# FDA approves Tecentriq as first ctDNA MRD-guided adjuvant treatment for MIBC

Market Event Summary

Arshiya Bhatt, Ph.D. | May 2026

# FDA approval paves the way for precision treatment in adjuvant MIBC

## Background

- Despite curative-intent surgery and perioperative chemotherapy, approximately half of muscle-invasive bladder cancer (MIBC) patients experience disease recurrence following cystectomy.
- Current adjuvant treatment decisions are largely based on clinicopathologic staging, which may inadequately identify patients with true residual disease.
- Circulating tumor (ctDNA)-based molecular residual disease (MRD) testing has emerged as a promising strategy to identify patients with residual disease who are most likely to benefit from adjuvant therapy.

## Event

- On May 15, 2026, the FDA approved Tecentriq and its subcutaneous formulation as an adjuvant treatment for adults with MIBC who are ctDNA MRD-positive after cystectomy, as identified using the Signatera companion diagnostic assay.
- The approval was based on the Phase 3 IMvigor011 study, the first prospective Phase 3 trial to demonstrate a survival benefit using a ctDNA-guided treatment strategy in bladder cancer.
- Among ctDNA-positive patients identified using Signatera, adjuvant Tecentriq reduced the risk of disease recurrence or death (DFS) by 36% and the risk of death (OS) by 41% versus placebo.

## Clarivate's takeaways

### Unmet need

The post-cystectomy "watch and wait" period in MIBC is often associated with significant clinical uncertainty, as recurrence may not become detectable until disease burden is substantially higher. Current adjuvant treatment decisions are largely based on clinicopathologic staging, which may not fully capture underlying molecular residual disease risk.

### Medical practice changing

The approval marks an important step toward ctDNA-guided treatment in MIBC and could establish a broader precedent for ctDNA-guided treatment strategies across solid tumors.

### Commercial potential

The ctDNA-guided precision medicine positioning of Tecentriq may enable differentiated adoption in the MIBC landscape and strengthen its competitive positioning against other immunotherapy-based regimens such as Padcev + Keytruda.

 

# About the author

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Dr. Bhatt combines over a decade of experience across academic research and industry, translating complex scientific data into insights across the oncology landscape. Prior to joining Clarivate, she worked as a Solution Scientist at Merck, where she led strategic collaborations, provided tailored scientific solutions, and conducted in-depth market assessments for biopharmaceutical clients. She holds a Ph.D. in Cellular and Molecular Immunology and an M.Sc. in Molecular Biology from the Max Planck Research School in Germany. Her doctoral research focused on signaling pathways downstream of the B-cell antigen receptor.

## Clarivate coverage of bladder cancer and upper tract urothelial carcinoma

- Bladder Cancer and Upper Tract Urothelial Carcinoma | Disease Landscape & Forecast | G7 | last updated in April 2026
- Bladder Cancer and Upper Tract Urothelial Carcinoma | Current Treatment: Physician Insights | US | June 2024
- Bladder Cancer and Upper Tract Urothelial Carcinoma | Current Treatment: Treatment Sequencing | US | June 2024
- Unresectable Locally Advanced or Metastatic Bladder Cancer | Unmet Need | G7 | April 2026

 


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