



Leukaemia
Foundation®
VISION TO CURE
MISSION TO CARE

Accessing non-PBS Funded Blood Cancer Drugs in Australia

A discussion tool for you and your specialist



1800 620 420



leukaemia.org.au

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- Pharmacists.
- Haematologists.
- Allied health professionals.
- People affected by blood cancers.
- Various agencies dedicated to supporting people affected by blood cancer.

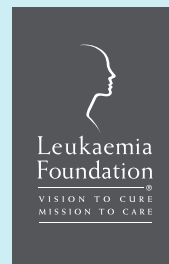
We would like to extend a special thank you to our project coordinator, Julia Renaud.

Every effort has been made to ensure the information in this publication is accurate at the time of publication. So many people from various organisations have helped the Leukaemia Foundation in the development of this booklet.

A special thank you also to all contributors who have the belief that people affected by blood cancer, in consultation with their specialist, are in the best position to decide what is in their own best interest for their health when they have been given enough information to do so.

The Leukaemia Foundation values feedback from people affected by blood cancer and the health care professionals working with them. If you would like to make suggestions or tell us about your experience from using this booklet, please contact the Head of Blood Cancer Support at info@leukaemia.org.au.

December 2015



Introduction

This booklet was written to help you, and your family, navigate the complex system for accessing new blood cancer drugs in Australia, particularly ones that have not been funded on the Pharmaceutical Benefits Scheme (PBS).

Australia has one of the world's best healthcare systems. Recent data indicates that our cancer patient survival rates are among the best in the world.

This system provides everyone with equal access to safe, effective and affordable drugs for standard treatments through the PBS. However, for a few Australians some new and promising treatment options may not yet be funded by our healthcare system.

It is sometimes possible to access new cancer drugs that are not PBS funded and the Leukaemia Foundation developed this booklet to support you as you discuss the alternative pathways to accessing new drugs with your specialist.

Research indicates that Australian patients with cancer want to be informed of all drug options, including unfunded options, regardless of their ability to pay (Mileshkin et al., 2009). Haematologists, however, may feel uncomfortable discussing expensive new therapies their patients may be unable to afford (Thomson et al., 2006). It is not always easy for a doctor to discuss drug options that might not be within your means to access, or would mean a considerable cost to you and your family when the outcome of the therapy is not known.

Investments in medical research have led to many dramatic advances in the way blood cancer is treated and will be treated in the future.

Our aim is to enable you to talk candidly with your specialist about the best drug to treat your cancer (or your family member's cancer), including new drugs and the access options available to you.

This booklet should not be taken as medical advice. Your treating specialist knows your medical needs and is the best person to advise you on your treatment.

A new blood cancer therapy may not always be right for you because the access pathways can be difficult, time-consuming and expensive. In addition, some new drugs are also still under evaluation and it may not be known how effective they are or what side-effects they may cause. New therapies may range from exciting breakthroughs, to an option that is not very different to existing therapies. Some alternate drug access options may be legal, but might have increased risks associated with them – such as counterfeit drugs.

At the Leukaemia Foundation, we believe you should be proactive in deciding, along with your specialist, the best treatment for your or your family's health. We encourage you to gather enough information so you can make an informed decision with your specialist about whether or not to choose treatment with a new drug.



*Talk to your doctor who
can help you make the
best decision about your
treatment options.*

If you have had difficulty accessing the therapy you need for your disease, you could consider notifying your local Federal MP to ensure they are aware of the issues you have faced.

Please visit www.leukaemia.org.au or call us on **1800 620 420** for further information, guidance, or if you have further questions about accessing new drugs. We are also interested in learning about your non-PBS funded drug access experience so we can help others.

We hope you find this booklet useful and we would appreciate any feedback from you so we can continue to serve you and your family better in the future.

References

Mileshkin, L., Schofield, P.E., Jefford, M., Agalianos, E., Levine, M., Herschtal, A., & Zalcberg, J.R. (2009). To tell or not to tell: The community wants to know about expensive anticancer drugs as a potential treatment option. *Journal of Clinical Oncology*, 27(34), 5830-5837.

Thomson, J., Schofield, P., Mileschkin, L., Agalianos, E., Savulescu, J., Zalcberg, J., & Jefford, M. (2006). Do oncologists discuss expensive anti-cancer drugs with their patients? *Annals of Oncology*, 17(4), 702-708.

Foundation staff with health professional qualifications provide patients and their families with information and support across Australia.

About the Leukaemia Foundation

The Leukaemia Foundation is Australia's peak body for blood cancer, funding research and providing free services to support people with leukaemia, lymphoma, myeloma, MDS, MPN and related blood disorders, and their families.

The Leukaemia Foundation provides a range of support services at no charge to patients and their family and friends. This support may be offered over the telephone, face-to-face at home, hospital or at our accommodation centres, depending on your location and your specific needs.

Since 1975, the Foundation has been committed to improving survival for patients and providing much needed support. The Leukaemia Foundation does not receive direct ongoing government funding, relying instead on the continued and generous support of individuals and corporations to develop and expand its services.



Research

The Leukaemia Foundation funds leading research into better treatments and cures for blood cancer. Through its National Research Program, the Leukaemia Foundation helped establish the ALLG Discovery Centre at the Princess Alexandra Hospital and the Leukaemia Foundation Research Unit at the Queensland Institute for Medical Research. In addition, we fund research grants, scholarships and fellowships for talented researchers, clinicians and allied health professionals.

Support services

The Leukaemia Foundation has a team of highly trained and caring Blood Cancer Support staff with qualifications and experience in nursing or allied health who work across the country. They can offer individual support and care to you and your family when it is needed.

Support Services may include:

Information

The Leukaemia Foundation has a range of booklets, fact sheets and other resources that are available free of charge. These can be ordered via the form at the back of this booklet or downloaded from our website www.leukaemia.org.au.

Education and support programs

The Leukaemia Foundation offers you and your family disease-specific and general education and support programs throughout Australia. These programs are designed to empower you with information about various aspects of diagnosis and treatment and how to support your general health and wellbeing.

Emotional support

A diagnosis of a blood cancer/disorder can have a dramatic impact on a person's life. At times it can be difficult to cope with the emotional stress involved. The Leukaemia Foundation's Blood Cancer Support staff can provide you and your family with much needed support during this time.



Blood Buddies

This is a program for people with a blood cancer or related disorder to be introduced to a trained ‘buddy’ who has been living with the same disease over a period of time. These Blood Buddies can share their strategies that have helped them in their blood cancer experience to support others.

Telephone discussion forums

This support service enables anyone, anywhere in Australia, who has been affected by a blood cancer, to share their experiences, provide tips, education and support to others in a relaxed forum. Each discussion is facilitated by a member of the Leukaemia Foundation’s Blood Cancer Support team, who has a background in haematology nursing or allied health. A bone marrow transplant forum and men’s forum are also available.

Accommodation

Some patients and carers need to relocate for treatment and may need help with accommodation. Leukaemia Foundation staff can help you to find suitable accommodation close to your hospital or treatment centre. In many areas, the Foundation’s fully furnished self-contained units and houses can provide a ‘home away from home’ for you and your family.

Transport

The Foundation also assists with transporting people to and from their hospital for treatment. Courtesy cars and other services are available in many areas across the country.

Practical assistance

The urgency and lengthy duration of medical treatment can affect you and your family's normal way of life and there may be practical things the Foundation can do to help. In special circumstances, the Leukaemia Foundation provides financial support for patients who are experiencing financial difficulties or hardships as a result of their illness or its treatment. This assistance is assessed on a case-by-case basis.

Advocacy

The Leukaemia Foundation is a source of support for you as you navigate the health system. While we do not provide treatment recommendations, we can support you while you weigh up your treatment options. We may also provide information on other options such as special drug access programs, and available clinical trials.

Contact us

The Leukaemia Foundation provides services and support in every Australian state and territory. Every person's experience of living with a blood disorder is different. Living with a blood disorder is not always easy, but you don't have to do it alone. Please Freecall **1800 620 420** to speak to a local Blood Cancer Support staff member or to find out more about our services. Alternatively, email info@leukaemia.org.au or visit www.leukaemia.org.au.



How to use this booklet

The Leukaemia Foundation helps people to learn about their disease and potential treatment options. We acknowledge that some people are happy to have little involvement in making decisions about their treatment, and some like to be very involved in all treatment decisions. The Foundation supports your right to choose your level of involvement.

If there is a drug that you would like to consider for your treatment, you need to find out if it is available in Australia. For some Australians, the easiest and most affordable pathway to gain early access to a drug that is not PBS funded is through a clinical trial.

However, there are several options to consider such as purchasing the drug at full cost (if it has been approved for registration in Australia through the Therapeutic Goods Administration [TGA]), or obtaining the drug at a reduced cost (or free) through 'compassionate' access programs run by hospitals or pharmaceutical companies. A final option is to discuss with your specialist access to drugs that are not approved in Australia but may be available overseas.

Learn about your disease and become a partner with your medical team rather than a patient.

Use this booklet as a guide to discover the pathways available for accessing new blood cancer drugs in Australia.

You will also find additional information about each of these pathways to help you decide if a new drug is the best treatment option for you (or your family member).

1. Understand the drug approval process (pages 14-22)

Before a new drug becomes available on prescription in Australia, it has to go through many years of development and testing as well as a rigorous regulatory approval process in Australia.

In the first section of this booklet, we provide a short overview of these processes. By reading this section, you will get a feel for where the medication you wish to access sits in this process.

2. Identify new drug access pathways

On pages 26 and 27, there is a decision support tool.

This diagram is designed to help you ask your specialist about how you can access a new blood cancer drug in Australia.

Follow the diagram to explore the different drug access options that might be suitable for you.

3. Ask about specific pathways

For each pathway listed on pages 26 and 27, there is a page number. Turn to this page for an in-depth decision support tool for that pathway.

Once again, follow the diagram to find out from your specialist if this pathway is accessible and suitable for you.

We also provide further information about the pathway and some frequently asked questions (FAQ).

If you find the pathway isn't suitable for your situation, return to the 'decision-making' diagram on pages 26 and 27 and follow the next pathway.



Background: the drug approval process in Australia

New drugs go through a rigorous process before they become available in Australia. This process helps ensure we have access to safe and effective medicines.

The first step in this process is research and development. Potential new drugs are first tested in the laboratory. This stage is known as preclinical trials. Here researchers assess their safety and feasibility before they are used in clinical trials with humans.

Potential therapies are then subjected to rigorous clinical trials, where drugs are given to people under carefully controlled and monitored conditions. Therapies usually undergo three phases of clinical trials to be deemed effective and safe, though this is not always the case.

Regulatory approval (market authorisation) declares that the data collected from clinical trials is proven to demonstrate the drug is effective and safe. This process is rigorous and independent to protect the safety of Australians who may use this therapy. Regulatory approval must be gained before the drug is made available to the Australian public.

In Australia, the drug sponsor (usually a pharmaceutical company) must apply for regulatory approval from the TGA. Once regulatory approval is granted, a drug is registered on the Australian Register of Therapeutic Goods (ARTG) and can be legally marketed and sold in Australia.

Pharmaceutical companies can also apply to have the cost of the drug subsidised by the Australian government on the PBS system, making it affordable to the majority of Australians who require it. Applications are made to the Pharmaceutical Benefits Advisory Committee (PBAC). This can be done any time after the TGA application has been submitted.

The TGA, the PBAC, and the PBS all play a critical role in providing Australians with access to safe, effective and affordable drugs.

The PBAC makes a recommendation to the Australian government about whether a medication is cost effective and therefore eligible for listing on the PBS. The Health Minister then decides if individual drugs will be added to the PBS or not. If a drug will cost the government more than \$20 million in expected subsidies in any one year of the first four years it is funded, the Federal Cabinet rather than the Health Minister will make the decision about whether to make the drug available on the PBS. Only drugs that have been approved for marketing in Australia by the TGA are eligible for PBS funding.

The role of the TGA

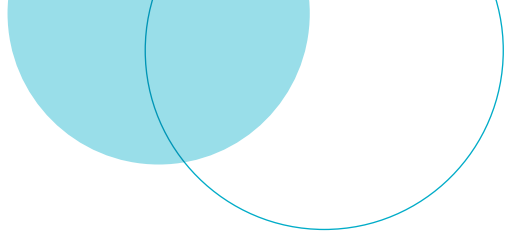
The TGA, which is part of the Commonwealth Department of Health, is responsible for administering the Therapeutic Goods Act 1989. This Act exists in order to ensure the quality, safety, effectiveness, and timely availability of therapeutic goods^{*} in Australia. Any product for which therapeutic claims are made must be included on the ARTG before it can be commercially supplied in Australia.

**a drug or medicine*

In order for a medicine to appear on the ARTG, a sponsor (i.e., the individual or company intending to supply the product) must lodge an application with the TGA. This application is accompanied by data that must show evidence of the safety, quality and effectiveness of the product. This submission is evaluated by the TGA and if approved, the therapeutic good is added to the ARTG and can be commercially supplied in Australia for an approved indication (medical condition or diagnosis).

The TGA cannot promote or seek the registration of therapeutic goods, as its role is to administer and regulate this process in response to submissions received from sponsors.

Nevertheless, the Act and its associated regulations provide a number of avenues through which 'unapproved therapeutic goods' (i.e., those not entered in the ARTG) may be lawfully supplied in Australia. In these circumstances, the TGA is unable to vouch for the quality, safety or efficacy of the unapproved product and its use is therefore regarded as 'experimental'. The Australian Government and its employees also cannot be rendered liable in respect of loss, damage or injury of any kind suffered by the person as a result of, or arising out of the use of that unapproved therapeutic good.



Avenues for accessing unapproved therapeutic goods include:

- The Special Access Scheme (Categories A and B) – refers to arrangements whereby individual patients may access unapproved therapeutic goods on a case-by-case basis. These arrangements vary according to a patient’s health status such that patients are classified as either Category A or Category B – the choice of classification rests with the prescribing medical practitioner.

www.tga.gov.au/hp/access-sas.htm

- Clinical trials.

www.tga.gov.au/industry/clinical-trials.htm

- Personal Importation Scheme – refers to arrangements whereby an individual may import, subject to specified conditions, unregistered therapeutic goods for their personal use (such as medicines) or for the use of a member of his/her immediate family.

www.tga.gov.au/personal-importation-scheme

- Authorised Prescriber Scheme – which allows approved medical practitioners authority to prescribe a specified unapproved medicine to patients who are identified by their medical condition. If a medical practitioner becomes an Authorised Prescriber they may prescribe the product to patients in their immediate care, within the indication specified, without seeking further approval from the TGA.

[www.tga.gov.au/how-become-
authorised-prescriber](http://www.tga.gov.au/how-become-authorised-prescriber)

In addition, the TGA also monitors products once they are on the market and are being used more widely in the community. It ensures manufacturers adhere to best practice standards (both in Australia and overseas) to maintain the high quality of drugs.



How does the TGA assess new drugs?

When applying for regulatory approval for a new cancer medication, the drug sponsor provides the TGA with comprehensive information about the drug, including the results from clinical trials as well as non-clinical data, such as information on the chemistry and purity of the drug. This information must show how effective and safe the medication is and what the patient benefits and risks are, as well as providing information to show that the drug has been manufactured to suitable quality standards.

It's important to note that the cost of a drug does not influence the TGA's decision whether or not to allow the medication to be registered in Australia.

www.tga.gov.au

Patients on clinical trials for breakthrough therapies have access to these new agents prior to approval by the PBAC.

The role of the PBAC and the PBS

The PBAC is an independent expert body appointed by the Australian government. Members include doctors, health professionals, health economists and a consumer representative. Its primary role is to recommend to the Health Minister which new medicines are cost effective at the price offered by the pharmaceutical company or sponsor.

Drugs considered cost effective by the PBAC may be listed on the PBS. If a drug is not considered cost effective by the PBAC it cannot be listed on the PBS. Drugs recommended for approval by the PBAC may not be listed on the PBS if the Australian Government and the pharmaceutical company cannot agree on issues such as price and conditions of supply.

Through the PBS, the government subsidises the cost of listed prescription medicines for all Australian residents and eligible overseas visitors.

Drug sponsors must make a submission to the PBAC for a drug to be considered for the PBS. The submission must include results from clinical trials showing the health benefits, the costs of the drug, and its side-effects compared to existing therapies.

When assessing a medicine for listing on the PBS, the PBAC takes into account:

- the medical conditions for which the medicine was approved for use in Australia
- how effective the medicine is compared to existing therapies
- how safe the medicine is compared to existing therapies
- the cost-effectiveness ('value for money') of the medicine compared to existing therapies
- patient and doctor feedback on their experience with the drug.

If the best drug for you is PBS-listed for your cancer, it will mean the drug is relatively affordable for you and easy for you to access, although some cancer drugs are restricted to particular patient groups and stages of disease.

www.pbs.gov.au

Frequently asked questions about the PBS

Q. Am I eligible for the PBS?

Australian citizens and permanent resident visa holders who hold a current Medicare card are eligible for the PBS. However, overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement (RHCA) are also eligible to access the scheme. Australia currently has RHCA with the United Kingdom, Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands, Finland, Norway, Belgium and Slovenia.

Q. How much will the drug cost?

The great thing about your drug being PBS-listed is you don't have to pay the full cost of the drug. The government pays a large amount for you. There are two payment rates for PBS-reimbursed medicines:

- for people in employment
- for concession card holders (pensioners, those on Centrelink/ other benefits).

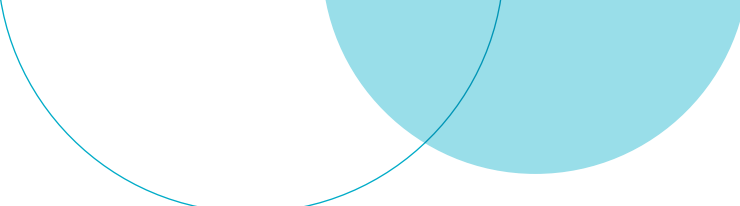
Veterans may have different funding arrangements. Actual costs are listed on the PBS website. Some pharmacies provide further discounts.


Q. Are there any restrictions on accessing PBS-listed drugs?

Yes, there are restrictions for specialised cancer drugs. Below are some restrictions you need to be aware of, although they may not affect you.

- If a drug is classed as a **'restricted medication'** you must meet the treatment indications.
- If your drug is classed as **'Authority Required'** your specialist needs approval from the Department of Human Services (Medicare) or the Department of Veterans' Affairs to prescribe you the drug. This usually occurs during your consultation. In some cases, your specialist only needs to include a prescription code. In other cases, they need to apply by telephone or online for approval.

Australian blood cancer patients need, expect and deserve timely and affordable access to new, innovative and effective drugs.

- 
- If your drug is classed as **‘Complex Authority Required’ (CAR)** your doctor must send an application to Medicare before prescribing you the drug. This application will include supporting evidence of your cancer diagnosis. You must sign the application to allow the government to collect information they require to authorise the use of the drug. After the initial prescription, your specialist will need to apply for the next prescription. It’s important you make an appointment with your specialist before your medication runs out. The government will stop providing the subsidised drug if it isn’t working to an agreed standard.
 - If your drug is an **‘S100 highly specialised drug’** only doctors who work with specialist hospital units can prescribe the medication (although a GP or non-specialist hospital doctor may prescribe the drug, under the guidance of your treating specialist, if you are in a maintenance phase of treatment). To receive the PBS subsidy for this drug, your script must be filled at the treating hospital (unless it’s a CAR drug).



*The PBS ensures all
Australians have access to
the best available medicines.*



Why is there a delay between clinical trials and new drugs being listed on the PBS?

The Australian health system provides us with a great degree of safety in accessing new medications. Independent decision-makers assess a new therapy to see that it works as well as its manufacturer claims it does, and is confident of the side-effect profile of each therapy. This does take some time.

When a drug successfully completes clinical trials, the pharmaceutical company that sponsors the drug must apply for regulatory approval from the TGA before marketing the drug.

In the past, most pharmaceutical companies applied for regulatory approval in the United States or in the large European markets before they applied for TGA approval in Australia, although a number of companies are now applying for approval in Australia at the same time as in Europe and North America. From a business point of view, Australia only constitutes around 1% of the international pharmaceutical market. The U.S. and Europe are much larger, and therefore more profitable.

Also, the rigorous regulatory approval process may also take longer here. The process for approving therapies is different in each country and may lead to variances in the time drugs are made available in each region. These are just a few reasons why there is often a delay between when new drugs are available overseas compared to Australia.

There is also often a further delay in drug availability between TGA approval and PBS listing. Historically, for cancer drugs, there has been a 14- to 31-month delay. A common reason is that pharmaceutical companies do not lodge the PBAC submission at the same time as the TGA submission. This can be for a number of reasons, and these reasons are not always transparent to the public.

Consumers provide unique and relevant perspectives that help measure the benefits of new medicines including quality of life and patient-reported outcomes.

Delays can also be due to negotiations around the pricing of the medication and/or uncertainty regarding clinical data provided to inform the PBAC decision-making process. For example, the PBAC often finds it difficult to recommend drugs that target rare cancers/cancer subtypes because there is not enough information available on the effectiveness and/or safety of the drug if there are very few patients who have been included in the trials. These cancers may only affect a small number of people and it is often difficult and costly for pharmaceutical companies to recruit enough patients in a reasonable period of time to run clinical trials for rare and less common cancers or cancer sub-types.

In some cases, a drug may never be listed on the PBS. This may be due to the PBAC not recommending the drug for listing. For example, the drug company and the PBAC or the Government may be unable to agree on the conditions of listing, such as price, or which patient groups or disease subtypes should be eligible for treatment. The most common reason the PBAC rejects PBS applications is due to the cost/benefit analysis.

Help get new drugs PBS listed

You can help the PBAC decide whether to list a particular blood cancer drug on the PBS.

When a drug is being considered for PBS listing, the PBAC wants to hear from people about their experience of the disease or condition, how it affects the way patients live their lives (quality of life), their experience of existing treatments including side-effects and why they think a new treatment would help them or others with the condition. In addition, if you have personal experience with the new drug (e.g., on a clinical trial or expanded access program), the PBAC is interested to know if it was effective in treating your cancer and if it improved your quality of life and/or treatment outcome.

The PBAC meets three times a year to consider new drug applications and advises the public about which medications are to be considered via its website. You can subscribe to receive PBS updates via email to keep up-to-date with the latest developments in drug approvals.

Contact the Leukaemia Foundation to find out how you can make a submission to the PBAC or go to the PBAC meeting agenda website.



Department of Veterans' Affairs (DVA)

The DVA issues health cards to veterans, war widows and their dependants to ensure their access to health care services. There are several DVA health card types, and each enables access to blood cancer therapies under the Repatriation Pharmaceutical Benefits Scheme (RPBS).

The therapies provided through this scheme include all drugs available on the PBS, plus a range of additional TGA-approved therapies. The RPBS may also fund, on a case-by-case basis, drugs not available on either the RPBS or the PBS.

To access therapies not available on the RPBS, your doctor must apply to the Veterans' Affairs Pharmaceutical Approvals Centre, providing details of your illness and the reason you need the therapy.

Applications submitted by this method are considered by the Repatriation Pharmaceutical Reference Committee, which advises the Repatriation Commission and Minister.

**[www.dva.gov.au/providers/
pharmacists#RPBS](http://www.dva.gov.au/providers/pharmacists#RPBS)**



What to consider when choosing the drug for you

Before making a decision with your specialist on the right treatment for you, we recommend asking your doctor for key information about each drug you are considering.

This information will help inform your decision, allowing you to weigh up the benefits versus the negatives.

There is no right or wrong answer. Your decision may be influenced by several factors, but it will be one that is the most suitable and works for you.

For example, you may prefer a drug that you can take at home or one that has fewer side-effects. Your prognosis, treatment costs, quality-of-life and side-effects are key factors that can affect your decisions.

If you feel you are running out of treatment options, speak to your doctor about having the genetics of your cancer analysed. Although still a developing diagnostic field of science, some services are available that match the genetic profile of a person's cancer to available drugs and clinical trials. This may identify a treatment option that has not yet been considered for you.

Suggested questions to ask your doctor about a drug:

- How will this drug benefit me compared to my other treatment options?
- What are the potential side-effects compared to my other treatment options?
- What will happen if I suffer serious side-effects as a result of the drug?
- Is the drug available to take as a tablet at home or do I need to visit the hospital or cancer centre for injections or infusions?
- How often will I need to take the drug?
- How much will the drug cost me?
- Why would/wouldn't you recommend treatment with this drug?
- Would I benefit from having my blood cancer genetically profiled?



Should I get a second opinion?

For many people, the course of treatment required to manage their blood cancer is the standard regimen. In some cases, there is more than one treatment option for a particular blood cancer. Each option may be with a different cancer target, have a different side-effect profile, and may be given into the vein (intravenously) or via a tablet.

It is reasonable for a person to directly ask their doctor if there are other options available outside of their treating centre. Some treatments or trials may not be available in your treatment centre and you may not automatically be made aware of options at other centres.

Before deciding on a treatment option, you can seek a second opinion – either to confirm your decision or to provide you with an alternative to consider. Seeking a second opinion is common and is not being disloyal or showing disrespect to your specialist. Many specialists consult each other on cases, so they are not offended if their patients do likewise.

When seeking a second opinion, many people like to ask their specialist or their GP to write them a referral to a specialist at the largest (or one of the largest) haematology treating hospitals in their state or territory.

This hospital will have a large, multidisciplinary team that is experienced in treating blood cancers and is likely to have a working knowledge of all treatment options. In addition, they also may be involved in clinical trials for new drugs.

Deciding on the best drug for your treatment

Ask your specialist to detail all the treatment options for treating your cancer, including new drugs unavailable through the Australian healthcare system. Follow the diagram for questions to ask your specialist, then turn to the relevant page for more information about the drug access pathway (and extra questions to ask). Unfortunately, there may not be any specific drug options for your particular circumstance. If this is the case, you should discuss what to do with your specialist.

Q: Is there a potentially better drug treatment available than the ones listed on the PBS or in standard practice?

Ask your specialist the key questions listed on page 24 about how this drug treatment differs from standard treatment, then decide if this new drug is likely to be a better treatment for you at this stage in your care.

No

Access a proven therapy subsidised on the PBS.

Yes

Q. Is the drug approved by the TGA?

Yes

Q. Can my doctor access it via the drug company free or at a reduced cost?

Yes

Turn to page 36.

Q. Is it accessible via a hospital Medicine Access Program (MAP)?

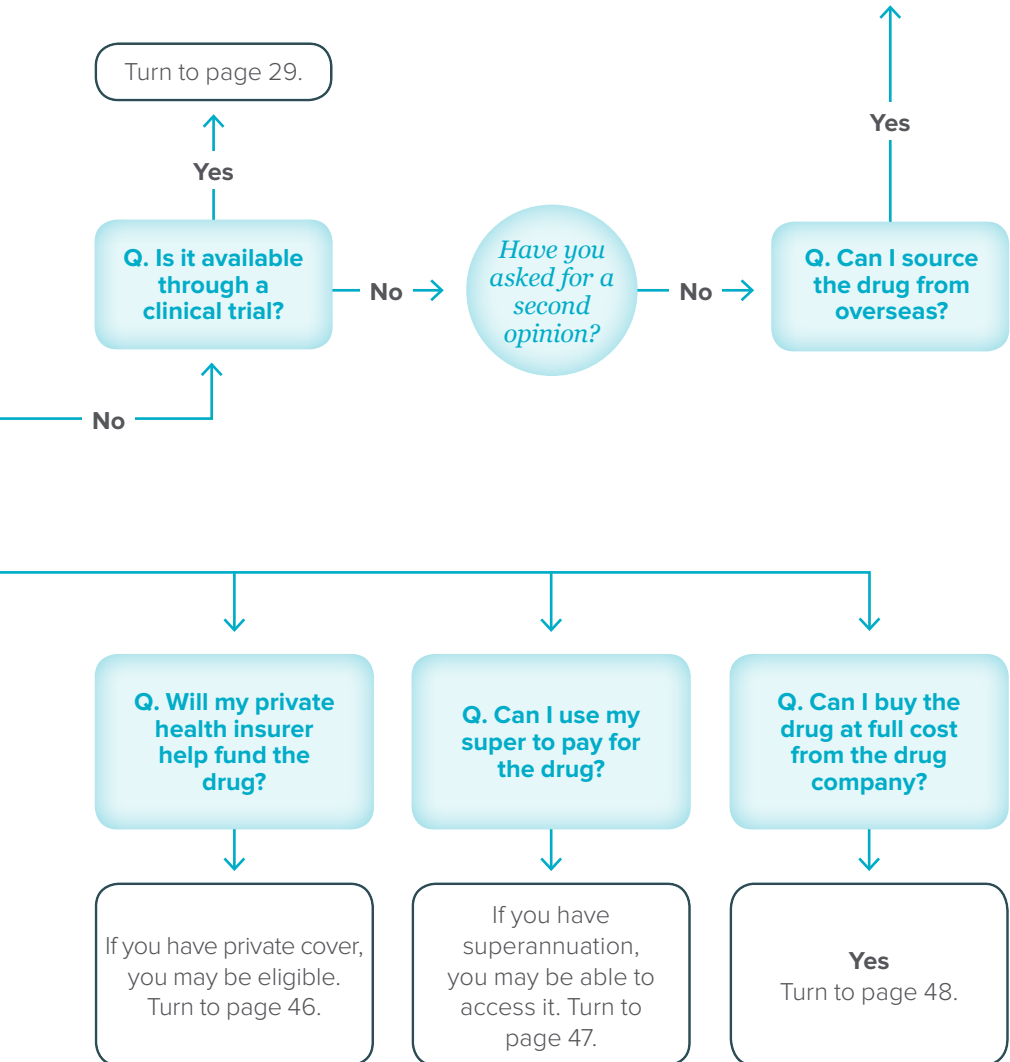
Yes

Turn to page 42.

You may be able to arrange to import the drug for your personal use under the Personal Importation Scheme. Further information is available from the TGA website.

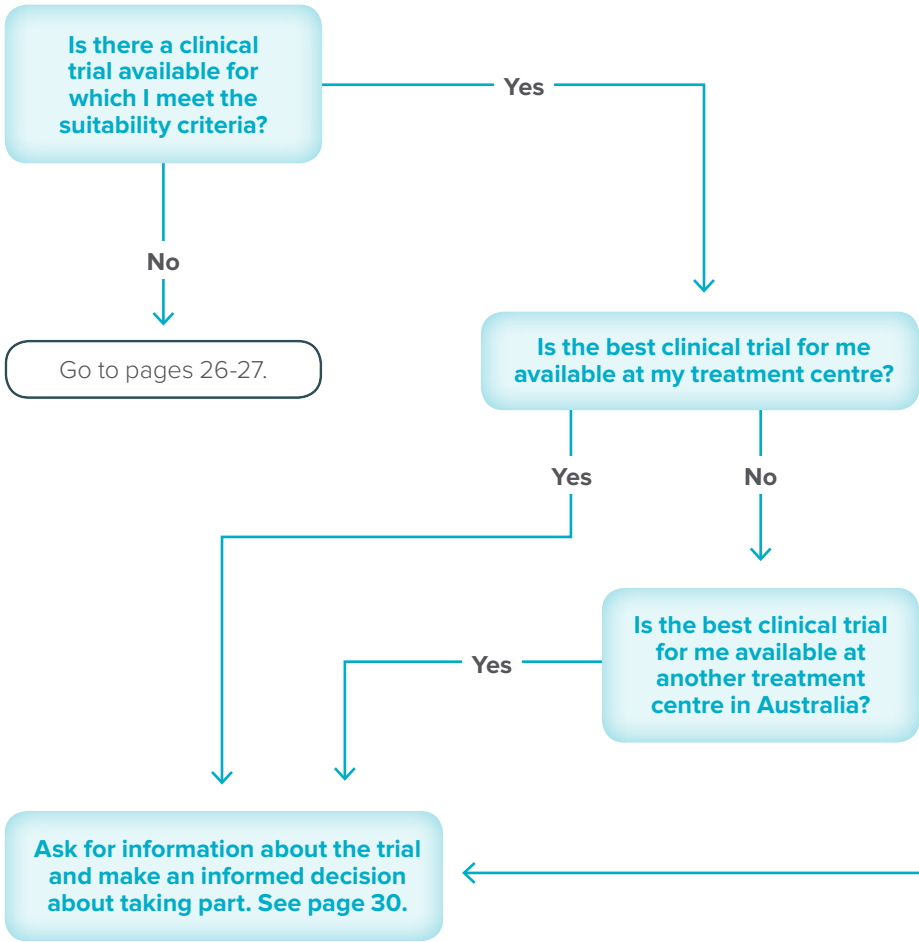
Under the Personal Importation Scheme, your doctor can apply for approval from the TGA through the Special Access Scheme to import the drug for you.

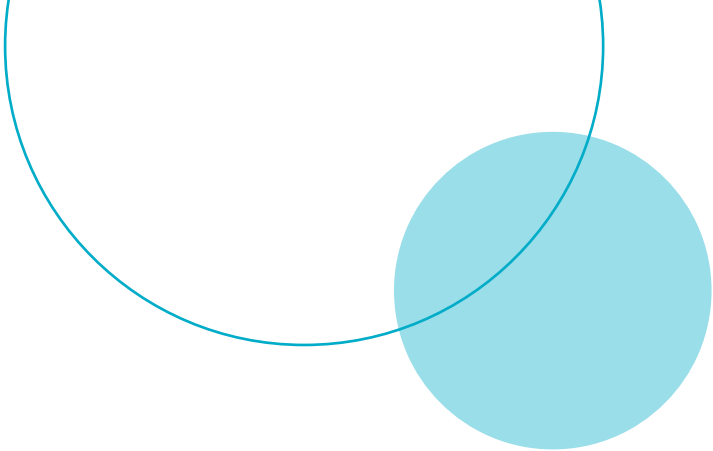
Turn to page 52.



Accessing the drug for me that is available through a clinical trial

Find out if a clinical trial, in which researchers are studying a new drug in humans, is the right pathway for you to access the best treatment. Talk through these questions with your specialist.





Is the best clinical trial for me available overseas?

No

Go back to pages 26-27.

No

Yes

No

Yes

Can your doctor gain access to the clinical trial for you – either here or overseas?

A clinical trial is a potential pathway for early access to a new blood cancer drug.

About clinical trials

A clinical trial is a research study involving human volunteers. Through these trials, clinicians assess a new drug or a new combination of drugs to see how safe and effective they are in humans. In most cases, the cancer drugs are compared against the current standard treatment used for that disease. Often, both the patients and the doctors are not told whether the patient is being treated with the research drug or not until an independent person analyses the data at a later stage.

The data gathered from clinical trials is necessary to work out how best to use the new drug, in whom, and for what particular condition. It is essential for the TGA's approval and the PBS listing of the medication or new drug combination.

Usually, a drug must successfully pass through three clinical trial phases before it can gain approval by regulatory authorities (such as the TGA in Australia).

Phase I and II trials involve a small number of volunteers and are designed to test the safety of the drug and how well patients can tolerate various dosages of the drug. Phase II trials also provide important information on how effective the research drug is in treating the disease. They are generally shorter in duration than Phase III trials.

Phase III trials are generally much larger, involving hundreds, sometimes thousands, of volunteers and may run over several years. However, in some cases Phase III trials may be for a smaller patient group and conducted over a shorter timeframe. Phase III trials are designed to measure the effectiveness of how the drug treats the disease, and the nature and likelihood of side-effects.



In recent times, regulators have approved certain drugs following Phase II trials, especially if the disease is a rare one or if it seems that the drug is having a much greater benefit than other available treatments.

All the drugs you have ever accessed have only been made available due to a large number of volunteers before you who were prepared to participate in clinical trials.

If you are interested in taking part in a clinical trial, the Leukaemia Foundation recommends you ask questions about the trial, what is required of you, the potential risks to your health, and the financial costs.

Find out more information about clinical trials

For up-to-date information about clinical trials, questions to ask and links to websites listing current trials, visit the international list of clinical trials, the Australian Government website on clinical trials, the Leukaemia Foundation website, and/or the Australasian Leukaemia & Lymphoma Group (ALLG) website:

- www.clinicaltrials.gov
- www.australianclinicaltrials.gov.au
- www.leukaemia.org.au/research/clinical-trials
- www.allg.org.au

You can also download the haematology clinical trials app, ClinTrial Refer ANZ. Search for it in your App Store or Google Play.

Just when I thought I was getting to the end of my treatment options, my doctor told me of a new clinical trial. Once again, I have hope.

Frequently asked questions about clinical trials

Q. Is the drug being tested in the clinical trial already licensed for use in Europe or the U.S., or available for use in Australia for a different disease?

If the drug is already licensed for use in both of these jurisdictions, you might consider that they have been deemed safe for use and they have proven their effectiveness. If the drug is available for use in Australia for a disease that is different to yours, you might consider that it is safe to use, but have less confidence in its effectiveness in your situation.

Q. How does it make a difference whether I participate in a Phase I, II or III trial?

Phase I and II trials have been developed to determine the safety of using a therapy. In Phase II it has already been deemed safe for use and has proven effectiveness in treating the disease. In Phase III trials, the new therapy is usually being compared to the best available therapy – but this is not always the case. The therapy options under evaluation are described in a trial's informed consent information. However, in some trials you may not know which treatment option you will receive; it may be the new therapy, the standard therapy or placebo, if no standard therapy is used. You should weigh up the risks with your treating team and make the best decision for you.

Q. Does my doctor have to be involved in a clinical trial for me to take part?

No, your doctor does not need to be involved for you to join. If your specialist isn't involved in the clinical trial, they will refer you to the specialist running the trial. This specialist will assess you to see if you meet the clinical trial criteria. If you do, they will provide you with all the information about the trial so you can make an informed decision about whether you still want to participate in the trial.

Q What if the clinical trial I want to join isn't at my treatment centre?

The process is the same: your specialist will refer you to the specialist running the trial. This specialist will assess you to see if you meet the clinical trial criteria. If you do, they may offer to enrol you in the trial.

You will have to attend the treatment centre running the trial and change to a new doctor to participate in a trial. This may involve additional travel and accommodation costs. You should ask the trial doctor about what costs are covered by participating in the trial. This may affect your decision.

Q. What if the best clinical trial for me is being run overseas?

You may be able to travel overseas to join the trial. If this is the case, you will have to pay for your treatment, travel, accommodation and medical costs. The costs of Australians taking part in overseas trials can often exceed \$100,000, plus the costs associated with travel and accommodation. You may be required to live overseas for the duration of the trial.

Your specialist can contact the international trial Chief Investigator to ask if you are eligible to be accepted onto their trial. It is then completely at the discretion of the Chief Investigator whether you are accepted onto the trial or not.

Q. Does a clinical trial involve more hospital visits?

It usually does. Being on a drug under evaluation, or drugs given in a new way can have some unexpected outcomes. For safety, it is important that you are closely monitored.

You will need to visit the hospital for your medication and you are likely to be asked to have additional tests and closer monitoring than the standard treatment. However, you will still receive ongoing medical care from a team of doctors, nurses, researchers, social workers and other health professionals.

The requirement for more frequent hospital visits is something to consider carefully if you have to travel a long distance to the clinical trial centre. Many clinical trials recognise the cost of this additional burden and are able to reimburse some of the travel and accommodation costs. If this is an issue for you, be sure to ask your doctor or the trial research nurse before signing up to the trial.

*Clinical trials
sometimes give access to
new therapies that have been
tested elsewhere but are not yet
available in Australia.*

Q. What does it cost to join a clinical trial in Australia?

In Australia, you don't have to pay any more to take part in a clinical trial over and above what you may pay for standard treatment. Any medical tests and medical care related to the trial are provided at no cost. Some studies compensate you for other expenses such as parking and travel. However, private health insurers often do not cover the costs related to a clinical trial, so you will need to check with your health care provider. If you experience side-effects from the drug, the costs of treating the side-effects are covered in the public health system. If you choose to pursue treatment in the private system, you may incur additional medical costs.

Q. What happens at the end of the trial – will I still be able to receive the drug?

There's no guarantee you will be able to continue receiving the drug when the clinical trial ends. However, for ethical reasons, pharmaceutical companies may continue treating trial patients who are benefiting from the treatment. For this reason, during the TGA and PBS approval processes, most pharmaceutical companies continue to make the drug available to clinical trial participants until it is readily available on the PBS.

The drug is usually supplied at no cost, for as long as you continue to benefit from the medication, and until it is PBS-listed. This will occur either through the trial, an expanded access program or a free-of-charge access program. If your cancer progresses or you experience too many side-effects, your specialist may recommend you stop treatment.

If the drug becomes listed on the PBS after you have started treatment, your doctor can apply to the PBAC for a 'grandfather' subsidy so that you can transition to treatment with the PBS-supplied drug stock. For more information: www.pbac.pbs.gov.au/appendixes/appendix-4.html.

Patient Assisted Travel Schemes (PATS) and clinical trials

If you are taking part in a clinical trial, be aware that none of the state or territory Patient Assisted Travel Schemes (PATS) provide a subsidy to cover rural, regional or remote patients travelling to a metropolitan hospital to take part in a trial. Even if the clinical trial covers the cost of the drug, rural, regional and remote patients must bear ongoing accommodation and travel expenses as well as the cost of other medications.

Questions about clinical trials to ask your specialist

- Is there a clinical trial for a drug which has data that indicates better outcomes for treating my disease than the standard available drugs?
- What is the purpose of this study? Has it been tested before?
- Am I eligible for the clinical trial(s)?
- Will participating in a trial affect my life insurance and medical insurance status?
- Is a suitable clinical trial available at my treatment centre (hospital) or would I need to travel to another centre in Australia or overseas?
- Can you talk me through the pros and cons of taking part in this clinical trial compared to taking the standard therapies?
- What would be required of me if I decided to participate?
- What are the costs associated with me participating in the clinical trial?
- Are there any travel, accommodation, parking or fare subsidies available to me if I participate in this trial?
- How long will the clinical trial last?
- Will I continue to receive the drug after the trial is completed?
- How will I know if the treatment is working?
- Can I still get access to regular medical care?
- What if I am given a placebo?
- What if I decide to pull out of the clinical trial? Can I do that at any time?
- Can you help me enrol in the clinical trial?
- If I join the clinical trial, will you remain as my treating specialist or would I need to change specialists to take part in the trial?
- If the trial is an overseas trial – is there any way to join this trial from Australia?

Accessing the drug for me with help from the pharmaceutical company

It may be possible to access new drugs at no cost or at a reduced cost through the pharmaceutical company that is marketing the drug. Work with your specialist to see if you can access the drug through this pathway.

Q: Will the pharmaceutical company make the drug available to you at no cost or at a reduced cost at your doctor's request?

Yes

No

- The pharmaceutical company is no longer providing the drug free/subsidised.
- The pharmaceutical company has limited stocks of the new therapy and these are only available for trial studies only.
- The drug is not available for Australian patients.
- Go back to the decision tool on page 26.

I'm not eligible for a clinical trial for this drug and the drug is not approved for my disease/condition.

Ask your specialist to contact the pharmaceutical company and ask them to supply you with the drug under their 'expanded access program' or compassionate access (if available).

The drug isn't approved by the TGA and there's no clinical trial.

The pharmaceutical company may be able to provide access under the TGA's special access provision. Your specialist will need to contact the pharmaceutical company.

Your specialist will also need to speak with their pharmacy and you may need approval from the hospital.

Alternatively, the pharmacy or hospital may be able to import the drug for you. Go to pages 50-51.

This drug has TGA approval but I can't afford it because it's not on the PBS.

The pharmaceutical company may make the drug available either free of charge or at a reduced cost.

Your specialist will need to contact the company. If they agree to make the drug available, your specialist will need to contact the pharmacy. Approval may be needed from the hospital.

Special rules about ongoing access are often associated with this method, e.g., access may only be given as long as you are showing a clinical response.

Many pharmaceutical companies make provision for providing access to new drugs at no cost or a reduced cost prior to them being listing on the PBS.

After the application has been submitted to the TGA for drug registration, pharmaceutical companies may consider requests to supply new drugs to patients free or at a reduced cost, on a case-by-case basis. The company may limit the number of treatment cycles they provide and/or the number of patients they make the drug available to before PBS listing. The companies have to abide by rules around this process as set out by the Australian Government and Medicines Australia.

It is becoming more common for pharmaceutical companies to offer a 'co-payment access' program. However, each company has different policies about access and you will need to ask your doctor to contact the company for cost information for your specific situation.

Frequently asked questions about drug access

Q. Can I call a pharmaceutical company and ask them about access to a drug?

Yes, anyone can ring the Medical Information line to ask questions, but only a doctor can submit a request for drug access.

I'm very glad of the pharmaceutical industry, which put me on a clinical trial at their expense.

Q. The best drug for me has TGA approval but there is no clinical trial for people in my situation in Australia. Will the pharmaceutical company supply me with the drug free of charge?

It depends entirely on the pharmaceutical company and any decisions it has made regarding the drug. However, many companies will consider requests on a case-by-case basis. Your doctor will need to contact the company directly and make a request (the company will not discuss the request with you). The company may choose to offer the drug at no charge, at a reduced cost, or at full price. The companies have to abide by rules around this process as set out by the Australian Government and Medicines Australia.

If the company agrees to make the drug available to you, your doctor will also need to speak to the pharmacy and your hospital.

Alternatively, since the company now has approval to market the drug in Australia, it may be available through your doctor and pharmacist but you may have to pay full price for it (which could run into several thousands of dollars per month).

Q. If the pharmaceutical company is not considering applying for PBS listing will it make the drug available in Australia?

If the pharmaceutical company is not considering applying for PBS listing of its drug, your doctor can still apply for access to it (each pharmaceutical company will have different processes for making the drug available or not). These drugs usually need to be purchased, but may be made available free in special cases.

Q. I wasn't eligible to take part in the Australian clinical trial for the best drug for me. Will the pharmaceutical company provide me with free access to the drug nevertheless?

Even if you weren't eligible for a clinical trial, pharmaceutical companies may provide access to the clinical trial drug through an 'expanded access program' or 'compassionate use program' if you have a serious or life-threatening condition. If the drug is not yet registered with the TGA for use within Australia, and the pharmaceutical company is willing to provide the drug through an expanded access/compassionate use program, your doctor will need to apply to the TGA under the Special Access Scheme in order to prescribe the drug to you. It is more common for the drug to be made available on a co-payment system, rather than free.

Q. I'm finishing a clinical trial. Will the pharmaceutical company continue to supply me with the drug when the trial ends?

There's no guarantee you will be able to continue receiving the drug when the clinical trial ends. However, for ethical reasons, pharmaceutical companies may continue treating trial patients who are benefiting from the treatment. For this reason, during the TGA and PBS approval processes, most pharmaceutical companies will continue to make the drug available to clinical trial participants.

The drug is usually supplied at no cost, for as long as you continue to benefit from the medication, until it is PBS-listed. This will occur either through the trial, an expanded access program or a free-of-charge access program. If your cancer progresses or you experience too many side-effects, your specialist may recommend you stop treatment.

If the drug becomes listed on the PBS after you have started treatment, your doctor can apply to the PBS for a 'grandfather' subsidy so you can transition to treatment with the PBS-supplied drug stock. For more information: www.pbac.pbs.gov.au/appendixes/appendix-4.html.

Q. If the pharmaceutical company won't provide me with the drug free of charge what do I do?

Pharmaceutical companies may not provide patients with free access to new drugs before they make an application for PBS listing. Even if the company has applied for PBS listing, it may not be in a position to supply you with the drug free. In this situation, you can look at buying the drug at full cost (see pages 48-49). If you have private health insurance, it may cover a small part of the cost of treatment (see pages 46-47). Your hospital MAP (see pages 42-45) may also part-fund your treatment.



Questions about accessing a drug to ask your specialist

- Is there a chance the pharmaceutical company would provide me with this drug at no cost or at a cheaper price?
- Will you call or write to the pharmaceutical company on my behalf?

The health system can feel so big and overwhelming. Sometimes I don't even know what questions to ask to get what I need.

Accessing the drug for me via a hospital Medicine Access Program (MAP)

If the best drug for you isn't listed on the PBS and you can't afford the cost of the drug, your treating hospital may agree to pay all or part of the cost of the drug through their Medicine Access Program (also known as Medicines Access Program), however, each hospital is different.

Q: Does my treating hospital have a Medicine Access Program?

Yes

Yes

Q. Will my specialist make a submission to the hospital to purchase the best drug for me via their MAP?

No

Do I choose to seek a second opinion?

Yes

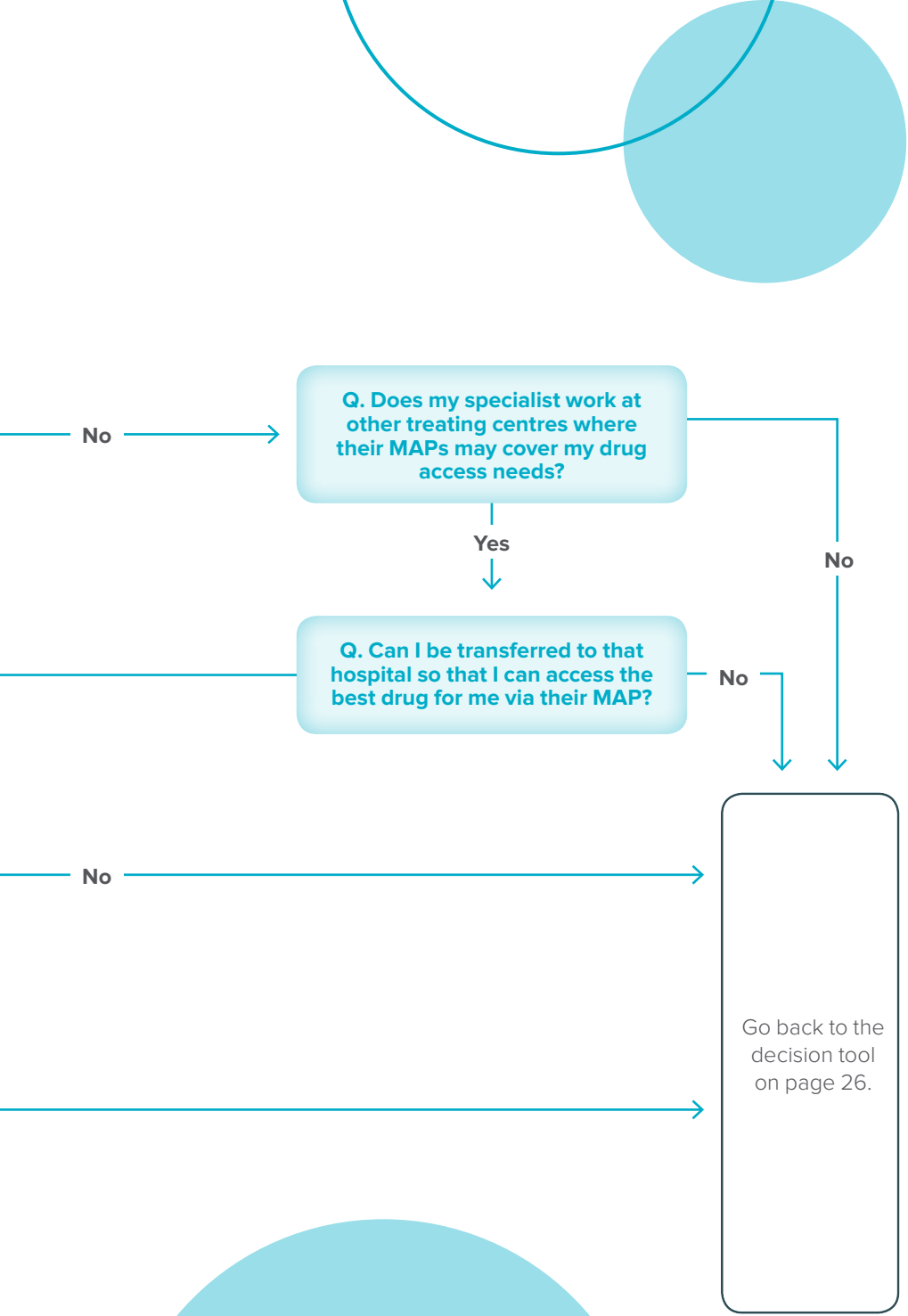
Yes

Q. Am I accepted onto MAP?

No

Yes

Start treatment



In Australia, some major public and private hospitals with specialist cancer treatment centres run a Medicine Access Program (MAP).

Through a MAP, some hospitals can provide specialist drugs not listed on the PBS to patients with a life-threatening disease.

The hospital pays for the drug from its operational budget. For this reason, the hospital must weigh up the potential patient benefits very carefully.

Access to drugs via a MAP is always conditional. Depending on the hospital's budget constraints and your response to the drug, they may choose to withdraw access to the drug at any time.

Every hospital's MAP operates differently. Drugs that are funded via a MAP can differ from hospital to hospital.

Frequently asked questions

Q. What drugs do hospitals include in a MAP?

Hospital MAPs include only TGA-approved, non-PBS drugs. Some hospitals have formal agreements with drug companies to supply the drugs in a MAP at a subsidised rate.

Q. How do I apply to a MAP?

To access a drug via a MAP, your doctor must recommend you to the hospital committee that is in charge of the program (usually a 'drugs and therapeutics committee' or an equivalent) that will decide if you are eligible.

Q. How do hospitals decide who's eligible for a MAP?

Each hospital has its own guidelines and policies for their MAP.

Generally, access to the program is decided on a case-by-case basis. The committee in charge of a MAP will take into account all the details of your situation, including other treatment options, the potential benefits to your health if you had access to the drug, your financial situation, and the hospital's budget constraints.



Q. How much will the drug cost me if it is provided through a MAP?

This is decided case-by-case. The hospital may pay for all or a portion of the cost of a drug made available via MAP. If your hospital refuses to fund your medication for you, be sure to ask if they would at least co-pay the cost of the drug with you, if you are financially able.

Q. Can I fill my prescription for a MAP drug at my local pharmacy?

No. MAP drugs are only made available from the hospital pharmacy.

Q. If I transfer to another hospital to access the best drug for me via its MAP, will I have to change doctors?

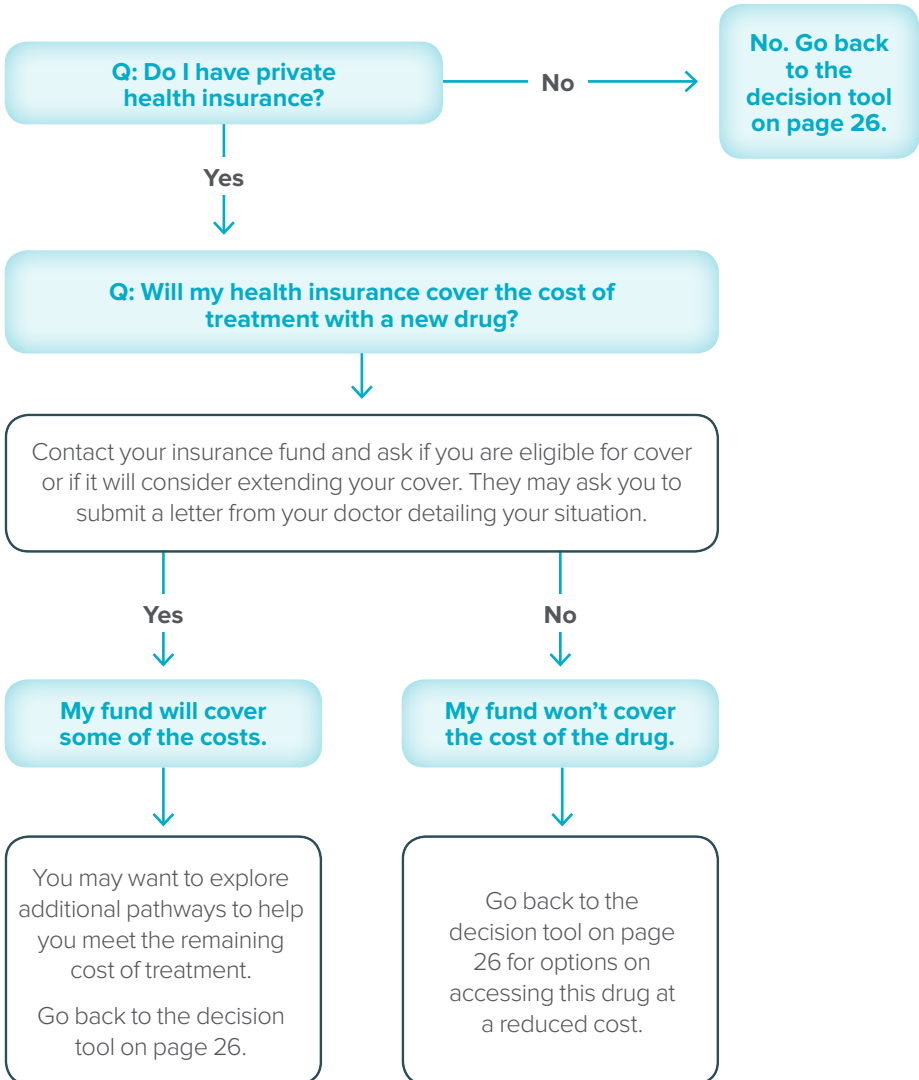
As a general rule, hospitals do not promote their MAP. If a hospital funds a particular drug on its MAP, it cannot afford to have patients coming from all over the country, utilising their MAP budget to access the therapy, when other hospitals are not funding it. For this reason, hospitals do not promote the drugs they fund, and only offer the therapies to patients who are normally treated at that centre. Many doctors work at several hospitals, so your doctor may be able to access MAP options from their various practices.

Questions about a MAP to ask your specialist

- Does my treating hospital have a MAP for my required therapy?
- (If it doesn't) Is there a nearby hospital that does have a MAP and, if so, can I transfer to this hospital?
- Will you apply to the hospital for me to enter that MAP?
- If the hospital cannot fully fund my therapy, is there an option for a co-payment method?

The drug for me may covered by private health insurance

Find out if your private health insurance will cover some of the cost of treatment with a drug not listed on the PBS. The amount covered for these therapies is often very limited.



If you have private health insurance, you may be able to claim some or all the cost of treatment with a new drug not listed on the PBS.

There are 36 private health insurance funds in Australia. If you belong to one of them, it may help cover the cost of a non-PBS listed drug.

Eligibility will depend on your fund and your level of coverage. You will also need to check if the drug is on your fund's list of exclusion drugs – these are drugs they will not cover.

Funds usually cap the amount they will reimburse for a new non-PBS drug.

Most funds require a co-payment for each prescription of a non-PBS drug. This is usually equal to the current 'non-concessional PBS co-payment' or about \$40 per prescription at the time this publication went to print.

In considering your claim, your fund may require a written request from your doctor detailing your situation.

Australian private health insurers only cover drugs with TGA approval. They do not cover the costs of taking part in a clinical trial.

To find out more, contact your private health fund directly or visit their website and search under 'frequently asked questions' or the membership guide.

Did you know?

Private healthcare insurance providers keep statistics on private hospital outcomes. You can ask your health insurance provider about private healthcare treatment centres that have the best health outcomes for your condition.

Tapping into your (or your partner's or parent's) superannuation

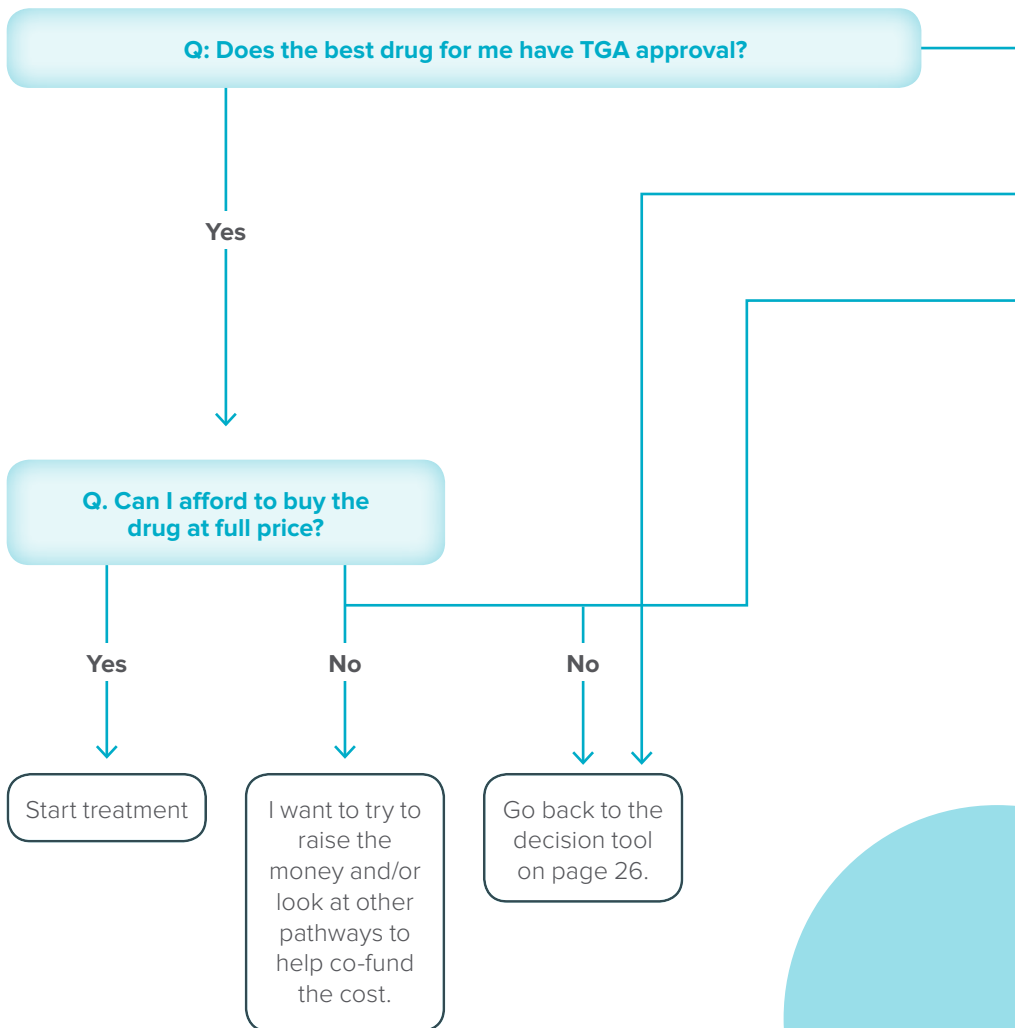
If you have an Australian superannuation fund, it may be possible to access this money to help pay for medical treatment with a new drug.

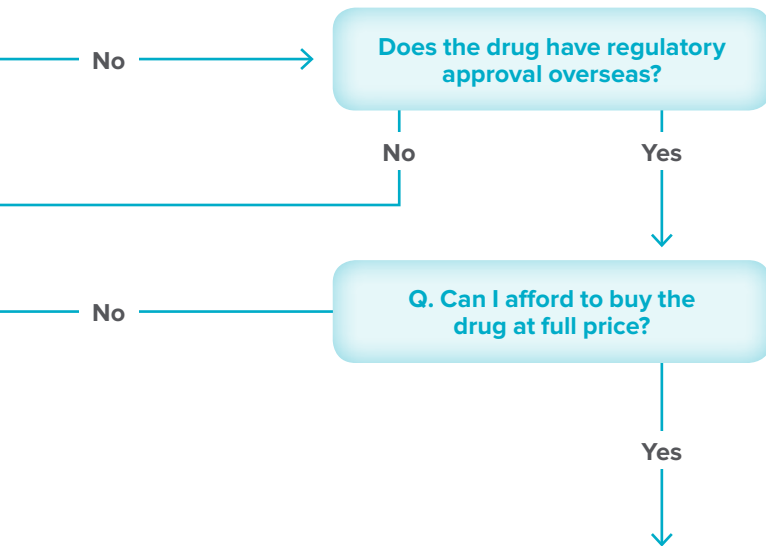
You may be eligible for an early release of your superannuation if you or your dependant has a life threatening illness and you or your dependant need assistance to meet the costs of medical treatment which is not readily available through the public health system or covered by insurance.

Talk to your financial advisor for more information or visit:

www.humanservices.gov.au/customer/enablers/centrelink/early-release-of-superannuation/compassionate-grounds-medical-treatment

Accessing the drug for me by buying and/or importing a drug at its full price





Your doctor can apply to the TGA Special Access Scheme for permission to import the medication for you.

Your treatment centre's pharmacy will then import the medication either directly from the pharmaceutical company or an international wholesaler. Many pharmacies will require payment for the medication prior to importation.

Once imported, a prescription from your specialist will be dispensed by the pharmacy for you.

Note: there is no GST payable on medications imported under the TGA Special Access Scheme.

In Australia, if a drug has TGA approval it is possible to purchase the drug from the pharmaceutical company if you have a prescription for it, and the pharmaceutical company is willing to make the product available.

If the best drug for you isn't approved for use in Australia yet, you can get special permission to buy the drug or import it from overseas if it's available for sale.

You also can look at importing TGA-approved drugs from overseas if they are cheaper.

a) Buying TGA-approved drugs at full price in Australia

If the best drug for you has TGA approval but is not listed on the PBS, your doctor can order the drug for your treatment from the pharmaceutical company. However, the drug won't be subsidised by the government, so you will have to pay the full cost.

b) Buying and/or importing drugs that are not TGA-approved

If a drug doesn't have TGA approval, you cannot legally buy it in Australia. However, the TGA has two avenues for Australians to obtain unapproved medicines: the 'Personal Importation Scheme' and the 'Special Access Scheme'.

Personal importation

It is important to first talk to your doctor about using this strategy to access drugs. Some therapies may interact with your other treatments, some therapeutic benefits may be untested in clinical trials, and the drug's side-effects could be dangerous or even fatal if you are not monitored by a health professional.

The TGA allows Australians to import an unapproved medicine without special TGA approval if: a family member or friend purchases the drug from the supplier on your behalf overseas and posts the medication to you, and the drug is for you or an immediate family member.

Under this scheme, you must not sell or supply the drug to anyone else and you can only import **three months' supply** (at the maximum dose recommended by the manufacturer) of the drug at one time.

There have been many examples of drugs that have been bought from overseas being counterfeit. They sometimes had limited drug, no drug, or even dangerous substances in the medication. Buyers should be very cautious about using this method of access, and should discuss this option in detail with their specialist before proceeding.

These restrictions also apply if you want to import a cheaper overseas version of a drug that is available in Australia.

- www.tga.gov.au/sites/default/files/access-personal-import-guidelines.pdf
- www.tga.gov.au/importing-mail-or-courier
- www.tga.gov.au/community-qa/buying-medicines-and-medical-devices-over-internet
- www.tga.gov.au/counterfeit-medicines-and-medical-devices

Can I import a drug if it's cheaper overseas?

It may be possible to buy your drug overseas at a cheaper price. Under the TGA Personal Importation Scheme, you can import up to three months' supply of the drug at any one time if someone you know overseas posts you the medicine (see FAQ in this section).

It's important to note that the TGA warns that there are risks in purchasing cheaper drugs from overseas. Drugs may not be manufactured to the same standards of safety, quality and efficacy. Sometimes medicines with the same name overseas can contain entirely different ingredients. Some overseas websites promote medicines that are either counterfeit or do not have the indicated amount of active ingredient.

You should discuss this option with your doctor before you make any overseas purchases. There can be great risks involved and you should ensure you are well informed of these risks first.

Special Access Scheme

The TGA Special Access Scheme (SAS) allows doctors to apply for permission to purchase unapproved drugs for patients, either through a pharmaceutical company in Australia or by importing the drug.

The arrangements provide for the import and/or supply of an unapproved drug for a single patient, on a case-by-case basis. Patients are grouped into two categories under the scheme:

- **Category A** patients are defined as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'. Medical practitioners can supply goods to very seriously ill patients without the approval of the TGA as long as the medical practitioner notifies the TGA within 28 days.

- **Category B** patients are all other patients who do not fit the Category A definition. Approval of an application to supply a product (provided on a form available at www.tga.gov.au/form/special-access-scheme#forms) is required from the TGA. Approval by the TGA is given on a patient-by-patient basis to reflect the needs of different patients. Wherever possible, applications should be made in writing.

With the exception of drugs of abuse, where the manufacture, possession, sale or use is prohibited by state or territory law, any unapproved therapeutic good can potentially be supplied via the SAS.

Applications under the SAS are made to the TGA by registered medical practitioners, preferably the treating doctor, who is best placed to determine the needs of the patient, including whether or not treatment with a particular product is required. Even if a patient asks to be treated with a particular unapproved product, a medical practitioner has the right to refuse to apply to obtain the product if he/she believes there is insufficient clinical justification to support the use of the product.

www.tga.gov.au/access-unapproved-therapeutic-goods-special-access-scheme

Frequently asked questions about buying/importing drugs

Q. How much do cancer drugs cost at full price?

It will vary, depending on the drug and the number of treatment cycles you need. However, whether you are buying the drug in Australia or from overseas, new blood cancer drugs are expensive.

Q. Do you have any suggestions for how to pay for this drug?

In a recent Leukaemia Foundation survey, people told us they covered the costs of buying new drugs by using their savings, superannuation, selling shares or assets, borrowing money, mortgaging their house, and/or fundraising.

In addition, people also told us they tapped into multiple drug access pathways to co-fund payment. For example: one woman was given a discount by the pharmaceutical company and her hospital MAP and private health insurer also contributed to the costs; the remaining costs were met through fundraising events held by her family.

It may be worthwhile talking with a financial advisor before making your final decision. You can also contact the Leukaemia Foundation for more information about your options.

Q. Is fundraising an option?

Yes, some people are successful at raising the money they need for treatment through community fundraising events and/or online crowd funding. However, there is no guarantee you will raise the money you need and it can be stressful and time consuming. Fundraising isn't an option that suits everyone.

Some organisations such as Rare Cancers Australia can assist with funds to access treatments but conditions apply.

Q. Should I check with the TGA before importing a drug personally?

Yes, in case the drug contains a substance prohibited under the Australian Customs (Prohibited Import) Regulations. If this is the case, you can only import the drug if your doctor applies to the TGA Special Access Scheme. Even if it is not a substance prohibited under the Customs (Prohibited Import) regulations, you are required to have a prescription by an Australian registered doctor. The TGA can provide advice about the potential dangers of importing medications.

Some Australian patients find themselves in a position where they must raise their own funds to access the best available medicines.

Q. How does my doctor apply to the TGA Special Access Scheme?

If you are seriously ill, your doctor can import a drug from overseas without the approval of the TGA as long as he/she notifies the TGA within 28 days, through the SAS Category A. However, if it is a substance prohibited under the Australian Customs (Prohibited Import) Regulations, an import permit is required. If you're not seriously ill, your doctor must apply to the TGA and fill in an SAS form. The TGA considers applications on a case-by-case basis.

Q. Will I need to pay import taxes and duties to Australian Customs?

If you are receiving the drugs via mail or courier, you will need to lodge an import declaration with Australian Customs only if the goods are worth more than \$1000. You may be liable for taxes and import processing charges. The drugs will not be delivered until the charges are paid.

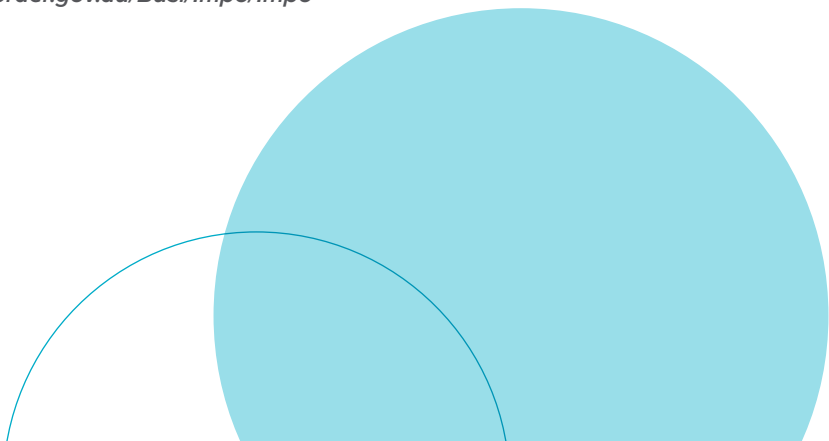
www.border.gov.au/Busi/Impo/Impo

Q. Do I have to declare anything to the Australian Quarantine & Inspection Service?

Yes, if the drug contains any material of biological origin (human, animal, plant or bacterial). You will need quarantine clearance before importing the drug.

Q. How can I verify the quality, safety and efficacy of a drug from overseas?

It is very difficult to verify the quality of therapies produced outside Australia. Some imported medications have been tested and found to have very little, or none, of the actual therapeutic drug purported to be in the medication. Speak with your doctor about the reputation of the supplier.



Questions about buying/ importing drugs to ask your specialist

- Is there a better drug available for me that we can consider purchasing in Australia or from overseas if it's cheaper or not available here?
- How much does the drug cost per treatment cycle and how many treatment cycles am I likely to need?
- If the best drug for me doesn't have TGA approval, are you willing to apply to the TGA Special Access Scheme for approval to purchase the drug for me?
- Should I look at personally importing the best drug for me?
- Can you advise me on the safety of the drug I want to import, and how to import it?



What about complementary medicines?

You may be considering adding complementary medicines to your treatment regimen. These include herbs, vitamins, minerals, nutritional supplements, homeopathic and certain aromatherapy preparations. It is not recommended for people to replace their treatment with complementary medicines as they have not been proven to be effective in fighting cancers.

Some complementary medicines are believed to help boost the immune system and overall health. As most blood cancers are actually cancers of the immune system, you need to understand the risks and benefits of 'boosting' it.

Some complementary medicines don't work well with cancer drugs. To ensure the best outcome for you, we recommend you talk to your doctor before you begin taking any complementary medicines.

Frequently asked questions about complementary medicines

Q. Does the TGA regulate complementary medicines?

Yes, the TGA regulates these medicines. However, while they must contain approved ingredients, most complementary medicines are considered low risk by the TGA. This means they are not checked for efficacy (i.e., whether they work for a particular condition) prior to being marketed in Australia.

www.tga.gov.au/complementary-medicine-regulation-basics



Q. What safety issues do I need to consider when taking a complementary medicine?

There are four main safety issues to consider.

- Critically, some complementary medicines can interact with your prescribed medication.
- Some individuals have increased the risk of their cancer spreading because they have ceased or not taken a prescription medicine to treat their cancer in favour of unproven therapies.
- There is a risk of contamination because the TGA monitors the manufacture of these medicines less stringently.
- There is often no clinical evidence for the complementary medicine having an impact on your disease. You can search for available clinical research information at: www.cochranelibrary.com.
- For more information about complementary therapy safety, visit www.nccih.nih.gov/health/safety.

Q. Can I import complementary medicines under the TGA Personal Importation Scheme?

Yes, you can. The same restrictions apply as for other medicines.

The TGA warns Australians not to order complementary medicines over the internet unless they know exactly what is in the preparation and have checked the legal requirements for its importation and use in Australia.

Useful contacts for financial advice

Treatment decisions that require a significant financial investment should not be taken lightly. There may be many emotional and physical pressures that can affect decisions at this time. Certain treatments may also affect a person's decision-making ability.

When assessing whether to invest in a new or trial treatment, you should seriously consider the possibility that the treatment may not be successful. In addition, you should also consider the impact of this investment on any dependants. You might like to listen to the advice of your trusted friends/family, your treating specialist, and consider seeking professional financial advice.

This listing provides contact details for organisations that provide help to patients, carers and their families. The information is correct at the time of printing but is subject to frequent changes and you should check the latest details.

Australian Government – Money Smart

www.moneysmart.gov.au

- Money management.
- Budget planner.
- Superannuation information.
- Information on credit, loans and debt.
- Helpful financial publications.

Australian Government – Department of Human Services

www.humanservices.gov.au

The central organisation for all government financial assistance. It is important to contact the correct department for assistance with your questions.

Centrelink

Centrelink information is now available through the Department of Human Services.

www.humanservices.gov.au

Telephone: **132 468**

Medicare

Information on Medicare is available on the Department of Human Services' website at

**[www.humanservices.gov.au/
customer/dhs/medicare](http://www.humanservices.gov.au/customer/dhs/medicare)**

Telephone: **132 011**

Early release of superannuation

For information and the application form 'Early Release of Superannuation on Specified Compassionate Grounds'.

**[www.humanservices.gov.au/
customer/services/centrelink/early-
release-of-superannuation](http://www.humanservices.gov.au/customer/services/centrelink/early-release-of-superannuation)**

Reciprocal Healthcare Agreements

For information on this program and participating countries.

www.humanservices.gov.au/customer/services/medicare/reciprocal-health-care-agreements

Telephone: **1300 131 060**

Email: **ERSBenquiries@humanservices.gov.au**

Claiming your superannuation account balance and disability insurance

This information is also available from the Department of Human Services.

www.humanservices.gov.au

Telephone: **1300 131 060**

Financial counselling

Financial counsellors may be contacted through Financial Counselling Australia for assistance with a variety of financial concerns.

www.financialcounsellingaustralia.org.au

Telephone: **1800 007 007**

Cancer Council

Cancer Council has a financial counselling service dedicated to supporting Australians with a cancer.

www.cancercouncil.com.au/get-support/legal-and-financial-assistance/

Telephone: **13 11 20**

Leukaemia Foundation of Queensland

Leukaemia Foundation of Queensland has a financial counselling service.

www.leukaemiaqld.org.au/our-services/support-and-advice/financial-matters/

Telephone: **07 3055 8233**

Banking Assistance

The Australian Bankers' Association provides a website with extensive information on financial literacy, consumer protection, managing your money, budgeting, the Code of Banking Practice, and how to resolve problems with your bank.

www.bankers.asn.au

Telephone: **02 8298 0417**

If you cannot resolve a dispute with your bank, you can contact the Financial Ombudsman Service at **www.fos.org.au** or telephone **1300 780 808**.

Department of Veterans' Affairs (DVA)

The DVA provides concession rates for PBS medicines for veterans, war-widows and their dependants through the Repatriation Pharmaceutical Benefits Scheme (RPBS). The DVA will consider providing additional financial support for medications not available on the scheme, if there is a clinical justification. Your doctor will need to make a request.

www.dva.gov.au

Telephone: **1800 552 580**



Abbreviations

ALLG	Australasian Leukaemia & Lymphoma Group
ARTG	Australian Register of Therapeutic Goods
DVA	Department of Veterans' Affairs
EAP	Expanded Access Program
FDA	Food and Drug Administration (U.S)
GP	General Practitioner
HTA	Health Technology Assessment
MAP	Medicine Access Program
MP	Member of Parliament
PATS	Patient Assisted Travel Schemes
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
RHCA	Reciprocal Health Care Agreement
RPBS	Repatriation Pharmaceutical Benefits Scheme
SAS	Special Access Scheme
TGA	Therapeutic Goods Administration



Making a donation



The Leukaemia Foundation is the only national not-for-profit organisation dedicated to the care and cure of patients and families living with leukaemia, lymphoma, myeloma and related blood disorders. The Foundation receives no ongoing government support and relies on the generosity of the community to support our Vision to Cure and Mission to Care.

How can I give?



ONLINE www.leukaemia.org.au



PHONE 1800 620 420



POST (complete this form or enclose cheque/money order and return)

The Leukaemia Foundation, Reply Paid 9954 in your capital city

Name	
Address	
Postcode	
Phone	Mobile
Email	

I enclose my gift of (please tick box)

\$30 \$50 \$75 \$100 \$250 Other \$

I wish to make a regular monthly donation of \$

Commencing on

/

/

*You can cancel at any time by calling 1800 620 420.

My cheque/money order made payable to the Leukaemia Foundation is enclosed.

I wish to pay with my credit card and my details are included below:

Visa MasterCard Diners Amex

Card Number

Expiry Date /

CVV

Cardholder's Name

Signature

Your privacy is important to us. That is why we treat your personal information with confidence. To learn more about how and why we collect and use any personal or sensitive information about you, please view our Notification Statement at www.leukaemia.org.au/privacy



Please send me a copy of the following booklets:

Leukaemia, Lymphoma, Myeloma, MDS, MPN and related blood disorders

Acute Lymphoblastic Leukaemia in Adults (ALL)

Acute Lymphoblastic Leukaemia in Children (ALL)

Acute Myeloid Leukaemia (AML)

Amyloidosis

Chronic Lymphocytic Leukaemia (CLL)

Chronic Myeloid Leukaemia (CML)

Hodgkin Lymphoma

Non-Hodgkin Lymphoma (NHL)

Myelodysplastic Syndrome (MDS)

Myeloma

Myeloproliferative Neoplasms (MPN)

Eating Well

Living with Leukaemia, Lymphoma, Myeloma, MDS, MPN and related blood disorders

Allogeneic Stem Cell Transplants (also called Bone Marrow Transplants)

Autologous Stem Cell Transplants

Young Adults with a Blood Cancer

My Haematology Diary

Accessing non-PBS Funded Blood Cancer Drugs in Australia

Books for children:

Tom has Lymphoma

Joe has Leukaemia

Ben's Stem Cell Transplant

Jess' Stem Cell Donation

Or information about:

The Leukaemia Foundation's Support Services

Giving at work

Monthly giving program

National fundraising campaigns

Volunteering

Receiving our newsletters

Leaving a gift in my will

Name

Address

Postcode

Phone

Mobile

Email



POST TO The Leukaemia Foundation, Reply Paid 9954 in your capital city



PHONE 1800 620 420



EMAIL info@leukaemia.org.au



FURTHER INFORMATION ONLINE www.leukaemia.org.au

This information booklet is produced by the Leukaemia Foundation and is one in a series on leukaemia, lymphoma, myeloma, MDS, MPN and related blood disorders.

Copies of this booklet can be obtained from the Leukaemia Foundation in your state by contacting us.

The Leukaemia Foundation is a not-for-profit organisation that depends on donations and support from the community. Please support our work.

December 2015

Contact us



1800 620 420



GPO Box 9954, IN YOUR CAPITAL CITY



info@leukaemia.org.au



leukaemia.org.au



Leukaemia
Foundation

VISION TO CURE
MISSION TO CARE