

New first-line treatment for advanced bladder cancer, which doubles survival versus platinum based chemotherapy, to be made available to patients on the NHS

Wednesday 20 August, 2025

Embargoed until 00:01 Thursday 21st August 2025

A combination of enfortumab vedotin (Padcev) and pembrolizumab (Keytruda) will be available on the NHS for people with advanced bladder cancer who are eligible to receive platinum chemotherapy.

Until now, for decades, patients with advanced urothelial cancer – a type of bladder cancer that begins in the cells that line the bladder – received platinum-based chemotherapy as a standard of care if they were fit enough and had good kidney and heart function.

The approval is based on results from the Phase 3 EV-302 clinical trial (also known as KEYNOTE-A39) where patients with advanced urothelial cancer treated with the combination of Padcev (enfortumab vedotin) plus the immunotherapy drug Keytruda (pembrolizumab) had survival durations nearly double those seen among people treated with traditional chemotherapy.

The clinical trial explored how effective and how safe enfortumab vedotin in combination with pembrolizumab was in patients with previously untreated unresectable locally advanced or metastatic bladder cancer (la/mUC).

In the study, 886 patients with locally advanced or metastatic urothelial cancer received either Padcev plus Keytruda or standard platinum-based chemotherapy. Tumours shrank in two thirds (68%) of participants assigned to the new combination compared with 44% of those who received chemotherapy.

The cancer completely disappeared—known as a complete response—in nearly 30% of patients treated with the combination compared with 12.5% of those given chemotherapy.

Progression-free survival—the time a patient lives with the disease where it does not get worse—was about twice as long in people given the combination—a median of 12.5 months compared with 6.3 months for those treated with chemotherapy. Overall survival was also about twice as long with Padcev plus Keytruda—a median of 31.5 months compared with about 16 months for chemotherapy.

Professor Alison Birtle, Honorary Clinical Professor & Consultant Oncologist and Fight Bladder Cancer Trustee

said, “I am absolutely delighted to see that the combination of Padcev and Keytruda in the treatment of patients with advanced or metastatic urothelial cancer, who are eligible for/fit for platinum containing chemotherapy, has been approved by NICE. This represents such a milestone for not just my own future patients, but everyone facing such a difficult diagnosis. As someone who has treated bladder cancer for more than 20 years this is a really significant development in our options for patients”

Ali Stunt, CEO of Fight Bladder Cancer: “This

decision is a significant advance for people facing the most aggressive form of bladder cancer at diagnosis. Access to this combination in the first line setting means patients will have a new treatment option that shows the potential to extend life and control disease for longer than chemotherapy alone.”

Melanie Costin, Director of Patient Engagement & Support at Fight Bladder Cancer: “For many patients and their families, an advanced bladder cancer diagnosis comes with few good options, today's decision definitely changes that. It means doctors can offer an effective first-line treatment on the NHS that has been shown to give people more time, and more time means more moments, more memories, and more chances to live fully despite the disease. This is a hugely important step forward!”

Padcev is a type of treatment called an antibody-drug conjugate (ADC). ADCs work by targeting a specific protein or receptor on the surface of a cancer cell and delivering a drug, typically a chemotherapy, directly to that cancer cell. This design allows the drug to destroy cancer cells while limiting harm to other cells in the body.

Notes to editors:

Related Sectors:

Health ::

Related Keywords:

Bladder Cancer :: Cancer :: NICE
:: New Treatment :: Cancer
Survival :: Padcev :: Keytruda ::

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Specialist clinicians, charity spokespeople (CEO) and bladder cancer patient experts can be available for further comment and/or interview

About bladder cancer

- Around 20,000 people are diagnosed with bladder cancer each year in the UK.
- Most people diagnosed with bladder cancer are over 60 years old. However, people of all ages can be affected by the disease.
- The main risk factor for bladder cancer is increasing age, but smoking and exposure to some industrial chemicals also increase the risk.
- Bladder cancer is more common in men, but can affect people of all ages and genders.
- Out of every 100,000 people, 56 men and 18 women are diagnosed with bladder cancer each year.
- Bladder cancer can often have a worse outcome in women. Women in England and Wales have between 15% and 45% higher odds of being diagnosed with advanced disease compared to men.
- Bladder cancer is usually identified based on visible blood in the pee or blood found on urine testing.

About Fight Bladder Cancer

- A UK-based patient-led charity, which started as a local support group in 2010 and has grown into one of the leading bladder cancer organisations in the UK.
- The charity aims to support people affected by bladder cancer, raise awareness about symptoms of bladder cancer so it can be caught early, campaign for research into this much-ignored cancer, and affect policy at the highest levels to bring about change in bladder cancer treatment.
- Our policy and advocacy work focuses on bringing together partners and patient advocates to drive positive and lasting changes
- Our primary area of focus is patient support. We also work on healthcare system improvements for the bladder cancer pathway from pre-diagnosis to treatment and beyond.
- Read more about the charity here: <https://www.fightbladdercancer.co.uk/>

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