

## Active substances set

**Search phrase:** nivolumab

Below you will find a list of active substances registered by the European Medical Agency (EMA) in the last 15 years, recommended by the European Society of Clinical Oncology (ESMO) and their reimbursement status in the country.

### Malignant stomach cancer

#### Nivolumab

Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy is indicated for the first-line treatment of adult patients with HER2-negative advanced or metastatic gastric, gastro-oesophageal junction (GEJ) or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS)  $\geq 5$ .

 **REIMBURSEMENT  
WITH RESTRICTIONS**

 **ESMO**

### Colon and rectum cancer

#### Nivolumab

Nivolumab in combination with ipilimumab is indicated for the treatment of adult patients with mismatch repair deficient or microsatellite instability-high colorectal cancer in the following settings: - first-line treatment of unresectable or metastatic colorectal cancer; - treatment of metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy.

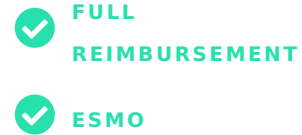
 **REIMBURSEMENT  
WITH RESTRICTIONS**

 **ESMO**

### Liver cancer

## Nivolumab

Hepatocellular carcinoma (HCC) Nivolumab in combination with ipilimumab is indicated for the first-line treatment of adult patients with unresectable or advanced hepatocellular carcinoma.



## Tracheal, bronchus, and lung cancer

### Nivolumab

Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy is indicated for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumours have no sensitising EGFR mutation or ALK translocation. Nivolumab as monotherapy is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer after prior chemotherapy in adults.

Nivolumab in combination with platinum-based chemotherapy is indicated for the neoadjuvant treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression  $\geq 1\%$ .



## Kidney cancer

### Nivolumab

Nivolumab as monotherapy is indicated for the treatment of advanced renal cell carcinoma after prior therapy in adults.

Nivolumab in combination with ipilimumab is indicated for the first-line treatment of adult patients with intermediate/poor-risk advanced renal cell carcinoma.

Nivolumab in combination with cabozantinib is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma.



## Malignant bladder cancer

## Nivolumab

Urothelial carcinoma Nivolumab in combination with cisplatin and gemcitabine is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma. Nivolumab as monotherapy is indicated for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy. Adjuvant treatment of urothelial carcinoma Nivolumab as monotherapy is indicated 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.

 **FULL REIMBURSEMENT**

 **ESMO**

## Hodgkin's disease

### Nivolumab

Nivolumab as monotherapy is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.

 **REIMBURSEMENT WITH RESTRICTIONS**

 **ESMO**