Keytruda® (pembrolizumab) – Expanded indication

- On June 19, 2018, the FDA approved Merck's Keytruda (pembrolizumab), for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10], or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
    - Previously, Keytruda was approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.
    - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
    - Keytruda is also indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

- Keytruda is also indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, microsatellite instability-high cancer, gastric cancer, and cervical cancer.

- The expanded indication for Keytruda was demonstrated in KEYNOTE 52, a study of 370 patients with locally advanced or metastatic urothelial carcinoma who were not eligible for cisplatin-containing chemotherapy. A total of 110 patients had tumors that expressed PD-L1 (CPS ≥ 10). The major efficacy endpoint was objective response rate (ORR).
    - The ORR was 47% (95% CI: 38, 57) in the 110 patients with tumors that expressed PD-L1.
    - The duration of response was not reached in this group of 110 patients (range in months: 1.4+, 17.8+).

- The recommended dosage of Keytruda in patients with urothelial cancer is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression.
    - Refer to the Keytruda drug label for dosing for all other indications.