
Oral Azacitidine for Acute Myeloid Leukaemia (AML)

**A Guide for
Patients**

Introduction

Azacitidine interferes with the formation of DNA, preventing the reproduction of cells in the body, particularly leukaemia cells who are multiplying quickly. If you have any questions about this AML treatment - this booklet covers the basics for you.

The booklet was written by our Patient Information Writer, Isabelle Leach.

If you are unsure if this booklet is the correct one for your azacitidine treatment, please check with your healthcare professional or call the helpline on 08088 010 444.

Throughout this booklet, you will see QR codes that will take you to the relevant webpage for further support. Open the camera app on your phone and hover it over the QR code to open the link (suitable for Android, iPhone 7 and above).

Alternatively, if you are not able to use QR codes and would like to be sent the relevant webpages as URLs, or you would like the list of references used for this booklet, please email communications@leukaemiacare.org.uk.

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About Leukaemia Care

Leukaemia Care is the UK's leading leukaemia charity. For over 50 years, we have been dedicated to ensuring that everyone affected receives the best possible diagnosis, information, advice, treatment and support.

Our services

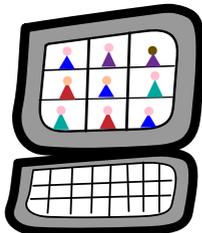
Helpline

Our helpline is available 9:00am - 5:00pm Monday - Friday. If you need someone to talk to, call **08088 010 444**.

Alternatively, you can send a message via WhatsApp on **07500 068065** on weekdays 9:00am - 5:00pm.

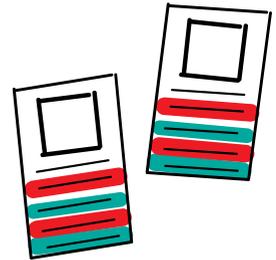
Support Groups

Our nationwide support groups are a chance to meet and talk to other people who have been affected by an ALL diagnosis. For more information about a support group local to your area, scan this QR code:



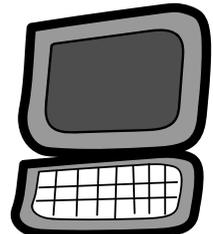
Buddy Support

We offer one-to-one phone support with volunteers who have had an ALL themselves or been affected by it in some way. You can speak to someone who knows what you are going through. For more information on how to get a buddy call **08088 010 444** or email support@leukaemicare.org.uk



Online Forum

Our HealthUnlocked online forum is a place for people to ask questions anonymously or to join in the discussion with other people affected by an ALL diagnosis. If you'd like to join, scan this QR code:



Webinars

Our webinars provide an opportunity to ask questions and listen to patient speakers and medical professionals who can provide valuable information and support. For information on upcoming webinars, scan this QR code:



Advocacy and Welfare

Our advocacy and welfare officers are here to help you find the support you need for many issues surrounding an ALL diagnosis. These include insurance, benefits and clinical trials. If you would like support from our advocacy or welfare officer, email advocacy@leukaemiacare.org.uk or call **08088 010 444**.

Patient magazine

Our magazine includes inspirational patient and carer stories as well as informative articles by medical professionals. To subscribe to our magazine, just scan this QR code:



Counselling Fund

Our fund helps ALL patients and their loved ones access professional help by offering a grant of up to £420 to go towards six sessions of counselling. To apply, scan this QR code:



Cost of Living Fund

This fund provides grants of up to £200 for essential living costs to patients and families affected by ALL. All applications must be made via the form which can be found by scanning this QR code:



Write a free will

Using our complimentary service, you can write a simple will so you know what happens to your estate when you die. Scan this QR code to start writing your free will today:



AML Patient Pathway

This flow chart represents the stages that a AML patient might follow during the course of their illness. Each of the steps in this diagram are explained our suite of AML information.

1. Diagnosis

Referral to haematologist for
diagnosis and/or treatment

2. Treatment

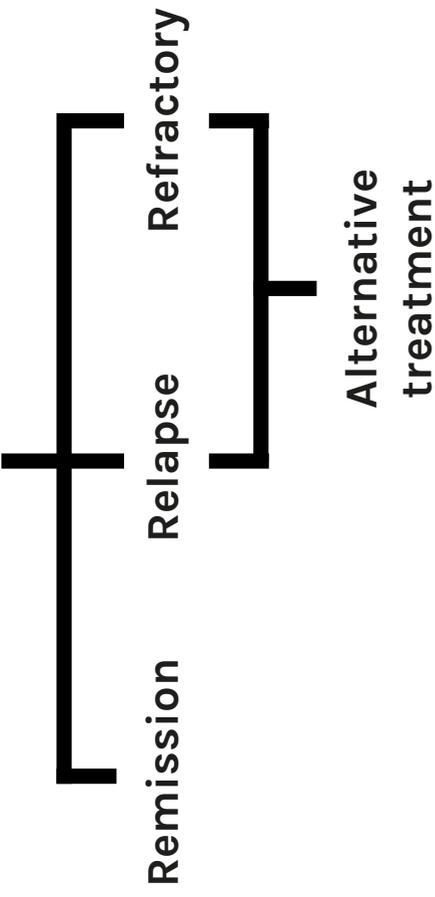
Induction



Consolidation



Maintenance



3. Supportive care

4. End of life care

Glossary of medical terms

Acute myeloid leukaemia (AML)

Rapid and aggressive cancer of the myeloid cells in the bone marrow.

Blood transfusion

A procedure in which whole blood or one of its components is given to a person through an intravenous line into the bloodstream. A red blood cell transfusion or a platelet transfusion can help some patients with low blood counts.

Bone marrow

The soft blood-forming tissue that fills the cavities of bones and contains fat, immature and mature blood cells, including white blood cells, red blood cells, and platelets.

Chemotherapy

Therapy for cancer using chemicals that stop the growth of cells.

Clinical trial

A medical research study involving patients with the aim of improving treatments and their side effects. You will always be informed if your treatment is part of a trial.

Consolidation (phase)

Treatment following remission intended to kill any cancer cells that may be left in the body (also called intensification phase).

Cytarabine

Antimetabolite drug which works by disrupting the DNA of cancer cells, thereby slowing or stopping their growth.

Induction (phase)

First treatment after diagnosis intended to kill the majority of the leukaemia cells and stimulate remission.

Maintenance

Treatment given to prevent cancer from coming back after it has disappeared following the first-line treatment.

Myelodysplastic syndromes (MDS), also called myelodysplasia

Myelodysplastic disorders occur when the bone marrow does not make enough normal blood cells. The blood cells made are not fully developed and not able to work normally. These blood cells include red blood cells which supply oxygen to the body's tissues, white blood cells which fight infection and platelets which help blood clot.

Myeloid

Relates to bone marrow.

Relapse

Relapse occurs when a patient initially responds to treatment, but after six months or more, the response stops. This is also sometimes called a recurrence.

Stem cell transplant

Transplant of stem cells derived from part of the same individual or a donor.

Summary: Oral azacitidine for AML

- Azacitidine is an anti-cancer drug used as maintenance treatment of AML adult patients who are:
 - Less than 65 years old
 - Not eligible/do not want a stem cell transplant (SCT)
- The aim of maintenance treatment is to kill any remaining leukaemia cells in the body. This is because leukaemia cells can cause a relapse if not destroyed.
- Azacitidine prevents the reproduction of cells in the body, particularly leukaemia cells.
- You receive one tablet of oral azacitidine each day. Each repeated cycle consists of a 14-day treatment period followed by a period of 14 days free of treatment (28-day treatment cycle). Your treatment period should consist for at least six cycles.
- As you achieve remission with oral azacitidine, your symptoms will lessen and your blood cell counts will become nearer to normal.
- If you do not achieve remission, you may receive:
 - Subcutaneous low-dose cytarabine twice daily for ten days per 28-day cycle.
 - Best supportive care.
 - New agents especially if you have primary refractory and high-risk MDS.



- Common side effects with oral azacitidine include:
 - Gastrointestinal (nausea, vomiting and diarrhoea)
 - Fatigue/asthenia
 - Neutropenia
- Your haematology team can manage your side effects. It is important that you mention any side effects as soon as possible.

What is oral azacitidine?

Azacitidine is an anti-cancer chemotherapy drug used for the maintenance treatment of adult patients with acute myeloid leukaemia (AML) who are not eligible for a stem cell transplant. Azacitidine interferes with the formation of DNA, preventing the reproduction of cells in the body, particularly leukaemia cells who are multiplying quickly.

Oral azacitidine is approved for maintenance therapy of adult AML patients who:

- Have achieved complete remission or complete remission with incomplete blood count recovery **AND**
- Are not candidates for, or choose not to proceed to, a stem cell transplantation (SCT)

In AML, there is an uncontrolled production of abnormal immature leukaemia cells. As these cells accumulate in the bone marrow, they can prevent the production of healthy red blood cells, platelets and white blood cells.

Initial treatment for AML often works for a short period but may not last very long. This is known as incomplete blood count recovery. Maintenance treatment with oral azacitidine can help you to stay in remission for longer and prevent relapse.

Who receives oral azacitidine?

Oral azacitidine is approved for the AML maintenance treatment of adult patients under the age of 65 years who are not eligible/ do not want to have a bone marrow stem cell transplant for AML.

How is oral azacitidine administered?

Oral azacitidine should be started and monitored under the supervision of a doctor experienced in the use of chemotherapeutic agents. Patients should receive anti emetic drugs to prevent nausea and vomiting as these side effects are very common for the first two weeks. The anti-emetic drugs can be omitted after 2 cycles, if there has been no nausea and vomiting.

You will receive one film-coated tablet of oral azacitidine once daily. Each repeated cycle consists of a treatment period of 14 days followed by a treatment free period of 14 days (28-day treatment cycle).

Your treatment with oral azacitidine should be given for at least six cycles, and then for as long as it is of benefit to you.

You will have blood tests before each cycle of treatment to monitor your blood cell counts, liver and kidneys. If your blood counts become too low or the kidney tests are not satisfactory, your next treatment cycle may be delayed or your dose of oral azacitidine may be adjusted.

Occasionally your haematology team doctor may adjust your dose of oral azacitidine or may delay your treatment for a short while. This may be because of the effects of the oral azacitidine on your body or on the leukaemia cells.

What are the side effects of oral azacitidine?

Everyone will experience different side effects with oral azacitidine. The most common side effects are shown below. It is important to report side effects to your doctor or nurse so they can manage and treat them effectively.

Oral azacitidine is used for the maintenance therapy in AML patients.

The most common adverse reactions with oral azacitidine reported in order of frequency (between 60.0% and 12.5%) were:

- Nausea
- Vomiting
- Diarrhoea
- Neutropenia
- Fatigue/asthenia
- Constipation
- Thrombocytopenia
- Abdominal pain
- Respiratory tract infection
- Arthralgia

Serious side effects occurred in 16.1% of patients receiving oral azacitidine. The most common serious side effects were:

- Febrile neutropenia
- Pneumonia

Management of side effects

Gastrointestinal side effects

You should be given anti-sickness medication before your

treatment to help nausea and vomiting, but if not, please request them from your doctor or nurse as these anti-emetics will help. You can manage the symptoms of diarrhoea or constipation with anti-diarrhoea drugs, laxatives and/or stool softeners as appropriate.

To manage your diarrhoea, you should:

- Drink plenty of water, but avoid alcohol and coffee.
- Eat small, frequent meals and take your time to eat.
- Eat fewer fibrous foods, such as cereals, raw fruits and raw vegetables.
- Avoid greasy, fatty food.
- Avoid spicy food.

Anaemia

Anaemia results from low red blood cell levels. This may make you feel tired and breathless. Let your doctor know if these symptoms become a problem, you may need a blood transfusion.

Increased risk of infection

Your increased risk of infection is due to low levels of the white blood cells which fight infection. Common types of infections are chest infections and pneumonia.

If you have any signs of infection as shown below contact your nurse or doctor straightaway as it is important to treat of infection as soon as possible.

- Fever (temperature 37.8°C or above)
- Shivering
- Breathlessness
- Sore throat
- Cough
- Needing to pass urine often

To minimise your increased risk of infection, you can try the following methods:

- Hand washing.
- Avoidance of people who are ill.
- Perform regular temperature checks using a thermometer. If your temperature exceeds 37.8°C, please contact your doctor or nurse and/or hospital team directly. If you cannot contact them for any reason, go to the hospital directly.
- Place high importance on personal hygiene.
- If you have a central line (also known as a Hickman line), keep the area around it clean and dry.
- Clean your teeth every day and check for sores in your mouth or other signs of infection.
- If you get injured and have a scrape or cut, make sure you clean it well.
- Let your doctor or hospital team know if you have a sore bottom, or whether it bleeds.

Fatigue

You may feel tired and lacking in energy. It is often worse towards the end of treatment and for some weeks after treatment has finished. Take rests when necessary. Gentle exercise such as walking can help.

Fertility, pregnancy and breastfeeding

There is no evidence of the effect of azacitidine on human fertility. Adverse effects on male fertility have been shown in animals. You should use effective contraception while taking oral azacitidine, and up to six months after treatment. You should also seek advice from your haematology team on the need for sperm storage or egg freezing prior to starting treatment.

There are no studies on the use of oral azacitidine in pregnant women, but studies in animals have shown harmful effects.

Advice is that pregnant women should not take oral azacitidine, especially during the first trimester.

It is not known if oral azacitidine is transmitted your breast milk. However, as a precaution, if you are taking oral azacitidine you should not breastfeed.

If you would like support and advice regarding your treatment, including dealing with side effects, you can speak to someone on our helpline by calling **08088 010 444**. We're available from 9:00am – 5:00pm Monday to Friday.

What happens after treatment with oral azacitidine?

Achieving remission

If your treatment with oral azacitidine has helped you achieve remission, your symptoms should lessen and your blood cell counts will return towards normal ranges.

Successful treatment of relapsed AML involves effective induction treatment that induces remission. This is followed by consolidation treatment to remove any remaining leukaemia cells in the body. This lessens the risk of relapse and increases survival.

Consolidation therapy may also be used as 'bridge treatment' to an allo-SCT. Conventional consolidation therapy includes intensive chemotherapy including a targeted drug.

Your haematology team may also use an allo-ASCT to keep you in remission if you are at high risk of relapse.

Other maintenance therapy strategies include chemotherapies, immunotherapies, hypomethylating agents and targeted treatments. Evidence of the benefit of maintenance therapy in patients with AML is limited, but hypomethylating agents have started to show promise as maintenance therapy and improve clinical outcomes.

Clinical trials can be a valid choice for patients, especially for those with refractory or relapsed AML.

You can read more about acute myeloid leukaemia (AML) in our dedicated booklet on the Leukaemia Care website. Scan the QR code to order our booklets:



Unsuccessful outcome

If, following your treatment with oral azacitidine, your AML has not gone into remission or you have relapsed after achieving remission, your consultant is the best person to discuss what other treatments are available, and help you decide the next course of action.

Knowledge of your type of disorder, your physical condition and any new treatments which could help you will guide your consultant's recommendations.

Options that may be available to you could include:

- Conventional care regimens such as:
 - Subcutaneous low-dose cytarabine twice daily for ten days per 28-day cycle.
- Best supportive care: This may include:
 - Blood product transfusions
 - Antibiotics with
 - Granulocyte colony-stimulating factor to increase levels of white blood cells

If you are relatively young and healthy, you may be offered:

- An Allo-SCT if you can withstand high-dose chemotherapy required to prepare your bone marrow for the transplant.
- Clinical trials can become a valid option for many patients, especially for those with refractory AML. Refractory AML is a persistent AML for which no treatment has had any effect.



Leukaemia Care is a national blood cancer charity supporting anybody affected by a blood cancer. This includes patients, family, friends and the healthcare professionals that support them.

To make a donation or become a regular giver, please visit www.leukaemiacare.org.uk/donate

Thank you!

Useful contacts and further support

There are a number of helpful sources to support you during your diagnosis, treatment and beyond, including:

- Your haematologist and healthcare team
- Your family and friends
- Your psychologist (ask your haematologist or CNS for a referral)
- Reliable online sources, such as Leukaemia Care
- Charitable organisations

Leukaemia Care

Leukaemia Care is the UK's leading leukaemia charity. For over 50 years, we have been dedicated to ensuring that everyone affected receives the best possible diagnosis, information, advice, treatment and support. We are here for everyone affected by leukaemia and related blood cancer types – such as myelodysplastic syndromes (MDS) and myeloproliferative neoplasms (MPN). We believe in improving lives and being a force for change. To do this, we have to challenge the status quo and do things differently.

Helpline: **08088 010 444**
www.leukaemiacare.org.uk
support@leukaemiacare.org.uk

Blood Cancer UK

Leading charity into the research of blood cancers.

0808 2080 888
www.bloodcancer.org.uk

Cancer Research UK

Leading charity dedicated to cancer research.

0808 800 4040
www.cancerresearchuk.org

Macmillan

Provides free practical, medical and financial support for people facing cancer.

0808 808 0000

www.macmillan.org.uk

Maggie's Centres

Offers free practical, emotional and social support to people with cancer and their loved ones.

0300 123 1801

www.maggiescentres.org

Citizens Advice Bureau (CAB)

Offers advice on benefits and financial assistance.

08444 111 444

www.adviceguide.org.uk

How you can help us

If you've been affected by AML, sharing your story can help others going through a similar situation and help the public to better understand.

Scan the QR to share your story:



Alternatively, you can email our Communications team at communications@leukaemiacare.org.uk.

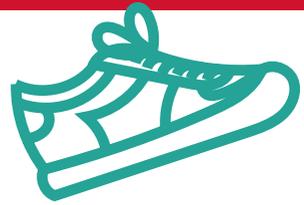
We are continually working to make sure our information is up to date and includes everything you need to help feel supported and empowered to advocate for yourself. With this, it is important for us to listen to any feedback you might have about our oral azacitidine for AML booklet.

Scan the QR to take you to our shop to leave a review of our booklet:



Alternatively, you can email our Communications team at communications@leukaemiacare.org.uk, call our office line on **01905 755 977** or write a letter to our Head Office at **Leukaemia Care, One Birch Court, Blackpole East, Worcester, WR3 8SG.**

Take on a challenge for Leukaemia Care



We have a range of fundraising challenges that you can get involved in to help us continue to provide care and support to those affected by a leukaemia, MDS or an MPN.

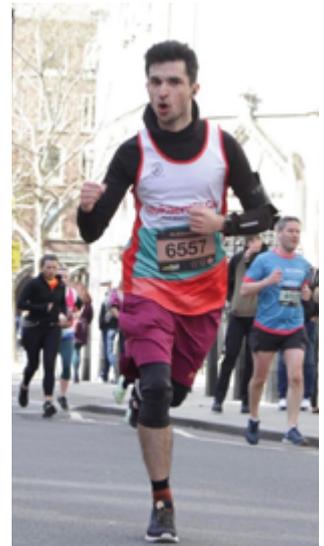
Running, swimming, cycling and adrenaline challenges are available to take part in, both in the UK and abroad. There really is something for everyone.

If you're interested in taking part in a challenge, speak to a member of our fundraising team by emailing fundraising@leukaemiacare.org.uk or calling **01905 755977**.

Alternatively, scan this QR code to find out all the ways you can get involved with Leukaemia Care:



"It was a pleasure to meet you and to take part in my first half marathon together with the Leukaemia Care team! I'm a scientist and work in immunology research. A dear family member passed away from leukaemia seven years ago this month, so I did this in his memory. I smashed my goal of under two hours with a final time of 1:53! I'm extremely happy, thank you so much for all your hard work and it was great to see you cheering us on along the track. I loved the look of the vests too! See you again, next year maybe!" - **Alexandru Bacita** ran **London Landmarks for Leukaemia Care in 2022**



Your gift today will ensure that Leukaemia Care can continue to offer support to leukaemia patients and those who love them

Yes, I want to make a regular gift to Leukaemia Care of £5 or £ a month starting on the 1st or the 15th of each month (please tick one).

Please note: the minimum for a direct debit is £2 a month.

Title:

First name or initial(s): Surname:

Full home address:

.....

Postcode: Phone:

Email:

Gift Aid Declaration: Please tick here if you want Leukaemia Care to reclaim the tax that you have paid on all your donations you make in the future or have made in the past four years.

Instruction to your Bank or Building Society to pay by Direct Debit

Name of Account Holder(s): /

Bank/Building Society account number:

Branch sort code:

Name and full postal address of you Bank or Building Society:

.....

Instruction to your Bank or Building Society: Please pay Leukaemia Care from the account detailed in this instruction subject to the safeguards assured by the Direct Debit Guarantee. I understand that this instruction may remain with Leukaemia Care and, if so, details will be passed electronically to my Bank/Building Society.

Signature(s): /

Date:

.....
This guarantee should be detached and retained by the payee.

The Direct Debit Guarantee



This Guarantee is offered by all banks and building societies that accept instructions to pay Direct Debits.

The efficiency and security of the scheme is mentioned and protected by your own Bank or Building Society.

If the amounts to be paid or the payment dates change, Leukaemia Care will notify you 10 working days in advance of your account being debited or as otherwise agreed.

If an error is made by Leukaemia Care or your Bank or Building Society, you are guaranteed a full and immediate refund from your branch of the amount paid.

You can cancel a Direct Debit at any time by writing to your Bank or Building Society. Please also send a copy of your letter to us.

Leukaemia Care is the UK's leading leukaemia charity. For over 50 years, we have been dedicated to ensuring that everyone affected receives the best possible diagnosis, information, advice, treatment and support.

Every year, 10,000 people are diagnosed with leukaemia in the UK. We are here to support you, whether you're a patient, carer or family member.

Want to talk?

Helpline: **08088 010 444**

(free from landlines and all major mobile networks)

Office Line: **01905 755977**

www.leukaemiacare.org.uk

support@leukaemiacare.org.uk

Leukaemia Care,
One Birch Court,
Blackpole East,
Worcester,
WR3 8SG

Leukaemia Care is registered as a charity in England and Wales (no. 1183890) and Scotland (no. SC049802).

Company number: 11911752 (England and Wales).

Registered office address: One Birch Court, Blackpole East, Worcester, WR3 8SG

Leukaemia Care
YOUR Blood Cancer Charity