National Centre for Pharmacoeconomics
NCPE Ireland

NCPE Plain English Summary

Drug name: Venetoclax *(pronounced: veh-NEH-toh-klax*) in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy.

Brand name: Venclyxto®

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 venetoclax used for?

Venetoclax is a cancer medicine used to treat adults with a blood cancer known as chronic lymphocytic leukaemia. Venetoclax can be used in combination with rituximab (another

cancer medicine) in patients who have received at least one previous treatment. It can also be used on its own in:

- patients with particular genetic changes (17p deletion or TP53 mutation) that make them unsuitable for chemo-immunotherapy (a type of cancer treatment). In these patients, Venclyxto is used when medicines known as B-cell receptor pathway inhibitors (ibrutinib and idelalisib) are not suitable or have failed.
- patients who do not have these genetic changes after treatments with chemo-immunotherapy and a B-cell receptor pathway inhibitor have both failed.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding venetoclax if 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 the medicine works as well or better than other ways to manage this condition. However, the price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is not value for money.

Next steps

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

Where can I get more information?

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

- the NCPE Technical Summary Document.
- Venclyxto® European Public Assessment Report (EPAR) – Medicine Overview or
- searching for the medicine name on our website (www.ncpe.ie);
- searching for the medicine name on the European Medicines Agency (EMA) website (www.ema.europa.eu).

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

Date published: November 2019