



National Centre for Pharmacoeconomics NCPE Ireland

NCPE Plain English Summary

Drug name: pembrolizumab (*pronounced: (pem-broh-LIH-zoo-mab)*), for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection.

Brand name: Keytruda ®

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?

The active substance in pembrolizumab is a monoclonal antibody which is a protein that has been designed to recognise and block a receptor ('target') called PD-1. Some cancers can make a protein (PD-L1) that combines with PD-1 to switch off the activity of certain cells of

the immune system (the body's natural defences) preventing them from attacking the cancer. By blocking PD-1, pembrolizumab stops the cancer switching off these immune cells, thereby increasing the immune system's ability to kill the cancer cells. Pembrolizumab is used to treat a number of different types of cancer, including melanoma, a type of skin cancer. Pembrolizumab may help to prevent the cancer from coming back after patients had surgery to remove the melanoma.

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

The NCPE has not received a Patient Organisation Submission associated with this submission.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we concluded that 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 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
- Pembrolizumab European Medicines Agency Medicines Overview Section - <https://www.ema.europa.eu/en/medicines/human/EPAR/keytruda#overview-section>
- 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.