

Glofitamab and GemOx (Gemcitabine, Oxaliplatin)

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for diffuse large B-cell lymphoma (DLBCL).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

- The immunotherapy portion of your treatment is called glofitamab.
- The chemotherapy portion of your treatment is called by its acronym: GemOx
 - **Gem:** Gemcitabine
 - **Ox:** Oxaliplatin

Treatment Name	How the Treatment Works	How the Treatment is Given
Glofitamab (gloh-FIH-tah-mab): Columvi (koh-LOOM-vee)	Binds immune cells (T-cells) and cancer cells together so T-cells can more effectively attack and destroy the cancer cells.	Injection under the skin (subcutaneous injection), usually in the stomach area (abdomen). It may also be injected into your thigh or another area of your body.
Gemcitabine (jem-SY-tuh-been): Gemzar (JEM-zar)	Stops cancer cells from making the instructions they need to grow and multiply, causing the cells to die.	Infusion into a vein (intravenous (IV) infusion).
Oxaliplatin (ok-SA-lih-pla-tin): Eloxatin (eh-LOK-sah-tin)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to multiply.	Infusion into a vein (intravenous (IV) infusion).

Note: A single dose of a medicine called obinutuzumab will be given to you on the first day of your first treatment cycle (Day 1 of Cycle 1).

Treatment Administration and Schedule: Treatment is typically repeated every 3 weeks. This length of time is called a “cycle”.

Due to the risk of cytokine release syndrome (CRS), you will receive glofitamab on a **"step-up dosing schedule"**.

- The "step-up dosing schedule" is when you receive the first 2 doses of smaller "step-up" doses of glofitamab during your first cycle of treatment (Cycle 1).
- You will receive your first full dose of glofitamab a week after your last step-up dose (this will be Day 1 of Cycle 2). You may be hospitalized for 24 hours after receiving your first step-up dose of glofitamab due to the risk of CRS and neurologic problems.
- If your dose of glofitamab is delayed for any reason, you may need to repeat the "step-up dosing schedule”.

Cycle 1

- Obinutuzumab is given on Day 1.
- Glofitamab is given on Days 8 and 15.
- Gemcitabine and oxaliplatin are given every 3 weeks.

Treatment Name	Cycle 1									
	Day 1	Day 2	...	Day 8	Day 9	...	Day 15	Day 16	...	Day 21
Obinutuzumab	✓									
Glofitamab				✓			✓			
Gemcitabine	✓									
Oxaliplatin	✓									

Cycle 2 to 8

- Glofitamab is given every 3 weeks.
- Gemcitabine and oxaliplatin are given every 3 weeks.

Treatment Name	Cycle 2										Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	...	Day 21	Day 1
Glofitamab	✓										✓
Gemcitabine	✓										✓
Oxaliplatin	✓										✓

Cycles 9 and Beyond

- Glofitamab is given every 3 weeks.

Treatment Name	Cycle 9										Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	...	Day 21	Day 1
Glofitamab	✓										✓

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 Cytokine Release Syndrome (CRS)	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help lower the risk of 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>Cytokine Release Syndrome (CRS) (Boxed Warning)</p>	<p>Description: CRS happens when your immune system becomes overactive. Most CRS events are mild, get better with treatment, and happen during the first few doses. However, some CRS events can be serious and life-threatening. Symptoms can include fever, chills, fatigue, headache, dizziness or feeling lightheaded, or difficulty breathing.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a symptom diary to record any new or worsening symptoms such as fever, chills, fatigue, or difficulty breathing. • Check vital signs regularly, including temperature, blood pressure, and heart rate. • Stay hydrated by drinking plenty of fluids to help manage symptoms and support overall health. • Your care team may prescribe medications to help manage symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Low blood pressure • Trouble breathing • Chills • Dizziness or lightheadedness • Fast heartbeat • Headache <p>Note: Your care team may have specific numbers for blood pressure, heart rate, and blood oxygen levels. If your numbers go beyond those limits, call your care team or get emergency help right away.</p>
<p>Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection</p>	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound-care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)

<p>Low Platelet Count (Thrombocytopenia)</p>	<p>Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Blow your nose gently and avoid picking it. • Brush your teeth with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Tell your care team or dentist before medical or dental procedures — you may need to pause treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Severe or sudden headache • Blood in your urine or stool • Blood in your spit after coughing
<p>Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)</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.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache
<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"> • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness

<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"> • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (like gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and slowly return to solid foods. • Your care team may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood or coffee-ground-like appearance in your vomit • Severe stomach pain that does not go away after vomiting
<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"> • Keep track of how often you go to the bathroom each day. • Drink 8–10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • 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. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea
<p>Liver Problems</p>	<p>Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal

<p>Numbness, Tingling, or Burning in Your Hands or Feet (Peripheral Neuropathy)</p>	<p>Description: Nerve pain and tingling are uncomfortable sensations from nerve damage or irritation. Pain may be sharp, burning, or deep. Tingling can feel like pins-and-needles or mild electric shocks, often in the hands, feet, arms, or legs.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a daily log of pain and sensations, noting triggers and what helps or makes it worse. • Check your feet every day for cuts, sores, blisters, or color changes, especially if numbness reduces feeling. • Wear comfortable, well-fitting shoes and avoid walking barefoot if sensation is reduced. • Protect hands and feet from extreme heat or cold. • Your care team may recommend or prescribe medicines, topical treatments, physical therapy, or supplements to help with symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • New or worsening “pins and needles,” burning, or numbness in your hands or feet • Trouble moving your arms or legs, or weakness • Problems with balance or frequent falls
<p>Sensitivity to Cold Temperatures</p>	<p>Description: Oxaliplatin can cause increased sensitivity to cold for several days after treatment (often 3–7 days). Cold exposure may cause discomfort, pain, numbness, or tingling in the hands, feet, mouth, or throat.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Avoid cold temperatures and cold objects for several days after treatment. • Do not eat or drink very cold foods or drinks; use a straw for cold liquids if needed. • Wear insulated gloves when handling cold items or reaching into the freezer. • Dress warmly in cold weather and cover your mouth with a scarf to warm inhaled air. • Protect hands and feet from cold exposure (warm socks, mittens, cushioned footwear). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Severe or persistent pain triggered by cold • Numbness or tingling that worsens or spreads • Trouble performing daily activities because of cold sensitivity • Unusual skin changes (discoloration, sores) after cold exposure • Cold sensitivity lasting longer than 7 days after treatment

Select Rare and Serious Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
<p>Severe Allergic Reactions (Boxed Warning)</p>	<p>Get emergency medical help right away if you develop any of the following signs or symptoms:</p> <ul style="list-style-type: none"> • Swelling of your lips, mouth, tongue, or throat • Trouble breathing or swallowing • Raised red areas on your skin (hives) • A very fast heartbeat • You feel dizzy or faint
<p>Neurologic Problems</p>	<p>Glofitamab can cause serious neurologic problems that can be life-threatening and lead to death. Neurologic problems may include Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Neurologic problems may happen days or weeks after you receive glofitamab.</p> <ul style="list-style-type: none"> • Headache • Agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real (hallucinations) • Trouble speaking, writing, thinking, remembering things, paying attention, or understanding things • Problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms • Numbness and tingling (feeling like "pins and needles") • Burning, throbbing, or stabbing pain • Changes in your handwriting • Seizures
<p>Heart Problems</p>	<ul style="list-style-type: none"> • Fast or irregular heartbeat • Dizziness • Feeling faint • Chest discomfort • Shortness of breath
<p>Lung Problems</p>	<ul style="list-style-type: none"> • Cough • Shortness of breath • Chest pain
<p>Posterior Reversible Encephalopathy Syndrome (PRES)</p>	<p>A neurologic condition called PRES can happen during treatment.</p> <ul style="list-style-type: none"> • Severe headache • Confusion • Weakness • Seizures • Blindness or change in vision
<p>Thrombotic Microangiopathy (TMA) and Hemolytic Uremic Syndrome (HUS)</p>	<p>TMA is a serious condition in which small blood vessels are damaged, leading to blood clots, low platelet counts, and destruction of red blood cells. HUS is a type of TMA that can damage the kidneys and other organs and may lead to life-threatening kidney failure.</p> <ul style="list-style-type: none"> • Loss of color in the skin • Extreme tiredness or weakness • Easy bruising or unusual bleeding (nose, mouth, gums) • Decreased urine output or blood in your urine • Swelling of the legs, feet, or ankles (or swelling of face, hands, full body) • Confusion, seizures, or stroke (weakness, numbness, trouble speaking) • New or worsening high blood pressure

<p>Severe Muscle Problems (Rhabdomyolysis)</p>	<ul style="list-style-type: none"> • Intense muscle pain, tenderness, swelling, stiffness, or weakness (especially in shoulders, thighs, or low back) • Dark red, brown, or tea-colored urine • You urinate less frequently than usual or not at all 	<ul style="list-style-type: none"> • Extreme tiredness or confusion • Nausea or vomiting • Fever • Fast heart rate
<p>Low Immunoglobulin Levels (Hypogammaglobulinemia)</p>	<ul style="list-style-type: none"> • Getting sick often (like colds or pneumonia) • Taking longer to feel better after being sick • Tiredness or weakness 	<ul style="list-style-type: none"> • Skin infections or rashes • Severe stomach-area (abdominal) pain or diarrhea • New or worsening allergies or other immune problems
<p>Injection-Site Reactions</p>	<ul style="list-style-type: none"> • Itching • Swelling • Bruising or bleeding 	<ul style="list-style-type: none"> • Pain • Rash or redness of the skin

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.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment, for 1 month after your last dose of glofitamab, for 6 months after your last dose of gemcitabine, and for 9 months after your last dose of oxaliplatin.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment, for 3 months after your last dose of gemcitabine, and for 6 months after your last dose of oxaliplatin.
- **Do NOT breastfeed** during treatment, for 1 week after your last dose of gemcitabine, for 1 month after your last dose of glofitamab, and for 3 months after your last dose of oxaliplatin.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **48 hours** after each dose of **gemcitabine** and for **6 days** after each dose of **oxaliplatin**: (Note: Glofitamab does not require special handling of body fluids and waste.)

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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