

YOUR Tisotumab vedotin-tftv (TIVDAK) ACTION PLAN

(to be filled out by a member of your oncology team)

Patient Name _____ Date _____
Full Name *Date*

Discussion of Typical Side Effects

- Changes in vision _____
- Eye redness _____
- Dry Eye _____
- Numbing and tingling _____
- Muscle weakness _____
- Wheezing, coughing, and trouble breathing _____
- Nausea _____
- Vomiting _____
- Skin rash _____
- Itching _____
- Skin peeling _____
- Bruising or bleeding _____
- Fever _____
- Hair Loss _____
- Fatigue _____
- Arthritis _____
- Anemia _____
- Muscle Pain _____

**Please share this important information with your caregiver and loved ones
so they can help support you during your treatment.**

Pfizer and Genmab

Support, financial assistance, and care coordination

855-4SECURE (855-473-2873)

<https://www.tivdahcp.com/support-and-resources>

TAKING THE MEDICATION

Tisotumab vedotin-tftv (TIVDAK)

HOW IT'S GIVEN:

- Tisotumab vedotin-tftv is given through your vein via an intravenous (IV) line. The treatment takes 30 minutes for the infusion, but expect the entire administration to take 60 minutes for the application of eye drops and cold packs on the eyes.
- Treatments are given every 3 weeks on an ongoing basis until disease progression or unacceptable toxicity. Your oncologist will decide if any change in your treatment is needed.
- You will need to have eye exams before your first treatment and every three weeks during your treatment with tisotumab vedotin-tftv. Your doctor may also order other imaging tests (e.g., magnetic resonance imaging [MRI], computerized tomography [CT] scans).
- It is important to keep appointments with your oncology team to receive your treatment. If you miss an appointment, call as soon as possible to reschedule and to receive instructions about what to do.
- The drug's payload is a CYP3A4 substrate. Avoid interactions with CYP3A4 inhibitors like grapefruit, clarithromycin, erythromycin, etc. as this may increase the risk for drug exposure and adverse reactions.

COMMON SIDE EFFECTS WITH TISOTUMAB VEDOTIN-TFTV:

Side effects may occur. Less than 15% of patients stop treatment because of side effects with tisotumab vedotin.

Even minor side effects could be serious, and you should report them all to your oncology team. The most common side effects of taking tisotumab vedotin are:

- Ocular toxicities (symptoms may change in vision, blurriness, feeling like a foreign particle is present, etc)
- Fever
- Fatigue
- Arthritis
- Skin rash
- Itching
- Muscle weakness or muscle pain
- Anemia
- Tingling or numbness
- Nausea
- Hair loss
- Flu-like illness
- Bruising or bleeding
- Skin peeling or blistering
- Wheezing, coughing, and trouble breathing
- Abnormal laboratory changes in measurements (likely in hemoglobin decrease, creatinine increase, aspartate aminotransferase, and alanine aminotransferase)

Tips for caregivers:

WHEN YOUR LOVED ONE IS GETTING TREATMENT IN THE HOSPITAL:

Even though the nurse will be checking in every few hours, you should be on the lookout for any sudden changes. Alert the nurse immediately if your loved one:

- Is having any trouble breathing, talking, or wheezing
- Seems confused or foggy
- Has severe nausea or vomiting
- Faints, falls, is very dizzy
- Has any sudden change in rash, intense itching or the rash is quickly getting worse

AVOID PREGNANCY:

You will need a pregnancy test before you start treatment with tisotumab vedotin-tftv. Use birth control during therapy and for 2 months after treatment if you are of childbearing age for females, 4 months for males. Tell your oncologist's office right away if you become pregnant or think you are pregnant, as the drug may cause harm to an unborn baby. You should not breastfeed during treatment and for at least 1 week after treatment has stopped because it is not known if it passes into breastmilk.

IMPORTANT SIDE EFFECTS

Your oncology team may discuss some side effects of tisotumab vedotin-tftv that can lead to serious problems if they aren't taken care of right away. These sections give information about possible symptoms, what you should tell your oncology team, when you should get immediate medical help, and any steps you can take to help ease the symptoms.

OCULAR ADVERSE REACTIONS

Tisotumab vedotin-tftv (TIVDAK)

Report immediately to your oncology team

What are the symptoms?

- Dry eye
- Foreign body sensation
- Excessive tearing or discharge
- Opacity or haziness of the eye
- Blurred vision
- Swelling in the eye
- Painful red eye
- Small pustules present
- Photophobia
- Redness of the eye

WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

When you are in a care facility

- When you first noticed the symptoms, what the symptoms were and if anything has changed since your nurse or oncology team member last checked in on you
- Any sudden change in your symptoms or if your symptoms become unexpectedly more severe
- If you have had any eye or vision problems in the past

Red flag(s):

- If you are unable to see, having serious difficulty with your vision, or are experiencing abnormal blurry vision
- If you have excessive discharge, red eyes, or eyes that are swollen shut

Eye care during treatment:

- Bring your eye drops to each intravenous infusion for administration of drops throughout the treatment. One drop of prednisolone 1% is given into each eye 10 minutes prior to the infusion.
- After applying 3 drops of the vasoconstrictor to each eye, apply cold packs fully over your eyes for the entire infusion.
- Change out cold packs as needed throughout the drug infusion. The eyes must remain cold until 20 minutes after the infusion.
- Make sure you are using prescription eye drops as described. The hydrating or lubricating eye drops are used for 30 days after the last dose of tisotumab vedotin-tftv. Do not skip doses.

Taking care of your eyes:

- Do not wear your contacts during treatment with tisotumab vedotin-tftv. Doing so will dramatically increase your risk for all side effects impacting your vision as a result.
- Tell your oncology team about all medications you are taking including any over the counter drugs, vitamins, herbal medicines, or other natural treatments.
- Don't take any new supplements, herbal remedies, vitamins, or medicines without talking to your doctor. Some seemingly harmless, non-prescription supplements could interfere with your medication working.
- Reduce lighting levels where possible and use sunglasses in strong light, like outdoors.
- Cold compresses on the eyes may help alleviate mild symptoms.

SKIN CHANGES

Tisotumab vedotin-tftv (TIVDAK)

Report immediately to your oncology team

What are the symptoms?

- Skin rash
- Skin swelling or peeling
- Blistering
- Hair loss or thinning
- Dry skin
- Skin redness
- Peeling
- Acne pustules present
- Abnormal itching

WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

When you are in a care facility

- When you first noticed the rash and if anything has changed since your nurse or oncology team member last checked in on you
- If you have had any skin problems in the past

Red flag(s):

- Any sudden change in your rash or if your rash is quickly getting worse
- If your skin is blistering, peeling and/or you have intense itching especially if it is interfering with your ability to sleep

When you are at home

- When you first noticed the rash
- What the rash looks like (eg, flat, bumpy, red, acne-like, hives)
- Where the rash is and how much of the body it is covering
- If the skin change is making it difficult for you to get dressed, perform daily activities, or sleep
- If you have had any skin problems in the past
- If you have started any new medications, supplements, or vitamins recently
- If you have been using a new soap or have been around new chemicals or animals recently
- What you have tried at home to manage the symptoms

Taking care of your skin:

- Avoid soap. Instead, use gentle, non-soap cleansers such as Cetaphil®
- Avoid hot showers or baths (short, lukewarm showers are fine)
- Apply a cool cloth to the area
- Apply a cooling cream with menthol or camphor to the area (refrigerate the cream first for even greater relief)
- Keep your fingernails short to protect your skin from damage if you scratch
- Apply a moisturizer that contains the ingredients urea or glycerin daily such as Aquafor® or CeraVe®
- Don't use lotions that have perfumes or dyes
- Protect your skin from the sun by wearing sunscreen, a hat, and UV-protective clothing and sunglasses
- Don't forget your hands and face
- Your oncology team may tell you to take an antihistamine by mouth or apply a corticosteroid cream to reduce the itching. You also may be prescribed an oral corticosteroid if your itching is more intense

PERIPHERAL NEUROPATHY

Tisotumab vedotin-tftv (TIVDAK)

Report immediately to your oncologist's office

What are the symptoms?

- Numbness in extremities
- Tingling in hands or feet
- Sensation of prickling
- Loss of coordination
- Difficulty walking
- Trouble standing up
- Inability to lift the foot well
- Difficulty gripping objects
- Muscle weakness or cramps
- Skin changes
- Fatigue
- Joint pain

WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

When you are in a care facility

- When you first noticed the differences in the feelings at your extremities
- When you first noticed the changes in your movements
- If you are feeling very tired, are falling or unable to perform daily routines
- If the symptoms are impacting your daily activities

Red flag(s):

- If you are having severe lack of coordination, dizziness, and falling, and particularly if symptoms come on suddenly
- Pain from any type of touch (e.g. a blanket covering the skin) and feels sharp, stabbing, burning, or throbbing
- If you have rapid ascending weakness

Call your oncologist's office immediately. If no one is available, go directly to the emergency room...

- If you suddenly develop an abnormal heart beat or notice any type of arrhythmia

Managing your side effects:

- Drink plenty of fluids and consider wearing compression stockings
- Have a care giver or loved one help you with arduous tasks during therapy
- Check with your health care provider before using any alternative therapies as the evidence supporting them isn't always reliable and some may even interfere with your current treatment
- If you experience numbness or tingling in your hands or feet, be careful performing activities like cooking, walking, and handling objects that could become dangerous to you (e.g. hot, heavy, or sharp objects)

NAUSEA/VOMITING

Tisotumab vedotin-tftv (TIVDAK)

Report immediately to your oncologist's office

What are the symptoms?

- Upset stomach
- Feeling like you are going to throw up
- Throwing up

WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

When you are in a care facility

- When your symptoms started and how long they have lasted
- If you have a fever, chills, and/or aches and pains as if you have the flu
- How much and what you have been eating and drinking over the past 24 hours
- If you might have been exposed to food poisoning or a stomach flu

Red flag(s):

- You've been throwing up for over a day or there is blood in your vomit
- You have a fever over 100.4°F
- You faint

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Managing Your Side Effects:

- Take over-the-counter anti-nausea products or any medications prescribed by your oncology team.
- Sucking on peppermint candy or ginger may provide relief for some.
- Before your second treatment, take any medications your oncology team has prescribed to prevent vomiting.
- Avoid solid foods. Instead eat soft, bland foods such as toast, pudding, rice, oatmeal, or crackers.
- Drink water, weak tea, clear broth, watered-down juice, or re-hydration drinks (Gatorade, Powerade, and Pedialyte), or suck on popsicles to prevent dehydration.
- Drink enough fluids to rehydrate and keep your urine a pale-yellow color.
- If you are throwing up, then you will need to drink more fluids to prevent dehydration.
- Instead of consuming three large meals, eat small, frequent meals during the day.

DIARRHEA

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Report immediately to your oncologist's office

What are the symptoms?

- Diarrhea or mushy stools
- Stools that are black or darker than normal, sticky, or have blood or mucus
- Changes in your bowel movements (more or less frequent)
- Tenderness, pain or cramping in the stomach
- New or worsening heartburn or indigestion
- Bloating in the stomach and/or gas
- Lack of interest in food
- Feeling very tired
- Fever

WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

If you have any symptoms listed **above**

- When you first noticed changes in your bowel movements
- What your bowel movements are like—hard, solid, soft, loose, or liquid
- What color your stool is—light or dark—and if there is blood or mucus in it
- How often you are having bowel movements
- If you wake up from sleep to have a bowel movement or if you have “accidents” when you don’t make it to the toilet in time
- If you have been losing or gaining weight without trying
- How much and what you are eating and drinking each day
- If you’ve ever had digestive/stomach problems before
- If the symptoms are interfering with your daily activities
- A list of medications (both prescribed and over the counter), and any vitamins or supplements you are taking. This includes all oral, inhaled, or topical medications
- Anything else you have tried at home to manage the symptoms

Red flag(s):

- If you have sudden, severe pain or tenderness in the stomach, especially if you also have a fever
- If you feel faint or your blood pressure drops quickly
- If you have blood in your bowel movement

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Taking care of your digestive system:

- Call your oncologist's office IMMEDIATELY if you develop bowel related changes such as: more frequent bowel movements than usual, loose, watery, or bloody bowel movements
- Take over-the-counter or prescription medications only AS INSTRUCTED by your oncology team; check with your team **BEFORE** taking any medications used to stop diarrhea such as Imodium, Pepto-Bismol, etc
- If you do develop bowel related changes, you may want to avoid spicy foods, high-fiber cereals, red meats, fats, dairy products, raw fruits (except bananas), vegetables, caffeine, alcohol, and sugar, as these can make symptoms worse
- Instead, eat bland foods such as bananas, pudding, rice, toast, oatmeal, or crackers
- Drink water, weak tea, clear broth, watered-down juice, Pedialyte, or sports drinks (such as Gatorade, Powerade, etc) or suck on popsicles to prevent dehydration
- Do not use laxatives or stool softeners if you are having more frequent bowel movements than usual or if your stools are soft or watery

BLEEDING OR BRUISING

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Report immediately to your oncologist's office

What are the symptoms?

- Blood coming from your nose
- Feeling of blood or liquid in the back of your throat
- Headache, nausea or vomiting
- Ease in bruising that is different from normal
- Fatigue, dizziness, or shortness of breath
- Insomnia or restless leg syndrome
- Bloody or black stools
- Blood appearing in urine
- Vaginal bleeding

WHAT YOU OR YOUR CAREGIVER SHOULD TELL YOUR ONCOLOGY TEAM MEMBER:

When you are in a care facility

- When your symptoms started and how long they have lasted
- If you have a fever, headache, or pain in another area of your body
- How much and what you have been eating and drinking over the past 24 hours along with your activities



Red flag(s):

- Excessive bleeding, especially from minor trauma that isn't stopped from direct pressure
- Changes in your mental status, heartrate, or breathing
- If you are experiencing what you might describe as the worst headache of your life
- Chest pains
- Soaking a pad once per hour

Call your oncologist's office immediately. If no one is available, go directly to the emergency room.

Managing Your Side Effects:

- If you accidentally cause a minor injury, you can apply direct pressure continuously for at least five minutes, and for up to 20 minutes to see if it resolves naturally
- Nasal saline applied three times daily may help minimize nose bleeds
- Avoid hot foods, strenuous activities, blowing your nose, or using your fingers around your nose
- For nosebleeds, sit with your head tipped slightly forward and apply light pressure by pinching the bridge of your nose for 10-15 minutes. Call your doctor if the bleeding will not stop after that.
- Manage feeling tired by pacing your daily activities and include rest between energy-draining activities

OTHER SYMPTOMS OR ABNORMAL BLOOD TESTS TO LOOK OUT FOR

Below are other symptoms that you can have when you take Tisotumab vedotin-tftv. Please call the office if you develop any of these symptoms and consider going directly to the Emergency Room if you have any of the red-flag symptoms.

	Symptoms or blood test problems	Red flags (Signs that something serious is going on that needs immediate attention)
	Liver problems (bruising or bleeding more easily, changes in the color of your stool or urine, stomach pain or swelling/bloating, yellowing of your skin or whites of your eyes, confusion, drowsiness, excessive sweating)	<ul style="list-style-type: none"> • If you have severe pain and/or swelling in your stomach, particularly if the pain is also on the upper right side of the stomach • Your skin or the whites of your eyes have turned yellow • You feel confused or foggy or very drowsy all day
	Cough or shortness of breath	<ul style="list-style-type: none"> • If you have sudden, severe trouble breathing, cough, or shortness of breath
	Fatigue (feeling weak, tired or have low energy)	<ul style="list-style-type: none"> • You're very drowsy all day or if you faint
	Joint pain	<ul style="list-style-type: none"> • Severe, unexplained joint pain that lasts for more than several days. • You also have a fever over 104.0 °F and you don't have a cold or flu
	Swelling (stomach or skin)	<ul style="list-style-type: none"> • If you also have a severe rash or intense itching • If you have severe stomach pain

PATIENT RESOURCES

ADDITIONAL INFORMATION RESOURCES

AIM at Melanoma Foundation (Ask an Expert program, patient symposia, drug resources, etc)
<https://www.aimatmelanoma.org/>

This is Living With Cancer

Health and wellness, personal stories and articles.

<https://www.thisislivingwithcancer.com>

NIH: National Cancer Center

<https://www.cancer.gov/types/cervical>

FINANCIAL ASSISTANCE

Pfizer Patient Assistance Program

Provides free Pfizer medicines to eligible patients through their doctor's office or at home.

<https://www.pfizerrxpathways.com/resources/patients>

Cancer Financial Aid Coalition

Facilitates communication, educates and advocates for patients.

www.cancerfac.org

Centers for Medicare and Medicaid Services (CMS)

Apply to determine if you are eligible for government assistance.

www.cms.gov or www.medicare.gov

1-800-633-4227

Lazarex Foundation

Provides assistance with travel costs for clinical trial participation. Ask your social work counselor for a referral if you have been consented to a clinical trial for melanoma.

www.lazarex.org

Needymeds

Database to search for free or low-cost medications, help with medical transportation and other resources.

www.needymeds.org

Patient Advocate Foundation

Provides assistance with mediation, financial stability, and other assistance. Funds subject to availability. Patient must meet their eligibility for financial assistance.

www.patientadvocate.org

1-800-532-5274

The Sam Fund for Young Adult Survivors of Cancer

Assists cancer survivors ages 21-39 with their transition into post-treatment life. This program distributes grants and scholarships in an effort to enable survivors to pursue goals.

www.thesamfund.org

info@thesamfund.org

PRESCRIPTION ASSISTANCE

CancerCare Co-Payment Assistance Foundation

Helps with the cost of medication. Availability of funds for patients with Stage IV melanoma subject to availability.

www.cancercarecopay.org

1-866-552-6729

Medicine Assistance Tool

Database to search for patient assistance resources offered by pharmaceutical companies.

www.medicineassistancetool.org/

Patient Advocate Foundation Co-Pay Relief

Provides direct financial support to patients who medically qualify. Availability of funds for patients with Stage IV melanoma subject to availability.

www.copays.org

1-866-512-3861

Good Days

Formerly known as the Chronic Disease Fund. Provides assistance with insurance co-pays, and prescription medications. Availability of funds for patients with Stage IV melanoma subject to availability.

www.mygooddays.org

HealthWell Foundation

For patients who cannot afford insurance premiums, co-payments, co-insurance, or other out-of-pocket health care costs. Availability of funds for patients with Stage IV melanoma subject to availability. Patient must also meet eligibility for financial assistance.

www.healthwellfoundation.org or grants@healthwellfoundation.org

1-800-675-8416

The Assistance Fund, Inc

Provides prescription copay and financial assistance, including health insurance premiums. Availability of funds for patients with Stage IV melanoma subject to availability.

www.theassistancefund.org

1-855-845-3663

PAN Foundation

Provides financial assistance to cover out-of-pocket treatment costs. Availability of funds for patients with Stage IV melanoma subject to availability.

www.panfoundation.org

1-866-316-PANF (7263)

Patient Assistance Program

Comprehensive database of patient assistance programs offering free medications.

www.rxassist.org

info@rxassist.org

HOUSING

American Cancer Society – Hope Lodge

Provides free housing during treatment appointments. Requires a referral from your social worker.

www.cancer.org/

1-800-227-6333

American Cancer Society – Extended Stay America

Partnership to offer discounted rooms for patients who have to be away from home for cancer treatment.

<https://www.cancer.org/about-us/our-partners/extended-stay-america.html>

1-800-227-2345

Healthcare Hospitality Network

Connects patients and their caregivers looking for lodging near their healthcare provider

<https://members.hhnetwork.org/locate-a-house>

1-800-318-8861

Joe’s House

Helping patients with cancer find lodging throughout the U.S.

<https://www.joeshouse.org/lodging?state=0>

1-877-563-7468

National Council of State Housing Agencies

Emergency rental assistance programs available by state. Federal grants still available in some areas.

<https://www.ncsha.org/emergency-housing-assistance/>

TRANSPORTATION (AIR AND GROUND)

Air Charity Network

Provides access for people in need who are seeking free air transportation to specialized health care facilities

<http://aircharitynetwork.org/>

1-877-621-7177

Corporate Angel Network

Nonprofit organization that helps cancer patients by arranging free travel on corporate aircraft

<https://www.corpangelnetwork.org/>

info@corpangelnetwork.org

1-914-328-1313

Medicaid

Ground transportation only. Sets up rides and provides mileage reimbursement for Medicaid patients only. 1-877-633-8747

Mercy Medical Angels

Provides free medical transportation (flights, gas cards, bus and train tickets) for patients with financial needs who need to travel more than 50 miles. Patients must meet their eligibility for financial assistance.

www.mercymedical.org/

Pilots for Patients

Provides free flights to people in need of medical treatment. Patient must be medically stable to fly and be ambulatory. Ask your social worker about a referral.

www.pilotsforpatients.org

1-318-322-5112

ADDITIONAL RESOURCES

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