Daratumumab and CyBorD (Cyclophosphamide, Bortezomib, and Dexamethasone)

Care Team Contact Information: ______________________________

Pharmacy Contact Information: ______________________________

Diagnosis: ______________________________

- This treatment is often used for multiple myeloma and amyloidosis, but 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

This treatment is often called by its acronym: “Dara-CyBord” or “Dara-VCd”

Dara-CyBorD

- **Dara: Dara**tumumab
- **Cy**: **Cy**clophosphamide
- **Bor**: **Bor**tezomib
- **D**: **D**examethasone

Dara-VCd

- **Dara: Dara**tumumab
- **V**: Bortezomib (**V**elcade)
- **C**: **C**yclophosphamide
- **d**: **D**examethasone

Treatment Name	How the Treatment Works	How the Treatment is Given
Daratumumab (DAYR-uh-TOOM-yoo-mab): Darzalex (DAR-zah-lex)	Helps your immune system find and attack cancer cells by targeting a specific protein on their surface.	Infusion into a vein (intravenous (IV) infusion).
Cyclophosphamide (SY-kloh-FOS-fuh-mide)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to multiply.	Capsules or tablets taken by mouth. OR Infusion into a vein (intravenous (IV) infusion).
Bortezomib (bor-TEH-zoh-mib): Velcade (VEL-kayd)	Blocks a part of the cell that helps break down proteins, which stops cancer cells from growing and causes them to die.	Infusion given into a vein. OR Injection given under the skin (subcutaneous injection) into the thigh or stomach-area (abdomen).
Dexamethasone (DEK-suh-MEH-thuh-sone)	Tells cancer cells to "self-destruct".	Tablet(s) taken by mouth. OR Infusion given into a vein.

Note: Your care team may use daratumumab and hyaluronidase (Darzalex Faspro) instead of daratumumab. Daratumumab and hyaluronidase is given as an injection under the skin (subcutaneous injection) into the stomach area (abdomen) over 3 to 7 minutes.

Treatment Administration and Schedule: Treatment is typically repeated every 4 weeks. This length of time is called a "cycle".

Cycles 1 and 2:

- Daratumumab given weekly on Days 1, 8, 15, and 22.
- Cyclophosphamide given weekly on Days 1, 8, 15, and 22.
- Bortezomib given weekly on Days 1, 8, 15, and 22.
- Dexamethasone given weekly on Days 1, 8, 15, and 22.

	Cycle 1									**Next Cycle**
Treatment Name	**Day 1**	**…**	**Day 8**	**…**	**Day 15**	**…**	**Day 22**	**…**	**Day 28**	**Day 1**
Daratumumab	✓		✓		✓		✓			✓
Cyclophosphamide	✓		✓		✓		✓			✓
Bortezomib	✓		✓		✓		✓			✓
Dexamethasone	✓		✓		✓		✓			✓

Cycles 3 to 6:

- Daratumumab given every 2 weeks on Days 1 and 15.
- Cyclophosphamide given weekly on Days 1, 8, 15, and 22.
- Bortezomib given weekly on Days 1, 8, 15, and 22.
- Dexamethasone given weekly on Days 1, 8, 15, and 22.

	Cycle 3									**Next Cycle**
Treatment Name	**Day 1**	**…**	**Day 8**	**…**	**Day 15**	**…**	**Day 22**	**…**	**Day 28**	**Day 1**
Daratumumab	✓				✓					✓
Cyclophosphamide	✓		✓		✓		✓			✓
Bortezomib	✓		✓		✓		✓			✓
Dexamethasone	✓		✓		✓		✓			✓

Cycle 7 and Beyond:

- Daratumumab given every 4 weeks on Days 1.

	Cycle 7									Next
Treatment Name	**Day 1**	**…**	**Day 8**	**…**	**Day 15**	**…**	**Day 22**	**…**	**Day 28**	**Day 1**
Daratumumab	✓									✓

See the information below if you are going to be taking cyclophosphamide by mouth

Your cyclophosphamide (and, if taken by mouth, dexamethasone) dosing instructions:

Treatment Taken by Mouth: Cyclophosphamide and Dexamethasone

- Cyclophosphamide comes in 2 capsule strengths (25 mg and 50 mg) and 1 tablet strength (50 mg). Your care team will tell you when and how much to take. They may adjust your doses if needed.
- Swallow cyclophosphamide tablets or capsules whole with water once a day. Do not open, break, or chew your capsules or tablets.
- Your dose is based on many factors, including your height and weight, overall health, and diagnosis.
- Cyclophosphamide may be taken with or without food. Drink lots of fluids with cyclophosphamide to prevent side effects and dehydration. If taken by mouth, dexamethasone should be taken with food.
- Take cyclophosphamide at about the same time each day in the morning. Do NOT take it at bedtime. If taken by mouth, dexamethasone should be taken in the morning.
- If you miss a dose of cyclophosphamide and it has been less than 12 hours since your usual time, take it as soon as you remember. Call your care team if you forget to take your dose. Do not take 2 doses at the same time.
- If you take too much cyclophosphamide, call your care team right away.

Storage and Handling of Cyclophosphamide and Dexamethasone

- Store cyclophosphamide and dexamethasone at room temperature, between 68°F and 77°F, in a dry location away from direct light.
- Keep cyclophosphamide and dexamethasone out of the reach of children and pets.
- Whenever possible, give cyclophosphamide to yourself and follow the steps below. If someone else gives it to you, they must also follow these steps:
    1. Wash hands with soap and water.
    2. Put on gloves to avoid touching the medication.
    3. Transfer the cyclophosphamide from its package to a small medicine or other disposable cup.
    4. Administer the medicine immediately by mouth with water.
    5. Remove gloves, if used, and throw them and medicine cup in household trash.
    6. Wash hands with soap and water.
- Do not open or break cyclophosphamide capsules or handle them any more than needed. If the contents of the capsule or crushed/cut tablets come in contact with your skin, wash the skin right away with soap and water.
- If you plan to use a daily pill box or pill reminder, contact your care team before using it.
    - When the box or reminder is empty, wash it with soap and water before refilling.
    - The person refilling the box or reminder should:
        - Wear gloves.
        - Wash their hands with soap and water after completing the task.
- Ask your care team how to safely throw away any unused cyclophosphamide. Do not throw it in the trash or flush it down the sink or toilet.

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 infusion-related reactions		
To help prevent or treat nausea and vomiting		
To help lower the risk of infections		
Other		

Brought to you by: ACCC Association of Cancer Care Centers™ HOPA Hematology/Oncology Pharmacy Association NCODA Network for Collaborative Oncology Development & Advancement ONS Oncology Nursing Society

Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	Description: WBCs help protect the body against infections. If you have a low WBC count, you may be at a higher risk of infection. Recommendations: • 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. Talk to your care team if you have: • 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 Platelet Count (Thrombocytopenia)	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. Recommendations: • 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. Talk to your care team if you have: • 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
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	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. Recommendations: • 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. Talk to your care team if you have: Shortness of breath Dizziness Fast or abnormal heartbeats Severe headache

Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • 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. Talk to your care team if you have: • 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
Nausea and Vomiting	Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause vomiting. 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 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 team may prescribe medicine for these symptoms. Talk to your care team if you have: • 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

Diarrhea	Description: Diarrhea is when you have loose, watery bowel movements more often than usual. The need to use the bathroom may occur urgently. Recommendations: • Keep track of how many times you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids every day, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid eating foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods. • Your care team may recommend medicine (such as loperamide) for diarrhea. Talk to your care team if you have: • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Bloody diarrhea
Constipation	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. Recommendations: • 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 care team tells you otherwise. • Exercise regularly. • Eat high-fiber foods like raw fruits and vegetables. • Your care team may recommend medicine (such as polyethylene glycol 3350 or senna) for constipation. Talk to your care team if you have: • Constipation that lasts 3 or more days • Constipation after 48 hours, even after using a laxative

Nerve Problems in Your Arms, Hands, Legs, or Feet (Peripheral Neuropathy)	Description: Nerve pain and tingling are uncomfortable sensations caused by nerve damage or irritation. Pain may be sharp, burning, or deep, while tingling feels like pins-and-needles or mild electric shocks, often in the hands, feet, arms, or legs. Recommendations: • Track your pain levels, sensations, and any triggers or factors that make the pain worse or better. • Check your feet daily for any injuries or changes, especially if you have numbness or tingling that affects your feeling. • Your care team may prescribe or recommend medicine for symptoms. Talk to your care team if you have: • “Pins and needles” or burning feeling in your hands or feet • Trouble moving your arms or legs • Trouble keeping your balance
Infusion-Related Reactions	Description: An infusion reaction is a bad response that happens during or not long after getting medicine into a vein. Get medical help right away if you develop any of the following symptoms of infusion reaction during or after your infusion: • Chills or shaking • Itching, rash, or flushing • Trouble breathing or wheezing; tongue-swelling • Dizziness or feeling faint • Fever of 100.4°F (or 38°C) or higher • Pain in your back or neck
Injection Site Reactions	Description: An injection reaction is a bad response that happens during or not long after getting medicine through an injection. Skin reactions at or near the injection site are possible. Symptoms may include itching, swelling, bruising, pain, rash, bleeding, or redness. Talk to your care team if you have: • Chills or shaking • Itching, rash, or flushing • Trouble breathing or wheezing; tongue-swelling • Dizziness or feeling faint • Fever of 100.4°F (or 38°C) or higher • 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	
Heart Problems	• Swelling of your stomach-area (abdomen), legs, hands, feet, or ankles • Shortness of breath • Nausea or vomiting • New or worsening chest discomfort, including pain or pressure	• Weight gain • Pain or discomfort in your arms, back, neck, or jaw • Protruding neck veins • Breaking out in a cold sweat • Feeling lightheaded or dizzy
Dizziness or Lightheadedness (Hypotension)	• Dizziness	• Lightheadedness
Lung Problems	• Cough • Shortness of breath	• Chest pain
Changes in Blood Sugar	High or low blood sugar may occur during treatment. This risk is higher for people who take medicine for diabetes. Signs and Symptoms of High Blood Sugar (Hyperglycemia): • Frequent urination • Drowsiness • Increased thirst • Loss of appetite • Blurred vision • Fruity smell on your breath • Confusion • Nausea, vomiting, or stomach pain • It becomes harder to control your blood sugar	Signs and Symptoms of Low Blood Sugar (Hypoglycemia): • Dizziness • Confusion or difficulty concentrating • Feeling sweaty, shaky, or hungry • Tiredness
Liver Problems	• Yellowing of your skin or the whites of your eyes • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen)	• Dark urine (tea colored) • Bleeding or bruising more easily than normal
Bladder Irritation	Cyclophosphamide can cause irritation and damage to your bladder. To reduce this risk, drink plenty of fluids and urinate frequently for a few days after each dose of cyclophosphamide. • Blood in the urine • Painful urination • Urinating more frequently	• Stomach (abdominal) or pelvic pain • Fever of 100.4°F (38°C) or higher

Herpes Reactivation	• Blisters on your lips or around your mouth • Blisters on and around your genitals • Fever of 100.4 °F (38°C) or higher • Flu-like symptoms, such as fatigue, headache, and muscle aches
Posterior Reversible Encephalopathy Syndrome (PRES)	A neurologic condition called PRES can happen during treatment with bortezomib. • Severe headache • Confusion • Weakness • Seizures • Blindness or change in vision
Progressive Multifocal Leukoencephalopathy (PML)	PML is a rare, serious brain infection caused by a virus that can happen in people who receive bortezomib. People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. • Confusion • Dizziness or loss of balance • Difficulty walking or talking • Decreased strength or weakness on one side of your body • Vision problems, such as blurred vision or loss of vision
Thrombotic Microangiopathy (TMA)	TMA is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs, and may lead to death. • Fever of 100.4°F (38°C) or higher • Brusing • Nose bleeds • Tiredness • Decreased urination
Tumor Lysis Syndrome (TLS)	Tumor lysis happens when cancer cells break apart and flood your bloodstream with chemicals and toxins faster than your body can get rid of them. TLS is a group of conditions that affect your heart, kidneys, and muscles. • Severe nausea, vomiting, or diarrhea • Urinating smaller amounts or dark-colored urine • Muscle cramps or twitching • Rapid heartbeats or chest pain • Confusion or weakness • Seizures
Risk of New Cancer	There is a risk of developing new cancers during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms of new cancers.

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 can 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.
- Treatment may **harm an unborn baby**.
  - If you are able to become pregnant, take a pregnancy test before starting treatment.
  - Use an effective method of birth control during treatment with Dara-CyBorD, for 3 months after your last dose of daratumumab, for 7 months after your last dose of bortezomib, and 1 year after your last dose of cyclophosphamide.
  - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partner(s) could become pregnant, use an effective method of birth control—such as condoms—during treatment with Dara-CyBorD and for 4 months after your last doses of bortezomib and cyclophosphamide.
- **Do NOT breastfeed** during treatment with Dara-CyBorD, for 2 months after your last dose of bortezomib, and for 6 weeks after your last dose of cyclophosphamide.

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 cancer 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 doses of **cyclophosphamide and bortezomib.** Note: When daratumumab is used by itself, you do not need to take these precautions.

- People who are pregnant 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.
- **Changes in blood tests.**
  Daratumumab can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of daratumumab. Your care team will do blood tests to match your blood type before you start treatment with daratumumab. Tell all of your healthcare providers that you are being treated with daratumumab before receiving blood transfusions.
- **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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