Keytruda® (pembrolizumab) – Updated indication

- On August 31, 2021, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy.
    - Previously, Keytruda was approved 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 (CPS ≥10) as determined by an FDA-approved test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
    - The FDA has converted this indication from an accelerated to a full (regular) approval.
- The updated indication was based on the KEYNOTE-361 study, which evaluated Keytruda as monotherapy and in combination with chemotherapy for the first-line treatment of patients with advanced or metastatic urothelial carcinoma who were eligible for platinum-containing chemotherapy. The study did not meet its pre-specified dual primary endpoints of overall survival or progression-free survival, compared with standard of care chemotherapy.
    - This label update also follows the FDA's Oncologic Drugs Advisory Committee meetings held earlier this year as part of an industry-wide evaluation of indications based on accelerated approvals that have not met their post-marketing requirements. As previously announced, members voted (5 to 3) in favor of maintaining the accelerated approval of Keytruda for its first-line bladder indication.
- Keytruda is also approved for urothelial carcinoma for the following uses:
    - 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
    - Treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.
- In addition to urothelial carcinoma, Keytruda is also approved for melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, MSI-H or dMMR colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.
- The recommended dose of Keytruda for use in urothelial carcinoma is 200 mg intravenously every 3 weeks or 400 mg every 6 weeks. Keytruda should be administered until disease progression, unacceptable toxicity, or for up to 24 months.

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- Refer to the Keytruda drug label for dosing for its other indications.

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