



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/CHMP/50600/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Jaypirca pirtobrutinib

On 27 February 2025, 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 Jaypirca. The marketing authorisation holder for this medicinal product is Eli Lilly Nederland B.V.

The CHMP adopted a new indication to include treatment of adults with relapsed or refractory chronic lymphocytic leukaemia. The full indications for Jaypirca will be as follows:²

Jaypirca as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor.

Jaypirca as monotherapy is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukaemia (CLL) who have been previously treated with a BTK inhibitor.

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 Summaries 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

