

# Lifileucel

**Care Team Contact Information:** \_\_\_\_\_

**Pharmacy Contact Information:** \_\_\_\_\_

**Diagnosis:** \_\_\_\_\_

- This treatment is often used for melanoma.
- It may also be used for other reasons.

**Goal of Treatment:** \_\_\_\_\_

- Treatment is typically given only once.

## Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Lifileucel (LIH-fih-LOO-sel): Amtagvi (am-TAG-vee)  This treatment is also called “tumor-infiltrating lymphocyte” or “TIL” therapy.	Uses your own immune cells (T-cells) taken from your tumor, which are grown and activated, and then put back into your body to help fight the cancer	Infusion given into a vein (intravenous (IV) infusion).

## Treatment Administration and Schedule

- Lifileucel is made from tissue taken from your tumor that was removed by surgery.
- Your tumor tissue is sent to a manufacturing center to make lifileucel. It usually takes about 4 to 5 weeks from when the center receives your tissue until lifileucel is ready to ship, but the time may vary.
- Lifileucel is returned to your care team in 1 to 4 infusion bags that are made only for you.
- After the lifileucel arrives at your treating center, your care team will give lymphodepleting chemotherapy to prepare your body before your lifileucel infusion.

**After Getting Lifileucel**

- Beginning 3 to 24 hours after lifileucel is given, you may be given up to 6 doses of interleukin-2 (IL-2) every 8 to 12 hours by IV infusion. Your care team may discontinue IL-2 infusion any time if you have severe side effects.
- You may have to stay in the hospital until you have completed the IL-2 treatment, and you have recovered from any serious side effects associated with the lifileucel treatment.
- You should plan to stay within 2 hours of the location where you received your treatment for several weeks after getting lifileucel. Your care team will check to see if your treatment is working and help you with any side effects that occur.

**Appointments**

Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

**Supportive Care to Prevent and Treat Side Effects**

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help lower the risk of infusion-related reactions	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help your body make white blood cells to fight infections	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<p><b>Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)</b></p>	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections. It can sometimes take a long time for your WBCs to recover.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Wash your hands often and bathe regularly.</li> <li>• Avoid crowded places and close contact with people who are sick.</li> <li>• Follow food safety and wound care advice from your care team.</li> <li>• Your care team may prescribe medicine to help your WBCs recover.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Fever of 100.4°F (38°C) or higher</li> <li>• Chills</li> <li>• New or worsening cough or sore throat</li> <li>• Painful urination or signs of a urinary infection</li> <li>• Feeling much more tired than usual</li> <li>• Red, swollen, warm, or painful areas on the skin (possible skin infection)</li> </ul>
<p><b>Low Platelet Count (Thrombocytopenia) (Boxed Warning)</b></p>	<p>Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. It can sometimes take a long time for your platelets to recover.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Blow your nose gently and avoid picking it.</li> <li>• Brush your teeth gently with a soft toothbrush and keep good oral hygiene.</li> <li>• Use an electric razor for shaving and a nail file instead of nail clippers.</li> <li>• Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen).</li> <li>• Talk with your care team or dentist before medical or dental procedures.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• A nosebleed lasting more than 5 minutes despite pressure</li> <li>• A cut that continues to bleed</li> <li>• Heavy gum bleeding when brushing or flossing</li> <li>• Sudden or severe headache</li> <li>• Blood in your urine or stool</li> <li>• Blood in your spit after coughing</li> </ul>

<p><b>Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia) (Boxed Warning)</b></p>	<p>Description: RBCs and Hgb carry oxygen to your body’s tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak, very tired, or look pale. It can sometimes take a long time for your RBCs and Hgb to recover.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Aim for 7 to 8 hours of sleep each night.</li> <li>• Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired.</li> <li>• Balance activity and rest — stay as active as you can, but rest when needed.</li> <li>• Eat a balanced diet and follow any nutrition or supplement advice from your care team.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Shortness of breath</li> <li>• Dizziness or fainting</li> <li>• Fast or irregular heartbeats</li> <li>• Sudden or severe headache</li> </ul>
<p><b>Heart Problems (Boxed Warning)</b></p>	<p>Description: Treatment can cause heart rhythm problems (cardiac arrhythmia). Less commonly, treatment may cause heart failure (when the heart cannot pump well), blood clots in the heart, or a heart attack.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Stop smoking</li> <li>• Limit alcohol intake.</li> <li>• Follow your care team’s advice on diet, activity and fluid intake.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Chest pain, pressure, or tightness</li> <li>• New or worsening shortness of breath or trouble breathing</li> <li>• Rapid, very slow, or irregular heartbeats</li> <li>• Fainting, sudden dizziness, or near-fainting</li> <li>• Sudden swelling of the feet, ankles, or belly or sudden weight gain</li> <li>• Sudden severe weakness, confusion, or trouble speaking</li> </ul>

<p>Fatigue</p>	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you.</li> <li>• Ask family and friends for help with daily tasks and for emotional support.</li> <li>• Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being.</li> <li>• Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night.</li> <li>• Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Tiredness that affects your daily life or prevents you from doing normal activities</li> <li>• Tiredness that does not get better with rest</li> <li>• Dizziness or weakness along with severe tiredness</li> </ul>
<p>Swelling (Edema)</p>	<p>Description: Swelling and fluid retention can occur in different areas of the body, like the legs or hands. You might notice areas feel puffy or tighter than usual.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep a daily log of swelling and note any changes in size or location.</li> <li>• Elevate swollen limbs when resting.</li> <li>• Limit salt intake.</li> <li>• Stay active with regular, gentle exercises.</li> <li>• Avoid prolonged periods of sitting or standing without movement.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Swelling that suddenly worsens or spreads to other areas</li> <li>• Pain, redness, or warmth in the affected area</li> <li>• Signs of shortness of breath or difficulty breathing</li> <li>• Swelling is persistent and does not improve with home management</li> <li>• Unexpected weight gain</li> </ul> <p>Note: Your care team may ask you to contact them if your weight increases by a certain amount over a certain time period.</p>

<p>Low Blood Pressure (Hypotension)</p>	<p>Description: Treatment can cause low blood pressure. You may also have dizziness and decreased blood pressure when changing positions (orthostatic hypotension).</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Your care team will check your blood pressure before, during, and after the treatment and will watch you closely.</li> <li>Get up slowly from lying or sitting—sit on the edge of the bed for a moment before standing.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Fainting or loss of consciousness</li> <li>Severe or sudden dizziness or weakness</li> <li>Trouble breathing or chest pain</li> <li>Very fast or very slow heartbeat</li> </ul>
<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>Eat smaller, more frequent meals.</li> <li>Avoid fatty, fried, spicy, or highly sweet foods.</li> <li>Eat bland foods at room temperature and drink clear liquids.</li> <li>If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods.</li> <li>Your care team may prescribe medicine for these symptoms.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>Vomiting for more than 24 hours</li> <li>Nonstop vomiting</li> <li>Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)</li> <li>Blood or coffee-ground-like appearance in your vomit</li> <li>Severe stomach pain that does not go away after vomiting</li> </ul>

## Low Appetite

Description: Loss of appetite can lead to weight loss and low energy. Small changes in when and what you eat can help maintain strength and nutrition.

## Recommendations:

- Be as active as you can. Do light physical activity before a meal (check with your care team before starting an exercise program).
- Note times of day when your appetite is best and eat your largest meal then.
- Eat 5–6 small meals or snacks each day.
- Choose high-protein foods (beans, chicken, fish, meat, yogurt, tofu, eggs). Eat protein first during meals.
- Choose higher-calorie foods (avoid “low-fat”, “fat-free”, or “diet” options when trying to gain/maintain weight).
- If you feel full quickly, avoid drinking 30 minutes before a meal and drink liquids between meals; choose calorie-containing drinks rather than diet drinks.
- Have a bedtime snack that’s easy to digest (for example, peanut butter and crackers). If you have reflux, wait at least 1 hour before lying down.
- Try nutritious beverages (high-protein shakes or smoothies) if solid food is unappealing.
- Ask your care team about liquid nutrition supplements and ways to add protein or calories (protein powder, yogurt, ice cream).

## Talk to your care team if you have:

- Unintentional weight loss
- Little or no appetite for several days
- Excessive tiredness or low energy

<p>Diarrhea</p>	<p>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep track of how often you go to the bathroom each day.</li> <li>• Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise.</li> <li>• Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast).</li> <li>• If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods.</li> <li>• Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium).</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• 4 or more bowel movements than normal in 24 hours</li> <li>• Dizziness or lightheadedness while having diarrhea</li> <li>• Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine)</li> <li>• Bloody diarrhea</li> </ul>
<p>Rash or Itchy Skin</p>	<p>Description: Rash or itchy skin can cause redness, swelling, and a variety of bumps or patches (small red spots, welts, blisters, or scaly dry areas).</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep your skin moisturized with creams or lotions to reduce rash and itchiness.</li> <li>• Wear loose-fitting clothing.</li> <li>• Avoid perfumes and colognes, as they may worsen rash symptoms.</li> <li>• Limit time spent in the heat to prevent worsening symptoms.</li> <li>• Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn.</li> <li>• Wear long-sleeved clothing with ultraviolet (UV) protection and broad-brimmed hats.</li> <li>• Apply broad-spectrum sunscreen (UVA/UVB) with sun protective factor (SPF) 30 or higher as directed.</li> <li>• Use lip balm with SPF 30 or higher.</li> <li>• Avoid tanning beds.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Rash or itching that continues to worsen</li> </ul>

<p>Hair Loss (Alopecia)</p>	<p>Description: Hair loss or thinning may begin days to weeks after treatment starts and usually grows back later. New growth can be a different color or texture and may not look the same as before.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Consider a short haircut before treatment and use scarves, hats, or wigs for comfort and confidence.</li> <li>• Keep your head covered outdoors to protect it from the sun and cold; use sunscreen on your uncovered scalp.</li> <li>• Use gentle haircare: mild shampoo, soft brush, and avoid heat styling and harsh treatments.</li> <li>• Ask your care team about wig prescriptions or resources for head coverings.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• No hair regrowth months after treatment ends</li> <li>• Concern about hair changes or need help finding a wig or support resources</li> </ul>
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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
<b>Lung Problems (Boxed Warning)</b>	<ul style="list-style-type: none"> <li>• Cough</li> <li>• Shortness of breath</li> </ul>	<ul style="list-style-type: none"> <li>• Chest pain</li> </ul>
<b>Kidney Problems (Boxed Warning)</b>	<ul style="list-style-type: none"> <li>• Decrease in your amount of urine</li> <li>• Blood in your urine</li> </ul>	<ul style="list-style-type: none"> <li>• Swelling of your ankles</li> <li>• Loss of appetite</li> </ul>
Capillary Leak Syndrome (CLS)	<p>CLS happens when fluid and proteins leak from your small blood vessels into surrounding tissues. It requires immediate treatment to prevent a drop in blood pressure and other serious complications.</p> <ul style="list-style-type: none"> <li>• Swelling or puffiness and are urinating less than usual</li> <li>• Trouble breathing</li> <li>• Swelling of your stomach area (abdomen) and feeling of fullness</li> </ul>	
Internal Organ Bleeding (Hemorrhage)	<p>Lifileucel can cause bleeding inside the body, such as in the abdomen or brain. These internal bleeds can be life-threatening. Your care team may stop or not give the lifileucel infusion if internal bleeding is suspected, or if you cannot receive IL-2. If you have ongoing low platelets after treatment, your care team will closely monitor you for bleeding.</p> <ul style="list-style-type: none"> <li>• Sudden, severe stomach-area (abdominal) pain or swelling</li> <li>• Vomiting blood or coughing up blood</li> <li>• Black, tarry, or bloody stools</li> <li>• Sudden, severe headache, confusion, or trouble speaking or seeing</li> <li>• Sudden weakness, numbness, or trouble walking</li> </ul>	
Infusion-Related Reactions	<ul style="list-style-type: none"> <li>• Chills or shaking</li> <li>• Itching, rash, or flushing</li> <li>• Trouble breathing, wheezing, or tongue swelling</li> <li>• Dizziness or feeling faint</li> </ul>	<ul style="list-style-type: none"> <li>• Feeling of impending doom</li> <li>• Fever of 100.4°F (38°C) or higher</li> <li>• New or severe pain in your back or neck</li> </ul>

**Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.**



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