17 September 2026
EMADOC-1700519818-3366123
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tecvayli
teclistamab

On 17 September 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 Tecvayli. The marketing authorisation holder for this medicinal product is Janssen Cilag International NV.

The CHMP adopted a change to an existing indication as follows:[2]

Teclistamab is indicated

- as monotherapy for the treatment of adult patients with relapsed **or** ~~and~~ refractory multiple myeloma, who have received at least **one prior therapy.** ~~three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.~~

For information, the full indications for Tecvayli will be as follows:

Teclistamab is indicated:

- in combination with daratumumab for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy;
- as monotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior therapy.

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, removed text as strikethrough.

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