



Imfinzi® (durvalumab) – Indication withdrawal

- On February 22, 2021, [AstraZeneca announced](#) the [voluntary withdrawal](#) of the Imfinzi (durvalumab) indication for previously treated adult patients with locally advanced or metastatic bladder cancer. This decision was made in consultation with the FDA.
- In May 2017, Imfinzi was granted accelerated approval based on tumor response rates and duration of response data from Study 1108, a Phase 1/2 trial that evaluated the safety and efficacy of Imfinzi in advanced solid tumors, including previously treated bladder cancer. Continued approval was contingent on results from the DANUBE Phase 3 trial in the 1st-line metastatic bladder cancer setting, which did not meet its primary endpoints in 2020.
- AstraZeneca is notifying healthcare providers of this update. Patients with metastatic bladder cancer currently being treated with Imfinzi should consult with their healthcare provider regarding their ongoing care.
- This withdrawal does not impact other approved Imfinzi indications (non-small cell lung cancer and small cell lung cancer).



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.