Generic Name:
Pembrolizumab, atezolizumab
Trade Name:
Keytruda, Tecentriq
Company:
Merck, Genentech
Notes:

FDA has updated the prescribing information for pembrolizumab and atezolizumab to require use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible. Two different companion diagnostic tests were approved by FDA, one for use with pembrolizumab (Dako PD-L1 IHC 22C3 PharmDx Assay [Dako North America]) and one for use with atezolizumab (Ventana PD-L1 [SP142] Assay (Ventana Medical Systems)].

The second-line indications in urothelial carcinoma for both drugs remain unchanged.

The tests used in the trials to determine PD-L1 expression are listed in Section 14 of each drug label.

Medication Monitor Categories:
Alerts and Recalls