



Submitted by:
Neda Nguyen, PharmD
US Medical Affairs
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Phone: (925) 297-9120
Email: nguyen.neda@gene.com
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NCCN Guidelines Panel: Bladder Cancer

Dear NCCN Bladder Cancer Guidelines Panel:

Request:¹

On behalf of Genentech, Inc., this submission letter is provided to inform you of a recent change for the use of Tecentriq® (atezolizumab), with respect to the **NCCN Guidelines® for Bladder Cancer, Page BL-G 3 of 7.**

Rationale:^{1,2}

On March 7, 2021, Genentech announced that it is voluntarily withdrawing the U.S. indication for the use of Tecentriq for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.

Genentech's decision to withdraw this indication was done in consultation with the FDA, and is part of an industry-wide review of accelerated approvals for drugs with confirmatory trials that have not met their primary endpoint(s) and have yet to gain regular approval. This withdrawal does not impact Tecentriq's approved indications for first-line therapy in cisplatin-ineligible mUC or for other cancer types in the U.S. (NSCLC, SCLC, HCC, TNBC, and Melanoma).

A revised version of the Tecentriq U.S. Prescribing Information that reflects the revocation of this indication is currently pending. For further information, please refer to the associated Healthcare Provider Letter available at: <https://www.gene.com/medical-professionals/medicines/tecentriq>.

FDA Clearance:

- Tecentriq is FDA-approved for use in Urothelial Carcinoma (UC), Non-Small Cell Lung Cancer (NSCLC), Small Cell Lung Cancer (SCLC), Triple-Negative Breast Cancer (TNBC), Hepatocellular Carcinoma (HCC), and Melanoma.
- Please refer to the product prescribing information for the full FDA-approved indications and safety information, available at: https://www.gene.com/download/pdf/tecentriq_prescribing.pdf.

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If you have any questions, please contact us at the phone number and email provided above.

Respectfully submitted,
Neda Nguyen, PharmD

References

1. Tecentriq® [package insert]. Genentech, Inc.; South San Francisco, CA. February 2021.
2. Genentech, Inc. (2021, March 07). *Genentech Provides Update on Tecentriq U.S. Indication in Prior-Platinum Treated Metastatic Bladder Cancer* [Press release]. Retrieved from <https://www.gene.com/media/press-releases/14898/2021-03-07/genentech-provides-update-on-tecentriq-u>