NCPE Assessment

Plain English Summary

May 2024

Drug name: Pembrolizumab (pronounced: pem-broh-LIH-zoo-mab) for the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB or IIC melanoma and who have undergone complete resection.

Brand name: Keytruda®

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 pembrolizumab used for?

Pembrolizumab is a cancer medicine used to treat many different types of cancer. Pembrolizumab is mainly used in adults for cancers that are advanced, have spread or returned, are not responding to other treatments or cannot be removed by surgery. Pembrolizumab treatment can also be given before (neoadjuvant) or after (adjuvant) surgery. In this submission, we are considering the use of pembrolizumab to treat patients with early stage (Stage IIB or IIC) melanoma as adjuvant treatment (i.e. after surgery).

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding pembrolizumab 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 recommend that the HSE consider providing pembrolizumab if the HSE can agree a suitable price reduction with the pharmaceutical company. This is because 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, and we believe that the medicine is poor value for money.

Next steps

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

Where can I get more information?

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

- the NCPE Technical Summary Document
- The European Public Assessment Report for pembrolizumab (Keytruda®) – (EPAR)
- searching for pembrolizumab on our website (www.ncpe.ie)
- searching for pembrolizumab 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.