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# FDA expands perioperative Padcev plus Keytruda MIBC approval to include cisplatin-eligible patients

Market Event Summary

Arshiya Bhatt, Ph.D. | July 2026

# First and only platinum-free perioperative regimen approved across all MIBC populations

## Background

- Cisplatin-based neoadjuvant chemotherapy followed by radical cystectomy has remained the standard perioperative treatment for cisplatin-eligible muscle-invasive bladder cancer (MIBC) patients for over two decades, while cisplatin-ineligible patients have had limited treatment options. Since 2025, perioperative immunotherapy-based regimens have begun to receive FDA approval.
- In November 2025, the FDA approved perioperative pembrolizumab plus enfortumab vedotin for cisplatin-ineligible MIBC based on KEYNOTE-905 / EV-303, introducing the first perioperative PD-1 inhibitor plus ADC regimen in this setting.

## Event

- On July 10, 2026, the FDA expanded the approval of pembrolizumab (IV and SC) in combination with enfortumab vedotin as perioperative treatment for adults with MIBC regardless of cisplatin eligibility.
- The approval is supported by the Phase 3 KEYNOTE-B15 trial, in which the combination significantly improved event-free survival (HR 0.53), overall survival (HR 0.65), and pathological complete response (55.8% vs 32.5%) compared with neoadjuvant gemcitabine / cisplatin followed by radical cystectomy.
- Together with the previous approval, this label expansion establishes the combination as the first platinum-free perioperative regimen approved regardless of cisplatin eligibility.

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## Clarivate's takeaways

### Standard of care evolution

The expanded approval removes the historical treatment divide based on cisplatin eligibility, broadening the addressable MIBC population and positioning pembrolizumab plus enfortumab vedotin as a potential new perioperative standard of care that could challenge the long-standing cisplatin-based standard.

### Competitive differentiation

The platinum-free, cisplatin-agnostic label differentiates pembrolizumab plus enfortumab vedotin from the only other approved perioperative immunotherapy regimen, durvalumab plus gemcitabine-cisplatin, by enabling the combination to compete across the broader perioperative MIBC population. However, AstraZeneca's positive Phase 3 VOLGA results for perioperative durvalumab plus enfortumab vedotin in cisplatin-ineligible or cisplatin-declining patients could intensify competition, pending regulatory approval.

### Commercial opportunity

The expanded approval substantially broadens the addressable perioperative MIBC population, strengthening the long-term commercial opportunity for pembrolizumab plus enfortumab vedotin and supporting broader clinical adoption. However, real-world patient experience and long-term outcomes will be key determinants of its uptake in clinical practice.

 

# 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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