

Full Resource Library

AML Quick Facts

1-3

VYXEOS Quick Facts

4-6

VYXEOS Treatment Journey

7-11

Patient FAQs

12-15

Discussion Guide

16-19

What is acute myeloid leukemia (AML)?



AML is a type of leukemia in the blood and bone marrow that **affects blood cells**.

AML

AML is the **most common type of acute leukemia** found in adults.

19,520/yr

An estimated **19,520 new cases** of AML diagnosed in the United States in 2018.

Types of secondary AML (sAML)

Therapy-related AML (t-AML)

t-AML is AML that develops because of past cancer treatment, such as chemotherapy, radiation therapy, or immunotherapy.

AML with myelodysplasia-related changes (AML-MRC)

AML-MRC is AML that develops because of certain types of blood disorders, a specific genetic mutation, or the presence of certain abnormal blood cells.

WHAT IS VYXEOS?

VYXEOS is an intravenous (IV) chemotherapy used for the treatment of adults with certain types of newly-diagnosed acute myeloid leukemia (AML). These types include patients whose AML is related to previously received chemotherapy or radiation therapy (also called therapy-related AML, t-AML) and AML in patients who previously had certain types of blood disorders, have a specific genetic mutation, or have certain abnormal blood cells (also called AML with myelodysplasia-related changes, AML-MRC).

IMPORTANT SAFETY INFORMATION

WARNING: VYXEOS has different dosage recommendations from other medications that contain daunorubicin and/or cytarabine. Do not substitute VYXEOS for other daunorubicin and/or cytarabine-containing products.

VYXEOS should not be given to patients who have a history of serious allergic reaction to daunorubicin, cytarabine, or any of its ingredients.

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED Warning, and discuss with your doctor.

Vyxeos[®]
(daunorubicin and cytarabine) 44 mg/100 mg
liposome for injection per vial

AML Quick Facts

Roughly one-third of all AML cases are diagnosed as t-AML or AML-MRC.

Proper diagnosis of AML is determined by your doctor after reviewing symptoms, completing a bone marrow biopsy and blood cell count, and running certain tests.

68 years old

The average age of an AML patient is 68 years old.

Risk factors and symptoms of AML

Some known risk factors for AML include:

- smoking
- certain chemical exposures
- certain chemotherapy drugs
- radiation exposure
- certain blood disorders, such as myelodysplastic syndromes (MDS)
- genetic syndromes
- family history
- older age
- male gender

Some symptoms of AML in adults include:

- fever
- shortness of breath
- easy bruising or bleeding
- petechiae (red, purple, or brown spots on the skin)
- weakness or feeling tired
- weight loss or loss of appetite
- being more vulnerable to infection

IMPORTANT SAFETY INFORMATION, continued

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VYXEOS can cause heart-related side effects. Tell your doctor about any history of heart disease, radiation to the chest, or previous chemotherapy. Inform your doctor if you develop symptoms of heart failure such as:

- shortness of breath or trouble breathing
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- severe itching
- skin rash or hives
- swelling of the face, lips, mouth, or tongue

VYXEOS contains copper and may cause copper overload in patients with Wilson's disease or other copper-processing disorders.

VYXEOS can damage the skin if it leaks out of the vein. Tell your doctor right away if you experience symptoms of burning, stinging, or blisters and skin sores at the injection site.

VYXEOS can harm your unborn baby. Inform your doctor if you are pregnant, planning to become pregnant, or nursing. Do not breastfeed while receiving VYXEOS. Females and males of reproductive potential should use effective contraception during treatment and for 6 months following the last dose of VYXEOS.

The most common side effects were bleeding events, fever, rash, swelling, nausea, sores in the mouth or throat, diarrhea, constipation, muscle pain, tiredness, stomach pain, difficulty breathing, headache, cough, decreased appetite, irregular heartbeat, pneumonia, blood infection, chills, sleep disorders, and vomiting.

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VYXEOS Quick Facts

About VYXEOS (vix-e-ose)

sAML: *t-AML or AML-MRC*

VYXEOS is used to treat **2 types of secondary acute myeloid leukemia (sAML):** therapy-related AML (t-AML) and AML with myelodysplasia-related changes (AML-MRC).



VYXEOS is a combination of **2 chemotherapies, daunorubicin and cytarabine,** into tiny, bubble-like carriers called liposomes.



The VYXEOS **solution is purple.** It is given as an intravenous (IV) injection.

Induction and consolidation with VYXEOS



For first **induction therapy,** VYXEOS is given as an infusion for **90 minutes on Days 1, 3, and 5 of treatment.**



For **consolidation therapy,** VYXEOS is given as an infusion for **90 minutes on Days 1 and 3 of treatment.**

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You may receive up to **2 cycles of induction and 2 cycles of consolidation.**

In a clinical trial including older adult patients with t-AML or AML-MRC in which patients received either VYXEOS or the standard AML chemotherapy treatment

9.6 months vs 5.9 months

Approximately **half of the patients treated with VYXEOS were alive at 9.6 months** compared to 5.9 months for those treated with standard chemotherapy.^a

42% vs 28%

VYXEOS estimated survival at 1 year for patients was 42% compared to 28% for patients with standard chemotherapy.^a

38% vs 26%

38% of patients **achieved complete remission^b with VYXEOS** compared to 26% of patients with standard chemotherapy,^a meaning more patients responded to treatment with VYXEOS.

34% vs 25%

34% of patients **received a hematopoietic stem cell transplant (HSCT) with VYXEOS** compared to 25% of patients with standard chemotherapy.^a

^aStandard chemotherapy was cytarabine 100 mg/m² and daunorubicin 60 mg/m².

^bComplete remission is the disappearance of all signs of cancer in response to treatment. This does not always mean the cancer has been cured.

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Before treatment

1

Your doctor may perform multiple tests to determine what type of acute myeloid leukemia (AML) you have. If you receive a diagnosis of therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC), different treatment options may be discussed to ensure you receive the best care for you.

2

If your healthcare team decides you are a candidate for VYXEOS (vix-e-ose), treatment typically begins immediately.

Make your doctor aware of any important information before beginning treatment.

During treatment

VYXEOS is administered in 2 treatment phases, called induction and consolidation, as an intravenous (IV) infusion using a central IV line or a peripherally inserted central catheter. You may receive up to 2 cycles of induction and up to 2 cycles of consolidation, depending on your treatment plan. Your healthcare team will determine what is needed for you.

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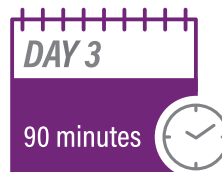
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During treatment, continued

1st induction

The first phase of treatment, known as first induction, is used to control the disease and reduce the number of leukemia cells (blasts) to achieve remission (a decrease in or disappearance of signs and symptoms of cancer). Most patients will require several weeks of hospital stay to monitor blood counts and manage potential complications.

- Given in a 1-week time period
- Days 1, 3, & 5 for 90 minutes



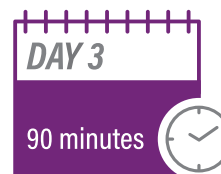
Days 14-21: Doctors may assess your bone marrow to see if VYXEOS is working by looking at how many blasts remain.

The next step will depend on the results of your bone marrow assessment. If there are still too many blasts left, you may begin **2nd induction**. If your results show you are in remission, you may go directly to **1st consolidation**.

2nd induction *(if needed)*

Second induction may be given if you did not reach remission after the first induction.

- Begins 2-5 weeks after 1st induction
- Days 1 & 3 for 90 minutes



Days 14-21: You will have a bone marrow assessment.

Depending on the results of your bone marrow assessment, you may begin **1st consolidation**.

IMPORTANT SAFETY INFORMATION, continued

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During treatment, continued

1st consolidation

Consolidation is the next phase of treatment, used to maintain remission and decrease the number of remaining blasts. This phase will begin as soon as possible after recovery from induction.

- Begins 5-8 weeks after start of last induction
- Days 1 & 3 for 90 minutes



Days 14-21: Your doctors may perform follow-up tests to determine whether you need a 2nd consolidation.

2nd consolidation *(if needed)*

Second consolidation may be given to maintain remission.

- Begins 5-8 weeks after start of 1st consolidation
- Days 1 & 3 for 90 minutes



Your doctors may perform follow-up tests.

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More treatment details



Although infusions do not occur daily, you will most likely be in the hospital for several weeks to monitor your blood count and manage any potential complications during treatment.



Second consolidation cycles are administered to ensure the disease remains controlled.



Your healthcare team may decide to administer VYXEOS in an outpatient setting based on the severity of the disease, your overall health, and how close you live to an infusion center. Your healthcare team will determine what is best for you.



Before consolidation can begin, doctors must assess cardiac function, complete blood counts, and liver and kidney function.



Absolute neutrophil count (ANC) and platelet count, which are measured with a blood test, will be assessed before consolidation to determine if consolidation is the next appropriate step.



The most common side effects reported by patients receiving VYXEOS include bleeding events, fever, rash, swelling, nausea, sores in the mouth or throat, diarrhea, constipation, muscle pain, tiredness, stomach pain, difficulty breathing, headache, cough, decreased appetite, irregular heartbeat, pneumonia, blood infection, chills, sleep disorders, and vomiting.

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Helpful tips during AML treatment



Feelings of sadness, anxiety, and loneliness are normal during treatment.

Talk with your doctor about these concerns. Your healthcare team can provide you with sources of information and advice.



Accept support.

Reach out to family, friends, and any support groups that may be able to offer advice and solace for those going through chemotherapy.



Stay positive.

Chemotherapy can leave you feeling lonely and worried about the future. Continue your normal hobbies as much as possible. Reading, doing puzzles, journaling, and meditating may help you maintain a positive attitude.



Stay physically active.

Take walks and engage in any fitness activities that are okayed by your doctor. Keeping your body in the best possible shape may help during treatment.



Eat healthy.

During chemotherapy, it is important to fuel your body with sources of vitamins and nutrients to keep energy levels steady.

IMPORTANT SAFETY INFORMATION, continued

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Patient FAQs

About acute myeloid leukemia (AML)



What is t-AML?

Therapy-related acute myeloid leukemia, also known as t-AML, is a type of secondary AML (sAML) that may occur in those who have previously been treated for cancer with chemotherapy, radiation therapy, or immunotherapy.

What is AML-MRC?

Acute myeloid leukemia with myelodysplasia-related changes, also known as AML-MRC, is a type of secondary AML (sAML) that may be present in those who have previously had certain types of blood disorders, have a specific genetic mutation, or have certain abnormal blood cells.

About VYXEOS (vix-e-ose)



How does VYXEOS work?

VYXEOS is an advancement in chemotherapy that combines 2 currently used therapies, daunorubicin and cytarabine, into tiny, bubble-shaped carriers called liposomes. The liposomes are taken up by leukemia cells (blasts) to a greater extent than by normal cells. Once inside, the liposomes release the drugs to help kill the blasts.

How is VYXEOS administered?

VYXEOS is given as an intravenous (IV) infusion using a central IV line or peripherally inserted central catheter. VYXEOS is given in cycles, known as induction and consolidation, and your doctor will determine how many cycles of treatment are needed based on your response.

What makes me eligible to receive VYXEOS treatment?

There are a variety of factors your healthcare team will consider when determining if you are a candidate for VYXEOS, such as your age, your overall health, and whether or not you have a confirmed diagnosis of t-AML or AML-MRC.

WHAT IS VYXEOS?

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Treatment with VYXEOS



Will I receive my treatment in the hospital or in an outpatient setting?

Your healthcare team may decide to administer VYXEOS in an outpatient setting based on the severity of the disease, your overall health, and how close you live to an infusion center. Your healthcare team will determine what is best for you.

How long will I be on treatment?

Although induction and consolidation phases only require 2 to 3 days of treatment per cycle, you will most likely be in the hospital for several weeks to monitor your response and manage any potential complications.

Can I do anything that will increase my positivity during treatment?

It is important to remain positive during treatment. Keep participating in hobbies, like puzzles or journaling, and any fitness activities you are deemed capable of by your doctor, such as walking.

What should I tell my doctor before treatment with VYXEOS?

Before treatment, you should tell your doctor of any known or suspected pregnancy, history of heart disease, history of copper-processing disorder, additional medications you may be taking, or history of treatment with an anthracycline.

What should I tell my doctor during treatment with VYXEOS?

During treatment, you should tell your doctor if you are experiencing fever; signs of infection; bruising; bleeding; signs of heart failure such as shortness of breath or trouble breathing and swelling or fluid retention; skin damage; signs of hypersensitivity reactions; or signs of anaphylaxis such as difficulty breathing, severe itching, skin rash, hives, or swelling of the face, lips, mouth, or tongue.

What are the possible side effects of VYXEOS?

The most common side effects of VYXEOS include bleeding events, fever, rash, swelling, nausea, sores in the mouth or throat, diarrhea, constipation, muscle pain, tiredness, stomach pain, difficulty breathing, headache, cough, decreased appetite, irregular heartbeat, pneumonia, blood infection, chills, sleep disorders, and vomiting.

These are not all of the possible side effects of VYXEOS. Be sure to speak to your healthcare team about any side effects you have. You will also have blood tests done to check for side effects during treatment with VYXEOS.

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Induction & consolidation with VYXEOS



What is the difference between induction and consolidation?

Induction is the first phase of treatment, used to control the disease and reduce the number of blasts to achieve remission (a decrease in or disappearance of signs and symptoms of cancer). Consolidation is the second, maintenance, phase of treatment, used to maintain remission and decrease the number of any remaining blasts.

Why might I need a second induction or consolidation?

Your VYXEOS dosing schedule is designed specifically for you by your healthcare team based on your response at certain benchmarks (like bone marrow assessments) during treatment.

Financial assistance



Will my insurance cover VYXEOS?

Ask your healthcare team about your insurance coverage for VYXEOS. You can also contact our dedicated reimbursement specialists at JazzCares, our patient support hotline. Call 1-855-5VYXEOS (1-855-589-9367) Monday through Friday from 9 AM to 8 PM ET.

Are there any financial assistance programs available to me?

Our patient support program, JazzCares, has dedicated specialists who are available to assist you with financial coverage options for VYXEOS. Contact our team at 1-855-5VYXEOS (1-855-589-9367) Monday through Friday from 9 AM to 8 PM ET for all questions regarding financial assistance options.

Who can answer specific questions I have regarding my treatment and insurance coverage?

Your healthcare team is the best source of information about treatment and insurance coverage with VYXEOS.

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Discussion Guide

You may have questions about acute myeloid leukemia (AML) and your treatment with VYXEOS (vix-e-ose) that you want to discuss with your doctor and healthcare team.

This discussion guide is designed to help you get the conversation started and ensure that you are comfortable discussing all aspects of your treatment.

Consider the following questions before your next check-in with your healthcare team:



How are you feeling since your last check-in?

How have you been dealing with your diagnosis?

What concerns you most about your diagnosis and treatment?

Do you have any specific questions for your doctor?

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Consider reviewing the following questions with your healthcare team:



How does my medical history affect my diagnosis and my treatment with VYXEOS?

Why is VYXEOS an appropriate treatment for me?

What does the timeline of my treatment look like as of right now?

Where will I receive my treatment?

IMPORTANT SAFETY INFORMATION, continued

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Consider reviewing the following questions with your healthcare team:



What are the possible side effects of treatment with VYXEOS?

How will we be able to tell if my treatment is working?

How can I prepare for my treatment with VYXEOS?

Where can I find a support community of others who have AML or related conditions?

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Consider reviewing the following questions with your healthcare team:



What kind of diet and exercise regimen do you recommend for me during treatment?

Do you have any guidance for my caregivers, family, and friends throughout this process?

IMPORTANT SAFETY INFORMATION, continued

VYXEOS contains copper and may cause copper overload in patients with Wilson’s disease or other copper-processing disorders.

VYXEOS can damage the skin if it leaks out of the vein. Tell your doctor right away if you experience symptoms of burning, stinging, or blisters and skin sores at the injection site.

VYXEOS can harm your unborn baby. Inform your doctor if you are pregnant, planning to become pregnant, or nursing. Do not breastfeed while receiving VYXEOS. Females and males of reproductive potential should use effective contraception during treatment and for 6 months following the last dose of VYXEOS.

The most common side effects were bleeding events, fever, rash, swelling, nausea, sores in the mouth or throat, diarrhea, constipation, muscle pain, tiredness, stomach pain, difficulty breathing, headache, cough, decreased appetite, irregular heartbeat, pneumonia, blood infection, chills, sleep disorders, and vomiting.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Jazz Pharmaceuticals at 1-800-520-5568.

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED Warning, and discuss with your doctor.