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Date of Request: April 15, 2021
NCCN Guidelines Panel: Bladder Cancer

On behalf of Gilead Sciences, Inc., I respectfully request the NCCN Bladder Cancer Guidelines Panel to review the enclosed data in consideration of guidelines placement for TRODELVY® (sacituzumab govitecan-hziy).

Specific Changes Requested within the Guidelines and Compendium

Please consider recommending the preferred use of sacituzumab govitecan-hziy for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. These changes pertain to Guidelines Section BL-G and the related discussion section.

FDA Clearance

TRODELVY is a Trop-2-directed antibody and topoisomerase inhibitor conjugate approved on April 13, 2021 for the treatment of adult patients with locally advanced or mUC who have previously received a platinum-containing chemotherapy and either PD-1 or PD-L1 inhibitor.[1] This indication is approved under accelerated approval based on tumor response rate and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Rationale

Sacituzumab govitecan-hziy is a new treatment option that will fulfill an unmet need for heavily-treated patients with mUC who develop resistance or intolerance to prior therapies. In support of the proposed change, sacituzumab govitecan-hziy was granted fast-track designation by the FDA. The FDA approval was based on results from the TROPHY-U-01 study. TRODELVY was initially approved for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease. TRODELVY was granted full approval by the FDA in this indication on April 7, 2021 based on the Phase 3 ASCENT study.

Clinical Summary

FDA approval for sacituzumab govitecan-hziy was based on an international, multi-center, open-label, Phase 2 study (TROPHY-U-01; NCT03547973) in patients with locally advanced or mUC who had received previous platinum-based and anti-PD-1/anti-PD-L1 therapies.[1] Treatment with sacituzumab govitecan-hziy (N = 112) resulted in an objective response rate (ORR) by independent review assessment of 27.7% (95% CI, 19.6–36.9), with 5.4% of patients experiencing complete response and 22.3% of patients experiencing partial response. Median DOR by independent review assessment among patients treated with sacituzumab govitecan-hziy was 7.2 months (95% CI, 4.7–8.6). Among the safety analysis population (N = 113), the most common adverse events (AEs) of any grade (incidence ≥25%) among patients treated with sacituzumab govitecan-hziy were diarrhea (72%), fatigue (68%), neutropenia (67%), nausea (66%), alopecia (49%), anemia, decreased appetite (41%), constipation (34%), vomiting (34%), and abdominal pain (31%). Fatal

AEs occurred in 3.6% of patients treated with sacituzumab govitecan-hziy, and 10% of patients permanently discontinued sacituzumab govitecan-hziy due to AEs.

The references listed below are in support of this proposed change. Thank you for your review and consideration.

Supporting Documentation

1. Immunomedics. Trodelvy® (sacituzumab govitecan-hziy) Prescribing Information. April, 2021.
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer V.2.2021. Accessed March 22, 2021.

Sincerely,

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Gilead Sciences, Inc.