

# FDA approves Padcev plus Keytruda as perioperative treatment for cisplatin- ineligible MIBC

Market Event Summary

# Approval marks first & only perioperative therapy for cisplatin-ineligible MIBC

## Background

- Neoadjuvant cisplatin-based chemotherapy plus radical cystectomy is standard of care for muscle-invasive bladder cancer (MIBC), but ~50% of patients are cisplatin-ineligible due to age, frailty, or comorbidities, leaving them with limited options and high recurrence risk.
- The cisplatin-ineligible patients typically undergo radical cystectomy without neoadjuvant therapy, and among all MIBC patients treated with surgery alone, ~50% experience disease recurrence, highlighting a significant unmet need.
- No perioperative immunotherapy regimen had previously demonstrated a clear survival benefit in cisplatin-ineligible MIBC.

## Event

- On November 21, 2025, the FDA approved Keytruda & Keytruda Qlex, each in combination with Padcev as perioperative therapy for cisplatin-ineligible MIBC patients.
- The approval was based on the Phase 3 KEYNOTE-905 / EV-303 trial, where the combination achieved a 60% reduction in the risk of event-free survival events (HR 0.40;  $p < 0.0001$ ) and a 50% reduction in the risk of death (HR 0.50;  $p = 0.0002$ ) vs. surgery alone. Median EFS and OS were not reached, compared with 15.7 months and 41.7 months for surgery alone.
- The combination showcased a 57.1% pathologic complete response rate, compared with 8.6% for surgery alone, and a safety profile consistent with the known side effects of both agents.

## Clarivate's takeaways



### Unmet need

Early FDA approval, months ahead of the expected April 2026 decision, highlights the unmet need in cisplatin-ineligible MIBC and underscores the strength of the survival benefit demonstrated by the combination.



### Medical practice changing

This regimen could set a new standard of care and is poised to reshape clinical practice by bringing the established ADC + PD-1 inhibitor combination for metastatic disease into an earlier curative-intent setting.



### Commercial potential

The simultaneous approval for Keytruda QLEX (SC) along with the IV formulation is notable as it may offer greater convenience (faster administration, less resource burden), which can drive rapid clinical adoption.

# About the author



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Dr. Bhatt combines a decade of academic research with industry experience to deliver actionable insights in oncology. Prior to joining Clarivate, she worked as a Solution Scientist at Merck Life Science Pvt. Ltd., where she spearheaded strategic collaborations, provided tailored scientific solutions, and conducted market assessments for various biopharma 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, where her research focused on studying the 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)*.
- Bladder cancer and upper tract urothelial carcinoma *Current Treatment: Physician Insights: US* - explores the current prescribing trends of medical oncologists treating bladder cancer and upper tract urothelial carcinoma.
- Bladder cancer and upper tract urothelial carcinoma *Current Treatment: Treatment Sequencing: US* - presents surveyed medical oncologists' most frequent treatment sequences for bladder cancer and upper tract urothelial carcinoma.
- Unresectable locally advanced or metastatic bladder cancer *Unmet Need* - provides detailed and expanded analysis insights into areas of unmet need in this specific subpopulation.



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