

# LIBTAYO® (cemiplimab-rwlc) PATIENT ACCESS AND REIMBURSEMENT SUPPORT PROGRAM: LIBTAYO SURROUND™



## Overview of LIBTAYO Surround

Regeneron and Sanofi are committed to providing patient access and reimbursement support for eligible U.S. patients prescribed LIBTAYO. To that end, the companies have launched LIBTAYO Surround, a comprehensive program designed to help provide this support.

LIBTAYO is approved for use in patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. For more information and full Prescribing Information, [click here](#), or please visit [www.LIBTAYO.com](http://www.LIBTAYO.com).

Please see Important Safety Information below.

## The 3 Core Components of LIBTAYO Surround

### 1. Patient Support

LIBTAYO Surround offers patient support that helps facilitate access to medication when eligible patients need assistance with out-of-pocket costs. This includes the Copay and Patient Assistance Programs for eligible patients:

- **Copay Program:** Eligible patients with commercial insurance may pay \$0 for LIBTAYO, which includes any product-specific copay, coinsurance, and insurance deductibles—up to \$25,000 in assistance per year. Conditions apply.\*
- **Patient Assistance Program:** Eligible patients who meet income requirements and are uninsured, lack coverage for LIBTAYO, or have fee-for-service Medicare Part B with no supplemental insurance coverage may receive LIBTAYO at no cost.\*\*

Patients taking LIBTAYO should always consult their physician about their disease and treatment plan.

### 2. Access and Reimbursement Support

LIBTAYO Surround provides assistance with access and reimbursement. This begins with a benefits investigation and continues through the approval and reimbursement process for eligible patients. Additional service offerings include prior authorization assistance, appeals support, and claims assistance for billing and reimbursement.

### 3. Product Support

LIBTAYO Surround provides support to healthcare professionals for product ordering and returns.

For more information on LIBTAYO Surround, please call 1-877-LIBTAYO (1-877-542-8296) Option 1 or visit [LIBTAYOhcp.com](http://LIBTAYOhcp.com).

\*The LIBTAYO Surround Copay Program is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, Veterans Affairs/Department of Defense, TRICARE, or similar federal or state programs. Not a debit card program. The program does not cover or provide support for supplies, procedures, or any physician-related service associated with LIBTAYO. General non-product-specific copays, coinsurance, or insurance deductibles are not covered. Additional program conditions apply. See [LIBTAYOhcp.com](http://LIBTAYOhcp.com) for more information. Patients are responsible for any out-of-pocket cost for LIBTAYO that exceeds the program assistance limit of \$25,000 per year.

\*\*Patients must have an annual gross household income that does not exceed the greater of \$100,000 per year or 500% of the federal poverty level (FPL). In 2018, 500% of the FPL was \$60,700 for a household of 1; \$82,300 for a household of 2; \$103,900 for a household of 3; and \$125,500 for a household of 4. For households exceeding 4 members, add \$21,600 for each additional member. Additional program conditions apply. See [LIBTAYOhcp.com](http://LIBTAYOhcp.com) for more information.

## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about LIBTAYO?

LIBTAYO is a medicine that may treat a type of skin cancer by working with your immune system. LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended.

Please see additional Important Safety Information throughout and accompanying [Full Prescribing Information](#), including [Medication Guide](#).

## IMPORTANT SAFETY INFORMATION, Continued

**Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse:**

- **Lung problems (pneumonitis).** Signs and symptoms of pneumonitis may include new or worsening cough, shortness of breath, and chest pain.
- **Intestinal problems (colitis) that can lead to tears or holes in your intestine.** Signs and symptoms of colitis may include diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky or that have blood or mucus; and severe stomach-area (abdomen) pain or tenderness.
- **Liver problems (hepatitis).** Signs and symptoms of hepatitis may include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea colored), bleeding or bruising more easily than normal, and feeling less hungry than usual.
- **Hormone gland problems** (especially the adrenal glands, pituitary, thyroid and pancreas). Signs and symptoms that your hormone glands are not working properly may include headaches that will not go away or unusual headaches, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, dizziness or fainting, feeling more hungry or thirsty than usual, hair loss, feeling cold, constipation, deeper voice, very low blood pressure, urinating more often than usual, nausea or vomiting, stomach-area (abdomen) pain, and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.
- **Kidney problems,** including nephritis and kidney failure. Signs of these problems may include decrease in your amount of urine, blood in your urine, swelling in your ankles, and loss of appetite.
- **Skin problems.** Signs of these problems may include rash, itching, skin blistering, and painful sores or ulcers in the mouth, nose, throat, or genital area.
- **Problems in other organs.** Signs of these problems may include headache, tiredness or weakness, sleepiness, changes in heartbeat (such as beating fast, seeming to skip a beat, or a pounding sensation), confusion, fever, muscle weakness, balance problems, nausea, vomiting, stiff neck, memory problems, seizures (encephalitis), swollen lymph nodes, rash or tender lumps on skin, cough, shortness of breath, vision changes, or eye pain (sarcoidosis), seeing or hearing things that are not there (hallucinations), severe muscle weakness, low red blood cells (anemia), bruises on the skin or bleeding, and changes in eyesight.
- **Rejection of a transplanted organ.** Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.
- **Infusion (IV) reactions that can sometimes be severe and life-threatening.** Signs of these problems may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling of passing out, back or neck pain, and facial swelling.

**Getting medical treatment right away may help keep these problems from becoming more serious.**

Your healthcare provider will check you for these problems during your treatment with LIBTAYO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may delay or completely stop treatment if you have severe side effects.

**Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you:**

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus;
- have had an organ transplant;
- have lung or breathing problems;
- have liver or kidney problems;
- have diabetes;
- are pregnant or plan to become pregnant; LIBTAYO can harm your unborn baby

### **Females who are able to become pregnant:**

- Your healthcare provider will give you a pregnancy test before you start treatment.
- You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of LIBTAYO. Talk with your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO.
- are breastfeeding or plan to breastfeed. It is not known if LIBTAYO passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of LIBTAYO include tiredness, rash, and diarrhea. These are not all the possible side effects of LIBTAYO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Regeneron Pharmaceuticals and Sanofi at 1-877-542-8296.

**Please see accompanying full Prescribing Information, including Medication Guide.**

### **What is LIBTAYO?**

LIBTAYO is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.

It is not known if LIBTAYO is safe and effective in children.

**For more information, please visit [www.LIBTAYO.com](http://www.LIBTAYO.com).**

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