158

Pembrolizumab 25mg/mL Concentrate for Solution for Infusion

Prescriber Criteria: Consultant Haematologist
Consultant Oncologist

Inpatient use:

- ***Melanoma***

- As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents aged 12 years and older.
- As monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB, IIC or III melanoma and who have undergone complete resection.

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

- As monotherapy for the first-line treatment of metastatic NSCLC in adults whose tumours express PD-L1 with a ≥ 50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations.
- In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of metastatic non-squamous NSCLC in adults whose tumours have no EGFR or ALK positive mutations.
- In combination with carboplatin and paclitaxel for the first-line treatment of metastatic squamous NSCLC.
- As monotherapy for the treatment of locally advanced or metastatic NSCLC in adults whose tumours express PD-L1 with a ≥ 1% TPS and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumour mutations should also have received targeted therapy before receiving pembrolizumab.

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

  As monotherapy for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory cHL who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.

- ***Urothelial carcinoma***

- As monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy.
- As monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10.

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

- As monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy for the first-line treatment of metastatic or unresectable recurrent HNSCC in adults whose tumours express PD-L1 with a CPS ≥ 1.
- As monotherapy for the treatment of recurrent or metastatic HNSCC in adults whose tumours express PD-L1 with a ≥ 50% TPS and progressing on or after platinum-containing chemotherapy.

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

- In combination with axitinib* or lenvatinib* for the first-line treatment of advanced RCC in adults.
- As monotherapy for the adjuvant treatment of adults with RCC at increased risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

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

- *Colorectal cancer (CRC)*

  As monotherapy for adults with MSI-H or dMMR CRC in the following settings:
  - first-line treatment of metastatic CRC
  - treatment of unresectable or metastatic CRC after previous fluoropyrimidine-based combination therapy.
- *Non-colorectal cancers*

  As monotherapy for the treatment of the following MSI-H or dMMR tumours in adults with:
  - advanced or recurrent endometrial carcinoma, who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation
  - unresectable or metastatic gastric, small intestine, or biliary cancer, who have disease progression on or following at least one prior therapy.

- ***Oesophageal carcinoma and HER2-negative gastroesophageal junction adenocarcinoma***

  In combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma, in adults whose tumours express PD-L1 with a CPS ≥ 10.

- ***Gastric or gastro-oesophageal junction adenocarcinoma***

  In combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥1.

- ***Triple-negative breast cancer (TNBC)***

- In combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery for the treatment of adults with locally advanced, or early-stage TNBC at high risk of recurrence.
- In combination with chemotherapy for the treatment of locally recurrent unresectable or metastatic TNBC in adults whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease.

- ***Endometrial carcinoma***

  In combination with lenvatinib* for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation.

- ***Cervical cancer***

  In combination with chemotherapy with or without bevacizumab, for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express PD-L1 with a CPS ≥ 1.

* Only pembrolizumab will be given because axitinib and lenvatinib are not available on the Government Formulary List.

Duration of Approval:
1 year