

**Nivolumab in the treatment of advanced or metastatic bladder cancer in patients contraindicated for treatment with cisplatin**

**Approved in COHERE meeting on 4 September 2018**

Recommendation by COHERE		Nivolumab is included in the range of services of the Finnish health care system as second-line or later therapy for the treatment of locally advanced or metastatic bladder cancer in adult patients who have previously been treated with a platinum-based cytostatic agent. A precondition for this recommendation is a discount in price, and the treatment can be implemented with the PD-1/PD-L1 inhibitor that has the lowest cost at the time, taking into account the cost of procurement and administration.
Grounds	Severity and prevalence of the health issue	Metastatic bladder cancer (urothelial carcinoma) is a serious disease that can lead to death. According to Fimea's estimate, 50–70 patients a year in second-line or later therapy ( $\geq 2$ ).
	Treatment options	Vinflunine or taxane can be used as second-line or later therapy in patients whose disease progresses after treatment with platinum. In addition to nivolumab, two PD-1 inhibitors, atezolizumab and pembrolizumab are indicated for second-line therapy.
	Effectiveness	It might be justified to use nivolumab as second-line or later therapy for locally advanced or metastatic urothelial carcinoma in patients who have been previously treated with platinum-containing agents. Compared to the existing treatment options, the expected added clinical benefit is limited. The benefit seems to manifest itself as a long-term response to therapy in patients who do respond to therapy (20–24% of patients).
	Safety	The use of nivolumab is associated with adverse effects generally related to the functioning of the immune system, such as pneumonitis, hepatitis, hyperthyroidism or hypothyroidism. The occurrence of adverse effects with nivolumab is lower than in therapy with cytostatic agents.
	Costs and impact on the budget	The pharmaceutical costs of a single course of therapy (14 days) at list price is approximately EUR 3,500. Second-line or later therapy: If 50–70 patients a year were given nivolumab or another PD-1/PD-L1 inhibitor, it would increase costs by EUR 1.8–3.8 million.
	Ethical and financial aspects as a whole	The intention is to share all available healthcare resources fairly among the people who need health care services. In particular, the adoption of expensive new methods is also assessed from the perspective of the available financial resources of the society and the health care system. The discounts given on the price of PD-1/PD-L1 inhibitors vary by hospital. It is justified to treat advanced bladder cancer with the drug that has the lowest cost at the time, taking into account the cost of procurement and administration.
Collection of further evidence	Data on the number of patients treated, duration of treatment and outcomes (as far as possible) should be collected and reported routinely.	
Diagnosis (ICD-10) codes	C67 Bladder cancer	
Background information and references	COHERE memorandum, Evaluation report by Fimea	