Pembrolizumab, Trastuzumab, and CAPOX (Capecitabine, Oxaliplatin)



Care Team Contact Information:	
Pharmacy Contact Information:	
Diagnosis:	

- This treatment is often used for stomach cancer, esophageal cancer, and cancer where the esophagus joins the stomach. However, it may also be used
 for other diagnoses.
- Your care team will perform tests for human epidermal growth factor receptor 2 (HER2) and programmed death ligand 1 (PD-L1) to make sure this treatment is right for you.

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 part of treatment is called pembrolizumab.
- The targeted therapy part of treatment is called trastuzumab.
- The chemotherapy part of treatment is called by its acronym: "CAPOX", "CAPEOX", or "XELOX"
 - CAP: Capecitabine
 - o OX: Oxaliplatin

Treatment Name	How the Treatment Works	How the Treatment is Given
Pembrolizumab (pem-broh-LIH-zoo-mab): Keytruda (kee-TROO-duh)	Boosts your immune system to help it attack cancer cells more effectively.	Infusion given into a vein.
Trastuzumab (tras-TOO-zoo-mab): Herceptin (her-SEP-tin), Hercessi, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera	Slows down or stops cancer growth by blocking a specific protein that cancer cells need to survive.	Infusion given into a vein.
Capecitabine (ka-peh-SY-tuh-been): Xeloda (zeh-LOH-duh)	Stops cancer cells from making the instructions they need to grow and multiply, causing the cells to die.	Tablets taken by mouth.
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 given into a vein.









Treatment Administration and Schedule: Pembrolizumab, trastuzumab, and oxaliplatin are typically given every 3 weeks. This length of time is called a "cycle". Capecitabine is typically taken 2 times a day on Days 1 to 14, followed by a 7-day break.

Pembrolizumab may be given every 3 weeks or every 6 weeks. Talk with your care team about your exact schedule.

Every 3 Weeks Dosing:

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								Cycle 1								Next Cycle
Treatment Name	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Days 15- 21	Day 1
						Treatme	nt Given a	t the Clin	ic or Hos _l	pital						
Pembrolizumab	~															/
Trastuzumab	~															\
Oxaliplatin	~															\
	Treatment Taken at Home															
Capecitabine AM dose	~	~	~	~	~	~	~	~	~	~	~	~	~	~	1 Week	~
Capecitabine PM dose	~	~	>	~	>	>	~	~	>	~	>	~	~	~	Break	>

Your capecitabine dosing instructions:

- Capecitabine comes in 2 tablet strengths: 150 mg and 500 mg. Your care team will tell you which tablets to take and may change your dose if needed.
- Your dose is based on many factors, including your height and weight, overall health, and diagnosis.
- Take capecitabine 2 times a day at the same time each day, about 12 hours apart.
- Take capecitabine with water within 30 minutes after finishing a meal.
- Swallow capecitabine tablets whole. Do not chew, cut, or crush the tablets. If you cannot swallow the tablets whole, tell your care team.
- If you vomit after taking a dose of capecitabine, do NOT take another dose at that time. Wait and take your next dose at your scheduled time.
- If you miss a dose of capecitabine, just skip the dose and then take your next dose at your scheduled time. Do NOT take an extra dose or 2 doses at one time.
- If you take too much capecitabine, call your care team or go to the nearest hospital emergency room right away.









Storage and Handling of Capecitabine

- Store capecitabine at room temperature between 68°F to 77°F (20°C to 25°C) in a dry location away from light.
- Keep capecitabine in a tightly closed container.
- Keep capecitabine and all medicines out of the reach of children and pets.
- Whenever possible, give capecitabine to yourself and follow the steps below. If someone else gives it to you, they must also follow these steps:
 - Wash hands with soap and water.
 - o Put on gloves to avoid touching the medication. Note: Gloves are not needed if you give the drug to yourself.
 - Transfer the capecitabine from its package to a small medicine or other disposable cup.
 - o Administer the medicine immediately by mouth with water.
 - o Remove gloves, if used, and throw them and medicine cup in household trash.
 - Wash hands with soap and water.
- If you plan to use a daily pill box or pill reminder, contact your care team before using it.
 - When the box or reminder is empty, wash it with soap and water before refilling.
 - o The person refilling the box or reminder should:
 - Wear gloves. Note: Gloves are not needed if you are refilling it yourself.
 - Wash their hands with soap and water after completing the task, regardless of whether gloves were worn.
- Ask your care team how to safely throw away any unused capecitabine. Do not throw it in the trash or flush it down the sink or toilet.

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 or vomiting		
Other -		









Common Side Effects

Side Effect	Important Information	
Infusion Reactions (Boxed Warning)	Description: An infusion reaction is a bad response that happens during or reaction with trastuzumab and oxaliplatin, and less frequently with pembrolizing determined the right away if you develop any of the following symptoms of the Chills or shaking Itching, rash, or flushing Trouble breathing or wheezing; tongue-swelling Dizziness or feeling faint Fever of 100.4°F (or 38°C) or higher Pain in your back or neck	umab.
Low White Blood Cell (WBC) Count and Increased Risk of Infection	Description: WBCs help protect the body against infections. If you have a lo Recommendations: • Wash your hands and bathe regularly. • Avoid crowded places. • Stay away from people who are sick. • Your care team may prescribe a drug that promotes the growth of WBCs.	w WBC count, you may be at a higher risk of infection. Talk to your care team if you have: Fever of 100.4 °F (38°C) or higher Chills Cough Sore throat Painful urination Tiredness that is worse than normal Skin infections (red, swollen, or painful areas)
Low Platelet Count	 Description: Platelets help the blood clot and heal wounds. If you have low precommendations: Blow your nose gently and avoid picking it. Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. Use an electric razor for shaving and a nail file instead of nail clippers. Avoid over-the-counter medications that may increase the risk of bleeding, such as NSAIDs. Talk with your care team or dentist before medical or dental procedures, as you may need to pause your treatment. 	Datablet counts, you are at a higher risk of bruising and bleeding. Talk to your care team if you have: Nosebleed lasting over 5 minutes despite pressure Cut that continues to bleed Significant gum bleeding when flossing or brushing Severe headaches Blood in your urine or stool Blood in your spit after a cough









Low Red Blood Cell (RBC)	Description: RBCs and Hgb help bring oxygen to your body's tissues and take away carbon dioxide. If you have low RBC counts or Hgb, you may feel weak, tired, or look pale.							
Count and Hemoglobin (Hgb)	 Recommendations: Get 7 to 8 hours of sleep each night. Avoid operating heavy machinery when tired. Balance work and rest, staying active but resting when needed. 	Talk to your care team if you have:						
Fatigue	 Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you. Ask your family and friends for help with daily tasks and emotional support. Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good. Make a regular sleep schedule and limit naps during the day so you can sleep better at night, aiming for 7 to 8 hours of sleep. Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents. 	Talk to your care team if you have: Tiredness that affects your daily life Tiredness all the time, and it doesn't get better with rest Dizziness and weakness, along with being tired						
Nausea and Vomiting	 Description: Nausea is an uncomfortable feeling in your stomach or the need Recommendations: 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 amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal). Slowly work up to eating solid food. Your care provider may prescribe medicine for these symptoms. 	 It to throw up. This may or may not cause vomiting. Talk to your care team if you have: Vomiting for more than 24 hours Vomiting that's nonstop Signs of dehydration (like feeling very thirsty, having a dry mouth, feeling dizzy, or having dark urine) Blood or coffee-ground-like appearance in your vomit Bad stomach pain that doesn't go away after vomiting 						









Low Appetite

Treatment can cause a low appetite, which means you may not feel like eating much. It's important to eat enough so your body gets the nutrients it needs to heal and stay strong. Eating healthy foods helps you feel better and recover faster.

Recommendations:

- Be as active as possible. Do some physical activity before a meal. Before starting an exercise program, talk with your care team.
- Take note of the times during the day when your appetite is best.
 Do not limit food when your appetite is good. Eat your largest meal when you feel the most hungry, whether it is breakfast, lunch, or dinner.
- Eat 5-6 small meals per day and snack anytime.
- Choose foods high in protein, such as beans, chicken, fish, meat, yogurt, tofu, and eggs. During meals, eat high-protein foods first.
- Choose foods that are high in calories. Do not select foods that are labeled "low-fat," "fat-free" or "diet."
- If you feel full quickly when eating, do not drink any liquids 30 minutes before a meal so you have more room for solid food.
 Then, drink liquids between meals. Choose liquids with extra calories, not diet drinks.
- Eat a bedtime snack. Choose something easy to digest, such as peanut butter and crackers. If you tend to experience reflux or heartburn, eat at least an hour before lying down.
- If food is not appealing, try a nutritious beverage, such as a highprotein shake or smoothie, instead of solid food.
- Ask your care team to recommend a liquid nutrition supplement.
 Add a scoop of protein powder, yogurt, or ice cream for added protein and calories.

Talk to your care team if you have:

- Weight loss
- No appetite
- Tiredness











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Mouth Irritation	Description: This treatment can irritate the lining of the mouth. In some case	s, this can cause redness, sores, pain, and swelling.
and Sores	 Recommendations: Rinse your mouth after meals and at bedtime, and more often if sores develop. Brush your teeth with a soft toothbrush or cotton swab after meals. Use a mild, non-alcohol mouth rinse at least four times daily (after meals and at bedtime). A simple mixture is 1/8 teaspoon salt and 1/4 teaspoon baking soda in 8 ounces of warm water. Avoid acidic, hot, spicy, or rough foods and drinks that may irritate your mouth. If you have mouth sores, avoid tobacco, alcohol, and alcoholbased mouthwashes. Your care team may prescribe medicine for these symptoms. 	Talk to your care team if you have: • Pain or sores in your mouth or throat
Diarrhea	Description: Diarrhea is when you have loose, watery bowel movements mo urgently. Recommendations: Keep track of how many times you go to the bathroom each day. Drink 8 to 10 glasses of water or other fluids every day, unless your care team tells you otherwise. Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast. Stay away from foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods. Your care team may recommend medicines (such as loperamide) for diarrhea.	Talk to your care team if you have: • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Bloody diarrhea







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Nerve Problems in	Description: Nerve pain and tingling are uncomfortable sensations caused by nerve damage or irritation. Pain may be sharp, burning, or deep, while tingling feels like pins-and-needles or mild electric shocks, often in the hands, feet, arms, or legs.						
Your Arms, Hands, Legs, or Feet	 Recommendations: Check your feet every day for cuts, blisters, or any changes, especially if they feel numb. Wear shoes that fit well. Talk to your care team about doing easy activities like walking, swimming, or biking to help your blood flow and keep you healthy. Your care team might give you medicine or suggest wearing compression socks to help. 	 Talk to your care team if you have: "Pins and needles" or burning feeling in your hands or feet Trouble moving your arms or legs Trouble keeping your balance 					
Sensitivity to Cold	Description: Oxaliplatin can make you sensitive to the cold for 3-7 days after other areas when exposed to cold weather or cold objects. It can be challen	· · · · · · · · · · · · · · · · · · ·					
Temperatures	 Recommendations: Avoid cold temperatures and cold objects Avoid cold drinks, ice, and cold food. Use a straw for cold liquids. Wear gloves when reaching into the freezer or handling anything cold. Dress warmly in cold weather, using gloves and a scarf to cover your mouth. 	 Talk to your care team if you have: Severe or persistent pain when exposed to cold temperatures. Numbness or tingling that worsens or spreads to other areas. Difficulty performing daily activities due to cold sensitivity. Any unusual symptoms, such as skin discoloration or sores, in response to cold. If your cold sensitivity lasts longer than 7 days after treatment. 					
Hand-Foot Syndrome	 Description: Hand-Foot Syndrome causes dryness, thickening, swelling, or lefeet. 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 that may dry out the skin or by doing dishes. Avoid tight-fitting shoes or socks. Avoid excess rubbing on hands and feet unless putting on lotion. Wear gloves when working with your hands. 	Talk to your care team if you have: • Painful blisters or calluses					







Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Sympton	ns
Heart Problems	Your care team should check your heart function before and during treat	tment.
(Boxed Warning)	 Swelling of your stomach-area (abdomen), legs, hands, feet, or ankles Shortness of breath Nausea or vomiting Weight gain of more than 5 pounds in 24 hours Pain or discomfort in your arms, back, neck, or jaw Protruding neck veins 	 Palpitations (rapid or irregular heartbeat) Dizziness or lightheadedness Chest discomfort or pain Fatigue Confusion Fainting or near-fainting spells Breaking out in a cold sweat
Lung Problems (Boxed Warning)	CoughShortness of breath	Chest pain
Liver Problems	 Yellowing of your skin or the whites of your eyes Severe nausea or vomiting, pain on the right side of your stomach area (abdomen) 	Dark urine (tea colored)Bleeding or bruising more easily than normal
Hormone Gland Problems	 Headaches that will not go away or unusual headaches Eye sensitivity to light Eye problems Rapid heartbeat Increased sweating Extreme tiredness Weight gain or weight loss Feeling more hungry or thirsty than usual 	 Urinating more often than usual Hair loss Feeling cold Constipation Your voice gets deeper Dizziness or fainting Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
Problems in Other Organs and Tissues	 Chest pain, irregular heartbeat, shortness of breath, swelling of ankles 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 	 Rash, itching, skin blistering or peeling, painful sore or ulcers in mouth nose, throat, or genitals Decrease in your amount of urine, blood in your urine, swelling of your ankles, loss of appetite Hearing loss, ear ringing (tinnitus), feeling fullness or pressure in the ears
Extravasation	Extravasation happens when medicine that is supposed to go into a veir and damage to the skin and tissues. • Pain, burning, or stinging at the infusion site • Swelling, redness, or blistering around the site	 Leaks out into the tissues around it. This can cause pain, swelling, Coolness or numbness in the area Decreased blood flow or tissue damage, potentially leading to ulcers or tissue death in severe cases







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.
 - o If you are able to become pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control
 - during treatment
 - for 4 months after your last dose of pembrolizumab
 - for 6 months after your last dose of capecitabine
 - for 7 months after your last dose of trastuzumab
 - for 9 months after your last dose of oxaliplatin
 - o If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - o If your partner(s) could become pregnant, use an effective method of birth control—such as condoms
 - during treatment
 - for 3 months after your last dose of capecitabine
 - for 6 months after your last dose of oxaliplatin

• Do NOT breastfeed

- during treatment
- o for 1 week after your last dose of capecitabine
- $_{\odot}$ $\,$ for 3 months after your last dose of oxaliplatin
- o for 4 months after your last dose of pembrolizumab
- for 7 months after your last dose of trastuzumab









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 **capecitabine** and for **6 days** after each dose of **oxaliplatin**:

- 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.
- **Do not take products that contain folic acid or folate analog products**, for example, leucovorin or levoleucovorin, during treatment with capecitabine, unless your healthcare provider instructs you to take them.
- Taking capecitabine with blood thinner medicines like warfarin increases the risk of bleeding.
 - Taking capecitabine with these medicines can cause changes in how fast your blood clots and can cause bleeding that can lead to death. This can happen as soon as a few days after you start taking capecitabine, or later during treatment, and possibly within 1 month after you stop taking capecitabine.
 - o Before taking capecitabine, tell your care team if you are taking warfarin or another blood thinner medicine.
 - o If you take warfarin or another blood thinner that is like warfarin during treatment with capecitabine, your care team should do blood tests more often, to check how fast your blood clots during and after you stop treatment with capecitabine. Your care team may change your dose of the blood thinner medicine if needed.
 - o Tell your care team right away if you develop any signs or symptoms of bleeding.
- Tell your care team about all your health problems.
 - This includes issues with your immune system, like Crohn's disease, ulcerative colitis, or lupus. Also, tell them if you have had an organ transplant, like a kidney or eye transplant. Let them know if you had a stem cell transplant from a donor, had radiation to your chest, or have a nerve problem like myasthenia gravis or Guillain-Barré syndrome.
- Your treatment might cause side effects that need medicine or a break from treatment.
 - Your care team may give you corticosteroids or hormone medicines to help. Sometimes, they may need to delay or stop your treatment if you have certain side effects.









Additional Information (Continued)

- 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 any DPD enzyme are at increased risk of sudden side effects that come on early during treatment with capecitabine and can be serious, and sometimes lead to death.
 - 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
 - People with some DPD enzyme may have an increased risk of serious side effects with capecitabine treatment that can sometimes lead to death.
 - Your care teams should talk with you about DPYD testing to look for DPD deficiency.
- This Patient Education Sheet may not describe all possible side effects.
 Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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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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