

Penpulimab, Gemcitabine, and Cisplatin

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for biliary tract cancer, but it may also be used for other diagnoses.

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

Treatment Name	How the Treatment Works	How the Treatment is Given
Penpulimab (pen-PUH-lih-mab)	Boosts your immune system to help it attack cancer cells more effectively.	Infusion given into a vein.
Gemcitabine (jem-SY-tuh-been): Gemzar (JEM-zar)	Slows down or stops the growth of cancer cells by interfering with the process that cancer cells need to make new building blocks for growth.	Infusion given into a vein.
Cisplatin (sis-PLA-tin): Platinol (PLA-tih-nol)	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: Treatment is typically repeated every 3 weeks. This length of time is called a “cycle”.

During the **first 6 cycles**, you will receive **ALL three treatments**:

Treatment Name	Cycle 1							Next Cycle
	Day 1	Day 2	Day 3	...	Day 8	...	Day 21	Day 1
Penpulimab	✓							✓
Gemcitabine	✓				✓			✓
Cisplatin	✓							✓

Starting **cycle 7**, you will receive **ONLY penpulimab**:

Treatment Name	Cycle 9							Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	...	Day 21	Day 1
Penpulimab	✓							✓

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	<div></div> <div></div> <div></div>	<div></div> <div></div> <div></div>
Hydration and other supportive care	<div></div> <div></div> <div></div>	<div></div> <div></div> <div></div>

Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count and Increased Risk of Infection (Boxed Warning)	<p>Description: WBCs help protect the body against infections. If you have a low WBC count, you may be at a higher risk of infection.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> 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. <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 Cough Sore throat Painful urination Tiredness that is worse than normal Skin infections (red, swollen, or painful areas)
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Boxed Warning)	<p>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.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> Shortness of breath Dizziness Fast or abnormal heartbeats Severe headache
Low Platelet Count (Boxed Warning)	<p>Description: Platelets help the blood clot and heal wounds. If you have low platelet counts, you are at a higher 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 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> 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

Nausea and Vomiting (Boxed Warning)	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause vomiting.</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 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 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
Numbness or Tingling in the Hands and Feet (Boxed Warning)	<p>Description: Peripheral neuropathy is when your nerves outside the brain and spine get hurt. This can make you feel numb, tingly, or in pain. It may also make it hard to keep your balance or feel things properly. Peripheral neuropathy can get better or go away over time after stopping or lowering the dose of the medicine. It may take months to fully heal, but you may start to feel better in a few weeks. Sometimes, however, the nerve damage can be permanent.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • "Pins and needles" or burning feeling in your hands or feet • Trouble moving your arms or legs • Trouble keeping your balance
Kidney Problems (Boxed Warning)	<p>Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. This may lead to acute kidney injury or long-term kidney failure. It can also cause low magnesium levels that last after treatment. These issues usually happen within days of getting the drug.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. <p>Your care team will give you fluids and electrolytes with your treatment.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
Fever and Flu-like Symptoms	<p>Description: Fever and flu-like symptoms often occur after gemcitabine infusions. Symptoms such as fever, chills, fatigue, and muscle aches typically begin within a few hours after the infusion and last about 1 to 2 days.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Take your temperature with a thermometer if you feel you have a fever. • Your care team may recommend over-the-counter medications to reduce fever and relieve discomfort. <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 • Fever lasting for more than 3 days • Any signs of infections, such as persistent cough, shortness of breath, or pain.

Constipation	<p>Description: Constipation means having a hard time passing stools or not going to the bathroom often. Your stools might feel hard and dry, which can make you uncomfortable or hurt.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how many times you move your bowels every day. • Drink 8 to 10 glasses of water or other fluids each day, unless your doctor tells you otherwise. • Try to stay active and get some exercise if you can. • Eat high-fiber foods like raw fruits and vegetables. • Your care team might suggest medication to help move your bowels. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Constipation that lasts 3 or more days • Constipation after 48 hours, even after using a laxative
Low Appetite	<p>Description: Low appetite means you don't feel like eating as much as usual. It's important to get enough nutrition and maintain a healthy weight because protein and calories are essential for recovery and feeling good.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • 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 hungriest, 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 high-protein shake or smoothie, instead of solid food. • Ask your healthcare team to recommend a liquid nutrition supplement. Add a scoop of protein powder, yogurt, or ice cream for added protein and calories. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Severe weight loss • Weight loss with severe fatigue or weakness

Hormone Gland Problems	<p>Description: Treatment can change how much hormones your body makes. Your care team might check some hormone levels at the beginning of treatment, at different times while you're being treated, or if you start showing symptoms.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 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
Fatigue	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 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

Select Rare or Serious Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Lung Problems	<ul style="list-style-type: none"> Cough Shortness of breath 	<ul style="list-style-type: none"> Chest pain
Liver Problems	<ul style="list-style-type: none"> Yellowing of your skin or the whites of your eyes Severe nausea or vomiting Pain on the right side of your stomach area (abdomen) 	<ul style="list-style-type: none"> Dark urine (tea colored) Bleeding or bruising more easily than normal
Intestinal Problems	<ul style="list-style-type: none"> Diarrhea (loose stools) or more frequent bowel movements than usual Stool that are black, tarry, sticky, or have blood or mucus 	<ul style="list-style-type: none"> Severe stomach-area (abdominal) pain or tenderness
Skin Problems	<ul style="list-style-type: none"> Rash Itching 	<ul style="list-style-type: none"> Skin blistering or peeling Painful sore or ulcers in mouth or nose, throat, or genital area
Ear Problems	<ul style="list-style-type: none"> Difficulty hearing high-pitched sounds (like certain consonant sounds, music, or birdsong) Ringing, buzzing, hissing, or other sounds in the ears when no external source is present 	<ul style="list-style-type: none"> Difficulty understanding speech, particularly in noisy environments A feeling of fullness or pressure in the ears Dizziness or balance problems
Problems in Other Organs and Tissues	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight Persistent or severe muscle pain or weakness, muscle cramps Low red blood cells, bruising
Infusion Reactions	<ul style="list-style-type: none"> Chills or shaking Itching or rash Flushing Shortness of breath or wheezing 	<ul style="list-style-type: none"> Dizziness Feeling like passing out Fever Back pain

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 might get pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment, for 6 months after your last dose of gemcitabine, and for at least 14 months after your last dose of cisplatin. Also, continue using birth control for 4 months after your last dose of penpulimab.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partners could be pregnant, use an effective method of birth control—such as condoms—during treatment, for 6 months after your last dose of gemcitabine, and for 11 months after your last dose of cisplatin.
- **Do NOT breastfeed** during treatment and for 4 months after your last dose of penpulimab.

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 anticancer 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 **cisplatin** and **gemcitabine**:

- Pregnant women 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.
- **The most common severe changes in laboratory test results** are decreased white blood cells, hemoglobin, and platelets.
- **Treatment may cause side effects that require medicines or pausing the therapy.**
Your care team may treat you with corticosteroids or hormone replacement medicines. Your care team may also need to delay or completely stop your treatment if you have certain side effects.
- **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.
- **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.

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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