21 May 2026
EMADOC-1700519818-3134776
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Padcev

enfortumab vedotin

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Padcev. The marketing authorisation holder for this medicinal product is Astellas Pharma Europe B.V.

The CHMP adopted a new indication as follows:[2]

Muscle invasive bladder cancer (MIBC)

Padcev, in combination with pembrolizumab, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adult patients with resectable muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy.

Unresectable or metastatic urothelial cancer

Padcev, in combination with pembrolizumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy.

Locally advanced or metastatic urothelial cancer

Padcev as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

[2] New text in bold.

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