

# LIBTAYO Surround<sup>®</sup> 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

## 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 [click here](#) for full Prescribing Information.

## LIBTAYO Surround® 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 of the 2 most common Centers for Medicare & Medicaid Services claim forms used to bill for drugs and services

- Centers for Medicare & Medicaid 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
- These sample forms are available at [LIBTAYOSurround.com](https://www.libtayo.com/surround) for quick reference

### Important Safety Information (cont'd)

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

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

No dose reduction for LIBTAYO is recommended. In general, withhold LIBTAYO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue LIBTAYO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated adverse reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids.

Withhold or permanently discontinue LIBTAYO depending on severity. 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.

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

## Billing codes for LIBTAYO® (cemiplimab-rwlc)

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.

### 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

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

\*Be as specific as possible when selecting codes.

†Codes for “unspecified” sites should generally be avoided.

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## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

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

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 [click here](#) for full Prescribing Information.

## Billing codes for LIBTAYO® (cemiplimab-rwlc) (cont'd)

### ICD-10-CM codes\* (cont'd)

#### Primary squamous cell carcinoma (cont'd)

<b>C44.622</b>	Squamous cell carcinoma of skin of right upper limb, including shoulder
<b>C44.629</b>	Squamous cell carcinoma of skin of left upper limb, including shoulder
<b>C44.721</b>	Squamous cell carcinoma of skin of unspecified lower limb, including hip†
<b>C44.722</b>	Squamous cell carcinoma of skin of right lower limb, including hip
<b>C44.729</b>	Squamous cell carcinoma of skin of left lower limb, including hip
<b>C44.82</b>	Squamous cell carcinoma of overlapping sites of skin
<b>C44.92</b>	Squamous cell carcinoma of skin, unspecified†

## 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

<b>C44.01</b>	Basal cell carcinoma of skin of lip
<b>C44.111</b>	Basal cell carcinoma of skin of unspecified eyelid, including canthus†
<b>C44.1121</b>	Basal cell carcinoma of skin of right upper eyelid, including canthus
<b>C44.1122</b>	Basal cell carcinoma of skin of right lower eyelid, including canthus
<b>C44.1191</b>	Basal cell carcinoma of skin of left upper eyelid, including canthus
<b>C44.1192</b>	Basal cell carcinoma of skin of left lower eyelid, including canthus

\*Be as specific as possible when selecting codes.

†Codes for "unspecified" sites should generally be avoided.

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## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

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

**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. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

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

## Billing codes for LIBTAYO® (cemiplimab-rwlc) (cont'd)

### ICD-10-CM codes\* (cont'd)

#### Basal cell carcinoma (cont'd)

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

\*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 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. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

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

## Billing codes for LIBTAYO® (cemiplimab-rwlc) (cont'd)

### 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.

### ICD-10-CM codes\*

#### Non-small cell lung cancer

<b>C33</b>	Malignant neoplasm of trachea
<b>C34.00</b>	Malignant neoplasm of unspecified main bronchus <sup>†</sup>
<b>C34.01</b>	Malignant neoplasm of right main bronchus
<b>C34.02</b>	Malignant neoplasm of left main bronchus
<b>C34.10</b>	Malignant neoplasm of upper lobe, unspecified bronchus or lung <sup>†</sup>
<b>C34.11</b>	Malignant neoplasm of upper lobe, right bronchus or lung
<b>C34.12</b>	Malignant neoplasm of upper lobe, left bronchus or lung
<b>C34.2</b>	Malignant neoplasm of middle lobe, bronchus or lung
<b>C34.30</b>	Malignant neoplasm of lower lobe, unspecified bronchus or lung <sup>†</sup>
<b>C34.31</b>	Malignant neoplasm of lower lobe, right bronchus or lung
<b>C34.32</b>	Malignant neoplasm of lower lobe, left bronchus or lung
<b>C34.80</b>	Malignant neoplasm of overlapping sites of unspecified bronchus and lung <sup>†</sup>

\*Be as specific as possible when selecting codes.

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

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## 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.

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## Billing codes for LIBTAYO® (cemiplimab-rwlc) (cont'd)

### ICD-10-CM codes\* (cont'd)

#### Non-small cell lung cancer (cont'd)

<b>C34.81</b>	Malignant neoplasm of overlapping sites of right bronchus and lung
<b>C34.82</b>	Malignant neoplasm of overlapping sites of left bronchus and lung
<b>C34.90</b>	Malignant neoplasm of unspecified part of unspecified bronchus or lung†
<b>C34.91</b>	Malignant neoplasm of unspecified part of right bronchus or lung†
<b>C34.92</b>	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.

### CPT code

<b>96413</b>	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

<b>0335</b>	Chemotherapy administration, IV
<b>0510</b>	Clinic
<b>0636</b>	Drugs requiring detailed coding
<b>0761</b>	Treatment room

### 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:

<b>J9119</b>	Injection, cemiplimab-rwlc, 1 mg
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**Effective July 1, 2023,** the JZ modifier may be required for reporting there was no discarded drug.

## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

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

##### Immune-mediated hepatitis: (cont'd)

For hepatitis with no tumor involvement of the liver: Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 8 times the upper limit of normal (ULN) or if total bilirubin increases to more than 1.5 and up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 8 times the ULN or total bilirubin increases to more than 3 times the ULN.

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## Billing codes for LIBTAYO® (cemiplimab-rwlc) (cont'd)

### 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	61755-008-01 (350 mg/7 mL)
GTINs	00361755008013 (350-mg/7-mL case)
	00361755008018 (350-mg/7-mL carton)
UPC	361755008018 (350 mg/7 mL)

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.

## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

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

##### Immune-mediated hepatitis: (cont'd)

For hepatitis with tumor involvement of the liver: Withhold LIBTAYO if baseline AST or ALT is more than 1 and up to 3 times ULN and increases to more than 5 and up to 10 times ULN. Also, withhold LIBTAYO if baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to 10 times ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times ULN or if total bilirubin increases to more than 3 times ULN. If AST and ALT are less than or equal to ULN at baseline, withhold or permanently discontinue LIBTAYO based on recommendations for hepatitis with no liver involvement.

Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

**Immune-mediated endocrinopathies:** For Grade 3 or 4 endocrinopathies, withhold until clinically stable or permanently discontinue depending on severity.

- **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

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## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

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

##### Immune-mediated endocrinopathies: (cont'd)

- **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
- **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. Withhold LIBTAYO for Grade 2 or 3 increased blood creatinine, and permanently discontinue for Grade 4 increased blood creatinine. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

**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. Withhold LIBTAYO for suspected SJS, TEN, or DRESS. Permanently discontinue LIBTAYO for confirmed SJS, TEN, or DRESS. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

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

## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

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

**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. Withhold for Grade 2 neurological toxicities and permanently discontinue for Grades 3 or 4 neurological toxicities. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids
- **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, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant 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.

## Important Safety Information (cont'd)

### 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 [click here](#) for full Prescribing Information.

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** (1.877.542.8296) **Option 1**, Monday–Friday, 8 AM–8 PM Eastern time.

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