



NCPE Plain English Summary

Drug name: Nivolumab (*pronounced nye-vol-ue-mab*) for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

Brand name: Opdivo®

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 nivolumab used for?

Nivolumab is a cancer medicine used to treat a number of different types of cancer, including melanoma, a type of skin cancer. Nivolumab is used to treat adults whose skin cancer has spread to other parts of the body or cannot be surgically removed. It is also used in patients

who have had surgery for the removal of skin cancer that has spread to lymph nodes or elsewhere in the body.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding nivolumab 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.

We have received a Patient Organisation Submission from Melanoma Support Ireland about nivolumab and shared it with the HSE. This submission will form part of the data that the HSE considers.

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 nivolumab. The HSE makes the final decision on reimbursement.

Where can I get more information?

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

- the [NCPE Technical Summary](#)
- Opdivo European Public Assessment Report (EPAR) – [Summary for the public](#)
- 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.

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