NCPE Assessment

Plain English Summary
September 2023

Drug name: Abemaciclib

(pronounced uh-BEH-muh-SY-klib) in combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence

Brand name: Verzenios®

HTA ID: 22020



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 abemaciclib used for?

Abemaciclib is a cancer medicine used to treat men and women with early breast cancer after surgery where the cancer has spread to the lymph nodes (node-positive) and who display other features indicating a higher risk for the cancer to come back. Abemaciclib can only be used when the cancer cells have certain types of receptor (called hormone receptors) on their surface (HR-positive) and do not produce abnormally large quantities of another receptor called HER2 (HER2-negative). It is used together with a hormonal medicine,

such as tamoxifen or an aromatase inhibitor. In women who have not yet reached menopause, a medicine called a luteinising hormone-releasing hormone agonist should also be given.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding abemaciclib 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 <u>criteria</u> 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 recommend that that the HSE consider providing this medicine if the HSE can agree a suitable price reduction with the pharmaceutical company. We believe the medicine may work 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 abemaciclib. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information abemaciclib the following online options:

- the NCPE Technical Summary Document
- Verzenios® European Public Assessment Report (EPAR) <u>Summary for the public</u>
- searching for abemaciclib on our website (<u>www.ncpe.ie</u>);
- searching for abemaciclib 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