Vusolimogene Oderparepvec and Nivolumab

Patient Education Sheets
Understanding Your Cancer Treatment

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for a type of skin cancer called melanoma.
- 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
Vusolimogene Oderparepvec (voo-soh-LIM-oh-jeen OH-der-pair-EP-vek): Tudriqev (TOO-drih-kev)	Slows down or stops the growth of cancer cells by using a modified virus that directly kills cancer cells and boosts the immune system.	Injection directly into the tumor (intratumoral).
Nivolumab (nih-VOL-yoo-mab): Opdivo (op-DEE-voh), Opdualag	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 nivolumab and hyaluronidase (Opdivo Qvantig) instead of nivolumab. Nivolumab and hyaluronidase is given as an injection under the skin (subcutaneous injection) into the stomach area (abdomen) or outer thigh over 3 to 5 minutes.

Treatment Administration and Schedule

Treatment is typically repeated every 2 weeks. This length of time is called a "cycle." Your first treatment cycle is given without nivolumab. You may receive up to 7 cycles with vusolimogene oderparepvec and nivolumab, followed by treatment with nivolumab alone every 4 weeks. Your care team will tell you how many treatment cycles you will receive and how long you will continue taking nivolumab.

☐ **Cycle 1**

- Vusolimogene oderparepvec is given on Day 1.

	Cycle 1								Cycle 2
Treatment Name	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**…**	**Day 14**	**Day 1**
Vusolimogene oderparepvec	✓								✓

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Treatment Administration and Schedule (Continued)

☐ **Cycles 2 to 8**

- Vusolimogene oderparepvec is given on Day 1.
- Nivolumab is given on Day 1.

	Cycle 2								Cycle 3
Treatment Name	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**…**	**Day 14**	**Day 1**
Vusolimogene oderparepvec	✓								✓
Nivolumab	✓								✓

☐ **Cycle 8 and Beyond**

- Nivolumab is given on Day 1.

	Cycle 8								Cycle 9
Treatment Name	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**…**	**Day 28**	**Day 1**
Nivolumab	✓								✓

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
Supportive care used to treat or prevent side effects		

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Common Side Effects

Side Effect	Important Information
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: Red blood cells carry oxygen throughout your body. Low levels can make you feel tired, weak, dizzy, or short of breath. 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
Infections	Description: Treatment may increase your chance of getting an infection. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Keep any catheter/port site clean and dry. Follow all instructions provided by your care team. 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)
Fever and Chills	Description: Fever is common with this treatment. Recommendations: • Take your temperature with a thermometer if you feel like you have a fever. • Your care team may recommend medicines for fever. Talk to your care team if you have: • 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

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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
Nausea and Vomiting	Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit. 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 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. Talk to your care team if you have: • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood in your vomit or vomit that looks like coffee grounds • Severe stomach pain that does not go away after vomiting

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<table>
<tr><td>Diarrhea</td><td>Description: Diarrhea means having bowel movements more often than usual. Your stools may also be loose or watery.

If you have diarrhea:
Keep track of how often you have diarrhea.
Drink 8 to 10 glasses of water or fluids each day. Do this unless your care team tells you otherwise.
Eat small meals with low-fiber foods. Try bananas, applesauce, potatoes, chicken, rice, or toast.
Avoid high-fiber foods. These include raw vegetables, fruit, and whole grains.
Avoid foods that may cause gas. These include broccoli and beans.
Avoid milk, yogurt, and other dairy foods.
Avoid spicy, fried, or greasy foods.
Your care team may recommend medicine for diarrhea. One example is loperamide (Imodium).
Talk to your care team if you have:
An increase of 4 or more bowel movements than usual in one day
Dizziness or lightheadedness while you have diarrhea
Signs of dehydration, such as feeling very thirsty, dizzy, or having dark urine
Blood in your stool</td></tr>
<tr><td>Muscle, Bone, or Joint Pain</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. Bone pain is a deep, aching or sharp pain in or around a bone that may worsen with movement or pressure.

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>
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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Herpes Infection or Reactivation	Vusolimogene oderparepvec is made from a modified herpes simplex virus type 1 (HSV-1), which commonly causes cold sores. It may cause a new herpes infection or cause a previous herpes infection to become active again. Herpes may cause sores around your mouth, genital area, or other parts of your body. The virus may also spread to other people through direct contact with the injection site, dressings, or body fluids. Avoid touching or scratching the injection site and keep it covered as directed by your care team. Caregivers should wear gloves when changing dressings. Tell your care team if you have had a herpes infection in the past. • New cold sores or blisters on or around your lips or mouth • Blisters or sores around your genital area • Small bumps that turn into blisters or sores on other parts of your body
Capillary Leak Syndrome (CLS)	CLS happens when fluid and proteins leak from your small blood vessels into surrounding tissues. It requires immediate treatment to prevent a drop in blood pressure and other serious complications. • Swelling or puffiness and are urinating less than usual • Swelling of your stomach area (abdomen) and feeling of fullness • Trouble breathing • Dizziness or feeling faint • A general feeling of tiredness
Liver Problems	• 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
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 or tightness

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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
Skin Problems	• Rash • Itching	• Skin blistering or peeling • Painful sores or ulcers in the mouth, nose, throat, or genital area
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 • Low red blood cells, bruising
Infusion-Related Reactions	Your care team may slow or temporarily stop the infusion if you have a reaction. Treatment may be permanently stopped for a severe reaction. • 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 Procedure Complications	Serious problems can happen during or after vusolimogene oderparepvec injection, including bleeding, infection, or injury to nearby organs. Injections into tumors in the lung may cause a collapsed lung (pneumothorax). • Fever of 100.4°F (38°C) or higher • Chills • Increasing redness, swelling, warmth, or pain at the injection site	• Heavy or uncontrolled bleeding • New or worsening chest pain • Shortness of breath or trouble breathing • Coughing up blood

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.

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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, for 90 days after your last dose of vusolimogene oderparepvec, and for 5 months after your last dose of nivolumab.
        - 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 vusolimogene oderparepvec and nivolumab, and for 90 days after your last dose of vusolimogene oderparepvec.
- **Do not breastfeed** during treatment, for 90 days after your last dose of vusolimogene oderparepvec, and for 5 months after your last dose of nivolumab.

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.
- **Keep your injection sites covered for at least 48 hours after treatment with vusolimogene oderparepvec**. This helps prevent the spread of HSV-1 to other people.
    - Avoid touching or scratching the injection sites or dressings.
    - If a dressing falls off, replace it with a new one.
    - Wear gloves when removing or changing dressings.
    - Wash your hands well with soap and water before and after changing dressings.
    - Place used dressings, gloves, and cleaning materials in a sealed plastic bag before throwing them in the household trash.
    - Avoid direct contact with injection sites, dressings, or body fluids.
    - If accidental contact occurs, wash the affected area well with soap and water.
- **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 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.
- **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.

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Notes

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Scan the QR code below to access this education sheet.

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