

**IMPORTANT
PRESCRIBING
INFORMATION**

May 2021

Subject: Tecentriq® (atezolizumab) indication in prior-platinum treated, locally advanced or metastatic bladder cancer has been removed from United States Prescribing Information

Dear Health Care Provider:

This letter is to inform you about an important change to the Tecentriq (atezolizumab) label for the treatment of prior-platinum locally advanced or metastatic bladder cancer.

If you have received the previous letter (dated March 2021), the purpose of this communication is to inform you that the prior-platinum locally advanced or metastatic urothelial carcinoma (mUC) indication has now been formally withdrawn and the Tecentriq United States Prescribing Information (USPI) has been updated to reflect this.

Indications

Genentech, a member of the Roche Group, announced on Monday March 8, 2021 that they are voluntarily withdrawing the U.S. indication for Tecentriq for the treatment of locally advanced or metastatic urothelial carcinoma (mUC) in patients whose disease has progressed during or following platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy. This decision was made in consultation with the U.S. Food and Drug Administration (FDA) as part of an industry-wide review of accelerated approvals with confirmatory trials that did not meet their primary endpoint(s) and have yet to attain regular approval.

This change does NOT impact other approved Tecentriq indications in the US, including for patients with cisplatin-ineligible mUC whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 5\%$ of the tumor area) or for patients with mUC who are ineligible for any platinum-containing chemotherapy, regardless of PD-L1 status.

Prescriber Action

A [Dear Patient Letter](#) is enclosed. If you haven't done so, please share this letter with your patients who are currently receiving Tecentriq for the treatment of prior-platinum advanced bladder cancer and discuss the impact of the withdrawal of this indication on their treatment plans.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events or side effects related to the use of these products to Genentech at 1-888-835-2555.

Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Company Contact Point

You may also contact the Genentech Medical Communications department at 1-800-821-8590 if you have any questions about the information contained in this letter or the safe and effective use of Tecentriq.

This letter is not intended as a complete description of the benefits and risks related to the use of Tecentriq. Please refer to the enclosed [full prescribing information](#) and [medication guide](#).

Sincerely,

A handwritten signature in black ink that reads "Jamie Freedman". The signature is written in a cursive style with a long horizontal flourish at the end.

Jamie Freedman MD, PhD
Head of U.S. Medical Affairs