NCPE Assessment

Plain English Summary

July, 2026

Drug name: Acalabrutinib (pronounced uh-KA-luh-BROO-tih-nib), in combination with venetoclax with or without obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL)

Brand name: Calquence®

HTA ID: 25040

NCPE
National Centre for Pharmacoeconomics, Ireland

What is the NCPE?

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

How do we make our recommendations?

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

- Does the new medicine work better than other treatments available in Ireland?
- Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
- Does the new medicine reduce the need for patients to be hospitalised?
- Does the new medicine improve the quality of a patient's life over other treatments available in Ireland?
- Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients' day-to-day experience of living with a disease.

What is **acalabrutinib** used for?

Acalabrutinib is a cancer medicine used in adults to treat chronic lymphocytic leukaemia (CLL), a blood cancer affecting B cells (a type of white blood cell). For this assessment, acalabrutinib is used combined with another cancer medicine, venetoclax, with or without obinutuzumab (which is also another cancer medicine) in patients who have not had previous treatment for CLL. This assessment considered the use of this regimen in patients who do not have the 17p deletion or TP53 mutations.

Acalabrutinib may also be used on its own in patients with CLL who have had previous treatment, but this is not being assessed here.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding acalabrutinib, for this indication, unless its cost effectiveness (value for money) can be improved. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional criteria outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we concluded that it is not clear that the medicine works as well or better than other ways to manage this condition. The price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is very poor value for money.

The HSE considers a number of factors along with our recommendation when deciding whether to provide this medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data about acalabrutinib. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about acalabrutinib from the following online options:

- the NCPE Technical Summary Document
- Calquence® European Public Assessment Report (EPAR) – Calquence | European Medicines Agency (EMA)
- searching for acalabrutinib on our website (www.ncpe.ie);
- searching for acalabrutinib on the European Medicines Agency (EMA) website

(www.ema.europa.eu).

Please refer to the HSE website for updated information on the reimbursement status of this medicine.