

Zolbetuximab and FOLFOX (Leucovorin, Fluorouracil (5-FU), Oxaliplatin)

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for cancer of the stomach (gastric cancer) or cancer located where the esophagus joins the stomach (gastroesophageal junction (GEJ) cancer).
- It may also be used for other reasons.
- Your care team will perform tests to make sure treatment is right for you. These tests will look for negativity for human epidermal growth factor receptor 2 (HER2) and positivity for claudin (CLDN) 18.2.

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 targeted therapy part of the treatment is zolbetuximab.
- This chemotherapy part of this treatment is called by its acronym: FOLFOX (pronounced "FOL-foks").
 - **FOL:** Leucovorin (**F**olinic Acid)
 - **F:** Fluorouracil
 - **OX:** Oxaliplatin

Treatment Name	How the Treatment Works	How the Treatment is Given
Zolbetuximab (ZOL-beh-TUK-sih-mab): Vyloy (VY-loy)	Slows down or stops cancer growth by blocking a specific protein that cancer cells need to survive.	Infusion into a vein (intravenous (IV) infusion).
Leucovorin (LOO-koh-VOR-in)	Helps fluorouracil (5-FU) bind more tightly to its target inside cancer cells. This allows it to stay and fight longer.	Infusion into a vein (intravenous (IV) infusion).
Fluorouracil (floor-oh-YOOR-uh-sil) It is also called "5-FU".	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). It is often given in two parts: first, a quick, concentrated dose (called a "bolus"), followed by a continuous infusion through a pump over 2 days (46-48 hours).
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).

Treatment Administration and Schedule: Treatment is typically repeated every 2 weeks. This length of time is called a “cycle”.

- Note: The continuous infusion of fluorouracil (5-FU) is given over 2 days (46-48 hours), ending on Day 3.

Treatment Name	Cycle 1							Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	...	Day 14	Day 1
Zolbetuximab	✓							✓
Oxaliplatin	✓							✓
Leucovorin	✓							✓
Fluorouracil (5-FU) Bolus	✓							✓
Fluorouracil (5-FU) Continuous Infusion	→	→	→					→

- After receiving a certain number of cycles, your care team may remove the oxaliplatin from your treatment plan.

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 prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help prevent allergic reactions and infusion reactions	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help prevent hand-foot syndrome (HFS)	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<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 gently 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). • Talk with 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 • Sudden or severe 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>Mouth Sores or Irritation (Mucositis or Stomatitis)</p>	<p>Description: Treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Rinse your mouth after meals and at bedtime; rinse more often if sores develop. • Brush your teeth gently with a soft toothbrush or use a cotton swab after meals. • Use a mild, non-alcohol mouth rinse at least 4 times daily (after meals and at bedtime). Example: 1/8 teaspoon salt + 1/4 teaspoon baking soda in 8 oz warm water. • Avoid acidic, hot, spicy, rough, or crunchy foods and drinks that can irritate your mouth. • Avoid tobacco, alcohol, and alcohol-based mouthwash. • Your care team may prescribe medicines or mouth treatments to help with pain and healing. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Painful mouth sores or throat pain • Trouble eating or significant weight loss

<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. Nausea and vomiting can sometimes be severe with zolbetuximab. Nausea and vomiting happen more often during the first treatment cycle.</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 (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually 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>Low Appetite</p>	<p>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.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • 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). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Unintentional weight loss • Little or no appetite for several days • Excessive tiredness or low energy

<p>Stomach-Area (Abdominal) Pain</p>	<p>Description: Abdominal pain is when you feel discomfort or pain in the belly area.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Severe abdominal pain
<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 to 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). • 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. • 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>Constipation</p>	<p>Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Track how often you have bowel movements each day. • Drink 8 to 10 glasses of fluids daily, unless your care team says otherwise. • Stay active and exercise regularly. • Eat more high-fiber foods (such as raw fruits, vegetables, and whole grains) unless advised otherwise. • Your care team may recommend laxatives such as polyethylene glycol (Miralax) or senna. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Constipation lasting 3 or more days • No bowel movement 48 hours after using a laxative

<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

Hand-Foot Syndrome (HFS)

Description: HFS causes dryness, thickening, swelling, or blisters of the skin on the palms of your hands and soles of your feet. HFS can lead to a loss of fingerprints, which could impact your identification.

Recommendations:

- Keep hands and feet moisturized with a non-scented moisturizing cream.
- Applying urea 10% or 20% cream twice daily to the affected area may be helpful.
- Avoid exposure to hot water on the hands and feet in showers or baths, or when doing dishes, as this may dry out the skin.
- Avoid tight-fitting shoes or socks.
- Avoid excessive rubbing of hands and feet unless applying lotion.
- Wear gloves when working with your hands.

Talk to your care team if you have:

- Painful blisters or calluses on your hands or feet

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
<p>Allergic Reactions, Including Anaphylaxis (Boxed Warning), and Infusion-Related Reactions</p>	<p>Oxaliplatin and zolbetuximab can cause serious allergic reactions, including anaphylaxis. Your care team will monitor you during and after your infusions.</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) • Chills or shaking • A very fast heartbeat • You feel dizzy or faint • Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck 	
<p>Heart Problems</p>	<ul style="list-style-type: none"> • Swelling of your stomach area (abdomen), legs, hands, feet, or ankles • Shortness of breath • Nausea or vomiting • New or worsening chest discomfort, including pain or pressure • Weight gain • Pain or discomfort in your arms, back, neck, or jaw • Protruding neck veins • Breaking out in a cold sweat • Feeling lightheaded or dizzy • Fast, slow, or irregular heartbeat 	
<p>Lung Problems</p>	<ul style="list-style-type: none"> • Cough • Shortness of breath • Chest pain 	
<p>Liver Problems</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>Problems in Other Organs and Tissues</p>	<ul style="list-style-type: none"> • Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs • Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight • Persistent or severe muscle pain or weakness, muscle cramps 	

**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 with zolbetuximab and FOLFOX, 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 with zolbetuximab and FOLFOX, and for 6 months after your last dose of oxaliplatin.
- **Do NOT breastfeed** during treatment with zolbetuximab and FOLFOX, for 3 months after your last dose of oxaliplatin, and for 8 months after your last dose of zolbetuximab.

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 **6 days** after each dose of **oxaliplatin** and **48 hours** after each dose of **fluorouracil (5-FU)**. (Note: Zolbetuximab 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

- **Boxed Warning: People with deficiencies in the enzyme dihydropyrimidine dehydrogenase (DPD) may experience serious side effects.**
 People with certain changes in a gene called "DPYD" may have a deficiency of the DPD enzyme. Some of these people may not produce enough DPD enzyme, and some of these people may not produce the DPD enzyme at all.
 - People who do not produce enough DPD enzyme are at increased risk of serious and potentially life-threatening side effects during treatment with fluorouracil (5-FU).
 - Call your care team right away if you develop any of the following symptoms and they are severe, including:
 - Sores of the mouth, tongue, throat, and esophagus
 - Diarrhea
 - Low white blood cell counts
 - Nervous system problems
 - Your care team should talk with you about DPYD testing to look for DPD deficiency.
- **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.
- Talk with your care team about whom to contact if your **fluorouracil (5-FU) pump doesn't work properly**. Do not ignore any pump alarms.
- **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.



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