Tarlatamab

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for small cell lung cancer (SCLC).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue 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
Tarlatamab (tar-LA-tah-mab): Imdelltra (im-DEL-trah)	Binds immune cells (T-cells) to cancer cells so T-cells can more effectively attack and destroy them.	Infusion into a vein (intravenous (IV) infusion).

Treatment Administration and Schedule
Treatment is typically repeated every 4 weeks. The length of time is called a “cycle.”

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

- The step-up dosing schedule is when you receive a smaller dose of tarlatamab on Day 1 of your first treatment cycle (Cycle 1).
- You will receive the full treatment dose of tarlatamab on Day 8 and Day 15 of Cycle 1. You will receive the full treatment dose 1 time every 2 weeks after Day 15 of Cycle 1.
- If your dose of tarlatamab is delayed for any reason, you may need to repeat the step-up dosing schedule.

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Treatment Administration and Schedule (Continued)

Cycle 1

- Tarlatamab is given on Days 1, 8, and 15.

Treatment Name	Cycle 1								
	Day 1	…	Day 8	…	Day 15	…	Day 21	…	Day 28
Tarlatamab	✓ (Step-Up Dose)		✓ (First Treatment Dose)		✓				

Cycles 2 and Beyond

- Tarlatamab is given on Days 1 and 15.

Treatment Name	Cycle 2									Next Cycle
	Day 1	…	Day 8	…	Day 15	…	Day 21	…	Day 28	Day 1
Tarlatamab	✓				✓					✓

Due to the risk of CRS and neurologic problems you will receive the following **monitoring** during treatment.
Note: The time that you are monitored may be different than the times listed below. Observation times may be longer if you develop side effects.

- **For Day 1 and Day 8 of Cycle 1 doses**, your care team may monitor you for **22 to 24 hours** from the start of the tarlatamab infusion in an appropriate healthcare setting that can manage these side effects.
  - You should remain within 1 hour of an appropriate healthcare setting for a total of 48 hours from the start of the tarlatamab infusion after your Day 1 and Day 8 of Cycle 1 doses and be accompanied by a caregiver.
  - Do not drive yourself home after treatment until your care team tells you it is safe. Arrange for someone else to drive you.
- **For Day 15 of Cycle 1 and Cycle 2 doses**, your care team may watch you for **6 to 8 hours** after the tarlatamab infusion.
- **For Cycle 3 and Cycle 4 doses**, your care team may watch you for **3 to 4 hours** after the tarlatamab infusion.
- **For Cycle 5 and later doses**, your care team may watch you for **2 hours** after the tarlatamab infusion.

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 an appointment, call your care team as soon as possible to reschedule it.

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)		
To help prevent or treat nausea and vomiting		
Other		

Common Side Effects

Side Effect	Important Information
Cytokine Release Syndrome (CRS) (Boxed Warning)	Description: CRS happens when your immune system becomes very active after treatment. 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. Recommendations: • Keep a symptom diary to record any new or worsening symptoms such as fever, chills, fatigue, or difficulty breathing. • Your care team may ask you to monitor your temperature, blood pressure, heart rate, or oxygen level. • Stay hydrated by drinking plenty of fluids to help manage symptoms and support overall health. • If you develop CRS, do not drive or operate dangerous machinery until your care team says it is safe. • Your care team may prescribe medications for CRS. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Trouble breathing • Chills • Dizziness or lightheadedness • Fast heartbeat • Headache 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.
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection. Recommendations: • 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. Talk to your care team if you have: • 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)

Low Platelet Count (Thrombocytopenia)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: • 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. Talk to your care team if you have: • 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
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	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 or very tired, or may make you look pale. Recommendations: • 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. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • 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. Talk to your care team if you have: • 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
Constipation	Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain. Recommendations: • 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. Talk to your care team if you have: • Constipation lasting 3 or more days • No bowel movement 48 hours after using a laxative
Liver Problems	Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment. Talk to your care team if you have: • 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

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Taste Changes	Description: Your sense of taste may change. Foods you used to like may not taste good. Some foods may taste strange or like metal. Recommendations: • Choose foods that look and smell good to you. • If food tastes like metal, try using plastic forks and spoons. • Use herbs, spices, or a little juice to add flavor. • Suck on mints or chew gum to freshen your mouth. • Brush your teeth with a soft toothbrush before and after eating. • Do not smoke. Talk to your care team if you have: • Trouble eating • Weight loss
Low Appetite or Weight Loss	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 or 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

<table>
<tr><td>Muscle or Joint Pain or Weakness</td><td>Description: Muscle pain is soreness, aching, cramps, stiffness, tenderness, or weakness in one or more muscles. Joint pain is pain, stiffness, swelling, or reduced movement where two bones meet.

Recommendations:
Keep a pain diary: note pain levels, locations, and activities that make it better or worse.
Do gentle exercise (walking, stretching, yoga) to maintain mobility and strength. Check with your care team before starting a new activity.
Use a warm compress for stiff muscles or a cold pack to reduce swelling and numb pain—use what helps the area.
Your care team may recommend or prescribe medicines, including over-the-counter pain relievers.
Talk to your care team if you have:
Pain you cannot control with usual measures
Swelling, redness, or warmth in a joint
New weakness
Trouble walking or moving</td></tr>
<tr><td>Changes in Electrolytes</td><td>Description: Treatment may cause low levels of magnesium, potassium, and sodium in your blood. It may also cause high levels of sodium in your blood. Your care team will perform blood tests to check for these changes and will treat you if needed.

Talk to your care team if you have:
Severe or worsening tiredness, extreme sleepiness, or trouble doing your usual daily activities
New or worsening muscle weakness, cramps, spasms, twitching, or tremors
Numbness or tingling in your fingers, toes, or around your mouth
Severe constipation or strong stomach-area (abdominal) pain
Nausea, vomiting, or loss of appetite (especially with headache or confusion)
Irregular, fast, or pounding heartbeat, or chest pain
Severe dizziness, lightheadedness, fainting, or loss of consciousness
New or worsening confusion, trouble thinking clearly, restlessness, irritability, or agitation
Severe headache, seizures, or sudden trouble walking or keeping your balance
Difficulty breathing or shortness of breath
Intense thirst, very dry mouth, much less urine than usual, or dark urine
Rapid heartbeat or very low blood pressure</td></tr>
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Infusion-Related Reactions	Description: An infusion reaction is a bad response that can happen during or shortly after receiving medicine through a vein. Recommendations: • Your care team may prescribe medicines before your infusion to help reduce your risk of infusion reactions or make any infusion reaction less severe. • You may be monitored for infusion reactions during each infusion. • Your care team may slow down or stop your infusion, or completely stop treatment if you have an infusion reaction. Get medical help right away if you develop any of the following during or after your infusion: • Chills or shaking • Itching, rash, or flushing • Trouble breathing, wheezing, or tongue swelling • Dizziness or feeling faint • Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Neurologic Problems (Boxed Warning)	Treatment can cause serious neurologic (brain and nerve) problems that can be life-threatening and may lead to death. These problems can include a condition called Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Neurologic problems may occur days or weeks after treatment. Your care team may refer you to a specialist who treats neurologic problems. If you develop neurologic side effects, do not drive or operate dangerous machinery until your care team says it is safe. • 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
Allergic Reactions	Tarlatamab can cause allergic reactions that can be severe. Go to the nearest emergency room or get medical help right away if you develop any signs or symptoms of a severe allergic reaction during treatment with tarlatamab. • Shortness of breath or trouble breathing • Pain or tightness in your chest and back • Wheezing • Coughing • Feeling lightheaded or dizzy • Rash

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:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment and for 2 months after your last dose of tarlatamab.
        - 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 tarlatamab.
- **Do not breastfeed** during treatment and for 2 months after your last dose of tarlatamab.

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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HOPA Hematology/Oncology Pharmacy Association
NCODA Network for Collaborative Oncology Development & Advancement
ONS Oncology Nursing Society

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