

Cladribine, Cytarabine, and Venetoclax

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for acute myeloid leukemia (AML).
- 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
Cladribine (KLAD-rih-been)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to multiply.	Infusion into a vein (intravenous (IV) infusion).
Cytarabine (sy-TAYR-uh-been): Ara-C (ar-uh-SEE) This is also called “low-dose ara-C” or “LDAC”.	Stops cancer cells from making the instructions they need to grow and multiply, causing the cells to die.	Injection under the skin (subcutaneous injection) into the stomach area (abdomen), thighs, or the back of the upper arm.
Venetoclax (veh-NEH-toh-klax): Venclexta (ven-KLEK-stuh)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Tablets taken by mouth.

Treatment Administration and Schedule

Treatment is typically divided into 2 parts: induction and consolidation. Both induction and consolidation last for 28 days. This length of time is called a “cycle”.

Depending on how you respond to induction, your care team may have you repeat it before moving on to consolidation.

Treatment Administration and Schedule (Continued)

Induction

- Cladribine is given 1 time each day on Days 1 to 5.
- Cytarabine is given 2 times a day on Days 1 to 10.
- Venetoclax is taken by mouth on Days 1 to 21, followed by 7 days off treatment.
 - When you first start venetoclax, your care team will start venetoclax at a low dose. Your dose will typically be increased daily over 4 days up to the full dose. Follow your care team's instructions carefully while increasing to the full dose.

Treatment Name	Induction, Days																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	21-28
Cladribine	✓	✓	✓	✓	✓																	
Cytarabine Morning	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓												
Cytarabine Evening	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓												
Venetoclax	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1-Week Break

Consolidation Courses 1, 4, 5, 8, 9, 12, 13, 16, and 17

- Cladribine is given 1 time each day on Days 1 to 3.
- Cytarabine is given 2 times a day on Days 1 to 10.
- Venetoclax is taken by mouth on Days 1 to 21, followed by 7 days off treatment.

Treatment Name	Consolidation Courses 1, 4, 5, 8, 9, 12, 13, 16, and 17, Days																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	21-28
Cladribine	✓	✓	✓																			
Cytarabine Morning	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓												
Cytarabine Evening	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓												
Venetoclax	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1-Week Break

Consolidation Courses 2, 3, 6, 7, 10, 11, 14, and 15

- Azacitidine is given on Days 1 to 7.
- Venetoclax is taken by mouth on Days 1 to 21, followed by 7 days off treatment.

Treatment Name	Consolidation Courses 2, 3, 6, 7, 10, 11, 14, and 15, Days																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	21-28
Azacitidine	✓	✓	✓	✓	✓	✓	✓															
Venetoclax	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1-Week Break

Your venetoclax dosing instructions:

- Venetoclax comes in 3 tablet strengths: 10 mg, 50 mg, and 100 mg.
- When you first take venetoclax, you may need to take venetoclax at a hospital or clinic to be monitored for tumor lysis syndrome (TLS).
- Take venetoclax 1 time a day at about the same time each day.
- Take venetoclax with a meal and water.
- Swallow venetoclax tablets whole. Do not chew, crush, or break the tablets. Tell your care team if you have trouble swallowing the tablets.
- If you miss a dose of venetoclax and it has been less than 8 hours, take your dose as soon as possible. If you miss a dose of venetoclax and it has been more than 8 hours, skip the missed dose and take the next dose at your usual time.
- If you vomit after taking venetoclax, do not take an extra dose. Take the next dose at your usual time the next day.
- If you take too much venetoclax, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Venetoclax

- Store venetoclax at or below 86°F (30°C).
- Keep venetoclax in its original packaging or container to protect it from moisture.
- People who are or may become pregnant should avoid handling venetoclax without gloves.
- Keep venetoclax and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused venetoclax.

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 Tumor Lysis Syndrome (TLS)	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help lower the risk of infections	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<p>Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)</p>	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 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)
<p>Low Platelet Count (Thrombocytopenia) (Boxed Warning)</p>	<p>Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 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

<p>Swelling (Edema)</p>	<p>Description: Swelling and fluid retention can occur in different areas of the body, like the legs or hands. You might notice areas feel puffy or tighter than usual.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a daily log of swelling and note any changes in size or location. • Elevate swollen limbs when resting. • Limit salt intake. • Stay active with regular, gentle exercises. • Avoid prolonged periods of sitting or standing without movement. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Swelling that suddenly worsens or spreads to other areas • Pain, redness, or warmth in the affected area • Signs of shortness of breath or difficulty breathing • Swelling is persistent and does not improve with home management • Unexpected weight gain <p>Note: Your care team may ask you to contact them if your weight increases by a certain amount over a certain time period.</p>
<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • 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. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood or coffee-ground-like appearance in your vomit • Severe stomach pain that does not go away after vomiting
<p>Pain</p>	<p>Description: Pain is an uncomfortable feeling that can happen anywhere in your body and can vary in intensity. It can be sharp, throbbing, aching, or burning, and it may feel like discomfort or pressure.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a pain diary to track the frequency, duration, and intensity of your pain. • Your care team may recommend medicines for pain. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Uncontrolled pain

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia) (Boxed Warning)	<ul style="list-style-type: none"> • Fatigue • Weakness • Pale or dull skin • Shortness of breath • Dizziness or lightheadedness 	<ul style="list-style-type: none"> • Cold hands and feet • Irregular heartbeat • Headaches • Chest pain
Heart Problems	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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
Progressive Multifocal Leukoencephalopathy (PML)	<p>PML is a rare, serious brain infection caused by a virus that can happen in people who receive cladribine. 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.</p> <ul style="list-style-type: none"> • 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 	
Tumor Lysis Syndrome (TLS)	<p>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.</p> <ul style="list-style-type: none"> • Severe nausea, vomiting, or diarrhea • Urinating smaller amounts or having dark-colored urine • Muscle cramps or twitching • Rapid heartbeats or chest pain • Confusion or weakness • Seizures 	
Infusion-Related Reactions	<ul style="list-style-type: none"> • Chills or shaking • Itching, rash, or flushing • Trouble breathing, wheezing, or tongue swelling • Dizziness or feeling faint 	<ul style="list-style-type: none"> • Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck

**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, for 30 days after your last dose of venetoclax, and for 6 months after your last dose of cladribine.
 - 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 cladribine, cytarabine, and venetoclax, and for 6 months after your last dose of cladribine.
- **Do NOT breastfeed** during treatment, for 1 week after your last dose of venetoclax, and for 48 hours after your last dose of cladribine.

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 dose of **cladribine and cytarabine**: (Note: Venetoclax does not require special handling of body fluids and waste.)

- 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.
 - **You should not receive a “live vaccine”** before, during, or after treatment, until your care team tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your care team. These vaccines may not be safe or may not work as well during treatment.
- **You should not drink grapefruit juice, eat grapefruit, Seville oranges (often used in marmalades), or starfruit** during treatment with venetoclax. These products may increase the amount of venetoclax in your blood.
- **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: May 26, 2026

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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