Active substances set

Search phrase: pembrolizumab

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

Pembrolizumab	Pembrolizumab as monotherapy is indicated for the treatment of the following microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) tumours in adults with unresectable or metastatic gastric, small intestine, or biliary cancer, who have disease progression on or following at least one prior therapy. Pembrolizumab, in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction (GEJ) adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1. Pembrolizumab, in combination with fluoropyrimidine and platinum -containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2 -negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1.	REIMBURSEMENT WITH RESTRICTIONS ESMO

Colon and rectum cancer

Pembrolizumab	Pembrolizumab as monotherapy is indicated for adults with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in the following settings: - first-line treatment of metastatic colorectal cancer; - treatment of unresectable or metastatic colorectal cancer after previous fluoropyrimidine-based combination therapy.	REIMBURSEMENT WITH RESTRICTIONS ESMO

Tracheal, bronchus, and lung cancer

Pembrolizumab	Pembrolizumab, in combination with platinum -containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults. Pembrolizumab as monotherapy is indicated for the adjuvant treatment of adults with non -small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum-based chemotherapy. Pembrolizumab as monotherapy is indicated for the first-line treatment of metastatic non-small cell lung carcinoma in adults whose tumours express PD-L1 with a ≥ 50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations. Pembrolizumab, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma in adults whose tumours have no EGFR or ALK positive mutations. Pembrolizumab, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of metastatic squamous non-small cell lung carcinoma in adults. Pembrolizumab as monotherapy is indicated for the treatment of locally advanced or metastatic non-small cell lung carcinoma 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.	REIMBURSEMENT WITH RESTRICTIONS ESMO

Malignant breast cancer

Pembrolizumab

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

REIMBURSEMENT WITH RESTRICTIONS

ESMO

Kidney cancer

Pembrolizumab

Pembrolizumab, in combination with axitinib, is indicated for the first-line treatment of advanced renal cell carcinoma in adults. Pembrolizumab, in combination with lenvatinib, is indicated for the first-line treatment of advanced renal cell carcinoma in adults. Pembrolizumab as monotherapy is indicated for the adjuvant treatment of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

REIMBURSEMENT WITH RESTRICTIONS

ESMO

Malignant bladder cancer

Pembrolizumab

Pembrolizumab, combination with enfortumab vedotin, is indicated for the first-line treatment of unresectable or metastatic urothelial carcinoma in adults. Pembrolizumab as monotherapy is indicated for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherap. Pembrolizumab as monotherapy is indicated 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.

REIMBURSEMENT WITH RESTRICTIONS

ESMO

Hodgkin’s disease

Pembrolizumab	Pembrolizumab as monotherapy is indicated for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.	NO REIMBURSEMENT ESMO