Raising *awareness*
Giving *support*
Searching *for a cure*

Lymphoma Australia

Frequently Asked Questions

Government consultation regarding new therapies for untreated CLL / SLL*

Chronic Lymphocytic Leukaemia and Small Lymphocytic Lymphoma

1. How do medicines get subsidised in Australia?

In Australia, medicines are registered for use by the Therapeutic Goods Administration, which means they are considered effective and safe for use in Australia. However, many medicines are expensive and need to be publicly funded before they are widely available for use in Australia.

A government advisory committee called the Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for deciding whether to recommend a medicine for public subsidy.

Once this committee provides a positive recommendation, it is then up to the Federal Government to list the medicine on the Pharmaceutical Benefits Scheme (PBS.)

This committee includes doctors, health professionals, health economists and consumer representatives.

When a new treatment is considered, there is an opportunity for those with the condition, as well as their carers and family, to have their say on how this medicine would benefit them.

2. What are the government committee considering?

The Pharmaceutical Benefits Advisory Committee (PBAC) is considering whether to recommend that new non-chemotherapy treatments should be added to the PBS for the treatment of people with newly diagnosed, untreated CLL / SLL.

If these medicines are approved, there will be chemotherapy free options available for the first time for Australians with untreated CLL/SLL on the PBS. Until now, oral treatments have been only available for people for people whose cancer has progressed following initial treatment.

3. Why is this important?

Currently, people who are newly diagnosed with CLL/SLL are commonly treated with chemotherapy. However, it is known that a proportion of people with particular mutations do not respond well to chemotherapy.

4. Who should submit to the PBAC consultation?

Anyone living with CLL/SLL (newly diagnosed, having undergone chemotherapy, or those whose cancer has progressed following treatment or does not respond to treatment) can respond to this consultation. The committee also welcomes submissions from carers and family members of those living with CLL/SLL.

5. What are the two treatments that are being considered for public funding?

The two treatment regimens being considered for public funding are:

- **Ibrutinib** (also known as **Imbruvica,** which has been available for several years as a once-a-day tablet for people with relapsed CLL/SLL or as compassionate access). This is now being combined with another oral treatment called **venetoclax** (also known as **Venclexta**). This new combination treatment is taken orally once a day for 15 months.

- **Acalabrutinib** (also known as **Calquence**), in combination with **obinutuzumab** (also known as **Gazyva**, administered as an infusion), for people with newly diagnosed, untreated CLL/SLL who are considered unsuitable for fludarabine-based chemoimmunotherapy.

6. Which treatment should I request the committee recommend funding for?

You can submit in favour of **one or both** treatment options. You may wish to submit in favour of one of the treatment options if you have been treated with ibrutinib or acalabrutinib after your cancer has spread following initial treatment. If you wish to submit in favour of both treatments, you will need to complete the online form twice as you can only select one medicine at a time.

Alternatively, you can download the online form, complete it (for one or both therapies) and email it to the committee. *See question 9for more information on how to submit.*

7. What is Lymphoma Australia advocating for?

Lymphoma Australia is advocating for both treatment regimens to be made available for people with newly diagnosed CLL/SLL. We believe that the choice of treatment should be a decision for the treating clinician in discussion with the person undergoing treatment.

The committee is considering the therapies for different groups. Ibrutinib plus venetoclax is being considered for all newly diagnosed CLL/SLL patients. It involves taking tablets once-a-day for 15 months and the tablets can be taken at home. It does not require an infusion.

Acalabrutinib plus obinutuzumab is being considered for some newly diagnosed people who are unlikely to respond to chemotherapy. It is an oral therapy (acalabrutinib) plus an infusion (obinutuzumab).

8. What should I say in my submission?

The PBAC welcomes input from patients, carers, health professionals, consumer groups or organisations and members of the public on medicines submitted for PBAC consideration.

The committee asks for you to be as specific as possible in your submission. The consultation asks about **your experience** of living with CLL/SLL, your experience of treatments, and **your expectations** regarding the impact that new treatments will have on your life, including what you see as the advantages and disadvantages of the new treatment. The committee disregards submissions that are duplicative and simply call for access to new therapies.

9. How can I have my say?

To have your say, go to the following link **before 21 September:**

https://ohta-consultations.health.gov.au/ohta/online-comments-to-pbac-november-2022

You can **either complete the survey online** – in which case you are only able to select one treatment (ibrutinib OR acalabrutinib). You can complete the only form twice if you want to submit in favour of both treatments.

Alternatively, you can **download the questions** from the link above *(see 'Related' at the bottom of the screen)* and complete the survey *(select ibrutinib or acalabrutinib or both)* and **email it to: commentsPBAC@health.gov.au**

The public consultation closes on 21 September.