



NCPE Plain English Summary

Drug name: Nivolumab (pronounced: nye-vol-ue-mab) plus ipilimumab (pronounced: ih-pih-LIH-myoo-mab) for the treatment of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy.

Brand name: Opdivo[®] plus Yervoy[®]

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 and ipilimumab used for?

Nivolumab is a cancer medicine that is mainly used when cancers are advanced, unresectable (cannot be removed by surgery), have spread to other parts of the body (metastatic), or when other treatments do not work. In some cancers, it is only given to patients whose tumours are described as microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR). In this assessment, we are considering the use of nivolumab in combination with ipilimumab (another cancer medicine), to treat colorectal cancer that has

spread, and that is determined to be MSI-H or dMMR. The place in therapy of this treatment is for patients who have already received a combination of chemotherapies, including a fluoropyrimidine-based therapy (a specific type of cancer medicine) for metastatic disease.

What recommendation has the NCPE made to the HSE?

We recommend that the HSE consider not providing this medicine unless the HSE can agree a suitable price reduction with the pharmaceutical company. 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 not providing this medicine (nivolumab plus ipilimumab) unless 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, we cannot clearly assess how much better this medicine is compared with other ways of managing this condition. This is because an added benefit has not been sufficiently shown in the data presented by the pharmaceutical company. 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. The HSE considers a number of factors along with our recommendation when deciding whether to provide this medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013.

Next steps

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

Where can I get more information?

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

- The NCPE Technical Summary Document.
- Opdivo® European Public Assessment Report (EPAR) [Summary for the Public](#).
- Searching for nivolumab or ipilimumab on our website (www.ncpe.ie).
- Searching for nivolumab or ipilimumab 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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