

SUBMISSION TO PHARMAC ON TIME LIMITED VENETOCLAX AND IBRUTINIB AND VENETOCLAX AND OBINUTUZUMAB

On behalf of Chronic Lymphocytic Leukaemia Advocates of New Zealand (CLLANZ) we are submitting on the proposal to fund two treatment combinations for first line treatment of chronic lymphocytic leukaemia (CLL) – **Time limited Venetoclax and Ibrutinib and Venetoclax and Obinutuzumab**. We do so on behalf of CLL patients, their caregivers, and haematologists with a specialist interest in this field.

We welcome the fact that these treatments are being offered as frontline therapy to patients with CLL and see this as an important first step towards ensuring that CLL patients in New Zealand can receive the more advanced treatments that are available in almost all OECD countries, rather than having to suffer the rigours of FCR treatment and then relapse before becoming eligible for these new treatments.

Having both combinations of Ibrutinib and Venetoclax and Obinutuzumab with Venetoclax funded will now enable haematologists to deliver much safer and more effective CLL treatment as first-line treatment to patients at all ages.

There are a few recommendations that we would like to make — some are quite specific whilst other are broader concepts that we would like Pharmac to consider.

1. In terms of the wording for Venetoclax duration, it should be made clear that the 12 months on the full dose of venetoclax does not include the 5-week ramp up period.
2. We are also proposing that one section of the criteria for Ibrutinib + Venetoclax be modified thus:

the word *and* in the criteria should be changed to *and/or*. (*Indicated in red*). Our reasoning is set out further below.

Our suggested wording is as follows:

Person is currently on treatment with Ibrutinib and/or Venetoclax and met all of the following criteria prior to commencing treatment; or

Both of the following:

Person has previously untreated CLL; and

Ibrutinib is to be administered at a maximum dose of 420 mg daily for 3 (28 day) cycles

This would be in keeping with the Health Minister's wish that people who have been self-funding drugs are not disadvantaged. There are a few patients who have been funding single agent Ibrutinib who we feel should have the option of changing to time-limited Ibrutinib and Venetoclax.

3. There will be some patients who, because of the side effect profile of ibrutinib would be keen to self-fund a second-generation BTK inhibitor with the venetoclax. This should be allowed in keeping with the Minister's expressed wish that those people willing to self-fund should not be disadvantaged.

Therefore, for the section for Venetoclax approval would read

'Both of the following: 2.1. Person has previously untreated chronic lymphocytic leukaemia; and 2.2. Venetoclax is to be administered in combination with a BTK inhibitor'

This would result in no increased expenditure for Pharmac and indeed would lead to a cost-saving for the organisation. The data show that these second-generation BTKis are equally efficacious but are associated with less side effects – evidence supplied in the references below.

4. There may be some e.g. elderly patients who get clinically significant side effects with V+I or V+O It is therefore essential that Pharmac acknowledges that, where clinically significant adverse side effects have previously occurred, there is the option for a single agent continuous BTKi to be available through the NPPA system.

It would be most appropriate for this to be a second-generation BTKi, especially if the documented side effect is cardiac. We note that Ibrutinib isn't even registered in the USA because of its side effect profile, whereas Acalabrutinib is. We would like Pharmac to work with the companies who make the second-generation BTKi to look at funding these.

5. Finally, we request Pharmac to consider making V+I or V+O available as options alongside Venetoclax and Rituximab for people who have relapsed having had FRC as first-line treatment under the old funding arrangements. The feedback from especially rural patients is that travelling to the nearest hospital for Rituximab to be given intravenously can cause significant hardship with both patient and partner needing to take time off work etc. It would also mean that patients could be treated at home thus freeing up hospital facilities.
6. For relapsed patients, we assume the wording 'Individual has received at least one prior immunochemotherapy for CLL' prior to getting ibrutinib will be removed.

In closing we thank Pharmac for the opportunity to make a submission on this proposal. It represents major progress in the treatment of CLL patients in New Zealand and we welcome the introduction of these combination treatment regimens and thank all the staff for their hard work in making this possible.

Your sincerely.

Ruth Spearing

Chair

CLLANZ

1 March 2026

References-

1. Acalabrutinib/venetoclax (2025 randomised controlled trial, AMPLIFY)

<https://www.nejm.org/doi/full/10.1056/NEJMoa2409804>

2. Acalabrutinib/venetoclax was approved by FDA in February 2026:

<https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-acalabrutinib-venetoclax-chronic-lymphocytic-leukemia-or-small-lymphocytic-lymphoma>

3. Zanubrutinib/venetoclax (2025 single arm trial, SEQUIOA Arm D; not yet FDA approved):

<https://ascopubs.org/doi/10.1200/JCO-25-00758>