifier "N4" when entering an NDC code, usually when filing a paper claim

**44** Enter the appropriate CPT (96413) and HCPCS (J9119) codes and modifiers for procedures, services, and supplies, as required by the specific payer. Medicare and most payers require waste to be reported. Enter HCPCS code J9119 and use modifier JZ to indicate no wastage<sup>3,4</sup>

**46** Indicate the number of LIBTAYO service units administered. J9119 has a unit descriptor of 1 mg; report 350 units of the code when billing for the full dose of LIBTAYO. **Note:** billing units may vary by payer. **Please check with your payer** for the appropriate billing units to be used

**67** Enter the specific ICD-10-CM diagnosis code(s)

**80** Add further information to box 44 or its electronic equivalent only when an "unlisted procedure" code or "not otherwise classified" code must be used

\*CMS 837I (not shown) is the electronic equivalent of CMS-1450/UB-04. It should be used if you submit your claims electronically.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

Immune-mediated endocrinopathies: (cont'd)

- 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

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

Immune-mediated endocrinopathies: (cont'd)

- 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
- 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 paresthesia, and autoimmune neuropathy
- 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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.



## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

#### 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.

#### 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](#).

**References:** 1. Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 26: completing and processing form CMS-1500 data set. Updated June 6, 2024. Accessed March 6, 2025. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf> 2. Centers for Medicare & Medicaid Services. Medicare Program. Discarded drugs and biologicals JW modifier and JZ modifier policy. Frequently asked questions. Accessed March 6, 2025. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf> 3. Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 25: completing and processing the form CMS-1450 data set. Updated December 20, 2023. Accessed March 6, 2025. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf> 4. McKesson. The pros and cons of the "buy and bill" model of pharmaceutical distribution: what's appropriate for your practice? January 6, 2022. Accessed March 6, 2025. <https://mms.mckesson.com/content/insights/the-pros-cons-of-the-buy-and-bill-model-of-pharmaceutical-distribution-whats-appropriate-for-your-practice/>

For any questions or concerns, or to report side effects with a Regeneron product for patients enrolled in LIBTAYO Surround, please contact LIBTAYO Surround at **1.877.LIBTAYO** (1877.542.8296) **Option 1**, Monday–Friday, 8 AM–8 PM Eastern time.

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**LIBTAYO**<sup>®</sup>  
(cemiplimab-rwlc)  
Injection 350 mg