205

Nivolumab 10mg/mL Concentrate for Solution for Infusion

Prescriber Criteria: Consultant Haematologist
Consultant Oncology

Inpatient use:

- ***Melanoma***

- As monotherapy or in combination with ipilimumab for the treatment of advanced (unresectable or metastatic) melanoma in adults.
- As monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

- ***Non-small cell lung cancer (NSCLC)***

- In combination with ipilimumab and 2 cycles of platinum-based chemotherapy for the first-line treatment of metastatic NSCLC in adults whose tumours have no sensitising EGFR mutation or ALK translocation.
- As monotherapy for the treatment of locally advanced or metastatic NSCLC after prior chemotherapy in adults.
- In combination with platinum-based chemotherapy for the neoadjuvant treatment of resectable NSCLC at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥1%.

- ***Malignant pleural mesothelioma (MPM)***

  In combination with ipilimumab for the first-line treatment of adult patients with unresectable MPM.

- ***Renal cell carcinoma (RCC)***

- As monotherapy for the treatment of advanced RCC after prior therapy in adults.
- In combination with ipilimumab for the first-line treatment of adult patients with intermediate/poor-risk advanced RCC.
- In combination with cabozantinib* for the first-line treatment of adult patients with advanced RCC

- ***Classical Hodgkin lymphoma (cHL)***

  As monotherapy for the treatment of adult patients with relapsed or refractory cHL after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin (BV)*.

- ***Head and neck squamous cell carcinoma (HNSCC)***

  As monotherapy for the treatment of recurrent or metastatic HNSCC in adults progressing on or after platinum-based chemotherapy.

- ***Urothelial carcinoma***

- As monotherapy for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy.
- As monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥1%, who are at high risk of recurrence after undergoing radical resection of MIUC.

- ***Mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) colorectal cancer (CRC)***

  In combination with ipilimumab for the treatment of adult patients with dMMR or MSI-H CRC after prior fluoropyrimidine-based combination chemotherapy.

- ***Oesophageal carcinoma***

- In combination with ipilimumab for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) with tumour cell PD-L1 expression ≥1%.
- In combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic OSCC with tumour cell PD-L1 expression ≥1%.
- As monotherapy for the treatment of adult patients with unresectable advanced, recurrent, or metastatic OSCC after prior fluoropyrimidine- and platinum-based combination chemotherapy.
- In combination with fluoropyrmidine- and platinum-based combination chemotherapy in adult patients with HER2-negative advanced or metastatic oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5.
- As adjuvant treatment of adult patients with oesophageal cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy.

- ***Gastro-oesophageal junction cancer***

- In combination with fluoropyrimidine- and platinum-based combination chemotherapy in adults with Her2-negative advanced whose tumours express PD-L1 with a CPS ≥5.
- As adjuvant treatment of adult patients gastro-oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy.

- ***Gastric cancer***

  Licensed in combination with fluoropyrimidine- and platinum-based combination chemotherapy in adult patients with HER2-negative advanced gastric cancer whose tumours express PD-L1 with a CPS ≥5.

* Only nivolumab will be given because cabozantinib and BV are not available on the Government Formulary List.

Duration of Approval:
1 year