

NCPE Assessment

Plain English Summary

February 2024

Drug name: Nivolumab
(pronounced niv-ol-umab) as monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression $\geq 1\%$, who are at high risk of recurrence after undergoing radical resection of MIUC.

Brand name: Opdivo[®]

HTA ID: 22046

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 in a number of different cancers. Nivolumab can be used on its own and, for some cancers, it is used together with other cancer medicines such as chemotherapy. In this report we are considering nivolumab used on its own to help to prevent urothelial cancer (a cancer of the bladder and urinary tract) from coming back after patients have had treatment with surgery with or without chemotherapy.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding nivolumab unless 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 it is not clear that nivolumab works as well or better than other ways to manage this condition. The price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is very poor 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 Document
- Opdivo® European Public Assessment Report (EPAR) – [Summary for the public](#) or
- searching for nivolumab on our website (www.ncpe.ie);
- searching for nivolumab 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