

LIBTAYO Surround™ billing and coding essentials



This resource serves as a reference guide for the common terms related to coverage, reimbursement, billing, and coding for LIBTAYO

Indications and Usage

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

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 and usually occur during treatment; however, they can also occur after discontinuation. Early identification and management are essential to ensuring safe use of PD-1–blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

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

Billing and coding essentials

Overview of the major health plans

This overview includes private/commercial payers and government payers, such as Medicare, Medicaid, Veterans Affairs, and TRICARE

This section includes coverage factors for LIBTAYO and how LIBTAYO Surround can help support a benefits investigation to help ensure all initial coverage requirements have been met before treatment begins

Payer coverage considerations

Key terms for accurate billing

This section provides an overview and descriptions of the key terms with which you and your staff will need to be familiar for accurate billing and coding for LIBTAYO

Have a billing or reimbursement question? Call 1-877-LIBTAYO (1-877-542-8296) Option 1, Monday–Friday, 8 AM–8 PM Eastern time

Overview of the major health plans

Medicare

Medicare is the federal health insurance program that provides health insurance for¹:

- People aged ≥65 years
- Younger people with certain disabilities
- People with end-stage renal disease (permanent kidney failure requiring dialysis or a transplant)

Medicare provides coverage of healthcare services through 4 categories¹

Part A

Covers services such as inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home healthcare

Part B

Covers certain doctors' visits, physician-administered drugs, outpatient care, medical supplies, and preventive services

Part C

Is offered by private managed care companies that contract with Medicare to provide Part A and Part B benefits. These plans are called Medicare Advantage plans and are operated much like a managed care plan. They typically offer prescription drug coverage under Part D in addition to Part A and Part B benefits

Part D

Provides prescription drug coverage to original Medicare, through a prescription drug plan (PDP). PDPs provide pharmacy benefits for prescription drugs taken by the patient at home

Private/commercial

Private/commercial plans insure patients who receive their health insurance purchased in either of 2 ways²

Through their employer or union

On their own, directly through a health insurance company

This includes health insurance purchased through Affordable Care Act healthcare exchanges

Most commercial insurers offer multiple plans, and coverage for procedures and/or drugs may vary depending on the details of that exact plan. Private insurance coverage policies for LIBTAYO and its administration may vary based on the plan type and benefit design.

Overview of the major health plans (cont'd)

Medicaid

Medicaid is a jointly funded, federal–state health insurance program. It covers low-income and/or disabled people and others who are eligible to receive federal income assistance. Eligibility criteria for Medicaid vary by state.³

Veterans Affairs and TRICARE

You may treat patients who have insurance through other government-sponsored programs, such as:

- **Veterans Affairs (VA):** Healthcare provided to qualified members of the military who have left active service. More than 200,000 healthcare professionals are employed by the VA, which covers approximately 9 million veterans⁴
- **TRICARE:** Private health insurance options for active-duty personnel, their families, activated National Guard and military reserve personnel, retired military personnel, and certain family members of active-duty or retired military personnel who have died^{5,6}

Potential drug coverage and reimbursement policies for LIBTAYO

LIBTAYO is typically administered in a physician's office or hospital outpatient setting and likely will be covered and reimbursed under your patient's medical benefit. However, specific coverage and reimbursement policies for each of the major health plans that cover Medicare, private/commercial, Medicaid, VA, and TRICARE patients will vary

LIBTAYO Surround can provide assistance if you have inquiries about how your patient's health plan may cover and reimburse for LIBTAYO. For more information, call 1-877-LIBTAYO (1-877-542-8296) Option 1, Monday–Friday, 8 AM–8 PM Eastern time, visit LIBTAYOhcp.com, or contact your local field Reimbursement Manager

Coverage considerations for LIBTAYO

LIBTAYO is administered via intravenous (IV) infusion; therefore, it is likely to be administered in a doctor's office, an outpatient hospital setting or, for non-Medicare patients, a free-standing infusion clinic. Policies, coverage requirements, and restrictions will vary among plans. Some of the criteria that may affect coverage and reimbursement for LIBTAYO include:

- The patient's health plan's coverage policy for LIBTAYO
- The patient's cost-sharing responsibility for LIBTAYO, as well as deductible and out-of-pocket maximum requirements
- Whether the medication is covered through the health plan's medical or pharmacy benefit
- The patient's health plan's coverage and authorization requirements, such as a prior authorization (PA) for LIBTAYO, if required
- The information required for the PA process
- Payer-preferred infusion sites
- Determination of the product acquisition options
- Accurate documentation about the patient's condition
- The payer's payment/reimbursement policies

Access and reimbursement support is available

Because of the variation in payers' coverage requirements, an initial benefits investigation is an important first step before a patient starts treatment with LIBTAYO.

LIBTAYO Surround is committed to delivering access and coverage solutions, including:

- Benefits investigation
- PA and appeal assistance
- Claims support for billing and reimbursement
- Resources for patients who need support with out-of-pocket costs
- Assistance with product ordering and returns

Please visit LIBTAYOhcp.com for more information about LIBTAYO Surround

Billing for LIBTAYO in the physician office and hospital outpatient settings

Once coverage for LIBTAYO has been determined and services have been rendered, you and your staff need to be familiar with how to bill for LIBTAYO so you will be reimbursed quickly and accurately. This is achieved by translating the information about the patient's diagnosis and the procedures and medical services rendered into alphanumeric codes to provide reliable, nationwide communication among healthcare providers and insurers. Information used to identify the correct diagnoses and procedure codes is taken from the patient's medical record, such as transcripts of physicians' notes as well as laboratory and radiologic results.⁷

This section provides an overview of the billing and coding terms you should be familiar with to accurately bill for LIBTAYO.

Refer to the *LIBTAYO Surround quick reference coding guide* for examples of codes for populating Centers for Medicare and Medicaid Services (CMS) billing forms

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

ICD-10-CM codes are used to identify a patient's diagnosis. Documentation of these codes is required for any entity covered by the Health Insurance Portability and Accountability Act of 1996.⁸

ICD-10-CM codes enable specificity in identifying health conditions. The current edition allows you to more precisely code for laterality, severity, and complexity of disease conditions, making more exact identification and tracking possible. It also improves the data available for measuring and tracking healthcare utilization and the quality of patient care.⁹

Characteristics of ICD-10-CM codes

ICD-10-CM codes comprise 3 to 7 alphanumeric characters. The more characters you are able to populate, the more specificity you are able to add to the diagnosis. Payers require coding to the highest level of specificity available.⁸

ICD-10-CM code format



ICD-10-CM codes are populated on CMS forms in the following boxes

CMS 1500	Box 21
CMS UB-04	Box 67

Billing for LIBTAYO in the physician office and hospital outpatient settings (cont'd)

Current Procedural Terminology (CPT) codes

CPT codes describe the procedures and services performed by physicians and other healthcare professionals.¹⁰

There are 2 types of CPT codes pertinent to LIBTAYO administration. These codes indicate services that require special considerations to prepare, administer, or dispose of the drug/biologic agent, requiring training and competency for the staff who administer them.¹¹

- **Therapeutic infusions and injections:** Codes pertaining to the administration of drugs and fluids other than for hydration
- **Chemotherapeutic infusions and injections:** Codes that apply to the administration of chemotherapy agents or substances such as monoclonal antibodies and other biologic response modifiers

Please note that payer policies regarding the use of codes may vary, so you should always check with the payer to ensure you have the complete list of codes you need. See the **LIBTAYO Surround quick reference coding guide** for the CPT codes that may apply to LIBTAYO.

CPT codes are populated on CMS forms in the following boxes

CMS 1500	24D
CMS UB-04	44

Healthcare Common Procedure Code System (HCPCS) level 2 codes

HCPCS codes describe certain services, procedures, and medical equipment not described by CPT codes.¹² These codes are important to know so you can properly bill for services rendered, such as medication injections.

Characteristics of HCPCS level 2 codes

HCPCS codes use a 5-character, alphanumeric format. Drugs that are administered by any route other than oral are typically reported using product-specific HCPCS codes beginning with the letter "J," followed by a 4-digit unique identifier.¹³ For new drugs, until a drug-specific code is assigned, a miscellaneous or "unclassified" code may be necessary.¹⁴

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

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

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

HCPCS level 2 codes are populated on CMS forms in the following boxes

CMS 1500	24D
CMS UB-04	44

HCPCS and CPT modifiers^{14,15}

HCPCS and CPT modifiers allow additional information about a procedure or service to be documented without needing to redefine the service provided. They provide information that may be important for accurate reimbursement and may help providers request additional payment, when necessary.¹³

The list of HCPCS and CPT modifiers is extensive. The following table shows examples of modifiers that may be applicable to drug and drug administration coding for LIBTAYO.

HCPCS and CPT modifiers are populated on CMS forms in the following boxes

JW (drug amount discarded/not administered to any patient)	CMS 1500: 24D CMS UB-04: 44
PN (nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital)	CMS 1500: not applicable CMS UB-04: 44
25 (Significant, separately identifiable evaluation and management service by the same physician or other qualified health care professional on the same day of the procedure or other service)	CMS 1500: 24D CMS UB-04: 44

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

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

Immune-mediated pneumonitis: Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%), and Grade 2 (1.3%). Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone \geq 40 mg/day or equivalent. Pneumonitis resolved in 62% of patients. 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.

Immune-mediated colitis: Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%). Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone \geq 40 mg/day or equivalent. Colitis resolved in 80% of patients. 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.

Billing for LIBTAYO in the physician office and hospital outpatient settings (cont'd)

National Drug Code

The National Drug Code (NDC) is a unique number maintained by the US Food and Drug Administration (FDA) to identify a drug's labeler, product, and trade package size. The US Department of Health and Human Services has adopted this code set as the standard for reporting drugs and biologics on standard transactions.¹⁰

NDC characteristics^{10,15}

NDCs have 2 formats:

- A 10-digit format assigned by the FDA when registering NDCs (eg, XXXXX-XXX-XX) (5-3-2)
- An 11-digit NDC format used for most payers on claim forms (eg, XXXXX-0XXX-XX) (5-4-2)

To convert an NDC from the 5-3-2 format, the product code or package code is often lengthened with a leading zero.

NDCs are populated in CMS forms in the following boxes

CMS 1500	24A (in the grayed-out area) above the dates
CMS UB-04	43

Place-of-service codes

These 2-digit codes provide information necessary to appropriately pay for professional service claims based on the setting in which services were rendered.¹⁶ For LIBTAYO, the place-of-service (POS) codes most likely to be needed are those for an office setting (code 11), a hospital's off-campus outpatient setting (code 19), or a hospital's main campus outpatient setting (code 22).

POS codes are populated in CMS forms in the following boxes

CMS 1500	24B (in the grayed-out area)
CMS UB-04	44

Revenue codes

Revenue codes represent services provided by hospital outpatient departments with specific accommodations or ancillary charges.¹⁷ They indicate where the procedure took place within the hospital. These 4-digit codes are required on **hospital claims only**.¹⁸

The following are examples of revenue codes that may be used for billing for LIBTAYO.

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

Revenue codes are populated on CMS forms in the following boxes

CMS 1500	Not applicable
CMS UB-04	42

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

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

Immune-mediated hepatitis: Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%). Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥ 40 mg/day or equivalent. Hepatitis resolved in 64% of patients. Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 10 times the upper limit of normal (ULN) or if total bilirubin increases up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times the ULN or total bilirubin increases to more than 3 times the ULN. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated endocrinopathies: Withhold LIBTAYO if clinically necessary for Grade 2, 3, or 4.

- **Adrenal insufficiency:** Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.2%)
- **Hypophysitis:** Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of 1 patient with Grade 3 hypophysitis
- **Hypothyroidism:** Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%); no patients discontinued hormone replacement therapy
- **Hyperthyroidism:** Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%); hyperthyroidism resolved in 38% of patients
- **Type 1 diabetes mellitus:** Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%); type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients

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)

Immune-mediated nephritis with renal dysfunction: Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%). Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone \geq 40 mg/day or equivalent. Nephritis resolved in all patients. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated dermatologic adverse reactions: Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%). In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone \geq 40 mg/day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of $<$ 1% in 534 patients who received LIBTAYO or were reported with the use of other PD-1–blocking and PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

- **Neurological:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy
- **Cardiovascular:** Myocarditis, pericarditis, and vasculitides
- **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 corticosteroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, and duodenitis
- **Musculoskeletal and connective tissue:** Myositis, rhabdomyolysis, and associated sequelae, including renal failure, arthritis, and polymyalgia rheumatica
- **Hematological and immunological:** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, and solid organ transplant rejection

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

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

- Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in \geq 2% of patients were cellulitis, sepsis, pneumonia, pneumonitis, and urinary tract infection. The most common Grade 3-4 adverse reactions (\geq 2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection, and fatigue
- LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness
- The most common adverse reactions (incidence \geq 20%) were fatigue, rash, and diarrhea

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

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

For any questions or concerns, or to report side effects with a Regeneron and Sanofi 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.