

YOUR LIBTAYO[®] (cemiplimab) ACTION PLAN

(to be filled out by a member of your oncology team)

For Squamous Cell Skin Cancer

Patient Name _____ Today's date _____
Full Name *Today's date*

Side effects discussed _____

Key points _____

Regeneron Pharmaceuticals
Libtayo Surround Program
1-877-542-8296
<https://www.libtayo.com/nscl/libtayo-surround>

TAKING THE MEDICATION

LIBTAYO® (cemiplimab)

HOW IT'S GIVEN:

- Libtayo is given through your vein via an intravenous (IV) line. The treatment takes 30 minutes
- Treatments are given every 3 weeks
- Your oncologist will decide how many treatments you need
- You will need to have blood tests before, during, and after treatment
- It is important to keep appointments with your oncology team to receive your treatment. If you miss an appointment, call as soon as possible to reschedule and to receive instructions about what to do.

PROBLEMS YOU MAY HAVE WHILE RECEIVING THE MEDICATIONS THROUGH THE IV LINE:

Some people may have a bad (allergic) reaction to the IV treatment itself. Tell your healthcare team member immediately if you have any of these symptoms during a treatment session:

- Chills or shaking
- Itching or rash
- Flushing (turning red)
- Difficulty breathing
- Dizziness
- Fever or feeling hot
- Feeling like you are going to pass out

COMMON SIDE EFFECTS OF LIBTAYO:

Even minor side effects could be serious and you should report them all to your oncologist's office. The most common side effects of taking Libtayo are:

- Rash
- Diarrhea
- Thyroid issues
- Liver problems

REPORT ANY CHANGES IN HOW YOU FEEL TO YOUR ONCOLOGIST'S OFFICE:

Even small changes in your health or the way you feel that don't seem like a big deal may be a sign of a serious side effect. Don't "tough it out" or try to manage it yourself if you think you are having a side effect—report it immediately! Getting it checked out early may prevent it from becoming a bigger problem.

AVOID PREGNANCY:

Use birth control during therapy and for 4 months after your last treatment if you are of childbearing age. Tell your oncologist's office right away if you or your partner becomes pregnant or think you are pregnant while on Libtayo, as it can cause harm to an unborn baby.

IMPORTANT SIDE EFFECTS:

Your oncology team may discuss some side effects of Libtayo that can lead to serious problems if they aren't taken care of right away. These sections give information about possible symptoms, what you should tell your oncology team, when you should get medical help immediately, and any steps you can take to help ease the symptoms.

LUNG AND BREATHING PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Changes in breathing
- New or worsening cough
- New or worsening shortness of breath when you rest, walk or exercise
- Chest pain

What you should tell your oncology team member:

- When you first noticed the changes in your breathing or cough
- If you are feeling very tired, are wheezing (making a whistling sound when you breathe), or have a fever
- If the symptoms are interfering with your daily activities
- If you've ever had breathing problems before and if your existing symptoms are worse
- If you have respiratory allergies to pollen, trees, pets, or other things or food allergies and if you've recently been exposed to these allergens
- If you think you've been exposed to cold or flu viruses
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- Anything you have tried at home to manage the symptoms (such as an inhaler, cough medicine, etc)

Red flag(s):

- If you are having any trouble breathing, new or worsening cough, and particularly if symptoms come on suddenly
- Any chest pain

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your lungs:

- Avoid environments that can irritate your lungs or make it hard to breathe. For instance, if you work outdoors, pollen or chemicals may affect you. If you have a hobby like painting, use of certain chemicals might be a problem
- Wear a pollen mask or a respirator when you are around things that may irritate your lungs
- Adhere to any pre-existing asthma or allergy treatment plans during your cancer therapy
- Check with your oncology provider before using any steroid-based inhalers

DIARRHEA /STOMACH PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Diarrhea or mushy stools
- Stools that are black or darker than normal, sticky, or have blood or mucus
- Changes in your bowel movements (more or less frequent)
- Tenderness, pain or cramping in the stomach
- Nausea (upset stomach) and vomiting (throwing up)
- New or worsening heartburn or indigestion
- Bloating in the stomach and/or gas
- Lack of interest in food
- Feeling very tired
- Fever

What you should tell your oncology team member:

- When you first noticed the changes in your bowel movements
- What your bowel movements are like—hard, solid, soft, loose, or liquid
- What color your stool is—light or dark—and if there is blood or mucus in it
- If your stool floats
- How often you are having bowel movements
- If you wake up from sleep to have a bowel movement or if you have “accidents” when you don’t make it to the toilet in time
- If you have any of the other symptoms listed in the box above
- If you have been losing or gaining weight without trying
- How much and what you are eating and drinking each day
- If you’ve ever had digestive/stomach problems before
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If you have sudden, severe pain or tenderness in the stomach, especially if you also have a fever
- If you feel faint or your blood pressure drops quickly
- If you have blood in the your bowel movement

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your digestive system:

- Call your oncologist's office IMMEDIATELY if you are having frequent, watery or bloody bowel movements
- Take over-the-counter or prescription medications only AS INSTRUCTED by your oncology team; check with your team BEFORE taking any medications used to stop diarrhea such as Imodium, Pepto-Bismol, etc
- Avoid spicy foods, high-fiber cereals, red meats, fats, dairy products, raw fruits (except bananas), vegetables, caffeine, alcohol, and sugar
- Instead, eat bland foods such as bananas, pudding, rice, toast, oatmeal, or crackers
- Drink water, weak tea, clear broth, watered-down juice, Pedialyte®, or sports drinks (such as Gatorade®, Powerade®, etc) or suck on popsicles to prevent dehydration
- Do not use laxatives or stool softeners if you are having more frequent bowel movements than usual or if your stools are soft or watery

KIDNEY PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Changes in how often you urinate
- Pain or hesitation when you urinate
- Changes in the color of your urine, blood in your urine
- Pain in your upper back or abdomen and sides (flank pain)

What you should tell your oncology team member:

- How much and what you are drinking each day
- If you have pain in your lower stomach or back: Sharp or dull
- Constant or it comes and goes
- If you also have nausea or vomiting (throwing up)
- If you have a headache and/or a general feeling of being unwell
- If you have swelling in your ankles
- If you have a fever
- If you have lost your appetite
- If you've ever had urinary tract infections or kidney problems in the past
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If symptoms come on suddenly and you are in intense pain, have a high fever, or can't stop vomiting

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your kidneys:

- Drink lots of fluids every day
- Avoid alcohol and caffeine
- Check with your oncology provider before taking any non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, naproxen (such as Aleve®), and ibuprofen (such as Advil®, Motrin®) as they can affect kidney function

SKIN CHANGES

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- A skin rash with or without itching
- Skin burning or tightness
- Itching without a rash
- Skin blisters
- Peeling skin
- Painful or tender sores in your nose, mouth, throat, genital or rectal areas

What you should tell your oncology team member:

- When you first noticed the rash or itchiness
- What the rash looks like (is it flat, bumpy, red, acne-like, hives?)
- Where the rash is and how much of the body it is covering
- If the skin change is making it difficult for you to get dressed, perform daily activities, or sleep
- If you have had any skin problems in the past
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you have been using a new soap or laundry detergent, or have been around new chemicals or animals recently
- What you have tried at home to manage the symptoms

Red flag(s):

- If you have a rash that covers a large part of your body or that is quickly getting worse
- Blisters in your nose, mouth, throat, genital or rectal areas
- Skin that is peeling and/or intense or widespread itching
- If you have a rash along with fevers and/or chills

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your skin:

- Avoid soap. Instead, use gentle, nonsoap cleansers such as Cetaphil®
- Avoid hot water for bathing because it causes skin dryness. Instead, use lukewarm water
- Keep your fingernails short to protect your skin from damage if you scratch
- Apply a moisturizer that contains the ingredients urea or glycerin daily
- Don't use lotions that have perfumes or dyes
- Protect your skin from the sun by wearing sunscreen, a hat, and UV-protective clothing and sunglasses. Don't forget your hands and face

MOUTH PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Sensitivity or burning when you eat/drink
- Mouth pain affecting your tongue, gums, and the inner lining of the cheeks and lips
- Mouth sores
- Dry mouth, dry or thick saliva

What you should tell your oncology team member:

- When you first noticed the changes in your mouth
- Pain when eating, drinking, or swallowing
- If you have been losing or gaining weight without trying
- If you are waking up at night to sip water
- If your symptoms are worsening
- Any mouth or dental problems you currently have or have had in the past and how severe they were
- How much and what you are drinking each day
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you are using any lozenges for dry mouth
- If you are having difficulty swallowing, feel like you are choking, or feel like food is getting “stuck” because of dry mouth
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If you feel weak, dizzy, confused, or have intense pain

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your mouth:

- Drink lots of fluids every day
- Avoid hot, spicy, or acidic foods (such as tomatoes)
- Brush your teeth at least twice a day using a soft toothbrush. Avoid toothpaste with whitening agents
- Floss once a day
- Use mouth rinses, mints, or other products recommended by your dentist or oncology team to relieve your mouth symptoms
- Avoid mouthwashes that contain alcohol as they may make your symptoms worse
- Have regular dental checkups

LIVER PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Changes in your energy level (more tired)
- Yellowing of your skin or the whites of your eyes
- Change in the color of your stool (paler)
- Change in the color of your urine (darker, tea-colored)
- Abdominal pain, particularly on the upper right side of the stomach
- Bruising more easily
- Bleeding more easily
- Fever
- Confusion, drowsiness, feeling “foggy”
- Increased sweating
- Abdominal bloating

What you should tell your oncology team member:

- When you first noticed the symptoms above
- How severe the symptoms are
- If you have been losing or gaining weight without trying
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter, especially any product containing acetaminophen), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you drink alcohol and how much per day
- If you've ever had liver problems before
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If you have severe pain and/or swelling in your stomach
- You're unusually drowsy all day
- Your skin or the whites of your eyes have turned yellow
- You feel confused or foggy

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your liver:

- Drink lots of fluids every day
- Avoid or minimize alcohol intake
- Eat a well-balanced diet without too much fat and stay active to maintain a healthy weight
- Do not take more acetaminophen (example, Tylenol®) or prescription pain medication than recommended

PITUITARY GLAND PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Lack of energy
- Nausea/vomiting
- Headache
- Dizziness
- Confusion, drowsiness, feeling "foggy"
- Problems with your vision
- Changes in sexual function
- Fever

What you should tell your oncology team member:

- When you first noticed the symptoms above
- How severe the symptoms are
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you've ever had pituitary problems or have been diagnosed with a hormone problem in the past
- Anything else you have tried at home to manage the symptoms

Note: Remind or inform healthcare providers outside the oncology team that you are receiving cancer immunotherapy as it can affect your pituitary gland. This is particularly important if they are planning any scans of your head/brain.

Red flag(s):

- If you have severe head pain with vision changes, fever, nausea and vomiting, feeling "foggy," and/or unusually tired

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your pituitary gland:

- Eat a healthy diet and exercise regularly
- Continue taking any thyroid supplements you were prescribed prior to starting cancer therapy

THYROID PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Changes in your energy level (eg, more tired)
- Changes in your appetite (either you're more hungry or less hungry)
- If you have been losing or gaining weight without trying
- You are not able to tolerate hot or cold temperatures
- Changes in your mood, energy level, or behavior such as decreased sex drive, irritability, or forgetfulness
- Your heart races, seems to skip a beat, or flutters
- You have constipation or diarrhea
- Your skin is either drier or more oily than before
- Your hair is thinning

What you should tell your oncology team member:

- When you first noticed the symptoms above
- How severe the symptoms are
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you've ever had thyroid problems before
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If your thyroid gland (located in front of your windpipe) swells up or you feel a nodule (lump)

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your thyroid gland:

- Eat a healthy diet and exercise regularly
- Continue taking any thyroid supplements you were prescribed prior to starting cancer therapy

DIABETES (HIGH BLOOD GLUCOSE, HYPERGLYCEMIA)

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- More frequent urination
- Increased hunger
- Your breath smells sweet or fruity
- Weight loss
- Greater thirst
- You feel very tired
- Dry mouth

What you should tell your oncology team member:

- When you first noticed the symptoms above
- How severe the symptoms are
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter, particularly steroids such as prednisone, dexamethasone, and methylprednisone), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you've been told you have diabetes or pre-diabetes before
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If the symptoms are interfering with your daily activities
- You faint
- If you are excessively thirsty and urinating frequently

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your pancreas:

- Eat a healthy diet and exercise regularly

NERVE PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Weakness on one or both sides of the body (legs, arms, or face)
- New or worsening pain, numbness, or tingling in the hands or feet
- Trouble walking
- Difficulty writing
- Tremors (shakes)
- Trouble holding items (dropping things)
- Having a hard time getting dressed (eg, buttoning buttons)

What you should tell your oncology team member:

- When you first noticed the symptoms above
- How severe the symptoms are
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you've ever had similar symptoms before, walking problems, or diabetes
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If you have trouble breathing along with any of the symptoms listed above
- Feeling weak
- If you notice your eyelids droop
- Inability to walk or move a limb

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

JOINT PAIN, SWELLING, OR STIFFNESS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Joint pain
- Joint swelling
- Joint stiffness
- Redness around the joint
- Difficulty with walking or performing your daily activities

What you should tell your oncology team member:

- When these symptoms started, what brings them on, and how long they last
- Which joints are affected
- If the symptoms are affecting your ability to do your daily activities
- If you have ever had any joint problems in the past and are those symptoms worsening
- If you also feel unusually tired
- If you have any associated skin changes
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If you have sudden or severe onset of joint pain, swelling, or stiffness
- You fall and the joint looks deformed or you can't place weight on the joint (such as your ankle) or use it at all

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Managing of your side effects:

- Over-the-counter pain medications such as acetaminophen (Tylenol®) and/or anti-inflammatory medications such as ibuprofen (such as Advil®, Motrin®), naproxen (such as Aleve®), are commonly used to help pain and stiffness. Topical anti-inflammatory medications such as diclofenac (Voltaren) may be recommended. In some cases, stronger prescription medications may be necessary to help symptoms
- Apply an ice pack to swollen joints for 15 minutes several times a day
- Keep the joint above your heart whenever you can to reduce swelling
- Use elastic wrap or tape on the joint to support it
- Try to stay as active as possible. Do 30 minutes of low-to-moderate-intensity physical activity most days of the week. Also try to do resistance training (calisthenics or with weights), yoga, tai chi, QiGong, Pilates, aquatic exercise, or a focused dance program
- Avoid activities that cause pain

MUSCLE PAIN OR STIFFNESS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Muscle pain
- Muscle stiffness
- Easily tired from activity

What you should tell your oncology team member:

- When the symptom started and how it developed (slowly vs suddenly)
- Whether you did any activity that might have caused it
- Whether you have had an injury
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- Which muscles are affected
- If the symptoms are affecting your ability to perform your daily activities
- If you have had muscular problems previously and those existing symptoms are getting worse
- If, in addition to muscle symptoms, you also feel very tired or short of breath
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If you have sudden, severe, or continuous muscle pain or weakness
- Shortness of breath
- Feeling foggy or confused
- Unable to move your eyes or you notice your eyelids droop
- Any chest pain

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Managing of your side effects:

- Over-the-counter pain medications such as acetaminophen (Tylenol®) and/or anti-inflammatory medications such as ibuprofen (such as Advil®, Motrin®), naproxen (such as Aleve®), are commonly used to help pain and stiffness. Topical anti-inflammatory medications such as diclofenac (Voltaren) may be recommended. In some cases, stronger prescription medications may be necessary to help symptoms
- Apply heat or take a warm bath to relax the muscle
- Avoid activities that cause pain but do try to stretch and keep active

ADRENAL GLAND PROBLEMS

LIBTAYO® (cemiplimab)

Report immediately to your oncologist's office

What are the symptoms?

- Fatigue/low energy
- Muscle weakness
- Muscle pain
- Feeling dizzy/light headed
- Feeling confused/foggy
- Feeling faint or actually fainting
- Nausea/vomiting
- Darkening/bronzing of skin
- Craving salty foods/drinks
- Feeling irritable or depressed
- Loss of appetite
- Weight loss

What you should tell your oncology team member:

- When you first noticed the symptoms above and if they developed slowly vs suddenly
- How severe the symptoms are
- If the symptoms are interfering with your daily activities
- If you have recently been stressed or ill
- A list of medications (both prescribed and over the counter, particularly steroids such as prednisone, dexamethasone, and methylprednisone), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- If you've ever had adrenal problems before
- Anything you have tried at home to manage the symptoms

Red flag(s):

- If you faint (pass out)
- Are extremely confused or don't make sense to other people
- Are extremely weak
- Have severe vomiting/diarrhea
- Have sudden, severe pain in your lower back, belly, or legs

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your adrenal gland:

- If you have been diagnosed with an adrenal insufficiency, your healthcare team will educate you about wearing a medical alert bracelet and being prepared with stress doses of corticosteroids for surgery, severe illness, injury, etc.

OTHER SYMPTOMS TO LOOK OUT FOR

Below are other symptoms that you can have when you take LIBTAYO® (cemiplimab). We are very concerned about symptoms we have marked with a check mark. Please call the office if you develop any of these symptoms, and consider going directly to the Emergency Room if you have any of the red-flag symptoms.

✓	Symptoms	Red flags (Signs that something serious is going on that needs immediate attention)
	Appetite changes (not feeling hungry or wanting to eat)	<ul style="list-style-type: none"> If you have no appetite plus you feel faint, pass out, and/or have trouble thinking (cloudy thinking, confusion)
	Chest pain	<ul style="list-style-type: none"> Any chest pain should be evaluated immediately
	Feeling faint	<ul style="list-style-type: none"> If you feel faint, have pale skin, are short of breath, and/or your heart feels like it's beating fast or irregularly
	Fever	<ul style="list-style-type: none"> If you have a fever over 104.0°F If you also have breathing problems
	Headaches	<ul style="list-style-type: none"> If you have a very painful headache (the "worst headache of your life"), head pain that doesn't go away after a few hours, or head pain with fever, neck pain or stiffness, and/or rash If you have head pain and changes in vision
	Nausea	<ul style="list-style-type: none"> If you have uncontrolled nausea and it is limiting your ability to eat or drink
	Shortness of breath (difficulty catching your breath or getting enough air in your lungs)	<ul style="list-style-type: none"> If you have any trouble breathing or worsening of your existing symptoms If you have shortness of breath plus chest pain and/or fainting If you have shortness of breath and swelling of the legs or leg pain If you have shortness of breath, a cough that produces colored or bloody mucus, fever, sweating, or chills
	Sleep changes (difficulty falling or staying asleep)	<ul style="list-style-type: none"> Fatigue that is affecting your ability to function
	Vision and eye changes (blurry vision, double vision, or other vision problems; eye pain or redness)	<ul style="list-style-type: none"> Sudden and severe symptoms, such as sudden vision changes, eye pain, or redness

OTHER SYMPTOMS TO LOOK OUT FOR

(Continued)

✓	Symptoms	Red flags (Signs that something serious is going on that needs immediate attention)
	Vomiting (throwing up)	<ul style="list-style-type: none"> • If you go more than 24 hours without being able to hold down foods or liquids, and/or you vomit blood, your vomit looks like coffee grounds, or you have severe stomach pain
	Weight loss	<ul style="list-style-type: none"> • If you have no appetite plus you feel faint, pass out, and/or have trouble thinking (cloudy thinking, confusion)
	Weakness (general or in your muscles)	<ul style="list-style-type: none"> • If you also have headaches and dizziness • If weakness is on the face or one side of your body plus you have numbness, slurred speech, confusion, drooping in the face • If weakness is all over the body and you feel very tired and even faint, have a fever, and your heart is racing

RESOURCES

Financial Assistance

Regeneron Pharmaceuticals

Libtayo Surround Program

1-877-542-8296

<https://www.libtayo.com/nsclc/libtayo-surround>

Additional Information Resources

Skin Cancer Education & Research Foundation

<http://skincancerinfo.org>