

Active substances set

Search phrase: Malignant bladder cancer

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 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.	NO REIMBURSEMENT ESMO
Nadofaragene firadenovec	Nadofaragene firadenovec is indicated as monotherapy for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours.	NO REIMBURSEMENT ESMO

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 ≥ 1%, who are at high risk of recurrence after undergoing radical resection of MIUC.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Atezolizumab	Atezolizumab as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC): - after prior platinum-containing chemotherapy, or - who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression ≥ 5%.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Avelumab	Avelumab is indicated as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy.	FULL REIMBURSEMENT ESMO
Enfortumab vedotin	Enfortumab Vedotin, in combination with pembrolizumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy. Enfortumab Vedotin as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor.	FULL REIMBURSEMENT ESMO
Erdafitinib	Erdafitinib as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting.	FULL REIMBURSEMENT ESMO
Durvalumab	Muscle Invasive Bladder Cancer (MIBC) Durvalumab in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by Durvalumab as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC).	FULL REIMBURSEMENT ESMO