### BL-3 and BL-4

**Internal request:**
In response to the FDA approval of pembrolizumab for the treatment of patients with BCG-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy, the panel voted on the addition of pembrolizumab for this indication.

**External request:**
Submission from Merck & Co. Inc. (01/08/20) to include pembrolizumab as a treatment option for patients with BCG-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Based upon review of the data in the noted reference and the recent FDA approval, the panel consensus was to include pembrolizumab as an option for patients with BCG-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. This is a category 2A recommendation.

- U. S. Food and Drug Administration. Prescribing Information. KEYTRUDA® (pembrolizumab) injection, for intravenous use. 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125514s067lbl.pdf

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