PALVELUVALIKOIMA
Tjänsteutbudet | Choices in health care

Atetzolizumab in the treatment of advanced or metastatic bladder cancer in patients contra-indicated for treatment with cisplatin
Approved in COHERE meeting on 4 September 2018

Recommendation by COHERE		Atetzolizumab is not included in the range of services of the Finnish health care system as first-line therapy for the treatment of locally advanced or metastatic bladder cancer in patients contraindicated for treatment with cisplatin. Atetzolizumab is included in the range of services of the Finnish health care system as second-line or later therapy (≥2) 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	The prognosis of an advanced or metastatic bladder cancer (urothelial carcinoma) is usually poor. Fimea estimates that the number of patients receiving atetzolizumab or PD-L1 inhibitors might be 5–10 patients per year in first-line therapy and 50–70 patients per year in second-line or later therapy.
	Treatment options	Patients who are contraindicated for cisplatin therapy are treated with a combined treatment of carboplatin with gemcitabine (first-line therapy). In addition to atetzolizumab, pembrolizumab is indicated for first-line therapy. Vinflunine or taxane can be used as second-line or later therapy in patients whose disease progresses after treatment with platinum. In addition to atetzolizumab, two PD-1 inhibitors, nivolumab and pembrolizumab are indicated for second-line therapy.
	Effectiveness	*First-line therapy (in patients contraindicated for treatment with cisplatin)* Significant uncertainty exists concerning the efficacy of atetzolizumab as first-line therapy, and the research evidence is not sufficient to determine the medical justifiability. *Second-line or later therapy (after therapy with a platinum-containing based cytostatic agent)* Compared to the existing treatment options, the expected added clinical benefit is modest. The benefit seems to manifest itself as a long-term response to therapy in patients who do respond to therapy.
	Safety	The use of atetzolizumab is associated with adverse effects generally related to the functioning of the immune system, such as pneumonitis, hepatitis, hyperthyroidism or hypothyroidism. Patients treated with atetzolizumab have reported fewer adverse reactions than those treated with a cytostatic agent
	Costs and impact on the budget	The pharmaceutical costs of a single course of therapy (21 days) at list price is approximately: EUR 5,000 – First-line therapy: If 5–10 patients a year were given atetzolizumab or another PD-1/PD-L1 inhibitor instead of carboplatin-gemcitabine, it would increase costs by EUR 0.22–0.60 million. – Second-line or later therapy: If 50–70 patients a year were given atetzolizumab 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