

Belzutifan and Pembrolizumab

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for a type of kidney cancer called renal cell carcinoma (RCC).
- 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

Treatment Name	How the Treatment Works	How the Treatment is Given
Belzutifan (bel-ZOO-tih-fan): Welireg (WEL-ih-reg)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive in low oxygen conditions.	Tablet(s) taken by mouth.
Pembrolizumab (pem-broh-LIH-zoo-mab): Keytruda (kee-TROO-duh)	Boosts your immune system to help it attack cancer cells more effectively.	Infusion into a vein (intravenous (IV) infusion).

Note: Your care team may give you pembrolizumab and berahyaluronidase (Keytruda Qlex) instead of pembrolizumab. Pembrolizumab and berahyaluronidase is given as an injection under the skin (subcutaneous injection) into the stomach area (abdomen) or outer thigh over 1 to 2 minutes.

Treatment Administration and Schedule

Treatment is typically repeated every 3 or 6 weeks. This length of time is called a “cycle”.

Your belzutifan dosing instructions:

- Belzutifan comes in 1 tablet strength: 40 mg.
- Your dose might differ, but belzutifan is typically taken as three 40 mg tablets (120 mg total dose) by mouth once daily.
- Take belzutifan 1 time each day, around the same time each day.
- Take belzutifan with or without food.
- Swallow belzutifan tablets whole. Do not chew, crush, or split belzutifan tablets.

Treatment Administration and Schedule (Continued)

- Do not change your dose or stop taking belzutifan unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking belzutifan if you develop certain side effects.
- If you miss a dose of belzutifan, take it as soon as possible on the same day. Then take your next dose of belzutifan at your regular time the next day. Do not take extra tablets to make up for the missed dose.
- If you vomit after taking a dose of belzutifan, do not take an extra dose. Take your next dose at your regular time the next day.
- If you take too much belzutifan, call your care team or go to the nearest hospital emergency room right away.

☐ Option #1: Pembrolizumab Given Every 3 Weeks

Treatment Name	Cycle 1, Day																					Next Cycle
	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	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 1
Treatment Given at the Clinic or Hospital																						
Pembrolizumab	✓																					✓
Treatment Taken at Home																						
Belzutifan	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

☐ Option #2: Pembrolizumab Given Every 6 Weeks

Treatment Name	Cycle 1																					
	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	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	
Treatment Given at the Clinic or Hospital																						
Pembrolizumab	✔																					
Treatment Taken at Home																						
Belzutifan	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
Treatment Name	Cycle 1 (Continued)																					Next Cycle
	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30	Day 31	Day 32	Day 33	Day 34	Day 35	Day 36	Day 37	Day 38	Day 39	Day 40	Day 41	Day 42	Day 1
Treatment Given at the Clinic or Hospital																						
Pembrolizumab																						✔
Treatment Taken at Home																						
Belzutifan	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔

Storage and Handling of Belzutifan

- Store belzutifan at room temperature between 68°F and 77°F (20°C and 25°C).
- The belzutifan bottle has a child-resistant closure.
- The belzutifan bottle contains 2 desiccant canisters that help keep your medicine dry. Do not eat the desiccant canisters.
- People who are or may be pregnant should wear gloves when handling belzutifan.
- Keep belzutifan and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused belzutifan.

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		
Other		

Common Side Effects

Side Effect	Important Information
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 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, very tired, or 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
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

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Low Levels of Oxygen in Your Body (Hypoxia)	Belzutifan can cause severe low oxygen levels in your body, which may require you to stop treatment, receive oxygen therapy, or be hospitalized. Your care team will monitor your oxygen levels before you start and during treatment with belzutifan. - Shortness of breath or difficulty catching your breath - Dizziness or lightheadedness - Chest pain or chest tightness - Confusion - Fast or irregular heartbeat	
Intestinal Problems	Diarrhea (loose stools) or more frequent bowel movements than usual	- Stools that are black, tarry, sticky, or have blood or mucus - Severe stomach-area (abdominal) pain or tenderness
Kidney Problems	- Decrease in your amount of urine - Blood in your urine	- Swelling of your ankles - Loss of appetite
Lung Problems	- Cough - Shortness of breath	Chest pain
Skin Problems	- Rash - Itching	- Skin blistering or peeling - Painful sores or ulcers in the mouth or nose, throat, or genital area
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 - Persistent or severe muscle pain or weakness, muscle cramps

Infusion-Related Reactions	• 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
Injection-Site Reactions	• Itching • Swelling • Bruising or bleeding	• 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, Fertility, 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 affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- **Boxed Warning:** Treatment may **harm an unborn baby**.
 - If you are able to become pregnant:
 - Take a pregnancy test before starting treatment.
 - Use an effective form of non-hormonal birth control (contraception) during treatment with belzutifan and for 1 week after your last dose.
 - Birth control methods that contain hormones (such as birth control pills, injections, or transdermal system patches) may not work as well during treatment with belzutifan.
 - Talk to your care team about birth control methods that may be right for you during treatment with belzutifan.
 - Use an effective method of birth control during treatment and for 4 months after your last dose of pembrolizumab.
 - 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 pembrolizumab and belzutifan, and for 1 week after your last dose of belzutifan.
- **Do NOT breastfeed** during treatment, for 1 week after your last dose of belzutifan, and for 4 months after your last dose of pembrolizumab.

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.
- **Your treatment may 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.
- **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 care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

Updated Date: July 20, 2026

Scan the QR code below to access this education sheet.



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