Alerts and Recalls

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
June 25, 2018	
Pembrolizumab, atezolizumab	FDA is restricting the use of pembrolizumab and atezolizumab for patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy. These changes are the result of decreased survival associated with the use of pembrolizumab or atezolizumab as single therapy compared with platinum-based chemotherapy in clinical trials to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PD-L1). The labels of both drugs have been revised to reflect the restricted indications. The tests used in the trial to determine PD-L1 expression are listed in Section 14 of each label. FDA is reviewing the findings of ongoing analyses and will communicate new information about the PD-L1 assays and indications as it becomes available. In patients already receiving pembrolizumab or atezolizumab who are responding to treatment and are cisplatin ineligible, continuation of treatment could be considered, regardless of PD-L1 status. FDA has not changed the indications of pembrolizumab or atezolizumab for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant treatment. Patients taking pembrolizumab or atezolizumab for other approved uses should continue to take their medication as directed by their health professional.
(Keytruda, Tecentriq—Merck, Genentech)	
FDA restricts use of agents because of efficacy concerns	

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